26TH ESACT MEETING

MAY 5 - 8, 2019 COPENHAGEN, DENMARK

CELL CULTURE TECHNOLOGIES: BRIDGING ACADEMIA AND INDUSTRY TO PROVIDE SOLUTIONS FOR PATIENTS

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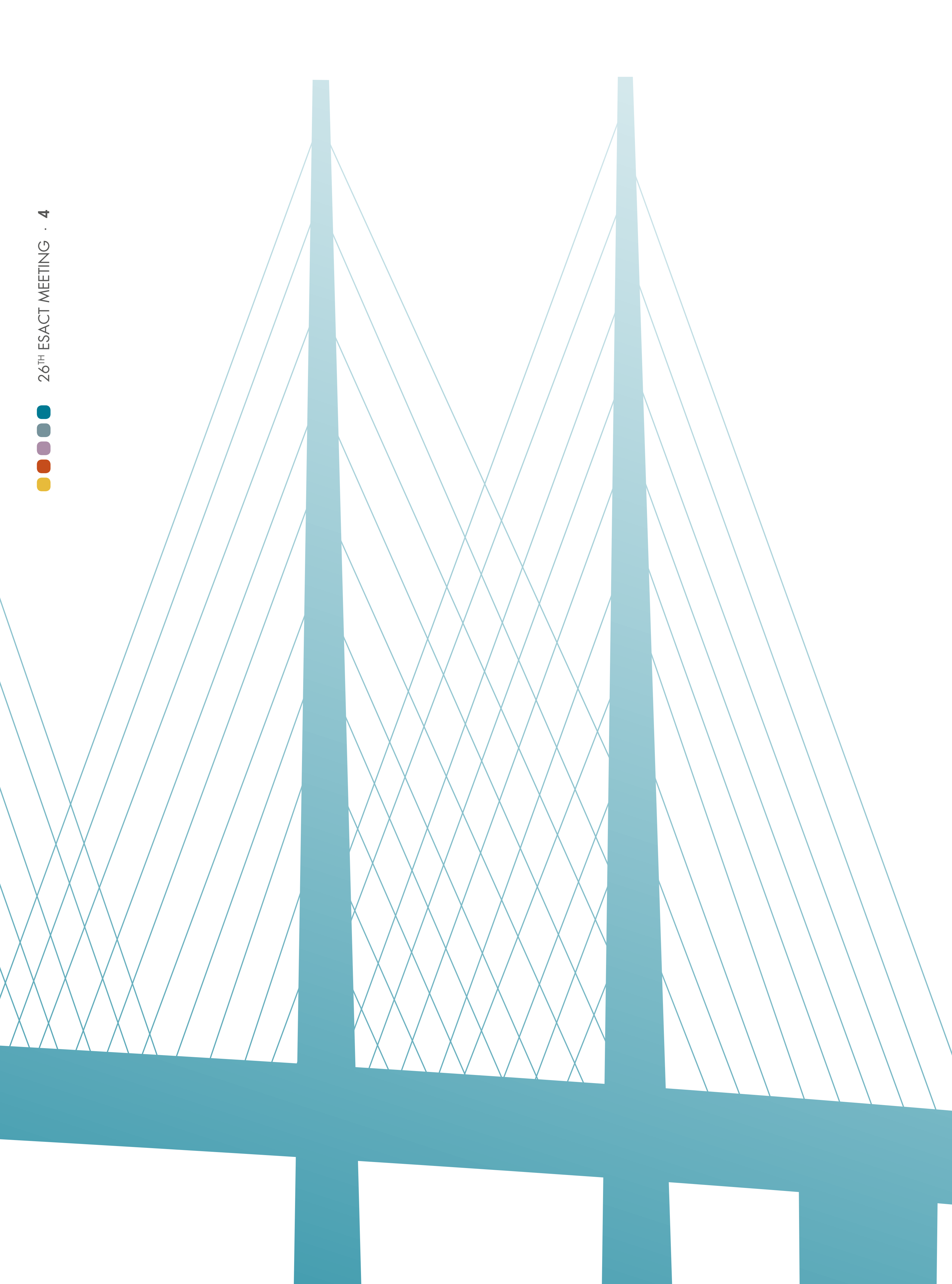

WELCOME FROM THE MEETING CHAIRPERSON

Dear participants, on behalf of the European Society for Animal Cell Technology (ESACT) and the local Organizing Committee, I have the great pleasure of welcoming you to the 26th ESACT Meeting placed in Copenhagen.

Is there really anything better than being able to invite 1000 of your closest scientific friends and collaborators to come for a visit? This was our thought in 2015, when we proposed to the ESACT Executive Committee that we would host the meeting in Copenhagen. For the last four years, we have all been looking very much forward to welcoming you as our guests in our lovely city, and we hope that you will have an excellent time here, and take advantage of the wonderful sights of both the conference and the city.

Planning and executing such an event takes a lot of dedicated people and people with a passion for ESACT, and we have had this in the elected ESACT Executive Committee, the always excellent ESACT Frontiers, all of our members of the Scientific Committee, and of course my fellow members in the Organizing Committee. It really has been a team effort and I am very grateful for having worked with so many wonderful people. I would like to thank all who worked so hard and passionately, providing valuable input, invaluable support, and time to make the 26th ESACT Meeting what it is. A special thank you should also be extended to our excellent support team at MCI Copenhagen, who from the word "go" provided the highest level of support and competence. Also worthy of praise is the fact that a lot of what you see and experience at the conference would not have been possible without the generous support of our sponsors, for which we are exceedingly grateful.

The main attraction of ESACT has always been the excellent Scientific Programme showing the latest advances in animal cell technology with strong representation of the best work from academia and industry. The programme was designed around five main topics, for which the Scientific Committee performed a blinded review of the abstracts and established a ranking based on the quality of the proposals. The ranking was used for the selection of the speakers and for the selection of the best poster abstracts competing for the poster prize. I would like to thank all that have contributed with abstracts, posters, and talks, and the Scientific Committee that lent their expertise and their valuable time to select the excellent contributions. I would also like to thank all the academics and companies that have proposed workshops and symposia for Sunday before the official opening.

As everyone that have attended ESACT Meetings before will know, the meetings are also known for their excellent networking events. This year, we have experimented with several new setups and concepts, designed to facilitate both informal and more focused networking in groups, as well as to give you good memories from Copenhagen to bring back home. There will be options for everything from group dinners to large receptions, from views of castles and waving to the Queen of Denmark to drinks at the harbor front. You might even want to challenge yourself or your supervisor to a thrilling trip in a rollercoaster. If this is your first visit to an ESACT Meeting, please accept my special welcome, and I encourage you to take full advantage of these events. Talk to new people, take advantage of the friendly and inclusive community. Many people have started their next big project at ESACT Meetings, met their next post doc, talked to their future employer, initiated friendships and new adventures together. Maybe you will be next. Welcome to the ESACT family!

On behalf of the Organizing Committee, I wish an outstanding ESACT Meeting!

Mikael Rørdam Andersen
Chairperson of the 26th ESACT Meeting

WELCOME FROM THE EXECUTIVE COMMITTEE

On behalf of the Executive Committee of the European Society for Animal Cell Technology (ESACT) it is our great pleasure to welcome you to Copenhagen for the 26th ESACT meeting.

ESACT meetings are well known for the various excellent opportunities for participants from around the world to contribute to the scientific plenary programme, the poster session, trade exhibition and workshops. We are convinced that this meeting will again fulfil your expectations, not only with regard to science and business but also for networking during the breaks and the social programme.

It is a long lasting tradition that the ESACT meeting organization is led by a local chairperson. For this meeting we delegated the task to a very special person, Mikael Rørdam Andersen, with whom the Executive Committee had the great pleasure to work during the last 4 years. Thank you Mikael for taking on this challenge and for all the time and energy dedicated to make this meeting a success.

We would furthermore like to warmly thank Anne B. Tolstrup, chair of the Scientific Committee. Thank you Anne for driving the Scientific Committee, for all the care you took paying attention to many details and for making this excellent programme possible.

Beyond that, smoothly running a meeting of this size and impact requires huge efforts from many individuals and different organizations. We thank the scientific committee for setting up a brilliant programme, the organizing committee for orchestrating all the different activities, the speakers, poster presenters and workshops organizers for their preparations, the exhibitors for setting up their booths and the sponsors for their generous support, and, last but not least, MCI – in particular Julie Drehn – for the overall planning, organization and for assisting all the committees.

We are excited that at the start of this meeting, we will present the Inaugural 2019 ESACT Innovation Award. Here we want to take the opportunity to thank Terry Papoutsakis, the ESACT Innovation Award Committee Chair and ESACT honorary member, for making this possible.

We wish all of you a meeting that meets your expectations, every success for your presentations, new impulses and fruitful interactions with other participants.

On behalf of the ESACT Executive Committee

Paula Alves
Chairperson

Hitto Kaufmann
Vice-chairperson

ESACT COMMITTEES

ESACT 2019 ORGANIZING COMMITTEE

Mikael Rørdam Andersen (Chair)
DTU Bioengineering, Technical University of Denmark, Denmark

Francesc Gòdia
Universitat Autònoma de Barcelona, Spain

Helene Faustrup Kildegaard
Novo Nordisk A/S, Denmark

Pia Møller Martensen
Aarhus Universitet, Denmark

Lena Nielsen
AGC Biologics A/S, Denmark

Søren K. Rasmussen (Head of the Social Programme)
Symphogen A/S, Denmark

Ali Kazemi Seresht
Novo Nordisk A/S, Denmark

Anne B. Tolstrup (Head of Scientific Committee)
BioProcess Technology Consultants, Inc (BPTC), Denmark

ESACT 2019 SCIENTIFIC COMMITTEE

Anne B. Tolstrup (Head of Scientific Committee)
BioProcess Technology Consultants, Inc (BPTC), Denmark

Paula Marques Alves
iBET, Portugal

Christian Clausen
Bioneer, Denmark

Alan Dickson
University of Manchester, UK

Scott Estes
Codiak, USA

Adrian Haines
Novimmune, Switzerland

Helene Faustrup Kildegaard
Novo Nordisk A/S, Denmark

Verena Lohr (ESACT Frontiers)
Sanofi, Germany

Kerstin Otte
University of Applied Sciences Biberach, Germany

Malin Parmar
Lund University, Sweden

Thomas Ryll
Immunogen, USA

Matthieu Stettler
Lonza AG, Switzerland

ESACT FRONTIERS

Simon Ausländer
Roche, Germany

Ricardo Valdés-Bango Curell
Dublin City University, Ireland

Paulo Fernandes
Autolus, UK

Verena Lohr
Sanofi, Germany

Emma Petiot
CPE-Lyon Engineer School, France

Ana Filipa Rodrigues
iBET, Portugal

Christopher Sellick
Kymab, UK

Igor Slivac
University of Zagreb, Croatia

ESACT EXECUTIVE COMMITTEE

Chairperson:
Paula Marques Alves
iBET, Portugal

Vice-Chair:
Hitto Kaufmann,
Sanofi Biologics, Germany

Secretary:
Nicole Borth
BOKU – University of Natural Resources and Life Sciences, Vienna, Austria

Treasurer:
Niall Barron
Dublin City University, Ireland

Francesc Gòdia
Universitat Autònoma de Barcelona, Spain

Véronique Chotteau
Royal Institute of Technology in Stockholm, Sweden

Alan Dickson
University of Manchester, UK

Stefanos Grammatikos
UCB Pharma, Belgium

Kerstin Otte
University of Applied Sciences Biberach, Germany

ESACT Office:
Birgit Marckhgott

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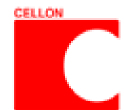
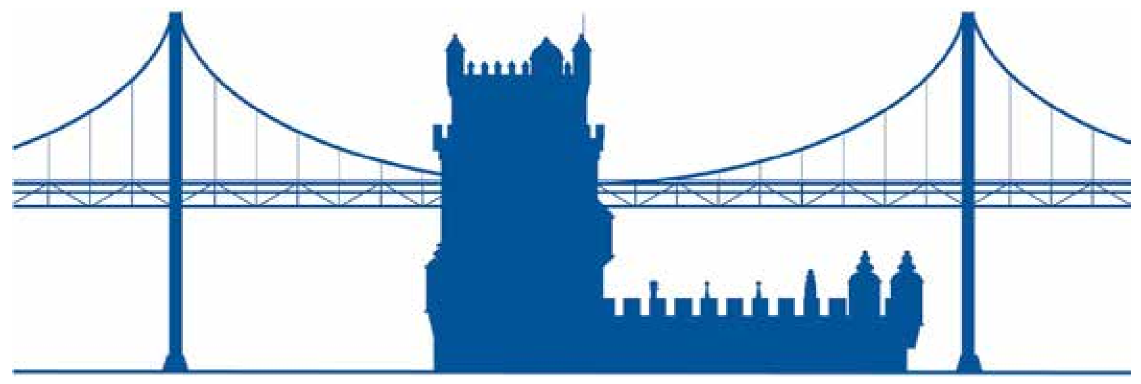


SPONSORS & EXHIBITORS



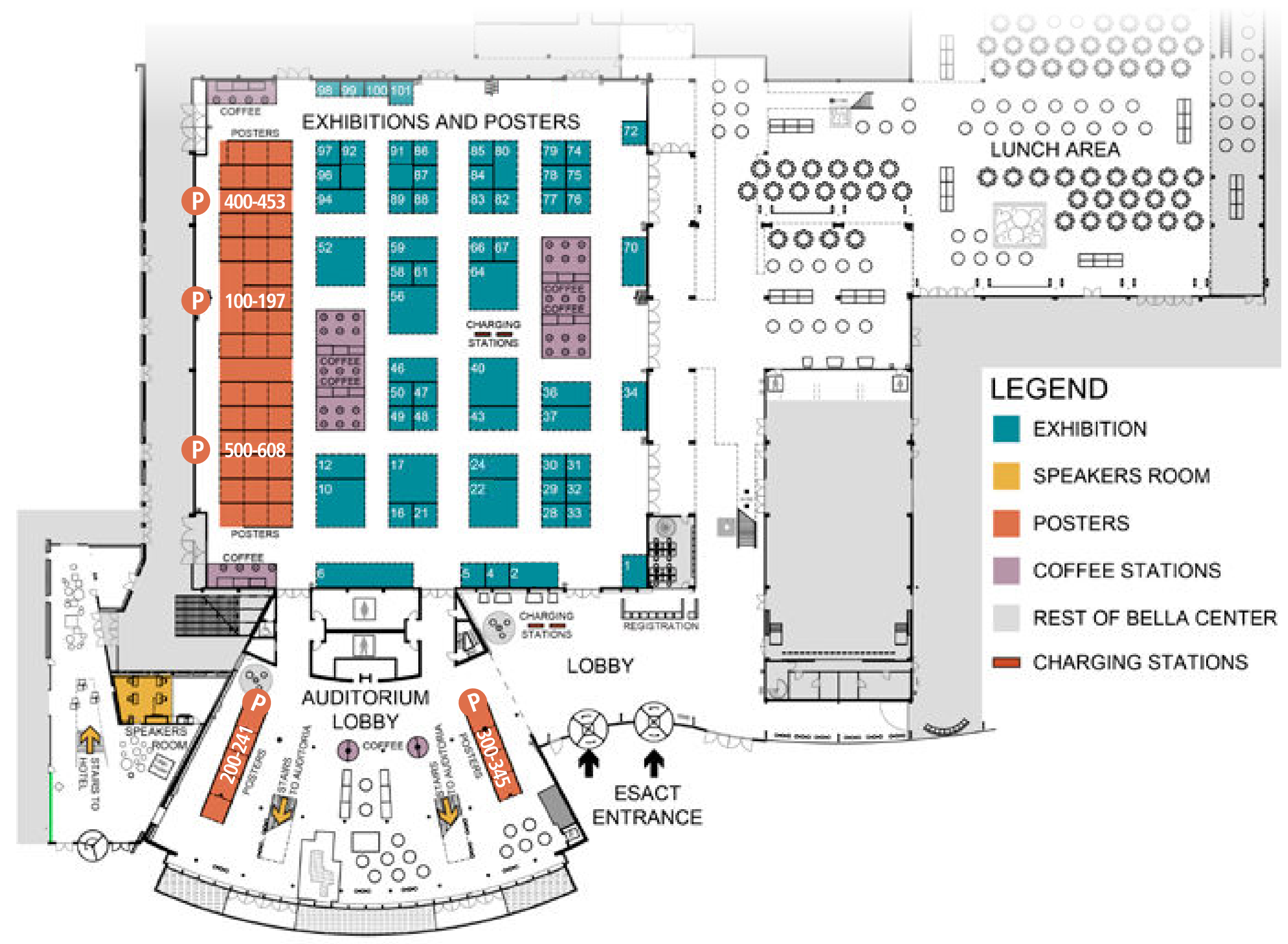
Lisbon, 20-24 June 2021

27th ESACT Meeting

www.esact2021.com

Save the date!!

EXHIBITION MAP & LIST



Company/Org	Booth #
4BioCell	85
Aber Instruments Ltd	43
ABLE Corporation	91
Adolf Kühner AG	12
Albumedix	87
ALIT Life Science – Shanghai RuiYu Biotech	101
ALS Automated Lab Solutions GmbH	72
Applikon Biotechnology	37
BASF	86
Beckman Coulter GmbH	22
Berkeley Lights	92
Bilfinger Industrietechnik Salzburg GmbH	2
BioConcept	10
Biological Industries	70
BIONET	78
Capricorn Scientific GmbH	29
C-CIT Sensors	58
Cellon SA	46
c-LEcta GmbH	98
Corning BV	1
cytena GmbH	28
DrM, Dr. Mueller AG	58
Entegris GmbH	83
Eppendorf AG	52
Evonik Industries AG	31
ExpreS2ion Biotechnologies	75
Flownamics	50
FrieslandCampina DOMO	82
FUJIFILM Irvine Scientific	59
GE Healthcare	64
GEN	99
Hamilton Bonaduz AG	77
Horizon Discovery	97
I&L Biosystems GmbH	80
INFORS HT	36
InSCREENeX GmbH	100
IPRASENSE	61
Kerry	48
MERCK	56
Mettler Toledo	88
Nexcelom BioScience	96
Nova Biomedical	16
Novo Nordisk Pharmatech A/S	17
PAIA Biotech GmbH	49
PALL BIOTECH	6
PneumaticScaleAngelus	21
POLYPLUS TRANSFECTION	89
PreSens Precision Sensing GmbH	4
REFINE TECHNOLOGY, LLC	84
Repligen	47
RESOLUTION Spectra Systems	66
Roche Diagnostics Deutschland GmbH	24
Sartorius Stedim Biotech GmbH	40
Securecell AG	76
Sera Scandia Biotech	30
Solentim Limited	33
Stobbe Tech A/S	34
Thermo Fisher Scientific	94
UGA	79
Valitacell	67
Xell AG	32
Yokogawa Electric Corporation	74

JAACT Japanese Association for Animal Cell Technology 日本動物細胞工学会

JAACT2020 Fuchu

"Animal Cell Technology for Health and Better life"

Period: November 17 (Tue)-20 (Fri), 2020

Venue: Fuchu no Mori Art Theater

1-2 Asada-machi, Fuchu-shi, Tokyo

Meeting Chairperson: Yutaka Miura

(Tokyo University of Agric. & Tech.)

Plenary Lectures: ESACT lectures, Topics about exosomes, TBD
Symposia: 6 sessions (mAb production, food functions, basic cell biology, one-cell analysis, omics science etc.)
Oral and Poster sessions
Technical seminars

http://www.jaact.org/en/

Fuchu-no-Mori Theater

https://www2.aeplan.co.jp/jaact2020/ (from June, 2019)

ESACT COURSES 2019

Courses

With a maximum of 30 participants per course, you will find a pleasant atmosphere that allows intensive exchanges and stimulating, in-depth discussions with colleagues and lecturers.

Application

Simply fill out the application form on our website. Shortly after the application deadline we will inform you whether you have been selected as a participant.

Apply until 15 June 2019 and take part!

Registration Fees

Registration fee covers accommodation in double rooms, full board, course materials and one organized bus transfer to and from the hotel to Barcelona Airport at a fixed time as well.

	academia	industry
ACT course	€ 1000	€ 1600
Vaccines Course	€ 1000	€ 1600
Drug Development Course	€ 800	€ 1400

Testimonials of participants

„The organisation of the course was excellent. Lecturers and all participants were cooperative, focussed and highly engaged. I really enjoyed the course.“ Mehmet S., Turkey

„I felt that the ESACT ACT Course gave me much needed insight into several aspects of Bioprocess Engineering and for me, as an academic researcher, the opportunity to interact with scientists and engineers working in industry was invaluable.“ Steve G, Canada

„The ESACT Course in Llafranc was a great opportunity to improve my knowlege in the Biotechnology area. The professors were very attentive and the structure of the course was very organized, providing us comfort and tranquility to enjoy the lectures.“ Nanditha V., India

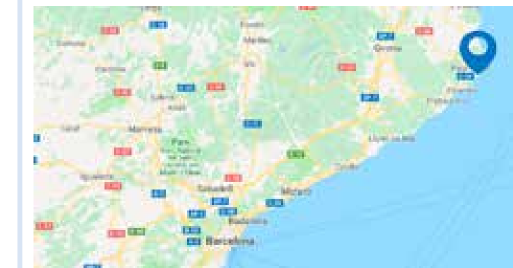
„I had the opportunity to improve my knowledge in Drug Development. It was a fantastic opportunity to interact with the most important researchers in this area. The lecturers were really attentive and excellent.“ André I., Uruguay

For more information and course programme: www.esact.org

Location

In the heart of the Costa Brava, only 120 km from Barcelona, in the middle of a wonderful scenery you can learn directly from your peers.

Join the ESACT Courses!



Getting there

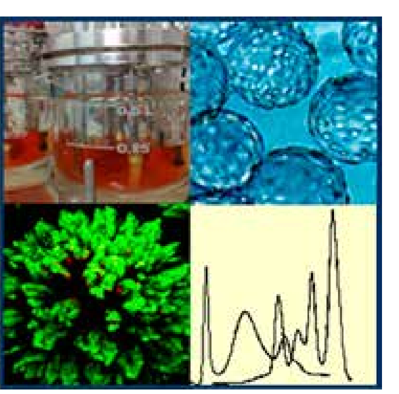
Easy to get there from Barcelona Airport (directly by bus transfer service) or from Girona Airport. More details on our website.

ANIMAL CELL TECHNOLOGY COURSE

9TH EDITION

22 - 26 Sept 2019

Llafranc, Costa Brava / Spain



Photos: www.ibet.pt

Organizers:
Francesc Gòdia, UAB, Spain
Paula Alves, iBET and ITQB NOVA, Portugal

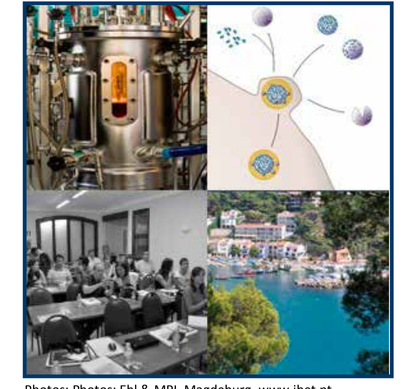
For more information and course programme:
www.esact.org

CELL CULTURE BASED VIRAL VACCINES COURSE

4TH EDITION

29 Sept - 3 Oct, 2019

Llafranc, Costa Brava / Spain



Photos: Photos: Ehl & MPI, Magdeburg, www.ibet.pt

Organizers:
Amine Kamen, McGill University, Canada
Yvonne Genzel, Max-Plank, Madeburg, Germany
Francesc Gòdia, UAB, Spain

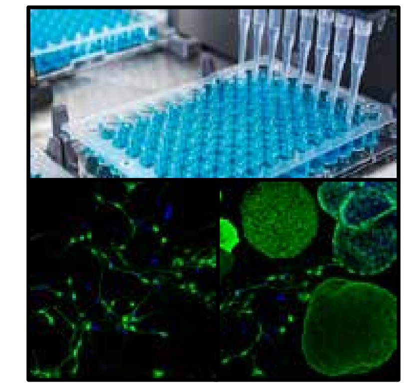
For more information and course programme:
www.esact.org

DRUG DISCOVERY COURSE

4TH EDITION

6 - 9 Oct, 2019

Llafranc, Costa Brava / Spain



Photos: www.ibet.pt

Organizers:
Catarina Brito, iBET and ITQB NOVA, Portugal
Hansjörg Hauser, HZI , Germany
Heinz Ruffner, Novartis, Switzerland

For more information and course programme:
www.esact.org

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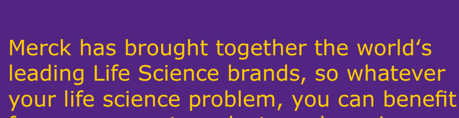
Take the right path upstream—the first time.

MerckMillipore.com/right-path-upstream



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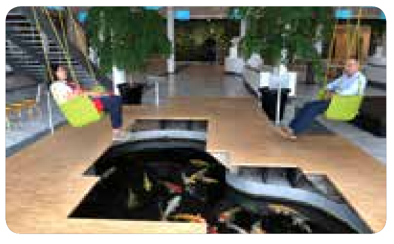
NETWORKING EVENTS



Exhibitors reception · SUNDAY 19:00-20:30

The traders reception and cocktail buffet will take place after the keynote lecture Sunday Evening in the exhibition hall and will be the official opening of the exhibition. The exhibition provides an opportunity to discover new technologies, materials and services within the field of animal cell technologies. Catch up with old friends and colleagues in a relaxed atmosphere.

Free evening · MONDAY EVENING

Monday evening is free. Catch the metro for a 10 min ride to the very center of the city and explore wonderful Copenhagen, recently nominated #1 Best in Travel 2019 by Lonely Planet, by your own. Get inspired for recommended dinner possibilities and activities currently going on in Copenhagen at the Copenhagen guide www.aok.dk. Check the information mail from the Chairperson for extra suggestions and practical information.

Tour in historic Copenhagen and dinner in Tivoli · TUESDAY 15:30-22:00

Tuesday afternoon will give you the opportunity to join a walking tour through the historic part of central Copenhagen including the picturesque Rosenborg Castle and the Queens winter residence, Amalienborg Palace. Small refreshments will be available throughout the tour at specific locations. You will need good navigation skills to reach them. After this activity, you will end in the world-famous Tivoli amusement park, the second oldest in the world. A three-course dinner will be served in two of Tivoli's most traditional Danish Restaurants. After dinner, the beautiful gardens, surroundings, and rides are available for pleasure, relaxation, and fun.

Plan transport (walk to Bella Center St and Metro to Nørreport Station) for arrival around 16:30 to 17:00. The walk will last approximately 2 hours. Map with directions will be given at registration. Remember conference badge and Tivoli ticket. If you are not participating in the Walk, join for dinner in Tivoli at 19:00. Find your way "home" by your own after Tivoli experience.

26th ESACT Congress dinner

WEDNESDAY 17:30-00:00

A very special event is planned for the Congress Dinner and for closing the meeting Wednesday evening at the Langelinie Pavillion Restaurant in the central Copenhagen waterfront area. The transportation to the restaurant by water (hopefully) will make the entry very special and initiate a fantastic evening. Therefore, reserve this evening for interactions with delegates and celebrations of the 26th ESACT meeting.

Instructions for transport and timing for canal boat departure will be given at registration but expect to leave 17:00 to 17:30 from Congress Center. Busses will leave from Langelinie Pavillion every 20 min from 21:20 to 00:20 to Bella Center. There will be one stop near Kgs. Nytorv if accommodation is in central Copenhagen.

Call for Applications for ACTIP Fellowships 2019-2020

"I am greatful for the pleasant experience to meet and discuss with innovative thinkers from many stakeholder companies in biopharma. The networking atmosphere was greatly intensified by an intimate atmosphere and joyful social program."

Michael Sokolov,
ACTIP fellow – Stockholm, December 2018

"It was a great pleasure to be part of the conference about topical subjects in animal cell technologies of biopharmaceutical companies and to present my research work to that expert audience"

Alina Handl,
ACTIP fellow – Düsseldorf, May 2018

"Being an ACTIP fellow was a wonderful privilege because we were exposed to pivotal and ground-breaking technologies, we visited a company that produces biosimilars, and we had plenty of time to meet inspiring leaders from the most relevant Cell-Biotech companies."

Gonçalo Rodrigues,
ACTIP fellow – Sopot-Gdansk, May 2017

photo credits: 1. Rentschler, 2. Sartorius, 3. Sartorius, 4. Merck Serono, 5. Sartorius, 6. Morphosys, 7. GSK Marburg

Call for Applications for ACTIP Fellowships 2019-2020

ACTIP (the Animal Cell Technology Industrial Platform) is an informal science-based forum of European companies employing animal cell technology in the development and production of biopharmaceuticals, vaccines and other preventative or therapeutic approaches (www.actip.org). Twice a year the ACTIP member company representatives, invited speakers and observer companies meet to discuss scientific research, development, technology and regulatory topics of mutual interest. The meetings take place in the hometowns of member companies (and sometimes on the premises) and are characterized by a friendly, open atmosphere that allows good interactions, networking and scientific discussions.

ACTIP opens up these informal industrial meetings to you, young scientists working on a project in biomanufacturing or related activity of industrial interest, i.e. development of new expression systems, new mammalian cell lines, cell culture processes, test development. ACTIP offers you the floor to present your project and personal expertise to our scientific community. This is not only an excellent opportunity to present your work to experts and being updated on relevant topics for your research, but also a great way to expand your personal network on a European scale.

The Fellowship consists of all costs paid to attend a two-day ACTIP meeting. The ACTIP Fellowships for the next two years will be awarded to young professionals following an evaluation by experts from the member companies. The awarded fellows will be invited to attend one of the ACTIP meetings taking place from winter 2019 to spring 2021. In order to be selected for such an opportunity, ACTIP invites you to send in an application for the ACTIP Fellowship.

How to apply?

Applicants should be younger than 40 years of age, educated to at least degree level in one of the disciplines underlying biomanufacturing, and based in Europe. The applicant should describe his/her involvement in a recent project on biomanufacturing or related activity of industrial relevance. Project descriptions should not exceed one A4 page. The application should be accompanied by a recent Curriculum Vitae with full contact details.
Both the project description and recent CV should be sent to:
Dr. Erwin van Vliet, Executive Secretary ACTIP, email: **exec.secr@actip.org**

Timeline

Applications can be sent from 27 May until 9 August 2019 (24:00 CET). Evaluations by ACTIP experts will take place from 10 August to 30 September 2019. Selected fellows will be notified by 15 October 2019. The shortlist of selected fellows will be published on the ACTIP website. The meetings to which the selected ACTIP fellows shall be invited will take place during the period from November 2019 to June 2021.

We look forward to receiving your applications!

IMPORTANT INFORMATION

VENUE

Bella Center, Copenhagen Congress Center
Center Boulevard 5
2300 Copenhagen

TECHNICAL SECRETERIAT

ESACT 2019, c/o MCI Copenhagen A/S
T +45 31 54 62 20 – Email: esact2019@mci-group.com

OFFICIAL LANGUAGE

The official language of the Meeting is English. No simultaneous translation will be provided.

BADGES AND SECURITY

It is essential that you wear your personal badge at all times while in the Meeting venue and events, as it is the official entrance pass to scientific sessions, and other Meeting activities.
For the Networking Events, it will also be necessary to present the corresponding Voucher that will be provided with the registration package.

DISCLAIMER

The European Society for Animal Cell Technology (ESACT) hereby provides notice to conference attendees and anyone else, that ESACT makes no warranty of any kind whatsoever, expressed or implied, that any information, materials, techniques or products or anything else presented at this conference is accurate, valid, adequate or fit for any purpose whatsoever. Meeting attendees are solely responsible for determining the validity, adequacy and fitness of any information, materials or products or anything else presented at this conference for any and all uses. Statements and descriptions made by ESACT at this conference and included in conference literature are informational only and are not made or given as a warranty. The views, opinions and statements made at the conference are solely those of the speakers and may not reflect the views of ESACT. Furthermore, speakers may have vested interests in the concepts and products they discuss.

It is further understood and agreed that ESACT shall not be liable whether in contract, in tort, under any warranty, in negligence or otherwise for any kind of claim for loss, damage or expense of any kind arising out of or resulting from the use of any information, materials, products or anything else presented at this conference, and under no circumstances shall ESACT be liable for special, indirect or consequential damages.
ESACT and/or its agents have the right to alter or cancel the conference or any of the arrangements, timetables, plans or other items relating directly or indirectly to the meeting without prior notice for any reason beyond their control. The conference and/ or its agents shall not be liable for any loss, damage, expenditure or inconvenience caused as a result of such alteration or cancellation.

INSURANCE AND LIABILITY

It is recommended that participants obtain adequate cover for travel, health and accident insurance before they depart from their countries. ESACT 2019 and MCI as organizers cannot accept responsibility for personal injuries, or loss of, or damage to, private property belonging to the meeting participants and accompanying persons.

REGISTRATION AND INFORMATION DESK OPENING HOURS

Sunday 5th May	08:00-20:00
Monday 6th May	08:00-20:00
Tuesday 7th May	08:30-15:30
Wednesday 8th May	08:30-17:00

SPEAKERS PREVIEW ROOM

Speakers have to provide their presentations in the Speakers Preview Room located on the ground floor in room 69. This has to be done no later than two hours before the scheduled time of the session.

SPEAKERS PREVIEW ROOM OPENING HOURS

Sunday 5th May	08:30-18:30
Monday 6th May	08:00-17:00
Tuesday 7th May	08:00-13:00
Wednesday 8th May	08:00-14:00

WIFI ACCESS

Network: bc guest (open network)

ACCESS TO THE MEETING

The delegate fee gives access to the following:

- Access to all the sessions of the ESACT Meeting
- Lunches
- Networking Events

Accompanying person fee gives access to:

- Lunches
- Networking Events

PERSONAL SAFETY

Copenhagen is among the top 10 safest capital cities in the world (www.worldscapitalcities.com), and in general you can walk in any public location at any time of day without fearing for your personal safety. You will see Copenhageners roaming the streets and parks alone and in groups at all hours. However, we still encourage you to have a care for personal safety and do not deliberately put yourself in unnecessary dangerous situations.

SOCIAL MEDIA/PHOTO/VIDEO POLICY

You may live tweet (#ESACT19) presentations and take pictures/videos of talks unless the speaker explicitly opts out by stating so at the start of his or her talk and/or has marked slides as Confidential. Taking photos and/or videos of posters without permission is strictly prohibited.
(See Poster Policy below).

POSTER POLICY

We expect all participants to treat the posters as the property of the presenter and not attempt to copy them in any way. In the case that a poster presenter wants to give everyone permission to take pictures of his or her work, official "Photography OK" stickers are available from the registration. Taking pictures, videos or otherwise reproducing the posters or any part thereof is not permitted without the permission of the presenter unless a "Photography OK" sticker is found on the poster.

CODE OF CONDUCT

For the ESACT 2019 Meeting, we have established a Code of Conduct to communicate a transparent set of guidelines and rules for acceptable behavior at the Meeting, and to make sure that the ESACT Meeting will continue to be a safe, inclusive, and welcoming environment for all participants and staff. All participants (regardless of their roles) are expected to follow the Code of Conduct at any part of the meeting, both at the official conference venue and at social events off site.

UNACCEPTABLE BEHAVIORS

Unacceptable behaviors include, but are not limited to:

- Intimidating, harassing, abusive, discriminatory, derogatory, or demeaning speech or actions by any participant and at all related events
- Harmful or prejudicial verbal or written comments or visual images related to gender, gender expression, gender identity, marital status, sexual orientation, race, religion, political orientation, socioeconomic, disability or ability status, or other personal characteristics.
- Violating the rules and regulations of the conference venue
- Sustained disruption of scientific sessions or other events
- Unwelcome and uninvited attention or contact
- Physical assault (including unwelcome touching or groping)
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- Photography of presentations or parts thereof when the presenter has explicitly stated that this is not allowed
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TAKING ACTION

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- Need to file a complaint? Please contact any Conference Organizer (as marked on their badges) or email Meeting Chair Mikael Rørdam Andersen at mr@bio.dtu.dk directly. All reports will be handled confidentially.

CONSEQUENCES OF NON-COMPLIANCE

Anyone asked by Conference Organizers, the venue or security staff, or law enforcement officers to stop unacceptable behavior is expected to comply immediately. Retaliation toward official staff or toward someone reporting an incident or after experiencing any of the following consequences will not be tolerated and may result in additional sanctions.

The consequences of non-compliance with the ESACT 2019 Code of Conduct may include:

- Immediate removal from the meeting without warning or refund
- Restrictions from future meeting attendance
- Incidents may be reported to the proper authorities

THE INAUGURAL 2019 ESACT INNOVATION AWARD

The ESACT Innovation Award is to recognize outstanding **innovators and contributors** to the field of Animal Cell Culture Technology (ACCT). ESACT has had a profound impact on the development of ACCT-based production of biologicals as human therapeutics as well as diagnostics. Over the years, several landmark contributions have been made by scientists and organizations associated with ESACT, yet, there has not been a mechanism to recognize such contributions and disseminate their impact. This Award aims to fill this need.

For the purpose of this Award and to provide clarity, ESACT defines "Animal Cell Culture Technology" as: Applied science, technologies, systems and processes that enable, facilitate or improve the use of cultured animal cells in research, diagnostic and therapeutic applications.

The Award is presented at the discretion of the ESACT Award Committee during the ESACT bi-annual Scientific Meeting. The award recipient is invited to present the **ESACT Innovation Award Lecture** at the ESACT Scientific Meeting immediately following the award presentation. The invitation to attend the ESACT Meeting includes all travel expenses, accommodations during the Meeting and a waiver of registration fees. The value of the Award will be a sum of 5000 together with a commemorative plaque.

ESACT Executive Committee members, as well as Award Committee members, are ineligible for the Award during the term of their respective Committee membership and for a two-year period thereafter. All other individuals or organizations that satisfy the Award criteria above are eligible for nomination for the Award.

Dr. Volker Sandig, MD, PhD

The Inaugural 2019 ESACT Innovation Award Recipient

Dr. Sandig is recognized for seminal fundamental and applied research in cell and vector biotechnology, and the development of innovative vaccine technologies. Notably, for instigating and developing the cell-line development program at ProBioGen, AG, which resulted in one of the leading CHO platforms, the co-development of the CHO-Freedom Kit with LTC (now Thermo-Fisher), and the development of glycoengineering technologies, and notably GlymaxX at ProBioGen.

In 1987, Dr. Sandig received his Diploma in Medicine (which corresponds to an MD) from the Second Institute of Medicine (Faculty of Medical Biology), Moscow, Russia, specializing in medical biochemistry. In 1992, he received his Ph.D. (doctor rerum naturalium) in Molecular Biology from Humboldt University Berlin, Germany. His postdoctoral training from 1992 to 1996 was at the Max-Planck-Institute for Biochemistry (Berlin-Buch), Germany, in the group pf Prof. Dr. Michael Strauss. From 1997 to 2000, he was visiting scientist first (in the lab of Tom Caskey, a pioneer gene-therapy lab) and, later, Senior Research Biologist (working on vaccine development) at Merck Research Labs in West Point, PA, USA. He returned to Germany as Vice President for Cell & Vector Biology at ProBioGen AG, Berlin, where he developed the cell-line program of the company. ProBioGen AG is an established Contract Development and Manufacturing Organization (CDMO) and technology provider, which started in 1994 as a diagnostics company. Dr. Sandig currently serves as CSO (Chief Scientific Officer) of ProBioGen. His work aims to modernize vaccine manufacturing processes through customized design of new cell lines from primary sources that support a wide range of human and animal viruses.

THE 2019 ESACT MEDAL

Dr. Christa Burger

Former Merck KGaA, Darmstadt, Germany.
The ESACT medal is being awarded to Dr. Christa Burger for many years of active support to the ESACT and her contributions in the field in target identification and assay development.

Christa Burger studied biology at the University of Konstanz, Germany. She started her scientific work as a doctoral researcher at the Institute of Genetics of Konstanz University. She worked with Prof. Ellen Fanning on the analysis of SV40 T antigen functions. In 1980 she received her PhD degree.

She continued basic research by moving to immunology of B cells and antibody selection joining the laboratory of Prof. Klaus Rajewsky at Cologne University as a Post-Doc. In 1988 she continued this subject as an instructor and Post-Doc at the University of Texas Southwestern Medical Center, Dallas.

In 1991, Christa was hired by Merck KGaA in Darmstadt as a lab manager. Several promotions within the company brought her to the department of Target Identification and Biotechnology in pre-clinical R&D. In this function she became involved in the development of antibody expression and production as well as in target identification and assay development. She was member of several EU- funded projects.

Christa encountered ESACT first time at 1996 during the Vilamoura meeting. Since then she is member of the society, participated in many ESACT meetings, also contributing to several of these meetings in different functions. She was a member of the organizing committee of the Dresden meeting in 2007. In 2014 she initiated and organized a new course on Compound screening in the ESACT LLfranc Advanced Courses, a course that developed towards Drug Discovery and is running for the 4th time in 2019.

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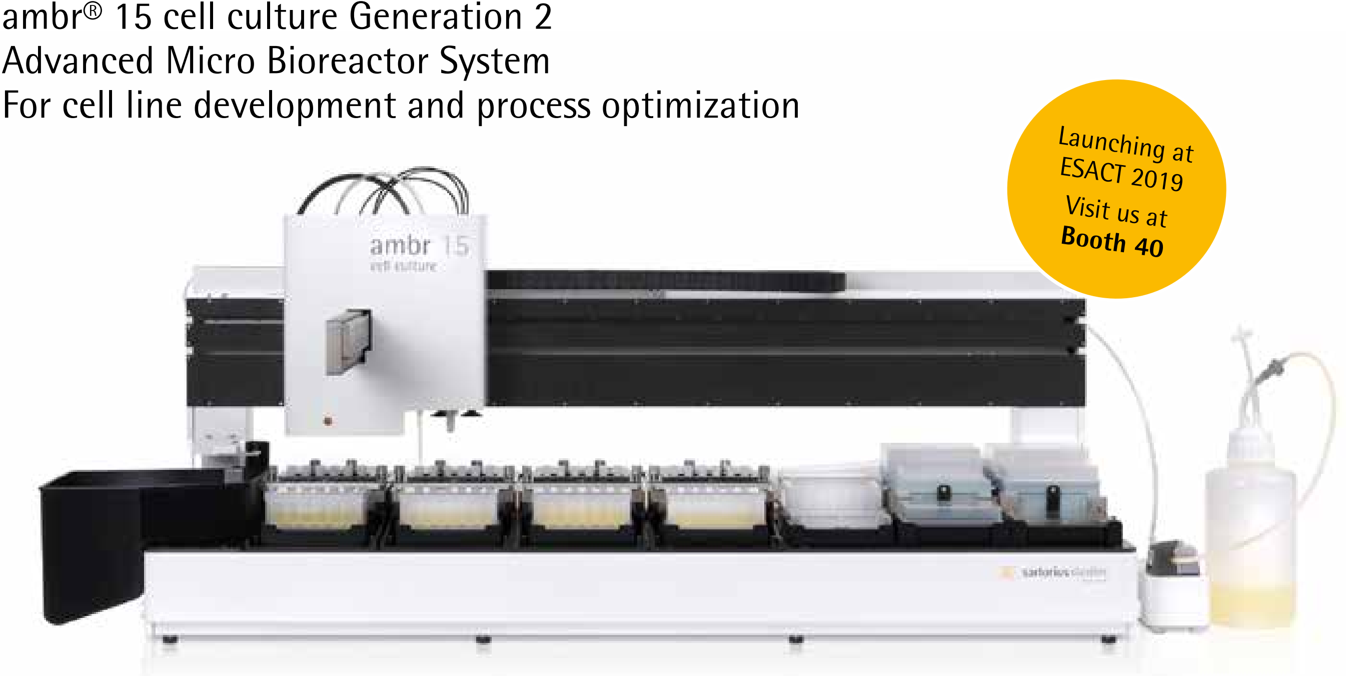

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Are you a PhD student or a PostDoc within 3 years of graduation? Do you want to present on Animal Cell Technology?

Do you plan to present at a conference other than the ESACT meeting?

Why not apply for an ESACT Grant?

ESACT Grants provide travel support for PhDs and young academic researchers within 3 years of their graduation from a PhD program. The following may be supported by an ESACT grant:

- Participation in courses and workshops that teach topics of relevance to Animal Cell Technology
- Participation in conferences and meetings to present results in the field of Animal Cell Technology, either as an oral or poster presentation
- Short term research stays at other academic labs

Participation in the ESACT Meeting or courses organized by ESACT is exempt for this program.

Grants provided are a contribution towards coverage of registration fee, accommodation or travel as documented (currently not more than 500 Euros for non-overseas locations and not more than 1000 Euros for overseas locations). In addition, each recipient is awarded a 4-years free ESACT membership.

To apply, please visit www.ESACT.org.

MEETING SCHEDULE

SUNDAY 5TH MAY

09:30-11:00
ACADEMIC SYMPOSIUM SESSION 1

11:00-11:30 Coffee Break

11:30-13:00
SPONSORED SYMPOSIUM SESSION 2

13:00-13:30 Lunch

13:30-15:00
SPONSORED SYMPOSIUM SESSION 3

15:00-16:00
Coffee break

16:00-17:30
OPENING SESSION
Innovation Award Lecture

17:30-19:00
SESSION 1:
Cell Engineering, novel technologies and the use of omics

19:00-20:30
EXHIBITORS RECEPTION

MONDAY 6TH MAY

09:00-10:30
SESSION 2:
Cell engineering, novel technologies and the use of omics

10:30-11:00 Coffee Break

11:00-12:30
SESSION 3:
Cell culture process controls and analytics

12:30-13:30
Lunch

13:30-15:00
POSTER SESSION 1
and Coffee
ODD NUMBERS

15:00-16:30
SESSION 4:
Use of viral- and non-viral vectors for generating new therapeutic products and vaccines

16:30-17:00
Coffee Break

17:00-17:30
SESSION 5: Use of viral- and non-viral vectors...

17:30-18:30
KEYNOTE 1 Peter Zandstra

18:30-20:00
POSTER SESSION 2
and Drinks

TUESDAY 7TH MAY

09:00-10:30
SESSION 6:
Cell culture process engineering, product quality and integration with downstream processing

10:30-11:00 Coffee Break

11:00-12:30
SESSION 7:
Development of cell-based technologies and therapeutics

12:30-14:00
Lunch and ESACT General Assembly

14:00-15:30
POSTER SESSION 3
and Coffee
EVEN NUMBERS

15:30-22:00
OUTING TO COPENHAGEN

WEDNESDAY 8TH MAY

09:00-10:30
SESSION 8:
Cell culture process controls and analytics

10:30-11:00 Coffee Break

11:00-12:30
SESSION 9:
Development of cell-based technologies and therapeutics

12:30-13:45
Lunch

13:45-15:15
SESSION 10:
Cell culture process engineering, product quality and integration with downstream processing

15:15-15:30
Short coffee break

15:30-17:00
KEYNOTE 2
Mathias Uhlen and Closing Ceremony

17:30-19:00
Transfer to Congress Dinner

19:00-00:00
CONGRESS DINNER AT LANGELINIE PAVILLONEN

WORKSHOP SESSIONS

WORKSHOP SUNDAY 5TH MAY 9:30-11:00 · AUDITORIUM 10

www.CHOgenome.org: where we are and where we might go

Organized by Nicole Borth, Kelvin Lee and Mike Betenbaugh

This workshop will be dedicated to the benefits of organism/cell line specific websites and the tools that currently are available at www.CHOgenome.org and tools/features that you may want to see implemented in the future. The workshop will include tutorials and a discussion on what the most important and urgent needs of the scientific community are with respect to CHO-omics. To help prepare this please fill in the survey on that your needs are:
https://docs.google.com/forms/d/1BaWmqA8V3LoyMPdVJOMUZGOXiTfqnvqIO1aiYGW8WKA/edit

WORKSHOP STRUCTURE:

- **9:30-10:00 Introduction and Keynote. Multi-omic resources for detailed discovery in mammalian cells**
  Kimberly Robasky, University of North Carolina at Chapel Hill

  We will discuss emerging resources wherein detailed data and tools are being released to gain insights into mammalian cells. These include NCI's Genomic Data Commons Portal (GDC), NIH's Genotype-Tissue Expression (GTEx), and NHLBI's Trans-Omics for Precision Medicine (TOPMed), as well as the Alliance for Genome Resources (AGR) and emerging single-cell atlas initiatives. We will provide examples for using these resources and for integrating omics data.

- **10:00-10:10 CHOgenome.org: Resources and Tools for the CHO Community**
  Madolyn Macdonald, University of Delaware

  This presentation will focus on how to use CHOgenome.org to access genome information for the Chinese hamster (CH) and CHO cells. CHOgenome.org currently hosts multiple genome assemblies for CH and CHO as well as several tools to search and visualize this data. We will provide an overview of the available CH and CHO genome assemblies with emphasis on the most recent reference genomes and annotations. We will then demonstrate how to find sequence, annotation, and protein information for a gene of interest from a particular assembly. We will also describe how to use the CHOgenome.org BLAST tool and the JBrowse viewer to gain further information. In addition, we will discuss and invite comments for future plans for the website.

- **10:10-10:20 The CHOmine and epigenome databases**
  Heena Dhiman, Austrian Center of Industrial Biotechnology

  This presentation will lead the audience through different additional available CHO specific websites to demonstrate how information can be extracted. One example is the CHOmine, an intermine toolbox that links different information databases available for genes, including different reference genomes, protein databases, KEGG and Gene ontology information. It enables linking between different gene IDs and thus help in quickly collecting all information for a gene from a single site. The epigenome database, on the other hand, enables a detailed look at the regulation of activity across a genome by providing data for 6 related CHO-K1 cell lines, including transcriptome, DNA methylation, calls for small mutations and larger scale structural variants such as translocations.

- **10:20-10:30 Resources for Metabolic Modelling**
  Nathan E. Lewis, University of California San Diego

  Biotherapeutic production in mammalian cells is a bioenergetically demanding task, wherein we culture the host cells to rapidly grow to high densities, all while requiring cells to produce large quantities of recombinant protein drugs. Given these demands, mammalian host cells are cultured in rich medium to provide ample nutrients for high growth and protein production. Systems biology models provide a framework to describe the uptake of these nutrients and quantify the metabolic fluxes as resourced are driven to growth and protein production. Here I will discuss a variety of tools that are publicly available to build and run models of mammalian metabolism to deepen ones understanding of and optimize mammalian metabolism.

- **10:30-11:00 A look into the future: Survey Results and Discussion**
  Moderator: Nicole Borth, BOKU University and Austrian Center of Industrial Biotechnology

  Briefly, a summary of the results of the survey on the use of CHO resources and the perceived needs of the scientific community in this field for the future, followed by discussion

ESACT/ACTIP WORKSHOP SUNDAY 5TH MAY 9:30-11:00 · AUDITORIUM 11

The digital transformation of animal cell culture technology

Prof. Dr. Michelangelo Canzoneri (Sanofi, ESACT representative) and Christine Mitchell-Logean (UCB, ACTIP representative)

The ongoing digital transformation is influencing the way process scientists approach the development of manufacturing cell lines and industrial cell culture processes. Recent advances made in the field of process miniaturization, parallelization, automation and control are implemented into highly efficient process development workflows. This workshop provides insights by experts from the biopharmaceutical industry about their ways of leveraging digitalization and machine learning. Key challenges around experimental designs, data and knowledge management strategies, statistical process models and decision-making tools in the development of manufacturing cell lines and cell culture processes will be highlighted. The presenters will illustrate their concepts with example case studies and will discuss about future outlooks and opportunities in this context.

WORKSHOP STRUCTURE

- **09:30 – 09:50 (+ 5 min discussion)**
  Colin Clarke (nibrt)

  Digitalizing Biopharmaceutical Manufacturing: A platform for Integrating the Industrial Internet of Things and Big Data Analytics
- **09:55 – 10:15 (+ 5 min discussion)**
  Michael Sokolov (DataHow)

  Towards Industry 4.0 – the role of smart model-based solutions for cell culture process digitalization and automation
- **10:20 – 10:40 (+ 5 min discussion)**
  Norbert Furtmann (Sanofi)

  Platformization of Multi-Specific Protein Engineering: Data-driven workflow support for high-throughput screening
- **10:45-11:00 Panel discussion**
  With all speakers

ESACT WORKSHOP ON EXTRACELLULAR VESICLES: SUNDAY 5TH MAY 9:30-11:00 · AUDITORIUM 12

EVs – the next generation complex biopharmaceutical

Co-chaired by Scott Estes, Ivan Wall, and Johannes Grillari

Extracellular vesicles have raised a strong interest recently as novel biopharmaceuticals. Thereby, 2 different lines of research and development are crystallizing, on the one hand the use of EVs as therapeutics per se, and on the other their use as drug delivery vehicle.

In regard to their use as complex biopharmaceutical, there is accumulating evidence for therapeutic activity in various disease models including stroke, myocardial infarction, osteoarthritis, or bone regeneration. They even have been used in a human graft versus host disease patient with extremely positive result. It is hypothesized that beneficial effects that were observed in clinical trials using e.g. mesenchymal stem cells (MSCs) might well be due to the secretome of these MSCs as opposed to direct incorporation of allogeneically transplanted MSCs. Considering more than 500 ongoing clinical trials using MSC based therapies, we can envision an ever increasing necessity of production systems for EVs.

Similarly, the use of EVs as drug delivery/targeting vehicles has by now produced promising results in animal models.

In order to give key insights into this fast evolving field, we here apply for a workshop to be held at ESACT2019 in Copenhagen, as we see a benefit for all experts in EV based biology and in animal cell culture technology to convene and discuss in order to boost and inspire the respective fields in the quest to produce, purify and finally bring EVs as novel biopharmaceuticals to the patients. Thereby, IW will introduce the basic biology of EVs and their isolation and processing; JG will outlined the potential cross-talk between different cells and tissues by EVs; BG will show their therapeutic potential and finally, SEA will highlight the EV potential as a drug delivery vehicle.

WORKSHOP STRUCTURE:

- **Advancing Bioprocessing of Exosomes**
  Ivan Wall, UK
- **Cross-talks in aging and age associated diseases: from EV biology to application**
  Johannes Grillari/BOKU/Evercyte, Vienna, Austria
- **MSC-EVs in regenerative Medicine: Heterogeneity of MSCs and resulting EV preparations**
  Bernd Giebel, University clinics Essen, Germany
- **Bioengineered EVs as a versatile platform for biomedical applications**
  Amir El Andaloussi, Karolinska Institutet, Stockholm, Sweden
- **Questions to the panel**

ESACT FRONTIERS WORKSHOP
SUNDAY 5TH MAY 9:30-11:30 · ROOMS 5/6

Design Thinking to foster innovation and creativity

Speaker and moderator: Guilherme Martins Vitorino (NOVA Information Management School, Portugal)
Chairs: Ana Filipa Rodrigues (iBET, Portugal) and Paulo Fernandes (Autolus, UK)

Design Thinking is a method to foster innovation and creativity by following a user-centric approach. Designing is giving form to an idea to conceive a more desirable product, service, process or organization and refining it into something that can be delivered reliably and efficiently. In addition to the consumer-related aspects, Design Thinking can leverage several aspects of technology, research and development, including creating new products and tools, conceiving new applications for old products, shortening product development cycle or establishing new models for productivity and collaboration.

ESACT Frontiers invites you to join a Design Thinking session especially conceived for the 26th ESACT meeting in Copenhagen. In this session, participants will be guided through the fundamental steps of Design Thinking with insightful explanations and examples. Dynamic exercises will engage participants to address challenges and identify opportunities for innovation, collaboration or unexpected value creation. As major outcome of the session, participants will recognize the use of Design Thinking as a useful methodology to create new technologies, capabilities, relationships, activities and materials in their own practice while contributing to shape the future of academia-industry interaction in the field of animal cell technology.

WORKSHOP STRUCTURE:

- Introduction
- Design Thinking principles
- Exercises:
  1. "Painstroming"
  2. Warm-up
  3. Strategic partnerships
  4. Challenge
- Closing

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GE HEALTHCARE SPONSORED WORKSHOP SUNDAY 5TH MAY 11:30-13:00 · AUDITORIUM 10

Intensifying cell culture operations – modern approaches to biopharma commercialisation

Moderator: Andreas Castan, GE Healthcare

Cell line development, process development and process intensification, advanced data analytics and automation are all important strategies manufacturers are using to optimize process efficiency. These steps, along with better approaches to heterogeneity in the pipeline, reductions in costs, and more flexible and agile manufacturing, are all necessary to meet the changing requirements of the biologics industry. During this session, our chairperson Andreas Castan Ph.D, Principle Scientist GE Healthcare Life Sciences, will join seasoned experts to present case studies on these topics and share their insights into overcoming obstacles

WORKSHOP STRUCTURE:

- **Baochuan Huang Ph.D,** Senior Director, Cell Culture Development & Manufacturing, **Kiniksa Pharmaceuticals** will detail media and process development efforts required to realize a high-performing and simplified retrofitted process for producing clinical materials.
- **Patrick Mayrhofer Ph.D**, Department of Biotechnology **BOKU,** Vienna will describe perfusion media and process development, as well as scale-up to pilot scale bioreactors to achieve process intensification.
- **Anurag Khetan Ph.D,** Site Director, Biologics Process Development **Bristol-Myers Squibb** will provide an overview of the process of getting from DNA to drug substance and discuss current challenges in early biologics process development.
- With growing attention on the impact of raw materials on cell culture performance, **Aaron Woolstenholme, GE Healthcare Life Sciences** will describe how installing a seamless connection for data transfer enables development and manufacturing teams to receive real-time data on their cell culture media and its quality.

BERKELEY LIGHTS SPONSORED WORKSHOP SUNDAY 5TH MAY 11:30-13:00 · AUDITORIUM 11

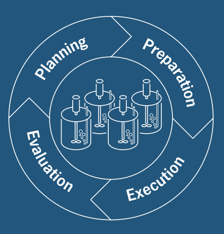
Rapid generation of clonal cell lines with superior titers using the Berkeley Lights Beacon Platform

The development of new antibody therapeutics will require rapid, scalable workflows to generate stable cell lines secreting production-level titers. To date, clone selection approaches are hampered by measurements that are not predictive of titer and stability in the downstream production environment.

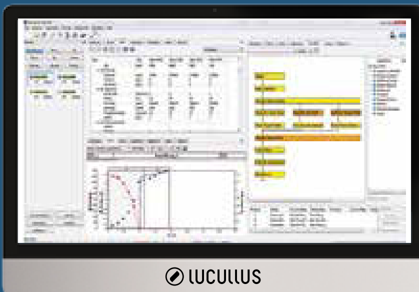
In this workshop, Berkeley Lights will introduce how the Beacon platform enables rapid selection of cell lines with titers superior to clones selected with alternative CLD methods. The Beacon CLD workflow enables generation of cell lines >99% monoclonality assurance in under 1 week, removing the need for multiple lengthy rounds of cloning. In addition, the workshop will demonstrate how the Beacon can measure clonal population dynamics in order to analyze and predict clonal stability over a typical 8-week scale up period.

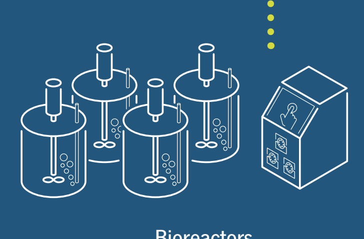
The Beacon platform is rapidly becoming the gold standard for CLD, with expanding adoption at AMGEN, GSK, Teva, Novo Nordisk, Shire, Selexis, Catalent, Sanofi, and several other pharma and CROs. Customers will co-present case studies demonstrating how the Beacon has both accelerated their CLD timelines and improved the yield of top-secreting clones.

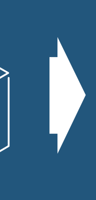
Digital Biotech Lab



Bioprocess Software



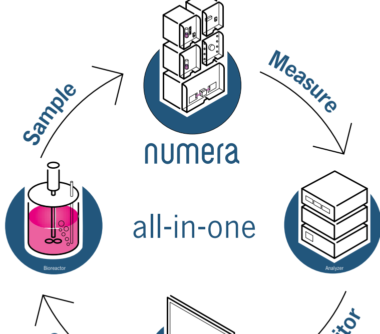




Bioreactors

Analyzers

Automated Sampling



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MERCK SPONSORED WORKSHOP 1
SUNDAY 5TH MAY 11:30-13:00 · AUDITORIUM 12

Facets of seed train intensification – a biopharma industry perspective

Moderator: Jennifer Campbell, Upstream Technical Specialist, Process Solutions, Merck

Process intensification is gaining traction in the biopharmaceutical industry especially in Upstream where flexibility, speed to manufacture and protein yields per run are triggering the shift from traditional fed-batch to perfusion-based processes. Even though perfusion-based production remains a challenge mainly due to the lack of robustness and reliability of current cell retention technologies, more and more drug manufacturers are considering the implementation of perfusion to intensify their seed train.

During this workshop we will explore different seed train intensification strategies (Perfused seed train and High Volume High Cell Density process intermediates etc., discuss the main challenges associated with them and have an end-user present a case study on how they have successfully intensified their seed train.

A live Q&A session will allow for an interactive exchange between the workshop attendees and the subject matter experts.

WORKSHOP STRUCTURE:

- **Intensified Seed: driving value towards the evolution of upstream processes**
  Habib Horry, Upstream Integration Marketing, Process Solutions, Merck
- **Advantages of specific cell culture media for expansion and N-1 perfusion.**
  Melanie Brandl, Proprietary Media, Process Solutions, Merck
- **Seed train process intensification by using a novel high cell density cryopreservation approach**
  Korbinian Morgenstern, Till Reinhardt, Rüdiger Neef, Mathias Käfer
  Process Sciences, Amgen Research (Munich) GmbH, München, Germany

Background and novelty: In the majority of mammalian cell culture processes, seed train unit operation accounts for the most part of the production period. The time increases substantially with production scale since additional expansion steps with increasing cell culture volumes are required to generate sufficient amount of cell mass for the next scale up step. While an extended pre-culture expansion time is a key source for process variability and pose a higher risk for contamination, process intensification strategies can help to reduce cycle time, process variability and contamination risk to a minimum.

The high cell density cryopreservation (HCDC) plays an important role in seed train process intensification by freezing cells at high concentration in specialized single-use bag assemblies. With the use of these frozen seed train intermediates the production cycle time, batch-to-batch variability and risk of contamination can be substantially reduced. As single cell source the seed train intermediates can be used at multiple stages in drug process development and manufacturing campaigns enabling a shorter turnover time and a higher flexibility.

Experimental approach: In this study, we determined the optimum conditions in terms of cell densities, freeze and thaw temperatures, and DMSO exposure for internally used CHO cell lines. A high cell density culture was generated in a perfused N-1 bioreactor and filled into customized single use bag assemblies at different conditions. The frozen N-1 seed train intermediates were then used to inoculate small scale batch and perfusion bioreactors to directly compare cell culture growth and productivity to a reference perfusion process using a standard seed train.

Results and discussion: In this study, we demonstrate that production bioreactors inoculated from frozen N-1 seed train intermediates in HCDC bags achieve an equivalent growth and production performance when it is compared to a reference perfusion process. Optimum conditions for bag fill, freeze and thaw were evaluated with a shake flask culture cryovial freezing experiment beforehand. In addition, the fill and freeze procedure was adjusted as well resulting in a more simplified handling of the HCDC bag assemblies.

SARTORIUS SPONSORED WORKSHOP
SUNDAY 5TH MAY 13:30-15:00 · AUDITORIUM 10

Driving value through intensified bioprocessing

Moderator: Miriam Monge, Sartorius Stedim Biotech

Summary: Cell culture Process Intensification is a hot topic, especially because it enables commercial scale production from flexible and low cost single-use facilities. As indicated in the BPOG technology roadmap, in many cases perfusion approaches are used for cell culture intensification, e.g. to generate high volume, high cell density cell banks, to minimize the number of seed train steps, or to inoculate the main bioreactors at high cell density to improve its volumetric productivity. Perfusion approaches are also used in the final N-stage bioreactors, dramatically increasing volumetric outputs and even achieving over 50 g/L (cumulative titer) in around 3 weeks.

However, to efficiently develop all these different perfusion approaches, especially when switching from regular Fed Batch approaches in early development, to perfusion enabled intensified approaches in late development requiring comparable product quality, has been cumbersome so far, in particular due to the lack of representative high throughput scaled-down perfusion process development tools.

Recently, suppliers like Sartorius Stedim Biotech, have launched new tools and services for efficient perfusion cell culture development and implementation at large scale.

In this workshop, we will demonstrate, through industry use cases, the comprehensive product and services toolbox developed by Sartorius Stedim Biotech enabling rapid development of robust intensified processes, including n-1 perfusion and n-stage perfusion approaches such as intensified Fed Batch or continuous perfusion. Results will be shared on the new ambr15, for clone and media screening in 'perfusion' mode, as well as ambr250 HT perfusion process development results. Furthermore, (very) high cell density seed train data from RM perfusion bioreactors up to 100 L scale (!) will be shared. Having a perfusion filter sheet welded into the bottom of the RM bag, these systems present a highly cost efficient seed train intensification alternative.

WORKSHOP STRUCTURE:

- **The latest tools for upstream process intensification and integration**
  Gerben Zijlstra (Sartorius Stedim Biotech)
- **Reduction of Unit Operations in Animal Cell Culture Processes**
  Detlef Eizenkraetzer, (Roche Diagnostics)
- **A Versatile Cell line Generation Toolbox for the Development of Intensified CHO Processes**
  Dirk Mueller, (Sartorius Stedim Biotech)
- **Simple and robust large-scale high-density perfusion seed culture expansion in an internal membrane-filtration single-use bioreactor**
  Viviane Salou (Novartis)

INFORS HT SPONSORED WORKSHOP
SUNDAY 5TH MAY 13:30-15:00 · AUDITORIUM 11

Very large-scale screening in micro-wells, smart data and a new digital solution – paths to the future.

Abstract: The topics which INFORS HT will present are about creating bridges to the future. Bioprocesses use very sophisticated equipment. That capability can be used to speed up product development and this is already happening. However, biotechnology has yet to fully embrace some concepts driving other industries.

In this session, we will present how new, very large-scale screening solutions push the need for better digitalization of bioprocesses. We will describe how bioprocessing data can be collected in a single repository and transferred through smart modeling tools to create information, support decision taking and create an automated process control feedback.

WORKSHOP STRUCTURE:

- **From Screening to Scaleup, a Platform for Handling a Range of Cell Culture Needs**
  Andrew Magno (INFORS HT, USA)
- **Moving bioprocess data towards smart data and into the cloud, the first steps**
  Eric Abellan (INFORS HT, CH)
- **Transforming bioprocess data into valuable information and proactive decision support through hybrid modeling**
  Michael Sokolov (Datahow AG, CH)

CHO Toolbox

Streamlining Process Development

For more than 75 years, Kerry has been delivering solutions to assist customers maximize yields and cell performance in biotechnological production systems.

The **CHO Toolbox** provides bioprocess solutions to ultimately help reduce process development time, resources and costs.

- Chemically Defined Media
- Chemically Defined Feeds
- Complex Supplements and Feeds

MERCK SPONSORED WORKSHOP 2
SUNDAY 5TH MAY 13:30-15:00 · AUDITORIUM 12

Upstream Bioprocess Development: Getting it Right the First Time

The first challenge in developing a new biologic drug is to select a partner who will develop the production cell line. The workhorse for biologic drug manufacture is the CHO cell line and the number of cell lines derived from CHO cells illustrate the diversity of the CHO-based systems. However, not all CHO cells are created equal, and the search for the best-producing clone is often compared with looking for a needle in a haystack. Certain strategies can be employed in the process of engineering CHO cells to increase the cells' productivity, with the goal being the selection of a clone that produces a high titer, high quality protein product. As time and cost are of essence in the quest to meet development timelines and advance to the next phase in the development lifecycle, to achieve the desired result, the need to establish the product's structural and functional characteristics is as important as the need to develop a high-expressing cell line. Collaborating with a partner that is able to provide a well optimised cell line development platform coupled with comprehensive bio analytical tests is a key to successful biological drug development.

This session will review strategies that can be applied in the process of cell line development, to improve cell productivity and achieve high titers, including expression cassette design and statistical methodologies, and investigate a few of the analytical approaches that may be applied during the various stages of the cell line development process. From defining the core structure, measuring impurities and glycan profiling with high-throughput techniques, such as CE-LIF, during the establishment of stable cell pools, to assessing the binding, structural and functional characteristics via sensitive SPR, Mass Spectrometry analytics and cell-based methods at the wider and final clone selection stage. In addition to this, the session will also attempt to interactively understand what future testing requirements may be, considering the conventional and new promising technologies that may be implemented during this process.

WORKSHOP STRUCTURE:

- **High-titer expression in CHO cells, importance of the cell type, expression cassette design and statistical approach**
  Murielle Verges, Upstream Process Development, Team Leader, BioReliance® End-to-End Solutions, Merck
- **Selecting the right candidate during clone characterisation with various analytical approaches**
  Daniel Galbraith, Head of Product Characterization Strategy, Merck

SCIENTIFIC PROGRAMME

SUNDAY 5TH MAY 2019

16.00-16.30 **OPENING SESSION**
Chairpersons: Mikael Rørdam Andersen and Paula M Alves

16.30-17.25 **O-001 THE INAUGURAL INNOVATION AWARD LECTURE**
Chairpersons: Terry Papoutsakis and Hitto Kaufmann

CELL ENGINEERING – A SMALL STEP FOR THE BIOTECHNOLOGIST, A LEAP FOR THE APPLICATION?
Volker Sandig, *ProBioGen, Berlin, Germany*

17.25-17.30 **SCIENTIFIC SESSIONS OPENING**
Chairperson: Anne B Tolstrup

17.30-19.00 **SESSION 1: CELL ENGINEERING, NOVEL TECHNOLOGIES AND THE USE OF OMICS**
Chairpersons: Helene Faustrup Kildegaard and Kerstin Otte
Sponsored by Horizon Discovery

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17.30-18.00 **O-002 MAMMALIAN SYNTHETIC BIOLOGY: FOUNDATION AND THERAPEUTIC APPLICATIONS**
Ron Weiss, *Massachusetts Institute of Technology, Cambridge, MA, USA*

18.00-18.20 **O-003 A NEWLY IDENTIFIED SMALL RNA REGULATES NGNA SIALYLATION IN CHO CELLS**
Simon Fischer[1,] *, Anna Wippermann[2], Shumin Yang[3], Sven Mathias[4], Patrick Richter[2], Julia van der Meer[5], Eike Zimmermann[6], Ingo Gorr[2], Martin Gamer[2], Harald Bradl[7]*
[1]BPAD Cell Line Development, [2]Early Stage Bioprocess Development, Boehringer Ingelheim, Germany, [3]Process Science BIFI, Boehringer Ingelheim Fremont, CA, United States, [4]IUniversity of Applied Sciences Biberach, Germany, [5]Genedata AG, Basel, Switzerland, [6]Analytical Sciences BIFI, Boehringer Ingelheim Fremont, CA, United States, [7]BPAD Cell Culture Development, Boehringer Ingelheim , Germany

18.20-18.40 **O-004 CHARACTERIZATION AND INACTIVATION OF ENDOGENOUS RETROVIRUSES IN CHO**
Pierre-Olivier Duroy[1,] *, Sandra Bosshard[1], Emanuel Schmid-Siegert[2], Samuel Neuenschwander [2], Ghislaine Arib[3], Philippe Lemercier[4], Flavien Buron[1], Jacqueline Masternak[1], Pierre-Alain Girod [3], Ioannis Xenarios[5], Nicolas Mermod[1]*
[1]LBTM, Université de Lausanne, [2]Vital-it, Swiss Institute of Bioinformatic, Lausanne, [3]Selexis SA, [4]Swiss-prot, Swiss Institute of Bioinformatic, Geneva, [5]Université de Lausanne, Lausanne, Switzerland

18.40-19.00 **O-005 AN INNOVATIVE CRISPR/ASCPF1 SCREEN IN CHO CELLS**
Valerie Schmieder[1 2], ***Neža Novak***[1 2]*, Heena Dhiman[1 2], Martina Baumann[1,], Gerald Klanert[1], Nicole Borth[2]*
[1]Austrian Centre of Industrial Biotechnology (ACIB), [2]University of Natural Resources and Life Sciences, Vienna, Austria

19.00-20.30 **EXHIBITORS RECEPTION**

MONDAY 6TH MAY 2019

09.00-10.30 **SESSION 2: CELL ENGINEERING, NOVEL TECHNOLOGIES AND THE USE OF OMICS**

Chairpersons: Kerstin Otte and Simon Ausländer (ESACT Frontiers)

Sponsored by Horizon Discovery

09.00-09.20 **O-006 OMICS FOR HIGH CELL DENSITY AND SHEAR STRESS IN PERFUSION PROCESSES**

Veronique Chotteau [1,2], *Caijuan Zhan* [1,2], *Gholamreza Bidkhori* [3], *Magnus Lundqvist* [4], *Leila Zamani* [5], *Hubert Schwarz* [1,2], *Ye Zhang* [1,2], *Magdalena Malm* [2,4], *Aman Mebrahtu* [4], *Adil Mardinoglu* [3], *Christopher Sellick* [6], *Richard Turner* [6], *Diane Hatton* [6], *Raymond Field* [6], *Paul Varley* [6], *Johan Rockberg* [4,7]

[1]Industrial Biotechnology – AdBIOPRO , Centre for Advanced Bioproduction by Continuous Processing, [2]Wallenberg Centre for Protein Research, [3]Science for Life Laboratory, [4]Protein Science, [5]Industrial Biotechnology, KTH, Stockholm, Sweden, [6]Biopharmaceutical Development, MedImmune, Cambridge, United Kingdom, [7]Wallenberg Centre for Protein Research, KTH, Stokholm, Sweden

09.20-09.40 **O-007 CHARACTERISATION OF BOTTLENECKS IN CURRENT CHO PRODUCTION CELL LINES**

Sven Mathias [1], *Simon Fischer* [2], *Anna Wippermann* [2], *René Handrick* [1], *Patrick Schulz* [2], *Martin Gamer* [2], *Kerstin Otte* [1]

[1]Institute of Applied Biotechnology, University of Applied Sciences Biberach, [2]Boehringer Ingelheim Pharma GmbH & Co KG, Biberach, Germany

09.40-09.55 **O-008 SYSTEMATIC EVALUATION OF SITE-SPECIFIC RECOMBINANT GENE EXPRESSION**

Nuša Pristovšek [1], *Saranya Nallapareddy* [1], *Lise Marie Grav* [1], *Hooman Hefzi* [2,3], *Nathan E. Lewis* [2,3], *Peter Rugbjerg* [1], *Henning Gram Hansen* [1], *Gyun Min Lee* [1,4], *Mikael Rørdam Andersen* [5], *Helene Faustrup Kildegaard* [1]

[1]The Novo Nordisk Foundation Center for Biosustainability, Technical University of Denmark, Kgs. Lyngby, Denmark, [2]Departments of Pediatrics and Bioengineering, [3]The Novo Nordisk Foundation Center for Biosustainability, University of California, San Diego, United States, [4]Department of Biological Sciences, KAIST, Daejeon, Korea, [5]Department of Biotechnology and Biomedicine, Technical University of Denmark, Kgs. Lyngby, Denmark

09.55-10.10 **O-009 OVERCOMING CELLULAR HETEROGENEITY DURING CELL LINE DEVELOPMENT**

Leon Pybus [1], *Christopher Knowles* [1], *Ellie Hawke* [1], *Nicholas Barber* [1], *Fay Saunders* [1]

[1]Mammalian Cell Culture, Process Development, FUJIFILM Diosynth Biotechnologies, Billingham, United Kingdom

10.10-10.15 **POSTER SPOTLIGHT – P-136 RECOMBINANT HUMAN BMP-4 PRODUCTION IN BMP RECEPTOR KNOCKOUT CHO CELLS**

Che Lin Kim [1,2], *Gyun Min Lee* [1,2]

[1]DTU Biosustain, The Novo Nordisk Foundation Center for Biosustainability, Lyngby, Denmark, [2]Biological Science, KAIST, Daejeon, Republic of Korea

10.15-10.20 **POSTER SPOTLIGHT – P-122 ANALYSIS OF CHROMATIN ACCESSIBILITY IN CHO CELLS USING ATAC-SEQ**

Krishna Motheramgari [1,2], *Paul Kelly* [1], *Niall Barron* [1], *Colin Clarke* [1]

[1]National Institute for Bioprocess Research and Training, [2]National Institute for Cellular Biotechnology, Dublin City University, Dublin, Ireland

10.20-10.25 **POSTER SPOTLIGHT – P-114 CHO GENOME MINING FOR SYNTHETIC PROMOTER DESIGN**

Yusuf Johari [1], *Adam Brown* [1], *Christina Alves* [2], *Yizhou Zhou* [2], *Chapman Wright* [2], *Scott Estes* [2], *Rashmi Kshirsagar* [2], *David James* [1]

[1]Chemical & Biological Engineering, University of Sheffield, Sheffield, United Kingdom, [2]Cell Culture Development, Biogen Inc, MA, United States

10.25-10.30 **POSTER SPOTLIGHT – P-168 METABOLIC ENGINEERING TO REDUCE GROWTH INHIBITORY BYPRODUCTS FORMATION**

Bhanu Chandra Mulukutla [1], *Jeffrey Mitchell* [2], *Lin Zhang* [2], *Pamela Pegman* [2], *Gregory Hiller* [1]

[1]Cell Culture Process Development, [2]Cell Line Development, Pfizer Inc, Andover, United States

10.30-11.00 COFFEE BREAK

11.00-12.30 **SESSION 3: CELL CULTURE PROCESS CONTROLS AND ANALYTICS**

Chairpersons: Matthieu Stettler and Adrian Haines

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11.00-11.30 **O-010 GLOBAL AMINO ACIDS METABOLIC PROFILING IN CHO CELLS WITH 13-C LABELING**

__Michael Betenbaugh__[1], Harnish Mukesh Naik[1], Venkata Gayatri Dhara[1], Jacqueline Gonzalez[2], Brian McConnell[2], Franklin Swartzwelder[3], Maciek Antoniewicz[2]

[1]Chemical & Biomolecular Engineering, Johns Hopkins University, Baltimore, [2]Chemical & Biomolecular Engineering, University of Delaware, Newark, [3]MilliporeSigma, St. Louis, United States

11.30-11.50 **O-011 BEACON CLD PLATFORM, FROM SINGLE CELL PRODUCTIVITY TO SMALL BIOREACTOR**

__Iris Bodenmann__[1], Amélie Mahé[1], Cédric Steimer[1], Valérie Le Fourn[1], Séverine Fagète[1], Pierre-Alain Girod[1]

[1]Selexis SA, Plan-les-Ouates, Switzerland

11.50-12.10 **O-012 CLOSING THE LOOP ON CELL CULTURE ANALYZER VARIABILITY**

__Shawn M. Lawrence__[1], Brandon D. Veres[1], Cassandra D. Murillo[1], Colin E. Orr[1]

[1]Preclinical Manufacturing and Process Development, Regeneron Pharmaceuticals, Inc., Tarrytown, NY, United States

12.10-12.15 **POSTER SPOTLIGHT – P-414 EFFECTIVE BIOREACTOR PH CONTROL USING ONLY SPARGING GASES**

__Sen Xu__[1], Linda Hoshan[1], Rubin Jiang[1], Joseph Moroney[1], Ashley Bui[1], Xiaolin Zhang[1], Ta-Chun Hang[1]

[1]Biologics Process Research & Development, Merck & Co., Inc., Kenilworth, NJ, United States

12.15-12.20 **POSTER SPOTLIGHT – P-443 COMPARING DIFFERENT AT-LINE ANALYTICS FOR ONLINE RAMAN SPECTROSCOPY**

__Wenzel Wellenbeck__[1], Alexander Woelke[1], Jens Traenkle[1], Jens Claßen[1], Steffen Kreye[2], Alexander Jockwer[2]

[1]PAT, [2]USP, Bayer AG, Wuppertal, Germany

12.20-12.25 **POSTER SPOTLIGHT – P-402 INVESTIGATING CHO SCALABILITY**

__Doug Marsh__[1], Adrian Stacey[2], SinYee Yau-Rose[2], Jochen Scholz[3], Steve Warr[1], Gary Finka[1]

[1]BPR, GSK, Stevenage, [2]Sartorius Stedim Biotech GmbH, Royston, United Kingdom, [3]Sartorius Stedim Biotech GmbH, Goettingen, Germany

12.25-12.30 **POSTER SPOTLIGHT – P-435 PROCESS-INDUCED CELL-CYCLE SYNCHRONIZATION**

__Johannes Möller__[1], Krathika Bhat[1], Ralf Pörtner[1], An-Ping Zeng[1], Uwe Jandt[1]

[1]Institute of Bioprocess and Biosystems Engineering, Hamburg University of Technology, Hamburg, Germany

12.30-13.30 LUNCH

13.30-15.00 **POSTER SESSION 1 AND COFFEE**

Presentation of odd number posters

15.00-16.30 **SESSION 4: USE OF VIRAL- AND NON-VIRAL VECTORS FOR GENERATING NEW THERAPEUTIC PRODUCTS AND VACCINES**

Chairpersons: Scott Estes and Anne B. Tolstrup

15.00-15.25 **O-013 DEVELOPING PRODUCTIVE AND SCALABLE LENTIVIRAL VECTOR PRODUCTION PROCESSES**

__Lesley Chan__, Vector Process Development, bluebird bio, USA

15.25-15.45 **O-014 ACCELERATED DEVELOPMENT OF PRODUCER CELL LINES FOR LV PRODUCTION**

Joana S Boura[1], *Laura JE Pearson*[1], *Louis Frost*[1], *Radmila Todoric*[1], *Alasdair Hood*[1], *Laura Dunne*[1], *Kyriacos A Mitrophanous*[1], *Hannah J Stewart*[1]
[1]*Oxford BioMedica, Oxford, United Kingdom*

15.45-16.05 **O-015 HT OPTIMISATION OF SCALABLE TRANSFECTION CONDITIONS FOR AAV PRODUCTION**

Bethany Kerr[1], *Helen Young*[1], *Grace Young*[1], *Sam Stephen*[1], *Natasha Lethbridge*[1], *Kevin Bowes*[2], *Vera Lukashchuk*[2], *George Prout*[2], *Philip Probert*[1]
[1]*CPI, Darlington,* [2]*Cobra Biologics, Keele, United Kingdom*

16.05-16.25 **O-016 ENABLING GENE AND CELL THERAPY: LENTIVIRAL VECTOR & CELL ENGINEERING**

Hélio Tomás[1 2], *Ana Filipa Rodrigues*[1 2], *Ana Sofia Formas-Oliveira*[1 2], *Tiago Vaz*[1 2], *Mariana V Ferreira*[1 2], *Elisa T Cabral*[1 2], *Rodrigo Nogueira*[1 2], *Manuel JT Carrondo*[1], ***Ana Sofia Coroadinha***[1 2 3]
[1]*iBET, Instituto de Biologia Experimental e Tecnológica,* [2]*Instituto de Tecnologia Química e Biológica António Xavier, Universidade Nova de Lisboa, Oeiras,* [3]*The Discoveries Centre for Regenerative and Precision Medicine, NOVA University Lisbon, Lisboa, Portugal*

16.25-16.30 **POSTER SPOTLIGHT – P-206 UNDERSTANDING VIRUS-LIKE PARTICLE (VLP) GENERATION IN HEK 293 CULTURES**

Irene González-Domínguez[1], *Eduard Puente-Massaguer*[1], *Laura Cervera*[1], *Francesc Gòdia*[1]
[1]*Departament d'Enginyeria Química Biològica i Ambiental, Universitat Autònoma de Barcelona, Barcelona, Spain*

16.30-17.00 **COFFEE BREAK**

17.00-17.30 **SESSION 5: USE OF VIRAL- AND NON-VIRAL VECTORS FOR GENERATING NEW THERAPEUTIC PRODUCTS AND VACCINES**

Chairpersons: Scott Estes and Anne B. Tolstrup

17.00-17.05 **POSTER SPOTLIGHT – P-223 A NOVEL TYPE OF DEFECTIVE INTERFERING PARTICLE FOR ANTIVIRAL THERAPY**

Marc Hein[1], *Sascha Young Kupke*[1], *Dietmar Riedel*[2], *Timo Frensing*[1 3], *Pawel Zmora*[1], *Udo Reichl*[1 3]
[1]*Bioprocess Engineering, Max Planck Institute for Dynamics of Complex Technical Systems, Magdeburg,*
[2]*Facility for Transmission Electron Microscopy, Max Planck Institute for Biophysical Chemistry, Goettingen,*
[3]*Chair of Bioprocess Engineering, Otto von Guericke University, Magdeburg, Germany*

17.05-17.30 **O-017 STRATEGIC PROCESS DEVELOPMENT ADDRESSING THE CHALLENGES AND OPPORTUNITIES IN BRINGING ADVANCED THERAPEUTICS TO MARKET**

Robert A. Baffi, *BioMarin, CA, USA*

17.30-18.30 **O-018 KEYNOTE LECTURE 1:**

Chairpersons: Paula M Alves and Mikael Rørdam Andersen

BOTTOM-UP AND TOP-DOWN ENGINEERING OF STEM CELLS FATE FOR DISCOVERY AND THERAPY

Peter W Zandstra, *University of British Columbia, Canada*

18.30-20.00 **POSTER SESSION 2 AND DRINKS**

TUESDAY 7TH MAY 2019

09.00-10.30 **SESSION 6: CELL CULTURE PROCESS ENGINEERING, PRODUCT QUALITY AND INTEGRATION WITH DOWNSTREAM PROCESSING**

Chairpersons: Alan Dickson and Thomas Ryll

Sponsored by Fujifilm Irvine Scientific

09.00-09.30 **O-019 HAPPY TOGETHER: THE BENEFITS AND APPLICATION OF A FULLY INTEGRATED BIOPROCESS**

Jeff Salm[1], *Raquel Orozco*[3], *Robert Kottmeier*[2], *Scott Godfrey*[3], *Jon Coffman*[3], *Rob Fahrner*[2], *Greg Hiller*[1]

[1]Bioprocess R&D, Pfizer, Andover, MA, USA. [2]Bioprocess R&D, Pfizer, Chesterfield, MO, USA. [3]Process Science, Boehringer Ingelheim, Fremont, CA, USA

09.30-09.35 **POSTER SPOTLIGHT – P-502 APPLICATION OF 2-COMPARTMENT SYSTEM TO STUDY LARGE-SCALE HETEROGENEITY**

Katrin Paul [1], *Bernd Mitic* [1], *Georg Scherfler* [1], *Christoph Herwig* [1]

[1]Institute of Chemical Engineering, TU Wien, Vienna, Austria

09.35-09.40 **POSTER SPOTLIGHT – P-602 ARE YOU FEEDING MORE CELLS THAN YOU THINK?**

Jana Mahadevan [1], *Delia Lyons* [1]

[1]MilliporeSigma, St. Louis, United States

09.40-09.45 **POSTER SPOTLIGHT – P-543 CELL CULTURE PROCESS PARAMETERS FOR MODULATING MAB AFUCOSYLATION**

Inn Yuk, Genentech, *South San Francisco, United States*

09.45-09.50 **POSTER SPOTLIGHT – P-517 ACCOUNTING ENZYME REGULATION IN PROTEIN GLYCOSYLATION MODELS**

Pavlos Kotidis [1], *Ioscani Jimenez del Val* [2], *Cleo Kontoravdi* [1]

[1]Chemical Engineering, Imperial College London, London, United Kingdom, [2]Chemical & Bioprocess Engineering , University College Dublin, Dublin, Ireland

09.50-10.10 **O-020 HIGH-DENSITY PERFUSION: IMPROVEMENTS IN PRODUCTIVITY & PRODUCT QUALITY**

Natalia Gomez [1], *Jonathan Lull* [1], *Sherry Yang* [1], *Yan Wang* [2], *Xin Zhang* [1], *Agatha Wieczorek* [1], *Haly Raharimampionona* [2], *Mike Pritchard* [1], *Diandra Martinez Cano* [1], *Michael Shearer* [1], *Chetan Goudar* [1]

[1]Amgen, Thousand Oaks, [2]Amgen, Cambridge, United States

10.10-10.30 **O-021 MAGNETIC BEAD PURIFICATION OF MAB FROM CHO CELL BROTH AT PILOT SCALE**

Nils Brechmann [1 2], *Per-Olov Eriksson* [3], *Kristofer Eriksson* [4], *Sven Oscarsson* [5], *Jos Buijs* [6], *Atefeh Shokri* [1 2], *Göran Hjälm* [1], *Véronique Chotteau* [1 2]

[1]AdBIOPRO, VINNOVA Competence Centre for Advanced BioProduction by Continuous Processing, [2]Cell Technology Group (CETEG), Dept. of Industrial Biotechnology, School of Engineering Sciences in Chemistry, Biotechnology and Health, KTH Royal Institute of Technology, Stockholm, [3]PE Bioprocess Consulting AB, Strängnäs, [4]Lab-on-a-Bead AB, Uppsala, [5]Dept. of Organic Chemistry, Stockholm University, Stockholm, [6]Dept. of Immunology, Genetics and Pathology, Uppsala University, Uppsala,

10.30-11.00 **COFFEE BREAK**

11.00-12.30 **SESSION 7: DEVELOPMENT OF CELL-BASED TECHNOLOGIES AND THERAPEUTICS**

Chairpersons: Malin Parmar and Paulo Fernandes (ESACT Frontiers)

Sponsored by Kerry

11.00-11.30 **O-022 BIOLOGY INSPIRED CELL THERAPY MANUFACTURING**

Nick Timmins, *BlueRock Therapeutics, USA*

11.30-11.50 **O-023 A FLEXIBLE 3D HUMAN HEPATIC CELL PLATFORM FOR MALARIA DRUG DISCOVERY**

Francisca Arez [1], *Sofia Rebelo* [1], *Diana Fontinha* [2], *Daniel Simão* [1], *Marta Machado* [2], *Tatiana Martins* [1], *Christoph Fischli* [3], *Claude Oeuvray* [4], *Manuel Carrondo* [1], *Matthias Rottmann* [3], *Thomas Spangenberg* [4], ***Catarina Brito*** [1], *Beatrice Greco* [4], *Miguel Prudêncio* [2], *Paula Alves* [1]

[1]*iBET, Instituto de Biologia Experimental e Tecnológica e Instituto de Tecnologia Química e Biológica António Xavier, Universidade Nova de Lisboa, Oeiras,* [2]*Instituto de Medicina Molecular João Lobo Antunes, Faculdade de Medicina, Universidade de Lisboa, Lisbon, Portugal,* [3]*Swiss TPH and University of Basel, Basel, Switzerland,* [4]*Merck Global Health Institute, Ares Trading S.A., Route de La Verrerie 6, CH-1267, Coinsins, Switzerland, a subsidiary of Merck KGaA, Darmstadt, Germany*

11.50-12.10 **O-024 ENGINEERING OF EXOSOMES FOR TARGETED DELIVERY OF THERAPEUTIC MICRO-RNAS**

Nikolas Zeh [1], *Helga Schneider* [1], *Benjamin Weis* [1], *Silke Wissing* [2], *Nicole Faust* [2], *Nicola Strempel* [2], *Kerstin Otte* [1]

[1]*University of Applied Sciences Biberach,* [2]*CEVEC Pharmaceuticals*

12.10-12.15 **POSTER SPOTLIGHT – P-327 BONE-MARROW EXPANDED MESENCHYMAL STROMAL CELLS FOR BONE GENERATION**

Joaquim Vives [1], *Ruth Coll* [2], *Núria Ribó* [2], *Luciano Rodríguez* [1], *Joan Garcia* [1]

[1]*Banc de Sang i Teixits, Barcelona, Spain,* [2]*Clinical Development, Banc de Sang i Teixits, Barcelona, Spain*

12.15-12.20 **POSTER SPOTLIGHT – P-308 GLYCOSYLATION VS RECEPTOR AFFINITY TO IMPROVE IFN4N ANTITUMOR ACTIVITY**

Agustina Gugliotta [1], *Natalia Ceaglio* [1], *Ricardo Kratje* [1], *Marcos Oggero* [1]

[1]*Centro Biotecnológico del Litoral. Facultad de Bioquímica y Ciencias Biológicas, Universidad Nacional del Litoral, Santa Fe, Argentina*

12.20-12.25 **POSTER SPOTLIGHT – P-342 INDUSTRIALIZING IMMUNO-ONCOLOGY THERAPEUTIC DISCOVERY PLATFORMS**

Betina Ricci [1], *Guido Capuccilli* [1], *Carl Bruder* [1], *Lukasz Gricman* [1], *Chris Smith* [2], *Karine Maillard* [3], *Yang-Chieh Chou* [4], ***Christoph Freiberg*** [1,]

[1]*Biologics, GENEDATA, Basel, Switzerland,* [2]*Biologics, GENEDATA, Boston, United States,* [3]*Biologics, GENEDATA, London, United Kingdom,* [4]*Biologics, GENEDATA, San Francisco, United States*

12.25-12.30 **POSTER SPOTLIGHT – P-339 EVALUATION OF HMSC-DERIVED EXTRACELLULAR VESICLES BY FTIR SPECTROSCOPY**

Maria Pereira [1], *Luís Ramalhete* [2], *Sandra Aleixo* [2], *Cláudia Lobato da Silva* [1 3], *Joaquim M.S. Cabral* [1 3], *Cecília Calado* [2], ***Ana Fernandes-Platzgummer*** [1 3]

[1]*Department of Bioengineering and iBB – Institute for Bioengineering and Biosciences, Instituto Superior Técnico, Universidade de Lisboa,* [2]*ISEL-Instituto Superior de Engenharia de Lisboa, Instituto Politécnico de Lisboa,* [3]*The Discoveries Center for Regenerative and Precision Medicine, Lisbon Campus, Instituto Superior Técnico, Universidade de Lisboa, Lisboa, Portugal*

12.30-14.00 **LUNCH AND ESACT GENERAL ASSEMBLY**

14.00-15.30 **POSTER SESSION 3 AND COFFEE**

Presentation of even number posters

15.30-22.00 **OUTING TO COPENHAGEN**

WEDNESDAY 8TH MAY 2019

09.00-10.30 **SESSSION 8: CELL CULTURE PROCESS CONTROLS AND ANALYTICS**
Chairpersons: Matthieu Stettler and Emma Petiot (ESACT Frontiers)
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09.00-09.30 **O-025 DEVELOPMENT AND APPLICATION OF A MASS SPECTROMETRY BASED MULTI-ATTRIBUTE METHOD FOR PROTEIN THERAPEUTICS**
***Jette Wypych**, Amgen, USA*

09.30-09.50 **O-026 INTEGRATION OF PAT WITH INTENSIFIED PERFUSION PLATFORM DEVELOPMENT**
***Shawn Barrett**, Sanofi, Framingham, United States*

09.50-10.10 **O-027 BRINGING ART CLOSER TO SCIENCE: A QUALIFIED CART IDENTITY ASSAY**
*Stephie Leung[1], Betty Fan[2], Danylo Sirskyj[1], Spencer Hoover[2], **Jessica Schwaber**[2]*
[1]GE Healthcare Fast Trak Toronto , [2]CCRM, Toronto, Canada

10.10-10.30 **O-028 CUSTOMISED PROCESS MODELS FOR CELL CULTURE PROCESSES**
***Harini Narayanan**[1] Michael Sokolov[1 2], Alessandro Butté[1 2], Massimo Morbidelli[1 2]*
[1]Institute of Chemical and Bioengineering, ETH Zurich, [2]DataHow AG, Zurich, Switzerland

10.30-11.00 **COFFEE BREAK**

11.00-12.30 **SESSION 9: DEVELOPMENT OF CELL-BASED TECHNOLOGIES AND THERAPEUTICS**
Chairpersons: Paula M Alves and Malin Parmar
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11.00-11.30 **O-029 CELL & VIRAL THERAPIES AND THE PROMISE TO SOLVE CURRENT MANUFACTURING CHALLENGES?**
***Uwe Gottschalk**, Lonza AG, Switzerland*

11.30-11.50 **O-030 A 3D KSHV LATENCY MODEL FOR IDENTIFICATION OF ANTIVIRAL COMPOUNDS**
*Tatyana Dubich[1], Anne Dittrich[1], Christoph Lipps[1], Tobias May[2], Marc Stadler[1], Thomas Schulz[3], **Dagmar Wirth**[1]*
[1]HELMHOLTZ CENTRE FOR INFECTION RESEARCH, [2]Inscreenex GmbH, Braunschweig, [3]Hannover Medical School, Hannover, Germany

11.50-12.10 **O-031 BONE BY DESIGN – VIA BIOASSEMBLIES OF CARTILAGE MICROTISSUE MODULES**
*Gabriella Nilsson Hall[1 2], Luis Mendes[1 2], Geris Liesbet[2 3], Frank Luyten[1 2], **Ioannis Papantoniou**[1 2]*
[1]Skeletal Biology and Engineering Research Centre, [2]Prometheus the division of Skeletal Tissue Engineering, KU Leuven, Leuven, [3]Biomechanics Research Unit, Université de Liège, Liège, Belgium

12.10-12.20 **O-032 MAPPING STRUCTURE AND BIOLOGICAL FUNCTIONS WITHIN MESENCHYMAL BODIES**
***Sebastien Sart**[1], Raphael Tomasi[1], Antoine Barizien[1], Gabriel Amselem[2], Ana Cumano[3], Charles Baroud[1]*
[1]Physical Microfluidics and Bioengineering, Institut Pasteur, Paris, [2]Laboratory of Hydrodynamics, Ecole Polytechnique, Palaiseau, [3]Laboratory for Lymphopoiesis, Institut Pasteur, Paris, France

12.20-12.30 **O-033** **IN VITRO MODELS TO DISCLOSE HUMAN CARDIAC PROGENITOR CELLS ACTION MODE**

Maria J. Sebastião [1 2], *Ivo Reis* [1 2], *Itziar Palacios* [3], *Margarida Serra* [1 2], *Patrícia Gomes-Alves* [1 2], *Paula M Alves* [1 2]

[1]iBET, Instituto de Biologia Experimental e Tecnológica, [2]ITQB-NOVA, Instituto de Tecnologia Química e Biológica António Xavier, Universidade Nova de Lisboa, Oeiras, Portugal, [3]Coretherapix, S.L.U. (Tigenix Group, Takeda), Tres Cantos, Spain

12.30-13.45 **LUNCH**

13.45-15.15 **SESSION 10: CELL CULTURE PROCESS ENGINEERING, PRODUCT QUALITY AND INTEGRATION WITH DOWNSTREAM PROCESSING**

Chairpersons: Thomas Ryll and Alan Dickson

Sponsored by Fujifilm Irvine Scientific

13.45-14.15 **O-034** **MAKE PERFUSION GREAT AGAIN**

Jean-Marc Bielser, *Merck Group, Lausanne, Switzerland*

14.15-14.35 **O-035** **CONTINUOUS PROCESSING USING A CHEMOSTAT CULTURE**

Sarwat Khattak [1], *Valerie Pferdeort* [1], *Tim Brantley* [1], *Kelly Wiltberger* [1], *Rashmi Kshirsagar* [2]

[1]Cell Culture Development, Biogen, RTP, [2]Cell Culture Development, Biogen, Cambridge, United States

14.35-14.55 **O-036** **INVESTIGATION OF MEDIA COMPONENTS ON PERFORMANCE OF CHO CELL CULTURES**

Ricardo Suarez Heredia [1 2], *Alexandros Kiparissides* [1 2]

[1]Advanced Centre for Biochemical Engineering, [2]Centre for Process Systems Engineering , University College London (UCL), London, United Kingdom

14.55-15.15 **O-037** **OPTIMIZING CHO CELL CULTURE PROCESSES USING PREDICTIVE DIGITAL TWINS**

Jakob Kirch [1], *Matthias Bohner* [1], *Kathrin Guenther* [1], *Manuel Ruff* [1], *Joachim Schmid* [1], *Shilpa Nargund* [1]

[1]Insilico Biotechnology AG, Stuttgart, Germany

15.15-15.30 **SHORT COFFEE BREAK**

15.30-16.30 **O-038** **KEYNOTE LECTURE 2:**

Chairpersons: Mike Betenbaugh and Helene Faustrup Kildegaard

THE HUMAN SECRETOME PROJECT – GENERATION OF ALL HUMAN SECRETED PROTEINS IN MAMMALIAN CELL CULTURES

Mathias Uhlen, *Science for Life Lab, Karolinska Institute and Royal Institute of Technology, Stockholm, Sweden.*

16.30-17.00 **ESACT2019 CLOSING SESSION**

ESACT Chairperson Mikael Rørdam Andersen

Poster Committee Chairs: Ricardo Valdes-Bango Curell, ESACT Frontiers and Nuša Pristovšek

17.30-19.00 **TRANSFER TO CONGRESS DINNER**

19.00-00.00 **CONGRESS DINNER AT LANGELINIE PAVILLION**

SPEAKER ABSTRACTS ORAL COMMUNICATIONS

O-001 THE INAUGURAL INNOVATION AWARD LECTURE CELL ENGINEERING – A SMALL STEP FOR THE BIOTECHNOLOGIST, A LEAP FOR THE APPLICATION?

Volker Sandig, *ProBioGen, Berlin, Germany*

During this lecture we will show and discuss how precise cell engineering steps targeting individual pathways can lead to new platforms with desired and planned but sometimes unexpected features that have implications for the products produced: a modified vaccine virus, an antibody with enhanced potency or simply higher yields.

O-002 MAMMALIAN SYNTHETIC BIOLOGY: FOUNDATION AND THERAPEUTIC APPLICATIONS

Ron Weiss

Massachusetts Institute of Technology, Cambridge, MA, USA

Synthetic biology is revolutionizing how we conceptualize and approach the engineering of biological systems. Recent advances in the field are allowing us to expand beyond the construction and analysis of small gene networks towards the implementation of complex multicellular systems with a variety of applications. In this talk I will describe our integrated computational / experimental approach to engineering complex behavior in a variety of cells, with a focus on mammalian cells. In our research, we appropriate design principles from electrical engineering and other established fields. These principles include abstraction, standardization, modularity, and computer aided design. But we also spend considerable effort towards understanding what makes synthetic biology different from all other existing engineering disciplines and discovering new design and construction rules that are effective for this unique discipline. We will briefly describe the implementation of genetic circuits and modules with finely-tuned digital and analog behavior and the use of artificial cell-cell communication to coordinate the behavior of cell populations. The first system to be presented is a multi-input genetic circuit that can detect and destroy specific cancer cells based on the presence or absence of specific biomarkers in the cell. We will also discuss preliminary experimental results for obtaining precise spatiotemporal control over stem cell differentiation for tissue engineering applications. We present a novel approach for generating and then co-differentiating hiPSC-derived progenitors with a genetically engineered pulse of GATA-binding protein 6 (GATA6) expression. We initiate rapid emergence of all three germ layers as a combined function of GATA6 expression levels and tissue context. We ultimately obtain a complex tissue that recapitulates early developmental processes and exhibits a liver bud-like phenotype that includes haematopoietic and stromal cells, as well as a neuronal niche. This complex organoid can be used for drug development and potentially for tissue transplantation.

O-003 A NEWLY IDENTIFIED SMALL RNA REGULATES NGNA SIALYLATION IN CHO CELLS

Simon Fischer *[1], *, Anna Wippermann [2], Shumin Yang [3], Sven Mathias [4], Patrick Richter [2], Julia van der Meer [5], Eike Zimmermann [6], Ingo Gorr [2], Martin Gamer [2], Harald Bradl [7]*

[1]BPAD Cell Line Development, [2]Early Stage Bioprocess Development, Boehringer Ingelheim Pharma GmbH & Co.KG, Biberach an der Riss, Germany, [3]Process Science BIFI, Boehringer Ingelheim Fremont Inc., Fremont, CA, United States, [4]Institute of Applied Biotechnology, University of Applied Sciences Biberach, Biberach an der Riss, Germany, [5]Genedata AG, Basel, Switzerland, [6]Analytical Sciences BIFI, Boehringer Ingelheim Fremont Inc., Fremont, CA, United States, [7]BPAD Cell Culture Development, Boehringer Ingelheim Pharma GmbH & Co.KG, Biberach an der Riss, Germany

Background and novelty: MAbs produced in CHO cells exhibit complex N-glycan patterns with only very little sialylation. Two different forms of sialic acids (NANA & NGNA) are found on glycoproteins produced in mammalian cells. Elevated levels of NGNA sialylation are immunogenic in humans thus making it a critical product quality attribute. Although CHO cells are reported to produce mAbs with <<5% NGNA we recently identified CHO cells capable of generating mAbs with >33% NGNA. Consequently, we started an in-depth characterization to identify the root cause for this atypical sialylation.

** Presenting Author*

Experimental approach: Two CHO cell lines producing the same mAb but with different NGNA sialylation levels were analyzed using DNA and (small) RNA deep sequencing to study changes in cell phenotypes. (Novel) regulatory RNAs and putative target genes were discovered followed by experimental validation. Small RNA transfections and genome editing experiments with subsequent sialylation analysis were carried out to examine the regulatory role of a newly identified small non-coding RNA (ncRNA) in CHO cells.

Results and discussion: Differential gene expression analysis revealed that the CMAH gene was highly expressed in the CHO cell line that exhibited increased NGNA levels, although CMAH was previously reported not to be expressed in CHO. A novel CHO-specific small ncRNA was discovered that exhibits a miRNA-like binding site on the CMAH mRNA and whose expression was completely lost in the cell line showing high NGNA levels. Enhanced NGNA levels correlated with increased CMAH and decreased ncRNA expression levels. Transfection of the novel ncRNA resulted in reduced NGNA levels. Specific genetic alterations were unraveled, which eventually contributed to the loss of the ncRNA, providing new unpublished insights into the regulation of NGNA sialylation in CHO cells. In conclusion, our study shows that genetic changes having profound impact on product quality can spontaneously occur in CHO cells.

O-004 CHARACTERIZATION AND INACTIVATION OF ENDOGENOUS RETROVIRUSES IN CHO

Pierre-Olivier Duroy *[1,*], Sandra Bosshard [1], Emanuel Schmid-Siegert [2], Samuel Neuenschwander [2], Ghislaine Arib [3], Philippe Lemercier [4], Flavien Buron [1], Jacqueline Masternak [1], Pierre-Alain Girod [3], Ioannis Xenarios [5], Nicolas Mermod [1]*

[1]LBTM, Université de Lausanne, [2]Vital-it, Swiss Institute of Bioinformatic, Lausanne, [3]Selexis SA, [4]Swiss-prot, Swiss Institute of Bioinformatic, Geneva, [5]Université de Lausanne, Lausanne, Switzerland

Background and novelty: Chinese hamster ovary (CHO) cells are the most commonly used protein production cell host for biopharmaceuticals. These cells are known to have budding type-C endogenous retroviruses (ERVs) embedded in their genome and to release retroviral-like particles in the culture supernatant. Although evidence for the infectivity of these particles is missing, their presence has raised safety concerns.

Experimental approach: As the genomic origin of these particles remains unclear, we systematically characterized the type-C ERV elements at the genome, transcriptome and viral particle level. After we used CRISPR-Cas9 genome editing in order to disrupted the gag gene of the expressed ERV group.

Results and discussion: We identified 173 type-C ERV sequences that clustered into two functionally conserved groups. Interestingly, transcripts from only one type-C ERV group were full-length with intact open reading frames, and corresponding viral RNA genomes were loaded into retroviral-like particles, suggesting that this group may produce functional viruses. Sequence analysis of the genomic RNA from viral particles indicated that it may result from few expressed ERV sequences.

Analysis of our CRISPR edited CHO-K1 clones mutations at the DNA and mRNA level led to the identification of a single ERV locus responsible for the release of viral RNA-loaded particles from CHO cells. Clones bearing a Gag loss-of-function mutation in this particular ERV locus showed a reduction of viral RNA-containing particles in the cell supernatant by over 250-fold. Notably, ERV mutagenesis did not compromise cell growth, cell size or recombinant protein production. Overall, our study highlights a new strategy to mitigate potential contaminations from CHO endogenous retroviruses during biopharmaceutical manufacturing.

Acknowledgements & Funding: This work was supported by a grant from the Swiss Government. Commission for Technology and Innovation, Selexis SA and by the University of Lausanne.

References: N. Mermod, P-O. Duroy, S. Bosshard, P. Le Mercier. Improved eukaryo-c cells for protein manufacturing and methods of making them. Patent WO 2017109177; June 29, 2017.

[*] Presenting Author

O-005 AN INNOVATIVE CRISPR/ASCPF1 SCREEN IN CHO CELLS

*Valerie Schmieder [1 2], **Neža Novak [1 2]**, Heena Dhiman [1 2], Martina Baumann [1], *, Gerald Klanert [1], Nicole Borth [2]*

[1]Austrian Centre of Industrial Biotechnology (ACIB), [2]University of Natural Resources and Life Sciences, Vienna, Austria

Background and novelty: Genetic studies are mainly focused on protein-coding genes, which make up around 3% of the mammalian genome. However, untranslated genes like long-non-coding RNA (lncRNA) also have an important role in the regulation of cellular processes that can have an enormous impact on the phenotype of cells. In order to investigate the link between genome and phenotype we here present the first functional CRISPR-mediated screening approach in CHO cells that is not based on frameshifts, but uses full deletion of genomic regions.

Experimental approach: A small-scale CRISPR/AsCpf1 deletion screen was performed targeting 500 lncRNAs found to be differentially expressed during batch cultivation, as well as 45 coding genes related to growth or productivity. Per target gene four different AsCpf1 paired single-guide RNAs (pgRNAs) were designed using an in-house developed in silico pipeline. The pgRNA library was then delivered into CHO cells via recombinase mediated cassette exchange, ensuring a single, unique pgRNA per cell. After introduction of AsCpf1, the cell pools were screened for effects of the genomic deletions on growth and productivity. The pgRNAs present after two sequential batch cultivations were PCR amplified and sent for next-generation sequencing to identify changes in pgRNA abundance.

Results and discussion: We successfully established and evaluated an in silico pipeline for the computational high-throughput design of pgRNAs guiding CRISPR/AsCpf1. Using this tool, a library of 2348 pgRNA sequences was generated and screened for effects on growth and productivity in CHO. Bioinformatical comparison of pgRNA representation of AsCpf1 versus Cas9 treated cells (as the non-targeting control) identified depleted targets genes, which were then knocked out from the genome individually to validate their effect on the phenotype. The here presented screening strategy was demonstrated for a small-scale deletion approach, but opens up the opportunity to study the entire CHO genome.

O-006 OMICS FOR HIGH CELL DENSITY AND SHEAR STRESS IN PERFUSION PROCESSES

***Veronique Chotteau [1 2]**, *, Caijuan Zhan [1 2], Gholamreza Bidkhori [3], Magnus Lundqvist [4], Leila Zamani [5], Hubert Schwarz [1 2], Ye Zhang [1 2], Magdalena Malm [1 4,] Aman Mebrahtu [4], Adil Mardinoglu [3], Christopher Sellick [6], Richard Turner [6], Diane Hatton [6], Raymond Field [6], Paul Varley [6], Johan Rockberg [4 7]*

[1]Wallenberg Centre for Protein Research, [2]Industrial Biotechnology – AdBIOPRO , Centre for Advanced Bioproduction by Continuous Processing, [3]Science for Life Laboratory, [4]Protein Science, [5]Industrial Biotechnology, KTH, Stockholm, Sweden, [6]Biopharmaceutical Development, MedImmune, Cambridge, United Kingdom, [7]Wallenberg Centre for Protein Research, KTH, Stokholm, Sweden

Background and novelty: Omics has the potential to reveal features pertinent for process development however this is still largely unexplored for perfusion processes. Understanding the effects of very high density and shear stress from the cell separation device is important for the intensification of these processes.

Experimental approach: – Proteomics and metabolomics were applied to explore cell biology changes from 10 to ≥ 200 x 106CHO cells/mL.

– The effect of shear stress from Alternating Tangential Flow Filtration (ATF) and Tangential Flow Filtration (TFF) at various flow rates were studied by transcriptomics in cultures of HEK293 cells expressing EPO.

Results and discussion: The extracellular proteome and metabolome from low and very high CHO cell densities showed highly consistent profiles. The proteomics data showed however an increase of structural proteins (e.g. cytoskeleton) with increasing cell density, associated with shear stress, explaining the cell diameter decrease observed at very high cell density [1]. Oxidative stress and changes in the glutathione metabolism were also observed at very high cell densities. Applying the CHO cell perfusion process to HEK293 cells revealed a higher sensitivity of these latter, leading us to study the shear stress caused by ATF and TFF by transcriptomics. Theoretical and experimental data showed that the average shear stress for ATF was 0.64 lower than for TFF. Among others, high shear caused cellular stress of cytoskeleton proteins and oxidative stress in HEK293 cells as observed for CHO cells. Surprisingly moderate shear stress had favorable effects on the cells such as increased transcription, protein phosphorylation and expression of EPO by recombinant HEK293 cells.

[*] Presenting Author

Acknowledgements & Funding: This work was funded by the Wallenberg Centre for Protein Research (Knut and Alice Wallenberg Foundation) and AstraZeneca-MedImmune.

References: [1] Zamani L, Lundqvist M, Zhang Y, Aberg M, Edfors F, Bidkhori G, Lindahl A, Mie A, Mardinoglu A, Field R, Turner R, Rockberg J, Chotteau V, 'High cell density perfusion culture has a maintained exoproteome and metabolome', 2018, Biotechnology Journal, 13:1800036

O-007 CHARACTERISATION OF BOTTLENECKS IN CURRENT CHO PRODUCTION CELL LINES

Sven Mathias* [1],, *Simon Fischer* [2], *Anna Wippermann* [2], *René Handrick* [1], *Patrick Schulz* [2], *Martin Gamer* [2], *Kerstin Otte* [1]

[1]Institute of Applied Biotechnology, University of Applied Sciences Biberach, [2]Boehringer Ingelheim Pharma GmbH & Co KG, Biberach, Germany

Background and novelty: The optimisation of production processes for therapeutic antibodies is a continuing challenge. Additionally, with the advance of more complex biological formats mammalian expression systems often show low performance. As a consequence, there is an urgent need to overcome any rate limiting step. Therefore, after having identified massive intracellular protein accumulation in various industrial production cells using fluorescence microscopy a detailed molecular characterization of the bottleneck was performed. The mechanistic understanding will facilitate rational approaches to overcome cellular production bottlenecks.

Experimental approach: The identified molecular bottleneck of intracellular protein accumulation in the early secretory pathway was characterized using electron microscopy, biochemical and transcriptomic analyses to address intracellular aggregation, inefficient antibody assembly and cellular adaptation processes. Further, antibody N-glycans were investigated to analyse appropriate processing and co-immunoprecipitation was used to identify proteins which are differentially bound to the investigated antibodies.

Results and discussion: The endoplasmic reticulum (ER) was identified to show massive protein accumulation hampering sufficient protein secretion. N-glycan analysis of the intracellular antibody identified trimmed high mannose glycans indicating partial degradation of the antibody. Whereas further detailed analyses excluded aggregation and antibody assembly to represent the rate limiting step, a variety of proteins were identified to bind differentially to the antibody. These data point towards domain folding to be the rate limiting step, which paves the way for cell line engineering using an specific array of differentially binding proteins to release secretion bottlenecks of difficult-to-express molecules, a regular phenotype easily identified by confocal or even high-throughput fluorescence microscopy.

O-008 SYSTEMATIC EVALUATION OF SITE-SPECIFIC RECOMBINANT GENE EXPRESSION

Nuša Pristovšek* [1],, *Saranya Nallapareddy* [1], *Lise Marie Grav* [1], *Hooman Hefzi* [2,3], *Nathan E. Lewis* [2,3], *Peter Rugbjerg* [1], *Henning Gram Hansen* [1], *Gyun Min Lee* [1,4], *Mikael Rørdam Andersen* [5], *Helene Faustrup Kildegaard* [1]

[1]The Novo Nordisk Foundation Center for Biosustainability, Technical University of Denmark, Kgs. Lyngby, Denmark, [2]Departments of Pediatrics and Bioengineering, [3]The Novo Nordisk Foundation Center for Biosustainability, University of California, San Diego, San Diego, United States, [4]Department of Biological Sciences, KAIST, Daejeon, Korea, Republic Of, [5]Department of Biotechnology and Biomedicine, Technical University of Denmark, Kgs. Lyngby, Denmark

Background and novelty: Many branches of biology depend on stable and predictable recombinant gene expression, that has been achieved in the recent years through targeted integration of the recombinant gene into defined integration sites. However, transcriptional levels of recombinant genes in characterized integration sites are controlled by multiple components of the integrated expression cassette. Lack of readily available tools has inhibited meaningful experimental investigation of the interplay between the integration site and the expression cassette. Such tools would provide an excellent opportunity for the generation of cell lines with predictable and desired recombinant gene expression.

Experimental approach: Here, we developed a CRISPR/Cas9-based toolbox that allows the construction of CHO cell lines with a site-specifically integrated landing pad comprising of a recombinant gene under defined 5′ proximal regulatory elements. Several expression cassettes were then recombined into the site-specifically integrated landing pad of an isogenic cell line using recombinase-mediated cassette exchange. We explored four different

** Presenting Author*

layers contributing to the final recombinant expression level, namely clonal background, chromosomal context, vector design, and type of recombinant protein by studying different parental clones, integration sites, 5' proximal regulatory elements and recombinant proteins, respectively.

Results and discussion: Using the developed toolbox, we were able to systematically analyze and rank the transcriptional outputs of different expression cassettes in a site-specific manner. A wide range of site- and vector-specific expression levels was observed whereby elements have been identified, providing desirable gene expression patterns and fidelity over long-term culturing. Therefore, this approach facilitates the generation of user-defined and product-specific gene expression patterns and can pave the way toward programmable mammalian cell engineering.

O-009 OVERCOMING CELLULAR HETEROGENEITY DURING CELL LINE DEVELOPMENT

Leon Pybus [1,*], *Christopher Knowles* [1], *Ellie Hawke* [1], *Nicholas Barber* [1], *Fay Saunders* [1]

[1]Mammalian Cell Culture, Process Development, FUJIFILM Diosynth Biotechnologies, Billingham, United Kingdom

Background and novelty: Reducing time to GMP manufacture poses a challenge for CHO cell line development (CLD) workflows that attempt to strike a balance between the speed of the process and the quality of the cell line produced. In this study, we investigated approaches to optimise this balance by (i) reducing the number of cloning steps whilst maintaining a high assurance of monoclonality, (ii) screening cellular heterogeneity in a predictive high-throughput mode early in CLD, and (iii) obtaining a host cell line that inherently exhibits desirable biomanufacturing attributes.

Experimental approach: We have evaluated the utility of a novel high-throughput microfluidic screening tool and have combined its single cell imaging, productivity screening, and disposition capabilities with plate-based imaging to provide further assurance of monoclonality in an intensified CLD process. We also evaluated the ability of directed evolution strategies to yield host cell lines with improved biomanufacturing relevant phenotypes. We auditioned different strategies and identified those that lead to recombinant cell lines with improved growth and expression capabilities whilst maintaining stable production of product with acceptable product quality attributes.

Results and discussion: In this study we demonstrated how to intensify CLD timelines without comprising cell line quality. By leveraging a new host cell line and novel new technologies we boosted our mAb titres 2-fold to > 10 g/L whilst reducing our CLD timeline from 25 to 10 weeks. This effectively shifted the bottleneck in CLD from the need for multiple screening/cloning steps to one that is primarily limited by cellular doubling time.

O-010 GLOBAL AMINO ACIDS METABOLIC PROFILING IN CHO CELLS WITH 13-C LABELING

Michael Betenbaugh [1,*], *Harnish Mukesh Naik* [1], *Venkata Gayatri Dhara* [1], *Jacqueline Gonzalez* [2], *Brian McConnell* [2], *Franklin Swartzwelder* [3], *Maciek Antoniewicz* [2]

[1]Chemical & Biomolecular Engineering, Johns Hopkins University, Baltimore, [2]Chemical & Biomolecular Engineering, University of Delaware, Newark, [3]MilliporeSigma, St. Louis, United States

Background and novelty: Chinese Hamster Ovary (CHO) cells require complex media for cell growth and protein production. Amino acids are the major components of cell culture media, however, relatively little is known about the metabolism of amino acids in CHO cell cultures.

Experimental approach: Here, we applied 13C-flux analysis tools to elucidate the metabolic flow of all 20 amino acids in CHO cell batch cultures that produced IgG using two different expression systems. Custom media formulations where each medium was depleted of a specific amino acid were used. A labeled 13C variant of the depleted amino acid was then added to the medium to trace each amino acid individually. Carbon flows were tracked throughout the growth phase and changes in amino acids metabolism were quantified when cells transitioned from growth phase to stationary phase.

Results and discussion: As the cells metabolized the labeled amino acids, this resulted in a redistribution of 13C-atoms which we quantified using GC-MS for both extracellular metabolites (including lactate, amino acids, by-products from amino acids catabolism) and intracellular metabolites (including free intracellular metabolites, lipids and carbohydrates). Differences in amino acids utilization were observed for two representative CHO cell lines. We are examining metabolic flows using 13C metabolic flux analysis to quantify changes in amino acids profiles in

[*] Presenting Author

the medium. This will allow us to calculate the fraction of each amino acid that was utilized for cell growth, metabolism and protein production. This approach can be used for elucidating how amino acids are processed from both basal media and feeds by different CHO expression systems in order to enhance productivity and media formulations while simultaneously characterizing its impact on cellular physiology.

Acknowledgements & Funding: We would like to acknowledge AMBIC member companies and the NSF I/UCRC grant number 1624684 for financial support and MilliporeSigma for provision of custom media.

O-011 BEACON CLD PLATFORM, FROM SINGLE CELL PRODUCTIVITY TO SMALL BIOREACTOR

Iris Bodenmann [1,*], *Amélie Mahé* [1], *Cédric Steimer* [1], *Valérie Le Fourn* [1], *Séverine Fagète* [1], *Pierre-Alain Girod* [1]

[1] *Selexis SA, Plan-les-Ouates, Switzerland*

Background and novelty: To support a rapid drug material supply of an increased number of biotherapeutic molecules that would enter clinical trials, the cell line development (CLD) is on the critical path for development of the manufacturing process for protein production. Clone productivity and manufacturability are the dominant criterion of the clones screening procedure during cell line development. The sooner the productivity can be assessed in conditions mimicking the bioreactor process, the most predictive the clone selection will be.

Experimental approach: By use of the Beacon® device combined with advanced gene transfection technologies and procedures, the number of monoclonal high producing cell lines identified from pools could be increased substantially.

Results and discussion: Selexis' platform allows now to monitor clones' growth from single cell and simultaneously evaluate the productivity level over a few days of cultivation. The predictability of these parameters for scale up was demonstrated in different vessels, including 24 deep-well plates, shake-flasks, and mini-bioreactors using the ambr15 system. This early clone assessment of productivity already at the nano-scale significantly reduced the time and effort associated with the development of high-performance clones.

Key features to the implementation of the Beacon® device were found to be the optimization of the bulk pool and development of the prediction tools for clone selection. Altogether, stable clones producing therapeutic proteins can be generate in a mere 8 weeks.

O-012 CLOSING THE LOOP ON CELL CULTURE ANALYZER VARIABILITY

Shawn M. Lawrence [1,*], *Brandon D. Veres* [1], *Cassandra D. Murillo* [1], *Colin E. Orr* [1]

[1] *Preclinical Manufacturing and Process Development, Regeneron Pharmaceuticals, Inc., Tarrytown, NY, United States*

Background and novelty: The biopharmaceutical industry relies heavily on analytical equipment for process understanding and operation decisions. Analytical equipment has inherent variability which can result in process and even product variation. In support of this abstract, the accuracy and precision of several cell culture analyzer assays are determined. This characterization of analytical variability not only supports an understanding of overall process variability, but has been further used as the basis for corrective actions statistically designed to reduce bias variability of process inputs in real time.

Experimental approach: Quality control (QC) standards served as a reference to verify the correctness of analytical measurements whose variability has been characterized across instruments and over time through process monitoring charts. A closed loop analytical control strategy both monitors and reduces measurement bias through a statistically guided calibration procedure. Statistically driven alarms are triggered based on the magnitude of deviation from the target of the QC measurement. Correction factors in the form of a slope and intercept are calculated and applied to experimental data to reduce analytical bias.

Results and discussion: A characterization study included five offline cell culture analyzers that were located at research and development facilities and subject to routine maintenance and calibration. Results revealed that measurement bias, primarily between analyzers, accounted for over a third of the total analytical variation. Combining principles of statistical process control (SPC) and process analytical technologies (PAT), a closed loop analytical control strategy was developed and deployed within the research laboratories leading to a bias reduction closely matching the bias values from the characterization study. While demonstrated with an offline cell culture analyzer, the concept of closed loop control is applicable to all analytical equipment.

[*] *Presenting Author*

O-013 DEVELOPING PRODUCTIVE AND SCALABLE LENTIVIRAL VECTOR PRODUCTION PROCESSES

Lesley Chan, *Vector Process Development, bluebird bio, USA*

With the rapid growth of the gene therapy field, the demand for lentiviral vectors (LVV) has increased exponentially. Current LVV production methods using transient transfection are robust but will ultimately be constrained volumetrically and temporally. Alternative production processes that use stable clonal cells lines may overcome these constraints. In this talk, I will present an overview of the challenges in LVV manufacturing and general strategies that can be used to enable a multi-day, continuous and scalable lentiviral vector production process. I will share examples of how the application of new technologies, tuning of operating parameters and modification of feed strategies can increase productivity and extend production durations.

O-014 ACCELERATED DEVELOPMENT OF PRODUCER CELL LINES FOR LV PRODUCTION

Joana S Boura *[1,*], Laura JE Pearson [1], Louis Frost [1], Radmila Todoric [1], Alasdair Hood [1], Laura Dunne [1], Kyriacos A Mitrophanous [1], Hannah J Stewart [1]*

[1]Oxford BioMedica, Oxford, United Kingdom

Background and novelty: While lentiviral vectors (LV) are a very potent tool for gene and cell therapies, their large scale production for clinical applications via transient transfection remains expensive and challenging. Production of LV using producer cell lines (PCLs) is desirable due to reduced costs, improved batch consistency and a more streamlined production process. Oxford BioMedica (OXB) has previously generated adherent PCLs which have subsequently been adapted to a suspension growth mode for ease of large-scale culture systems, however this adaption step is time-consuming. In combination with OXB's high throughput Automated Cell Screening System (ACSS), we describe a new cell line development platform enabling the generation of PCLs directly in suspension with accelerated timelines.

Experimental approach: The ACSS has already been successfully used in several adherent producer and packaging cell line generation campaigns, which has led to identification of clones producing LV at equivalent or greater titre to LV produced using current transient transfection processes. Here we describe the isolation and high-throughput evaluation of more than 350 suspension PCLs clones using the ACSS. The best 62 clones were then expanded and further screened. The two best of these suspension PCLs were selected as candidates and further characterised at higher scale.

Results and discussion: Selection of the best PCLs clones from a large scale suspension PCLs ACSS campaign led to the identification of suspension PCLs capable of producing LV with higher titres than those obtained from an adherent PCL clone that had been adapted to suspension growth mode. Moreover, LV produced from the best candidate suspension PCL clone yielded titres comparable to LV produced using the current transient transfection processes.

In conclusion, OXB now has a suspension cell line development platform capable of screening hundreds of clones for LV production in a significantly accelerated time frame.

O-015 HT OPTIMISATION OF SCALABLE TRANSFECTION CONDITIONS FOR AAV PRODUCTION

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Background and novelty: The continual expansion of the gene therapy market is reliant on large quantities of virus so the scalability of transfection processes is key. AAV (recombinant adeno-associated virus) is a common gene delivery system and it is often produced in adherent cells. Small scale production in static flasks is impractical for larger titre requirements. Developing a cost effective, high yield process that works for multiple serotypes would be an effective way of meeting industry demand. Using HT (high throughput) techniques we aimed to develop an optimised process that could be transferred to an adherent reactor for larger scale production.

[*] Presenting Author

Experimental approach: Triple PEI mediated transient transfection of HEK293T cells was carried out in chemically defined media on adherent surfaces. Small scale DOE (design of experiment) screens were performed at 96 and 12 well scales before being verified in T flasks. Factors such as media type, media volume and PEI:DNA ratios were all explored before a process was finalised. The process was then ran in the iCELLis nano reactor to ensure it was scalable and reproducible. Viral titre and full vs empty capsid ratios were calculated using commercial ELISA and qPCR kits.

Results and discussion: Initial screens focused on optimising conditions to improve yield, with the largest increase being a result of changing the transfection media. Other factors such as reducing plasmid quantity gave comparable results to the original process though were further investigated due to them lowering production costs. Alternative analytical assays had to be explored during screening as challenges arose due to the assays acting as a bottleneck. Moving between 2D flask and 3D reactor systems also posed challenges as some factors were difficult to scale. By using HT methods we have succeeded in developing a base platform for scalable AAV production that in future could be used for mass virus production.

Acknowledgements & Funding: CPI, Cobra Biologics and Innovate UK

O-016 ENABLING GENE AND CELL THERAPY: LENTIVIRAL VECTOR & CELL ENGINEERING

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Background and novelty: Advanced therapy medicinal products are transforming medicine providing alternative forms of treatment to often unmet medical needs. Cell and gene therapies frequenly require delivery technologies being lentiviral vectors one of the preferred choices when permanent modification of stem and T cells is required.

The ideal manufacturing process relies on stable producer cell lines and perfusion systems, enabling high cell density and long term productions, as performed for antibody or gammaretroviral vectors. In contrast lentiviral vector manufacturing relies on transient transfections and short term batch productions. By introducing innovative cell line and vector engineering strategies we established a novel generation of stable producer cell lines.

Experimental approach: Lentiviral vectors present the challenge of containing apoptosis-leading cytotoxic proteins. To address this obstacle we either eliminated or reduced the cytotoxicity of lentiviral vector components. Strategic novelties introduced in cell line development included: i) the use of a engineered gag-pro-pol and envelopes, ii) insertion of all 4 third generation lentiviral expression cassettes by chemical transfection using stringent selection (avoiding viral transduction), and iii) reduce clone screening to one step (enabling smart screening protocols). The final producer cell lines were characterized and the culture conditions studied aiming to extend bioreaction culture.

Results and discussion: Lentiviral producer cell lines constitutively and stably producing infective titers above 106 TU.mL-1.day-1 were successfully established. Bioreaction studies show sustained vector production over 10 days. These results validate the transition to continuous large-scale production systems qualifying the strengths and advantages of the strategies followed.

This work discusses lentiviral vectors production challenges as well as, strategies and technologies enabling its effective manufacturing.

** Presenting Author*

O-017 STRATEGIC PROCESS DEVELOPMENT ADDRESSING THE CHALLENGES AND OPPORTUNITIES IN BRINGING ADVANCED THERAPEUTICS TO MARKET

Robert A. Baffi, *BioMarin, CA, USA*

In the rapidly evolving field of therapeutic development, gene therapy has emerged as a frontrunner in the treatment of monogenic diseases. At the fore of gene therapy technologies, adeno-associated virus (AAV) is an optimal vector for the delivery of missing or defective genes to individuals lacking a healthy copy. While the potential therapeutic applications for gene therapy are vast, the ability of manufacturers to consistently produce a pure and potent product may be rate-limiting. Here, the development of a strategic process for rapid development of safe and efficacious therapeutic products is discussed in the context of valoctocogene roxaparvovec, an AAV5-mediated investigational gene therapy product for patients with severe hemophilia A. Gene therapy manufacturing techniques are expanding and evolving quickly and are likely to repeatedly outpace current regulatory guidelines. Therefore, Good Manufacturing Practice and compliance with regulatory guidance documents must be ensured as a minimum performance standard. We do this by leveraging comprehensive knowledge of the Product, Impurities, Process, and Equipment (the "PIPE") to ensure consistently high-quality of known products. Product: Viral species and serotype will partially inform expression system selection (i.e., human HEK 293 versus non-human Sf9 cell-line), as well as whether an adherent or suspension-cell system is used. In vivo animal studies demonstrated comparable efficacy of valoctocogene roxaparvovec in both expression systems, but with higher density and higher-titer outputs possible in a Sf9 system with potential for large-volume scale-up to support the treatment of large patient populations. Impurities: Advanced analytical methods detect product- and process-related impurities such as the percentage of empty capsids, aggregation heterogeneity, presence of residual DNA or proteins outside of capsids, presence of novel infectious or adventitious etiologies, evidence of cytopathogenicity, and more. Process: Thorough characterization of each manufacturing step enabled incremental process improvements that reduce the introduction of impurities and enhance the removal of unwanted byproducts, yielding higher potency product and allowing greater accuracy in dosing. Equipment: In-house manufacturing with state-of-the-art equipment allowed for a nimble and adaptive manufacturing process with constant recalibration to ensure that optimized processes are performed to the highest quality, on schedule, and at reduced cost. Conclusions: A focus on Product, Impurities, Process, and Equipment has demonstrated efficacy in overcoming challenges related to the determination of quality control and characterization strategies for gene therapy products, measures of potency, purity and viral removal and inactivation.

O-018 KEYNOTE LECTURE:
BOTTOM-UP AND TOP-DOWN ENGINEERING OF STEM CELLS FATE FOR DISCOVERY AND THERAPY

Peter W Zandstra, *University of British Columbia, Canada*

Regenerative medicine (RM) offers an opportunity to address the root causes of chronic diseases, which typically result from the breakdown of tissues maintained by stem cells (SC). Our program is building the next generation of RM therapeutics – living cells and tissues designed to treat specific indications. Our vision is to understand, at a fundamental level, the mechanisms by which complex tissues develop from SC, and to use this understanding to advance new cell therapies and regenerative medicines.

Our approach is based on three complementary thrusts. First, we are developing computer simulations of normal and diseased human tissue development. These simulations allow us to connect the genetic coding inside SCs to the environment that influences SC growth. These simulations will one day dramatically shorten the time it takes to develop new therapies for degenerative diseases. Second, we are rewiring the genetic code in SC, and engineering the environment around SC, to understand the key requirements of SC-based tissue development, and to increase the quantity and quality of cells SC produced. Third, with our partners, we are moving promising discoveries towards the clinic using advanced models of disease, focusing on testing specialized blood cells as blood cancer and autoimmune disease therapeutics.

Our work is revealing new rules that govern tissue development, generating new technologies for RM applications, and yielding new SC-based therapies.

** Presenting Author*

O-019 HAPPY TOGETHER: THE BENEFITS AND APPLICATION OF A FULLY INTEGRATED BIOPROCESS

Jeff Salm[1], *Raquel Orozco*[3], *Robert Kottmeier*[2], *Scott Godfrey*[3], *Jon Coffman*[3], *Rob Fahrner*[2], *Greg Hiller*[1]
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Significant productivity increases have been made in CHO-based cultures over the last decade. Fed-batch titers approaching 10 g/L are routinely reported as process limitations such as oxygen supply, carbon dioxide stripping, and nutrient depletion have been significantly improved. Better understanding of CHO cell metabolism, and contemporary approaches to perfusion cultures have addressed other limitations such as build-up of toxic metabolites and high volumes of perfusion media. These cell culture improvements have enabled cell densities above 100 e6 cells/mL and volumetric productivities exceeding 2 g/L/day. So what challenges remain?

In many cases, these more productive cultures have created significant challenges for downstream including manufacturing facility fit issues, increased impurity loads, and more difficult separations. Downstream process development scientists have employed simple solutions to handling the issues using larger chromatography columns combined with high capacity filters and novel resins. More recent strategies have included continuous capture from the bioreactor using Alternating Tangential Flow (ATF) filtration or Tangential Flow Filtration (TFF) and purification using 'continuous' chromatography approaches such as Simulated Moving Bed (SMB) or Periodic Counter Current (PCC) Chromatography. While these approaches have been successful, they have often resulted in higher costs and a more complex manufacturing operation.

Recently, Pfizer and Boehringer Ingelheim reported on a fully integrated approach to manufacturing. The holistic design approach looked to balance productivity, ease of development, regulatory concerns, and cost. The resulting system consists of a scalable short-duration perfusion upstream and fully integrated downstream capable of processing productivities of 1-4 g/L/day. In this talk, we will describe the new process highlighting the benefits of upstream and downstream process integration. Product quality data for material manufactured with 100 L prototype systems will show the robustness of the process. The implications of the system on our pipeline and manufacturing network will also be discussed.

O-020 HIGH-DENSITY PERFUSION: IMPROVEMENTS IN PRODUCTIVITY & PRODUCT QUALITY

Natalia Gomez[1,*], *Jonathan Lull*[1], *Sherry Yang*[1], *Yan Wang*[2], *Xin Zhang*[1], *Agatha Wieczorek*[1], *Haly Raharimampionona*[2], *Mike Pritchard*[1], *Diandra Martinez Cano*[1], *Michael Shearer*[1], *Chetan Goudar*[1]
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Background and novelty: Bispecific molecules target two antigens of interest to treat a disease. Bispecific protein scaffolds can be more complex than traditional monoclonal antibodies (MAbs) because two different sites/domains for epitope binding are needed. Because of this increased molecular complexity, bispecific molecules can be more prone to physical and chemical degradation compared to MAbs, leading to higher levels of protein aggregates, clipped species or modified resides in cell culture. In this study, we studied cell culture performance for three types of bispecific molecules. In particular, we investigated traditional fed-batch and intensified perfusion-based processes to understand the suitability of these for the production of bispecific molecules.

Experimental approach: We studied a total of six CHO cell lines. Each cell line was cultured in both an approximately 12-day fed-batch process and an approximately 40-day high-density perfusion process. Harvested cell culture fluid (HCCF) from each process was purified and analyzed for product quality attributes including aggregates, clipped species, peptide mapping and host cell protein content (HCP).

Results and discussion: Our studies showed that in average, the intensified perfusion process increased ~15-fold both the integrated viable cell density (IVCD) and the corresponding total harvested protein mass produced. Perfusion increased in average five-fold the daily volumetric productivity compared to fed-batch. Furthermore, product quality from the perfusion process was in general improved. This included up to 70% lower aggregates, 90% lower clipped species, 80% lower deamidated/isomerized residues and 80% lower HCP levels. In summary, the intensified perfusion process exhibited better productivity and product quality, highlighting the potential to use it as part of a continuous manufacturing process for bispecific scaffolds.

[*] *Presenting Author*

O-021 MAGNETIC BEAD PURIFICATION OF MAB FROM CHO CELL BROTH AT PILOT SCALE

Nils Brechmann [1 2,*], *Per-Olov Eriksson* [3], *Kristofer Eriksson* [4], *Sven Oscarsson* [5], *Jos Buijs* [6], *Atefeh Shokri* [1 2], *Göran Hjälm* [7], *Véronique Chotteau* [1 2]

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Background and novelty: Cultivation processes of antibody production are typically followed by the steps of cell clarification and antibody capture by protein A chromatography in packed columns. The steps are time consuming and the materials are expensive. Magnetic bead-based separation, which has been used for decades, shows interesting opportunities to reduce these steps, especially in pilot scale. In this study we design a novel proof-of-concept prototype pilot scale purification for affinity purification of monoclonal antibodies (mAbs) from non-clarified CHO cell broth. The commercially available LOABeads PrtA, high capacity magnetic protein A agarose beads, as well as a prototype pilot-scale magnetic separator were used in the development of the new process.

Experimental approach: Pilot-scale separation was initially tested in a mAb capture step from 26 L clarified harvest. Followed by two pilot-scale purification runs on non-clarified cell broth from fed-batch runs of 16 L

Results and discussion: Rapid mAb adsorption ≥ 96.6% was observed after one hour. The final process using 1 L of magnetic beads had an overall mAb yield of 86% and 16 times concentration factor. After this single protein A capture step, the mAb purity was similar to the one obtained by column chromatography, while the host cell protein content was very low, <10 ppm. Our results showed that this magnetic bead mAb purification process was a highly efficient single step, which directly connected the culture to the downstream process without cell clarification. Purification of mAb directly from non-clarified cell broth without cell separation can provide significant savings in terms of resources, operation time and equipment, compared to legacy procedure of cell separation followed by column chromatography step.

Acknowledgements & Funding: This work was supported by the Swedish Agency for Innovation Systems VINNOVA.

O-022 BIOLOGY INSPIRED CELL THERAPY MANUFACTURING

Nick Timmins, *BlueRock Therapeutics, USA*

BlueRock Therapeutics is an engineered cell therapy company with a mission to develop regenerative medicines for intractable diseases. BlueRock's cell differentiation technology recapitulates the cell's developmental biology to produce native cell therapies, which can be further engineered for additional function. Utilizing these cell therapies to replace damaged or degenerated tissue brings the potential to restore or regenerate lost function. This presentation will explore the link between developmental biology and BlueRock's differentiation technologies for manufacture of therapeutic cardiac and neural cells from pluripotent stem cells, briefly examining the potential for cell engineering strategies to enhance cell products and underlying manufacturing processes.

O-023 A FLEXIBLE 3D HUMAN HEPATIC CELL PLATFORM FOR MALARIA DRUG DISCOVERY

Francisca Arez [1], *Sofia Rebelo* [1], *Diana Fontinha* [2], *Daniel Simão* [1], *Marta Machado* [2], *Tatiana Martins* [1], *Christoph Fischli* [3], *Claude Oeuvray* [4], *Manuel Carrondo* [1], *Matthias Rottmann* [3], *Thomas Spangenberg* [4], ***Catarina Brito*** [1,*], *Beatrice Greco* [4], *Miguel Prudêncio* [2], *Paula Alves* [1]

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Background and novelty: The liver stage of Plasmodium infection is the first step of the parasite's life cycle in the mammalian host and constitutes the reservoir of dormant parasite forms termed hypnozoites, which are responsible for disease relapses. The lack of effective anti-plasmodial drugs targeting this stage of infection highlights the need for new preclinical models able to better predict the Plasmodium and host responses to drug treatments. Here, we present a scalable 3D human in vitro platform suitable for drug discovery targeting Plasmodium hepatic infection.

[*] *Presenting Author*

Experimental approach: The platform relies on human hepatic spheroids generated in bioreactors that sustain crucial hepatic features. The Plasmodium infection procedure was established in 3D static and stirred culture systems, and the dynamics of Plasmodium hepatic development was extensively characterized. As proof-of-concept of the potential of the developed platform in drug discovery, M5717, a compound under clinical development was used as case study.

Results and discussion: Our results demonstrate that P. berghei infects and develops in the hepatic spheroids, completely maturating into blood-infective merozoites in both infection systems. The IC50 of M5717 was determined in the 3D static infection system and was corroborated by in vivo studies that demonstrated the translational potential of the developed platform. Furthermore, using the scalable conditions optimized in the dynamic infection system, the M5717 time response was assessed in two different concentrations, demonstrating the compound's efficacy on the late stage of Plasmodium hepatic development. The flexible 3D infection platform developed is a promising tool to target human infectious Plasmodium strains including hypnozoites and it will contribute to development of new anti-plasmodial drugs.

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O-024 ENGINEERING OF EXOSOMES FOR TARGETED DELIVERY OF THERAPEUTIC MICRO-RNAS

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Background&Novelty: Exosomes are small membrane vesicles secreted from most cell types. They contain several molecules including microRNAs (miRNA) and are naturally taken up by cells in order to deliver these contents to recipient cells. These facts turn exosomes into interesting vehicles to transport therapeutics across cell membranes. miRNAs are small non-coding RNA molecules, which play a key in gene regulation and their deregulation is a common feature in cancer. However, bioavailability is significantly impaired due to many factors. In this context, exosomal delivery may display a novel strategy for targeted delivery of RNA therapeutics.

Experimental approach: The current study pursues the novel therapeutic concept of using exosomes as delivery vehicles for small non-coding RNA molecules by overexpression of the respective miRNAs in the host cell. miRNAs recently identified as pro-apoptotic in ovarian cancer cells were selected for this purpose. In addition, exosomes were further engineered in order to track the uptake of exosomes to the target cell. Human CAP-cells of not carcinogenic origin were used to study this approach.

Results&Discussion: Exosomal preparations of CAP-cells were examined to determine vesicle identity, size, morphology and concentration using dynamic light scattering, flow cytometry, western blotting and electron microscopy. Exosomes were successfully modified by stably overexpressing a CD63-GFP-fusion protein for tracking and miRNAs identified as pro-apoptotic into ovarian cancer cells. In addition, the loading of exosomes with overexpressed miRNAs was verified as well as delivery into the recipient cells. Finally, functional transport to recipient cells was demonstrated, confirming CAP exosomes as novel possible vehicles for pro-apoptotic miRNAs.

O-025 DEVELOPMENT AND APPLICATION OF A MASS SPECTROMETRY BASED MULTI-ATTRIBUTE METHOD FOR PROTEIN THERAPEUTICS

Jette Wypych, *Amgen, USA*

Historically, control strategies for protein therapeutics have typically relied on a comprehensive set of lot release tests for both the drug substance and drug product. Often many of the conventional release methods lack specificity, and frequently purity methods rely on peak profiles without measuring specific attributes. An integrated attribute focused product development strategy based on quality by design (QbD) principles with a defined target product profile (TPP) and quality target product profile (QTPP) benefits from innovative analytical approaches. This presentation will highlight progress in the development and application of a mass spectrometry based multi-attribute method (MAM), which provides direct product attribute measurements. The method can replace many of the less specific conventional methods and provides an enhanced approach to QbD. Today MAM has advanced as a quality control release method for clinical programs; MAM can further be envisioned as a process analytical technology with potential for advancing real time release testing.

[*] Presenting Author

O-026 INTEGRATION OF PAT WITH INTENSIFIED PERFUSION PLATFORM DEVELOPMENT

Shawn Barrett [1,*]

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Background and novelty: The Intensified Perfusion Platform (IPP) at Sanofi has minimized the need for extensive development work and optimization of early stage CHO perfusion bioreactor processes. This platform has enabled high cell density and sustainable volumetric productivity of multiple therapeutic proteins regardless of clonal differences or cell line process screening approach. However, during development it was often challenging to generate sufficient analytical data to achieve a high-level understanding of real time process dynamics. Additionally it has been difficult to capture critical cell culture process analytics at a frequency sufficient to identify process disturbances as they occur so that they can be appropriately controlled.

Experimental approach: To address these concerns we applied chemometric analysis to FTIR spectroscopic data from offline samples to enable development of a predictive model. Afterwards we implemented an automatic sampling system that increased our capacity for at-line process sample testing by 4 to 12-fold. These two approaches were then combined to improve the reliability of the chemometric model for use in real time inline analysis of perfusion harvest characteristics.

Results and discussion: Progress in applying the intensified platform to multiple biologics and implementation of the technologies to the platform will be discussed. Challenges in achieving model robustness and integrating the technology in-line for process control will be also be addressed.

O-027 BRINGING ART CLOSER TO SCIENCE: A QUALIFIED CAR-T IDENTITY ASSAY

Stephie Leung [1], *Betty Fan* [2], *Danylo Sirskyj* [1], *Spencer Hoover* [2], ***Jessica Schwaber*** [2,*]

[1]GE Healthcare Fast Trak Toronto , [2]CCRM, Toronto, Canada

Background and novelty: Analytics used to measure the safety and potency of cell therapy products are lagging behind cell therapy development and are typically tailored to each therapy. Cellular identity is a critical quality attribute and is primarily determined by flow cytometry, a technique often described as an art rather than science. Although chemistry-based assays allow for products manufactured with tight, reliable results from a controlled and defined process, biology-based ones are more cumbersome. For example, flow-based cellular identity analyses for final release of living cell products allow for ±30% variability. At CCRM/GE Fast Trak Toronto, we attempted to bridge this gap and deliver a biology-based assay that is robust, reproducible and of high resolution.

Experimental approach: We explored processes for designing, running, and analyzing a flow cytometry panel to reduce risk and variability in phenotyping CAR-T cells. This panel acted as an identity analytic to complement our in-house closed and automated CAR-T process and involved substantial collaboration with our GMP manufacturing team in setting assay requirements.

Results and discussion: We developed a flow panel to identify CD19 CAR expression using biotinylated protein in parallel with T-cell phenotypes: CD3, CD4, and CD8 plus markers for naïve, central memory, effector memory, effector, activated, and exhausted phenotypes. Robust gating strategies were developed using several positive controls, compensation adjustments, and FMOs. We used liquid handling robotics to automate time-consuming sample preparation and minimize in-process variability. This flow panel is broadly applicable to any CAR-T therapeutic and will guide future analytical development at CCRM/GE Fast Trak Toronto.

[*] Presenting Author

O-028 CUSTOMISED PROCESS MODELS FOR CELL CULTURE PROCESSES

Harini Narayanan [1,*], *Michael Sokolov* [1 2], *Alessandro Butté* [1 2], *Massimo Morbidelli* [1 2]
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Background and novelty: The need for rapid and efficient process development to meet market demands calls for the use of model-based methods to assist at various stages of development, monitoring and control of bioprocesses. Models can be used to simulate experiments in silico, replace analytics and track experiments, saving a lot of costs and time. Thus, efforts have been made to develop models from historical and online spectral and sensor data. Here it is worth noting that each application is unique and hence has distinct requirements. As a result, choice of models and supporting tools must be personalised to the addressed problem. We demonstrate tailored toolkits for use at different stages during the cell culture process.

Experimental approach: To realise this goal, several machine learning tools such as Principal Component Analysis (PCA) [1], Partial Least Squares (PLS) [2], Decision trees [3] and Artificial Neural Networks are used solely or in synergy with the mechanistic framework derived for instance from mass balances (known as Hybrid models [4]). Additionally, the process operating space can be further divided into specific regions for which independent predictive models can be built. We developed an algorithm to automatically define these process relevant regions and build local models specific to these regions.

Results and discussion: Through different case studies, each applying a distinguished toolkit, we demonstrate that :

1. For real-time detection of reactor failures, simple tools such as PCA is ideal [5].

2. Localised models show better predictive performance compared to the state-of-the-art PLS models, especially during process design when a wide range of operating conditions is tested.

3. For the design of experiments, process optimisation and scale-up, Hybrid models perform best due to its robustness, prediction accuracy and interpolation and extrapolation capabilities.

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O-029 CELL & VIRAL THERAPIES AND THE PROMISE TO SOLVE CURRENT MANUFACTURING CHALLENGES?

Uwe Gottschalk, *Lonza AG, Switzerland*

We are currently seeing a spread between the "commoditization" of biotech drugs with biosimilars coming online and emerging treatment options such as cell and gene therapy for which manufacturing standards are getting established.

Biomanufacturing processes have become generic, robust, and efficient but cannot be directly applied to new modalities and new manufacturing formats. The future of biomanufacturing is likely to rely more on innovation and flexibility than on traditional strength, such as large facilities and the financial muscle to invest in them. In this talk we will discuss:

- Lessons learned from MAb manufacturing are benefitting emerging areas of targeted therapies and vice versa
- Future formats in Gene- and cell therapy production will leapfrog current standards in biomanufacturing
- After single use technologies and continuous processing, patient scale manufacturing will be the next Innovation wave
- Change and technological transformation is accelerating

[*] *Presenting Author*

O-030 A 3D KSHV LATENCY MODEL FOR IDENTIFICATION OF ANTIVIRAL COMPOUNDS

Tatyana Dubich [1], Anne Dittrich [1], Christoph Lipps [1], Tobias May [2], Marc Stadler [1], Thomas Schulz [3], ***Dagmar Wirth [1],****
[1]HELMHOLTZ CENTRE FOR INFECTION RESEARCH, [2]Inscreenex GmbH, Braunschweig, [3]Hannover Medical School, Hannover, Germany

Background and novelty: Chronic infections with the episomal Kaposi's sarcoma herpesvirus (KSHV) give rise to tumors in immunocompromised patients. No targeted therapy is available. The investigation of the in vivo pathogenesis of this human specific virus and the identification of antivirals is compromised by the lack of in vitro and in vivo model systems.

Experimental approach: An in vitro KSHV model was established based on a proliferation controlled human endothelial cell line HuARLT representing primary-like properties and capable of forming functional human cell derived vessels in mice. 2D and 3D cultures were used to study viral pathogenesis and to validate novel compounds.

Results and discussion: KSHV infected HuARLT cells are characterized by loss of endothelial properties and invasive growth, mimicking the typical properties of KSHV infected cells from patients. Interestingly, 3D culture conditions are crucial for viral maintenance, while the virus is lost in 2D cultures, suggesting that cell specific properties are needed for viral dissemination both in vivo and in vitro.

A set of novel compounds was evaluated for both, antiviral activity and for inhibiting invasiveness in 3D culture. Various candidates were identified and validated in vivo. One of the compounds was confirmed to provide significant reduction of tumor formation in the humanized mouse model. Moreover, we show that the evaluation of in vitro invasiveness but not loss of viral copies can mimic and thus predict in vivo activity of compounds.

Together, we could recapitulate properties of Kaposi's sarcoma-derived cells from patients, suggesting that the new cell system represent novel model to study KSHV infection and a valuable tool for identifying and validating novel antiviral compounds in vitro and in vivo.

O-031 BONE BY DESIGN – VIA BIOASSEMBLIES OF CARTILAGE MICROTISSUE MODULES

Gabriella Nilsson Hall [1 2], Luis Mendes [1 2], Geris Liesbet [1 3], Frank Luyten [1 2], ***Ioannis Papantoniou [1 2],****
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Background and novelty: The field of Regenerative Medicine and Tissue Engineering seeks to build functional tissues ultimately replacing failing organs, thereby curing the patient. The lack of living building blocks is a major hurdle in the manufacturing of human scale functional living implants. The ability to produce large populations of small functional tissue niches that could be used for bottom-up assemblies of larger tissues would constitute a major step towards addressing this bottleneck.

Experimental approach: In this work thousands of "cartilage intermediate" microtissues were developed using adult progenitor cell populations. Cells in the microtissues appeared to undergo developmental processes in vitro mimicking those encountered in the embryonic growth plate and during fracture healing in vivo. Upon reaching a degree of "autonomy", as defined through genomics analysis, these microtissues were able to continue their biological program upon implantation. This resulted in the formation of bone organs without inappropriate contaminating tissue structures. This capacity was robustly exhibited either when implanted as single modules or in larger multimodular tissues, independent of the implantation site. Strikingly critical size murine long bone defects were healed within natural physiological time scales including a de novo bone marrow compartment. Implanted cells were present, demonstrating their critical role in the regenerative process.

Results and discussion: With these advancements, we believe that we contribute towards an era were multimodular tissue implants possessing 'design specifications' could be produced at a scalable and robust manner. This paves the way for the mitigation of unmet clinical challenges of large non healing tissue defects such as critical size bone non-unions. The µtissues could be viewed as a living 'bioink' allowing bottom up manufacturing of multimodular tissues with intricate geometric features and inbuilt quality attributes.

** Presenting Author*

O-032 MAPPING STRUCTURE AND BIOLOGICAL FUNCTIONS WITHIN MESENCHYMAL BODIES

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Background and novelty: Organoids that recapitulate the functional hallmarks of anatomic structures comprise cell populations able to self-organize cohesively in 3D. However, the rules underlying organoid formation remain poorly understood because a correlative analysis of individual cell fate and spatial organization has been challenging. Here, we use a novel microfluidic platform to investigate the mechanisms determining the formation of organoids by mesenchymal stromal cells (hMSCs) that recapitulate the early steps of condensation initiating bone formation.

Experimental approach: The immunophenotype of hMSCs was first characterized by flow cytometry. Next, hMSCs were sorted based on their level of expression of undifferentiated markers. hMSCs were then reseeded into a microfluidic platform for high-density organoid formation and in-situ analysis by quantitative imaging. Mesenchymal bodies (MBs) were mapped for structural organization

Results and discussion: The cell size correlates with the level of expression of undifferentiated markers, which is inversely linked to early commitment towards osteogenic lineage. Next we found that hMSCs self-organize in 3D in a developmentally hierarchical manner: the most undifferentiated cells are located in the core of the MBs; more osteogenically committed cells are found at the boundaries of the MBs. The early commitment of the cells helps the stabilization of adherens junctions in 3D, which initiates the cohesion of the MBs and modulates molecular signaling regulating the cells' biological functions. The MBs closely mimic the early steps of mesenchymal condensation by spontaneously adopting a hierarchical organization and osteo-endocrine functions. This study emphasizes the importance of resolving spatial heterogeneities within organoids to link organization and functional properties, enabling a better understanding of the mechanisms controlling their formation.

O-033 IN VITRO MODELS TO DISCLOSE HUMAN CARDIAC PROGENITOR CELLS ACTION MODE

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Background and novelty: Upon Acute Myocardial Infarction (AMI) and inherent Ischemia/Reperfusion (I/R) injury, endogenous cardiac progenitor cells (CPCs) are activated, contributing to myocardial repair through an auto/paracrine crosstalk between CPCs and cardiomyocytes (CMs) in stress. Transplantation of CPCs is being tested in clinical trials, and although improvements have been reported, the mechanisms of action of these cells are still mostly unknown.

Experimental approach: Our work combines the development of I/R in vitro human cell models with advanced mass spectrometry proteomic tools to further characterize hCPC and unveil associated regenerative mechanisms. hCPCs employed in the clinical trial CARE-MI (NCT02439398) were used.

Different strategies were explored to recapitulate I/R, including: use of human adult/mature cells, 3D culture and bioreactor technology. Firstly, we developed a transwell co-culture I/R model, with hCPCs and human induced pluripotent stem cell derived CMs (hiPSC-CMs). Following this work aiming at further improving the relevance of the I/R in vitro setup, 3D hiPSCCM cultures and bioreactors were combined, allowing the control/monitoring of critical environmental parameters.

Results and discussion: Important features of I/R injury were successfully captured, including hiPSC-CM death, cell ultra-structure disruption, as well as increased release of inflammatory cytokines. hCPCs response to I/R was probed using whole proteome analysis (including quantitative SWATH-MS), allowing to propose new pathways in the hCPCs-mediated regenerative process along I/R injury. Our data shows that our AMI-setup up-regulates hCPC proteins associated with migratory, proliferation and stress response-related pathways. Moreover, our results reinforce the idea that paracrine-mediated mechanisms are central for hCPC activation, with the enrichment of several paracrine signaling pathways.

[*] *Presenting Author*

O-034 MAKE PERFUSION GREAT AGAIN

Jean-Marc Bielser, *Merck Group, Lausanne, Switzerland*

This presentation will focus on perfusion cell culture for the production of recombinant proteins. Continuous biomanufacturing is a topic that is nowadays omnipresent in the literature and at most conferences, but why exactly?

Perfusion cell culture has been the workhorse of many biopharmaceutical companies already a few decades ago. Also at Merck, a number of commercial molecules are being manufactured in continuous mode for more than 30 years. Yet, the past decades were spent on fed-batch process development and optimization that quickly became state of the art. The first part of this presentation should help to understand what drives us back towards continuous manufacturing solutions.

Specific challenges but also opportunities of the modern state of perfusion technology will be addressed in a second part. A scale-down model for parameter screening in semi-continuous mode will be described and illustrated with a study using a number of different clones. Opportunities will be illustrated by comparing performances and quality attributes of the production of a fusion protein using batch-like and perfusion processes.

One of the major challenges that perfusion will have to face is the management of large media volumes. Not only is media optimization crucial in terms of cost of goods, but it is also a potential limitation in terms of operation. The final part of this presentation will discuss novel ideas to address this topic and hopefully convince the audience that yes, we can, make perfusion great again.

O-035 CONTINUOUS PROCESSING USING A CHEMOSTAT CULTURE

Sarwat Khattak [1,*], *Valerie Pferdeort* [1], *Tim Brantley* [1], *Kelly Wiltberger* [1], *Rashmi Kshirsagar* [2]

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Background and novelty: Operating a CHO culture in chemostat mode can improve volumetric productivity while maintaining product quality and cell viability over an extended period. Through the dilution control inherent to chemostats, we have gained an understanding of how the nutrient concentration modulates titer and viable cell density while maintaining product quality attributes comparable to a fed-batch product. The continuous nature of chemostat also ensures that the product quality attributes are not changing (or degrading) over time without the same investment in media and equipment as a perfusion process. In addition, no significant capital is required compared to an ATF/TFF perfusion-based process. This work is one of the first to demonstrate a continuous, manufacturing-feasible CHO process without the complexity of perfusion.

Experimental approach: In this work, we evaluated continuous dilution rates of 0.1-0.3 vessel volume per day (vvd) to achieve steady-state conditions. The glucose and amino acid composition in the dilution media was modulated to determine the effect on steady-state viable cell density, productivity, and product quality attributes. Chemostat performance was evaluated by product quality testing, cell cycle analysis and spent media analysis.

Results and discussion: Chemostat operation enabled steady state viable cell densities of 20-40 million cells/mL and a volumetric productivity (g/L/day) equivalent or better to the fed-batch process. We identified factors critical in maintaining productivity under steady-state and gained an understanding of how media composition can impact productivity and product quality attributes (charge variants, aggregation, and glycosylation). The chemostat process was successfully operated for 30-45 days.

Acknowledgements & Funding: None declared

[*] *Presenting Author*

O-036 INVESTIGATION OF MEDIA COMPONENTS ON PERFORMANCE OF CHO CELL CULTURES

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Background and novelty: Advances in cell culture media development has been critical for enabling high cell densities and titers achievable today. For further improvement potential and a deeper understanding of cellular metabolism, the aim of this project is to provide a platform for the development of cell culture media, as a research tool to understand the impact of individual nutrients and co-factors on cell culture performance.

Experimental approach: Initially, a detailed database of cell culture media formulations (MedLIB) was built and augmented with reported knowledge of biological action of media components. MedLIB was used to guide two approaches (top down and bottom up) for the development of a fully chemically defined cell culture media formulation (UCBE-CHO). Cell growth and productivity of the developed media was assessed in batch and fed batch cultures across 3 different CHO cell lines (mAb producing and native). An experimental analysis of intrametabolome was conducted to reveal behavioral differences against control commercial media (CD-CHO). Finally, the impact of 15 nutrient groups as perturbations in feed media (macromolecular and metabolic pathway based feeding strategies) was evaluated during fed-batch cultures in both media.

Results and discussion: The full formulation and characterization of basal media able to sustain growth and productivity in CHO cell cultures is presented. Multivariate analysis methods were applied to reveal differences of nutrient requirements, growth and metabolic profiles across cultivation conditions. Nutrient group perturbations studies in batch and fed-batch mode revealed particular nutrient groups of interest for tailored feeding strategies (increased cell density, titer and viability).The present framework represents an effort to offer insights for the systematic design, development and optimisation of metabolically balanced media and feeding strategies for improved cell growth and productivity.

O-037 OPTIMIZING CHO CELL CULTURE PROCESSES USING PREDICTIVE DIGITAL TWINS

Jakob Kirch [1],[*], *Matthias Bohner* [1], *Kathrin Guenther* [1], *Manuel Ruff* [1], *Joachim Schmid* [1], *Shilpa Nargund* [1]

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Background and novelty: Developing a cell culture process for production of biologics is a critical step during drug development. However, optimizing a cell culture process is challenging because the objectives such as high titer, high biomass and consistent/targeted product quality are interdependent and compete with each other. While statistical design of experiments and high-throughput small-scale bioreactors alleviate these challenges partially, considerable experimental effort and time is still required to develop a robust process. Here, we present the Insilico Digital Twin that can predict the media design and feeding strategy for optimizing one or more of these objectives using routine bioreactor data from a pre-defined number of experiments.

Experimental approach: The Insilico Digital Twin mimics the dynamics of a cell culture process by combining a model of the fed-batch/perfusion process and a model of the genome-scale metabolic network of CHO cells. This novel approach uses artificial intelligence (AI) to determine the dynamics between the extracellular metabolite concentrations and the intracellular flux distributions which results in breakthrough predictive power. Therefore, it can be used for predicting process performance and product quality in a multitude of experimental scenarios.

Results and discussion: In this presentation, we demonstrate the predictive power of the Insilico Digital Twin through two case studies. In the first, the titer of a CHO fed-batch process was increased by model-predicted media design and feeding strategy and in the second, the mAb glycosylation profiles from a CHO fed-batch process were improved through model-predicted media design. In conclusion, the Insilico Digital Twin is a versatile predictive tool that can be used to develop cell culture processes more efficiently.

[*] *Presenting Author*

O-038 KEYNOTE LECTURE:
THE HUMAN SECRETOME PROJECT – GENERATION OF ALL HUMAN SECRETED PROTEINS IN MAMMALIAN CELL CULTURES

Mathias Uhlen, *Science for Life Lab, Karolinska Institute and Royal Institute of Technology, Stockholm, Sweden.*

The Human Protein Atlas (HPA) is an international program with the aim to map of all the human proteins in cells, tissues and organs using integration of various omics technologies, including genomics, transcriptomics, antibody-based imaging, mass spectrometry-based proteomics and systems biology. The current version (www.proteinatlas.org) consists of three separate parts, each focusing on a particular aspect of the genome-wide analysis of the human proteins; (1) the Tissue Atlas showing the distribution of the proteins across all major tissues and organs in the human body, (2) the Cell Atlas showing the subcellular localization of proteins in single cells, and (3) Pathology Atlas showing the impact of protein levels for survival of patients with cancer. This year we plan to also launch a new Brain and a new Blood Atlas. All the data in the knowledge resource is open access to allow scientists both in academia and industry to freely access the data for exploration of the human proteome. We have used this resource to launch various efforts in the field of Precision Medicine. We have also launched a Human Secretome Project to produce in mammalian cell cultures all human secreted proteins (4). The progress of this project will be discussed and the results from phenotypic screening of this resource will be presented.

1. Uhlen et al (2015) Science 347: 1260419
2. Thul et al (2017) Science 356 (6340): eaal3321
3. Uhlen et al (2017) Science 357 (6352): eaan2507
4. Uhlen et al (2018) BioRxiv, https://doi.org/10.1101/465815

Keywords: Protein Atlas, Precision Medicine, Drug Development

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POSTER PRESENTATIONS

- Posters with odd numbers will be presented on Monday 6th May from 13:30-15:00.
- Posters with even numbers will be presented on Tuesday 7th May from 14:00-15:30.

* Presenting author

Posters selected for the ESACT poster prize competition

CELL ENGINEERING, NOVEL TECHNOLOGIES AND THE USE OF OMICS

P-100 CRISPR-BASED TARGETED EPIGENETIC GLYCO-ENGINEERING IN CHO CELLS

Nicolas Marx[1 2,], Clemens Grünwald-Gruber[1], Nina Bydlinski[1], Ly Nguyen[1 2], Heena Dhiman[1 2], Gerald Klanert[2], Nicole Borth[1 2]*
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P-101 VECTOR OPTIMIZATION – EXPRESSION OF A NOVEL FC-FUSION PROTEIN

Kimberly Mann[1,], Patricia Kumpey[1], Krista Cunningham[1], Trissa Borgschulte[2], Joe Orlando[1]*
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P-102 PROTEOMIC ANALYSIS OF CHO CELL CLONES PRONE TO PROTEOLYTIC CLIPPING.

Laura Bryan[1,], Michael Henry[1], Clair Gallagher[1], Niall Barron[2 3], Ronan M Kelly[4], Christopher C Frye[4], Matthew Osborne[5], Ciara O' Neill[5], Martin Clynes[1], Paula Meleady[1]*
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P-103 MANIPULATION OF ORGANELLE CONTENT FOR INCREASED PRODUCTIVITY

Eva Pekle[1 2,], Andrew Smith[1], Guglielmo Rosignoli[1], Claire Harris[1], Claire Pearce[3], Christopher Sellick[3], Mark Smales[2]*
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P-104 TRIPLE BENEFIT OF BHRF1-MODIFIED HYBRIDOMA CELLS

Marti Lecina[1 2,], Mariona Martinez[2], Ivan Martínez-Monge[2 3], Pere Comas[2], Antoni Casablancas[2], Carlos Paredes[2], Jordi J Cairó[2]*
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P-105 HOST CELL ENGINEERING STRATEGY FOR ADVANCED RECYCLING ANTIBODIES

Hisahiro Tabuchi[1,], Kosuke Nakayama[1], Hirokatsu Makitsubo[1]*
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P-106 FULLY AUTOMATED AND ENHANCED CLONE SCREENING AND EVALUATION

Sven Markert[1,], Klaus Joeris[1], Carsten Musmann[1], Peter Huelsmann[2]*
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P-107 CHO PROMOTERS IDENTIFIED BY RNA-SEQ FOR RECOMBINANT PROTEIN EXPRESSION

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P-108 CRISPR/CAS9 MEDIATED KO OF MICRORNAS FOR PRECISE CELL LINE ENGINEERING

Nadja Raab[1,], Sven Mathias[1], Kerstin Alt[1], René Handrick[1], Simon Fischer[2], Valerie Schmieder[3], Vaibhav Jadhav[3], Nicole Borth[4], Kerstin Otte[1]*
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P-109 EVALUATION OF AN LNCRNA DELETION SCREEN IN CHO CELLS

Neža Novak [1 2,], Valerie Schmieder [1 2], Heena Dhiman [1 2], Martina Baumann [1], Gerald Klanert [1], Nicole Borth [1 2]*

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P-110 INCREASING PROTEIN PRODUCTION UPON TARGETED INTEGRATION IN CHO CELLS

Daria Sergeeva [1,], Lise Marie Grav [1], Nuša Pristovšek [1], Lars Keld Nielsen [1 2], Helene Faustrup Kildegaard [1], Gyun Min Lee [1 3]*

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P-111 TRANSCRIPTIONAL REGULATION BY TRIPLEX MEDIATED LNCRNA INTERACTIONS

Heena Dhiman [1 2,], Inmaculada Hernandez [1 2 3], Neža Novak [1 2], Nicole Borth [1 2]*

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ESACT **P-112 USING CRISPR TO INCREASE HEK293 CAPABILITIES FOR BIOPROCESS INDUSTRY**

Ramon Román Roldán [1,], Joan Miret [2], Aida Roura [2], Sara Vitoria [2], Sara Botas [2], Antoni Casablancas [1], Martí Lecina [2], Jordi Cairó [2]*

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ESACT **P-113 A TOOL FOR COORDINATED OVEREXPRESSION OF MULTIPLE GENES IN CHO CELLS**

Peter Eisenhut [1 2,], Gerald Klanert [1 2], Marcus Weinguny [1 2], Laurenz Baier [1 2], Daniel Ivansson [3], Nicole Borth [1 2]*

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ESACT **P-114 CHO GENOME MINING FOR SYNTHETIC PROMOTER DESIGN**

Yusuf Johari [1,], Adam Brown [1], Christina Alves [2], Yizhou Zhou [2], Chapman Wright [2], Scott Estes [2], Rashmi Kshirsagar [2], David James [1]*

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P-115 KDELR1 GENE DYNAMICS AND OVER-EXPRESSION IN RECOMBINANT CHO CELLS

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ESACT **P-116 TRANSLATIONAL ENGINEERING THROUGH THE NON-CODING GENOME IN CHO**

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P-117 SUBCLONABILITY ENHANCEMENT OF CHO LEADS TO A BETTER GROWTH PHENOTYPE

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P-118 REDUCED CLONE VARIATION OF CHO CELLS BY SINGLE TARGETED INTEGRATION

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P-119 COMBINED EFFECT OF C-MYC AND XBP1S ON CHO CELLS RH-EPO PRODUCER.

Yesenia Latorre [1,], Natascha Gödecke [2], Hansjörg Hauser [3], Dagmar Wirth [2], Maria Carmen Molina [4], Julio Berrios [1], Claudia Altamirano [1 5]*

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P-120 FRUCTOSE METABOLISM IN HEK293: STUDY OF INTRACELLULAR FLUXES

Pere Comas Sanchez [1,], Paula Sanchez [1], Ivan Martinez Monge [1 2], Ramón Roman [1], Martí Lecina [1 3], Antoni Casablancas [1], Joan Albiol [1], Carles Solà [1], Jordi Prat [1], Jordi Joan Cairó [1]*

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ESACT **P-121 ANALYSIS OF TRANSLATION INITIATION IN CHINESE HAMSTER OVARY CELLS**

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P-122 ANALYSIS OF CHROMATIN ACCESSIBILITY IN CHO CELLS USING ATAC-SEQ

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P-123 EVALUATION OF NEW TECHNOLOGIES FOR IMPROVED CLONE SELECTION

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P-124 AVOIDING UNSTABLE TRANSGENE INTEGRATION IN HORIZON CHO CELL LINES

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P-125 RNAI BASED SELECTION TOOLS FOR CHO CELL LINE DEVELOPMENT

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P-126 EXPEDITING UPSTREAM STAGES OF PROTEIN BIOMANUFACTURER WITH UCOES®

Bethany Mccloskey[1,], Michael Anontiou[1], Joe Orlando[2], Kimberly Mann[2]*

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P-127 DISPENCELL, A NEW SOLUTION FOR ISOLATION OF SINGLE CELLS

Caroline Desmurget[1,], Frentzel Julie[1], Katarzyna Sobkowiak[1], Julien Douet[1], David Bruhlmann[1], Jonathan Souquet[1]*

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P-128 MATHEMATICAL OPTIMIZATION OF A CHO CELL GENOME-SCALE METABOLIC MODEL

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P-129 ELIMINATION OF THE WARBURG EFFECT IN CHINESE HAMSTER OVARY CELLS

Hooman Hefzi[1,], Ivan Monge[2], Soo Min Noh[3], Karen Julie La Cour Karottki[2], Nuša Pristovšek[2], Anders Hansen[2], Lars Nielsen[2], Gyun Min Lee[3], Helene Kildegaard[2], Bjørn Voldborg[2], Nathan Lewis[1]*

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P-130 ENGINEERING OF THE SECRETORY PATHWAY OF CHINESE HAMSTER OVARY CELLS

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P-131 MINIMIZING CLONAL VARIATION DURING CHO CELL LINE ENGINEERING

Lise Marie M. Grav[1,], Daria Sergeeva[1], Jae Seong Lee[1 2], Igor Marin de Mas[1], Nathan Lewis[3 4], Mikael Rørdam Andersen[5], Lars Keld Nielsen[1 6], Gyun Min Lee[1 7], Helene Faustrup Kildegaard[1]*

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P-132 ENHANCEMENT BY REDUCTION – PUSHING N-GLYCOSYLATION IN CHO CELLS

Nina Bydlinski[1,], Daniel Maresch[1], Michael Coats[1], Nicole Borth[1], Richard Strasser[1]*

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P-133 LACTATE REDUCTION IN CHO CELL CULTURES THROUGH THE METABOLIC ANALYSIS

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P-134 CELL LINE IMPACT ON ANTIGEN BINDING OF A THERAPEUTIC MAB

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P-135 EFFECTS OF MITOCHONDRIA RELATED GENES PGC1 AND DRP1 IN CHO METABOLISM

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P-136 RECOMBINANT HUMAN BMP-4 PRODUCTION IN BMP RECEPTOR KNOCKOUT CHO CELLS

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P-137 ENHANCING THE GALACTOSYLATION CAPACITY OF CHO CELLS

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P-138 MRNA TRANSFECTION OF CHO-K1 CELLS REVEALS PRODUCTION BOTTLENECKS

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P-140 SMALL RNA TOOLBOX PROMOTES ADVANCED CHO CELL ENGINEERING

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P-141 NOVEL PROMOTERS DERIVED FROM CHO VIA IN SILICO AND IN VITRO ANALYSIS

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P-142 TURBOCELL – A FAST WAY TO STABLE PRODUCTION CELL LINES

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P-143 FIND CHO-CELLS OF CHOICE: SELECTIVE CLONING IN CELL LINE DEVELOPMENT

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P-144 GENOMIC FINGERPRINTING OF CHO MANUFACTURING CLONES BY TARGETED NGS

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P-145 REGULATING EXPRESSION DURING SELECTION ENHANCES CHO POOL PRODUCTIVITY

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P-146 GENOMIC UNDERSTANDING OF VARIATION IN TRANSGENE EXPRESSION IN CHO

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P-147 TRACEABLE SINGLE CELL CLONING USING A NEW PIPETTING ROBOT

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P-148 IN VIVO EFFICACY OF RECOMBINANT FACTOR VII PRODUCED IN HUMAN CELL LINE

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P-149 TRANSCRIPTOMIC PROFILING OF CHO PARENTAL AND AB-PRODUCING CELL LINES

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P-150 AUTOMATING CELL LINE DEVELOPMENT: IDENTIFYING CLONES MORE EFFICIENTLY

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P-151 A HEK293 EXPRESSION SYSTEM FOR THE STABLE PRODUCTION OF GLYCOPROTEINS

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P-152 A NEW CHO EXPRESSION SYSTEM (CHO-C) FOR HIGH YIELD MAB PRODUCTION

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P-153 BOOSTING PRODUCTIVITY BY MITOSRNA ENGINEERING AND PROCESS ADAPTATION

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P-154 IMPROVED CELL LINE DEVELOPMENT WITH LEAP-IN TRANSPOSASE & VIPS IMAGING

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P-155 BIOGENIC MAGNETIC PARTICLES FOR MEMBRANE-BASED LIGAND PRESENTATION

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P-156 HEK293 ALLOW RESCUE OF PROTEINS THAT ARE DIFFICULT TO PRODUCE IN CHO

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P-157 IMPLEMENTATION OF THE BEACON PLATFORM FOR CELL LINE DEVELOPMENT

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P-158 ENHANCING CHO CELL LINE DEVELOPMENT BY RATIONAL IN SILICO OPTIMIZATION

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P-159 IMPACT OF NABU AND RA ON HISTONES AND NUCLEAR SIGNALING IN CHO CELLS

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P-160 BREAKTHROUGH CLD PLATFORM FOR BISPECIFIC ANTIBODIES EXPRESSION

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P-161 MONITORING THE FUNCTIONAL IMPACT OF CHO ENGINEERING USING CHEMSTRESS®

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P-162 CHARACTERISATION AND OPTIMISATION OF LV PRODUCER CELL LINES

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P-163 TARGETED KNOCK-IN INTO CHO CELL GENOME USING GENOME EDITING TOOLS

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P-164 MOLECULAR MECHANISM OF RECOMBINANT PROTEIN PRODUCTION INSTABILITY

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P-165 ACCUMULATIVE TRANSGENE INTEGRATION SYSTEM USING CRE-LOXP

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P-166 OPTIMIZED COMBINATION OF GENETIC ELEMENTS ENHANCING MAB PRODUCTION

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P-167 THE CELLCA CHO EXPRESSION PLATFORM FOR DEVELOPMENT OF BIOSIMILARS

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P-168 METABOLIC ENGINEERING TO REDUCE GROWTH INHIBITORY BYPRODUCTS FORMATION

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P-169 BISPECIFIC MOLECULE FORMATS AND CONCEPTS FOR CELL LINE DEVELOPMENT

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P-170 CO-AMPLIFICATION OF EBNA-1 AND PYLT FOR IMPROVING PROTEIN PRODUCTION

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P-171 IMPROVING ENERGY HOMEOSTASIS TO IMPROVE RECOMBINANT PROTEIN PRODUCTION

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P-172 PRODUCTION OF RECOMBINANT FACTOR VII IN NOVEL HUMAN CELL LINES

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P-173 LEAP-IN TRANSPOSASE MEDIATED STABLE CELL LINE DEVELOPMENT

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P-174 BIOLOGICALISATION: CELL AND NATURE-BASED DIGITAL MANUFACTURING

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P-175 DEVELOPMENT OF A PRODUCTION CELL LINE FOR PASYLATED HUMAN DNASE I

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P-176 AN ALTERNATIVE FLUX BALANCE APPROACH FOR MAMMALIAN MODELS

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P-177 FINDING STABLE GENOMIC LOCI IN CHO CELLS USING ATAC SEQUENCING

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P-178 SPEEDING UP THE CELL LINE DEVELOPMENT PROCESS USING NEW TECHNOLOGIES

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P-179 HOST CELL FROM SCRATCH

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P-180 METABOLOMICS INSIGHTS INTO KEY FACTORS INFLUENCING CHO GLYCOSYLATION

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P-181 FEASIBILITY STUDIES FOR USING THE BEACON IN CLD WORKFLOWS

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P-182 INNOVATIVE BIOENGINEERING SOLUTIONS TO THERAPEUTICS PRODUCTION.

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P-184 EVALUATION OF THE HT-NIC TECHNOLOGY TO GENERATE CLONAL CELL LINES

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P-185 SYSTEMATIC IDENTIFICATION OF KEY METABOLIC REGULATORS OF CELL FATE

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P-186 AUTOMATED MINI-POOL APPROACH FOR HIGH PRODUCING CELL LINE DEVELOPMENT

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P-187 STABILIZING EXPRESSION BY (EPI)GENETIC EDITING IN CHROMOSOMAL SITES

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P-188 CHARACTERISTICS OF NOVEL HOST CELL LINES FOR INTENSIFIED PROCESSES

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P-189 ACCELERATE CLINICAL ENTRY BY AUTOMATING CELL LINE DEVELOPMENT

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P-190 HIGH-EXPRESSING CHO CELLS VIA EXPRESSION CASSETTE DESIGN

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P-191 ENHANCED CHO CLONE SCREENING USING NGS + TARGETED LOCUS AMPLIFICATION

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P-192 ENGINEERED TRANSPOSASE DOUBLES TITER OF CHO PRODUCER CELL LINES

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P-193 THE CELLULAR IMPACT OF GLYCOENGINEERING

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P-194 OPTIMIZATION OF 2G UNIC TECHNOLOGY FOR DTE PROTEINS IN CHO GS CELLS

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P-195 COMPARISON OF CHINESE HAMSTER MULTI-TISSUE AND OVARY CELL PROTEOMES

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P-197 DOES CHO GENE EXPRESSION CHANGE IN RESPONSE TO EXPRESSED MAB VARIANT?

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NOTES

USE OF VIRAL- AND NON-VIRAL VECTORS FOR GENERATING NEW THERAPEUTIC PRODUCTS AND VACCINES

P-200 THE INFLUENCE OF THE CELL CULTURE MEDIUM ON MEASLES VIRUS PURIFICATION

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ESACT **P-201 CHALLENGING 2 CELL RETENTION DEVICES FOR VIRUS PRODUCTION IN PERFUSION**

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ESACT **P-202 INTEGRATED PROCESS FOR MDCK-BASED INFLUENZA VACCINE MANUFACTURING**

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P-203 EXPRESSION OF HEPATITIS B VIRUS SURFACE ANTIGEN IN MAMMALIAN CELLS

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ESACT **P-204 EXPLORING GENE TRAIT OF SUPERIOR INFLUENZA VIRUS PRODUCING MDCK CELLS**

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P-205 PRODUCING A NEW CLASS OF DEFECTIVE INTERFERING PARTICLES AS ANTIVIRAL

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ESACT **P-206 UNDERSTANDING VIRUS-LIKE PARTICLE (VLP) GENERATION IN HEK 293 CULTURES**

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P-207 INCLINED SETTLER FOR INFLUENZA A VIRUS PRODUCTION IN PERFUSION MODE

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P-208 BACULOVIRUS-FREE RECOMBINANT PROTEIN PRODUCTION IN INSECT CELL LINES

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P-209 TRANSIENT YELLOW FEVER VLP PRODUCTION USING HEK 293T IN A BIOREACTOR

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ESACT **P-210 VIRUS HARVESTING IN PERFUSION CULTURE: CHOOSING THE RIGHT MEMBRANE**

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P-211 CELL-BASED HCV VACCINE ELICITS NEUTRALIZING ANTIBODIES IN MICE

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P-212 BIOPROCESS STRATEGIES TO ENHANCE VLP PRODUCTION IN STABLE INSECT CELLS

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P-213 ADAPTIVE EVOLUTION OF INSECT CELLS FOR IMPROVED PRODUCTION OF HA VLPS

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P-214 PHYSIOLOGICAL CHARACTERIZATION OF HEK293 USING A PROTEOMIC APPROACH

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P-215 EXTRACELLULAR VESICLE CHARACTERIZATION DURING LENTIVIRAL PRODUCTION

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P-216 GENERATION OF A HEK293 PLATFORM TO PRODUCE ANTIGEN-PRESENTING GAG VLPS

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P-217 IMPROVING GENE THERAPY VECTOR BIOPROCESS THROUGH METABOLIC ENGINEERING

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P-218 CELL CULTURE SCALE-UP IN BIOBLU SINGLE-USE VESSELS

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P-219 DEVELOPMENT OF SUSPENSION ADAPTED VERO CELL CULTURE PROCESS TECHNOLOGY

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P-220 NON-VIRAL TRANSFECTION OF HUMAN T LYMPHOCYTES

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P-221 SCALABLE SINGLE-USE TECHNOLOGY TO MEET GENE THERAPY PRODUCTION DEMANDS

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P-222 A LOW-FOOTPRINT, INTEGRATED & AUTOMATED PLATFORM FOR VIRAL PRODUCTION

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P-223 A NOVEL TYPE OF DEFECTIVE INTERFERING PARTICLE FOR ANTIVIRAL THERAPY

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P-224 ACCELERATING LENTIVIRUS MANUFACTURING TO GMP COMPATIBLE BIOPROCESSES

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P-225 PRODUCTION OF INFLUENZA VIRUS-LIKE PARTICLES IN INSECT CELLS

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P-226 ANIMAL COMPONENT FREE ROTAVIRUS PRODUCTION USING MICROCARRIERS

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P-227 POLYMER VECTORS FOR GENE DELIVERY: INFLUENCE OF AMINE MOIETIES

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P-228 DEVELOPMENT OF A GMP ONCOLYTIC VIRUS MANUFACTURING PLATFORM PROCESS

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P-229 HEK293 CELL CULTURE AND ADENOVIRUS VECTOR PRODUCTION PLATFORM

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P-230 DEVELOPMENT OF AN OPTIMIZED ACF PRODUCTION PROCESS FOR SABIN IPV

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P-231 PRODUCTION OF SEASONAL INFLUENZA VACCINES USING SUSPENSION MDCK CELLS

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P-232 HIGH QUALITY TRANSFECTION REAGENTS FOR THERAPEUTIC VIRUS PRODUCTION

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P-233 SUSPENSION CAP-GT CELLS AS PLATFORM FOR AAV PRODUCTION

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P-234 THE IMPACT OF CELL DENSITY EFFECTS ON FOOT-AND-MOUTH DISEASE VIRUS.

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P-235 SYNERGISTIC EFFECT OF GLYCO-ENGINEERING AND VLP-DISPLAY OF VACCINE AG

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P-236 IMMUNOGENICITY OF A VECTORED VACCINE AGAINST NEWCASTLE DISEASE IN MICE

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P-237 A NOVEL VETERINARY RABIES VACCINE PRODUCED IN THE AVIAN CELL LINE

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ESACT **P-238 IMPROVING VACCINE PRODUCTION WITH A SERUM-FREE MEDIUM FOR FIBROBLASTS**

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P-239 IMPROVING RABIES VACCINE PURIFICATION PROCESS USING NOVEL FILTERS

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ESACT **P-240 POLYMERS FOR CELLS: SHEAR FORCE PROTECTION, NUTRIENT- & GENE DELIVERY**

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ESACT **P-241 NEW VIRAL AND NON-VIRAL PLATFORMS AND PROTOCOLS FOR T-CELL ENGINEERING AND MANUFACTURING**

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DEVELOPMENT OF CELL-BASED TECHNOLOGIES AND THERAPEUTICS

P-300 GENERATION OF TRASTUZUMAB ANTIBODY DRUG CONJUGATES AT DIFFERENT DARS

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P-301 COLLECTION OF STEM CELLS USING A SINGLE USE CENTRIFUGE UNIFUGE

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P-302 STRATEGIES TO MAXIMIZE THE PRODUCTION OF CAR-T CELLS

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P-303 ESTABLISHMENT OF 3D OVARIAN CANCER IN CO-CULTURE FOR DRUG SCREENING

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P-304 AN EX VIVO TUMOUR CULTURE PLATFORM FOR FUNCTIONAL DRUG TESTING

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P-305 IMPACT OF IGG AND FC RECEPTORS N-GLYCOSYLATION UPON THEIR INTERACTION

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P-306 HYBRID AGGLOMERATION OF INSULIN-PRODUCING BETA CELLS AND STEM CELLS

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P-307 RECEPTOR-MEDIATED CLEARANCE OF RECOMBINANT HUMAN DIAMINE OXIDASE

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P-308 GLYCOSYLATION VS RECEPTOR AFFINITY TO IMPROVE IFN4N ANTITUMOR ACTIVITY

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P-309 THE EFFECT OF TELOMERE SEQUENCES ON CHROMOSOMAL TRANSLOCATIONS

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P-310 IMPACT OF BEAD COLLISIONS ON HWJ-MSC EXPANSION PERFORMANCE

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P-311 A NEW DIMERIC BLOOD-BRAIN BARRIER PENETRATING TNF INHIBITOR

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P-312 HYPERGLYCOSYLATED EPO VARIANTS TO TREAT NEURODEGENERATIVE DISEASES

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P-313 ADVANCING MANUFACTURE OF HIPSC-HEP THROUGH BIOPROCESS UNDERSTANDING

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P-314 3-D BLADDER TUMOR MODELS USING HYDROGELS AND SCAFFOLD-FREE SYSTEM

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P-315 DEVELOPMENT OF TYPE I ALLEGY THERAPEUTICS FROM GREEN ASPARAGUS

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P-316 GMOPM: AN HGM-CSF-DERIVED PEPTIDE AS A NOVEL O-GLYCOENGINEERING TOOL

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P-317 CELL CULTURE EVALUATION OF EPO NEUROPROTECTION AND NEUROPLASTICITY

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P-318 NEUTRALIZING ACTIVITY OF A CHIMERIC ANTIBODY: GLYCOSYLATION IMPACT

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P-319 CAN CELL CULTURE TECHNOLOGIES HELP WITH DIFFICULT TO EXPRESS PROTEINS?

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P-320 TOWARDS MORE MATURE HPSC-CM VIA METABOLIC MODULATION IN 3D CULTURE

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P-321 SCREENING FOR FOODS THAT ACTIVATE REGULATORY T CELLS

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P-322 IMPROVED IN-VITRO DETECTION OF TOXIC LEACHABLES IN SINGLE USE MATERIAL

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P-323 CULTIVATION OF LARGE 3D BIOPRINTED TISSUES IN PERFUSION BIOREACTORS

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P-324 PROCESS TRANSFER FROM 250L SINGLE USE TO 5000L STAINLESS STEEL VESSEL

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P-325 RECAPITULATING DEREGULATED EXTRACELLULAR DYNAMICS IN CNS DISORDERS

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P-326 ESTABLISHMENT OF FAST-GROWING CELLS FROM CHINESE HAMSTER LUNG

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P-327 BONE-MARROW EXPANDED MESENCHYMAL STROMAL CELLS FOR BONE GENERATION

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P-328 SCALE-UP OF CLINICAL GRADE MULTIPOTENT MESENCHYMAL STROMAL CELLS

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P-329 ENHANCING SCALABILITY AND OSTEOGENIC POTENTIAL OF WHARTON'S JELLY MSC

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P-330 STEM CELL MANUFACTURE IN A DISPOSABLE BIOREACTOR WITH A BIOMASS SENSOR

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P-331 NOVEL BIOREACTOR SYSTEM FOR EXPANSION OF HUMAN MESENCHYMAL STEM CELLS

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P-332 EFFECT-BASED STUDY OF HUMAN PLATELET LYSATE IN VARIOUS CELL LINES

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P-333 IMPACT OF THE IMPELLER DESIGN ON MICROCARRIER HWJ-MSC EXPANSION

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P-334 3D HIPSC-BASED CARDIAC TISSUES FOR PRECLINICAL RESEARCH

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P-335 PERSONALIZED CELL LINES BY REPRODUCIBLE AND FUNCTIONAL IMMORTALIZATION

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P-336 NOVEL MURINE AND HUMAN INTESTINAL EPITHELIAL LINES

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P-337 A HIGH-THROUGHPUT SCREENING TOOL FOR MANUFACTURING OF T-CELL THERAPIES

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P-338 METABOLOMICS AS A QUALITY CONTROL TOOL FOR CHONDROGENIC MICROTISSUES

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P-339 EVALUATION OF HMSC-DERIVED EXTRACELLULAR VESICLES BY FTIR SPECTROSCOPY

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P-340 OPTIMIZATION AND CULTIVATION OF OVARY STROMA AND MATURATED OOCYTES

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P-341 DEVELOPMENT OF AN ANTI-HER2 PHAGE TO MONITOR UNTARGETED CELL PANNING

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P-342 INDUSTRIALIZING IMMUNO-ONCOLOGY THERAPEUTIC DISCOVERY PLATFORMS

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P-343 HPL IMPROVES BONE FORMING POTENTIAL OF ADULT PROGENITORS IN BIOREACTOR

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P-344 OPTIMIZATION OF RABIES VIRUS PRODUCTION IN VEROS CELL

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P-345 VIRUS RISK MITIGATION FOR STEM CELL-BASED CELL THERAPY PRODUCTS

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CELL CULTURE PROCESS CONTROLS AND ANALYTICS

P-400 CHO PRODUCED RFIX PTMS DIFFERENCES ON FED-BATCH & PERFUSION PROCESSES

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P-401 NEW WAYS TO DEPICT MULTIVARIATE DATA FROM GLYCO PROFILES ACROSS SCALES

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P-402 INVESTIGATING CHO SCALABILITY

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P-403 CHEMOMETRICS FOR ETANERCEPT BIOPROCESS MONITORING IN THE PAT CONTEXT

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P-404 BIOSENSORS FOR QUANTIFICATION OF INFECTIOUS LABEL-FREE VIRUSES

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P-405 SPR QUANTITATIVE ASSAY FOR INFLUENZA VACCINE PRODUCTION MONITORING

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P-406 ANALYTICAL METHODS TO ASSESS PRODUCT QUALITY OF LENTIVIRAL VECTORS

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P-407 ONLINE AND OFFLINE MONITORING OF CELL CULTURE TO EXAMINE CELL DEATH

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P-408 PREDICTING INDUSTRIAL CELL CULTURE SEED TRAINS – A BAYESIAN APPROACH

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P-409 DYNAMIC BIOMASS-BASED FEEDING IN AN INDUSTRIAL CHO FEDBATCH BIOPROCESS

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P-410 CHEMOMETRICS TO MONITOR CHO CELLS CULTURES QUALITY BY IN SITU NIRS

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P-411 TEMPERATURE DEPENDENT CELL NUMBER CONTROL IN BIOREACTORS

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P-412 HOW CELL CULTURE AUTOMATION TAKES USP DEVELOPMENT TO THE NEXT LEVEL

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P-413 EVALUATION OF KLA AS SCALE-UP PARAMETER FOR CHO CELL CULTURES

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P-414 EFFECTIVE BIOREACTOR PH CONTROL USING ONLY SPARGING GASES

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P-415 AN INTEGRATED PAT SOLUTION FOR MONITORING AND CONTROL

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P-416 CHEMSTRESS®: A NOVEL METHOD OF QUALITY CONTROL FOR CELL CULTURE MEDIA

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P-417 A NOVEL DATA ANALYSIS TOOL FOR CELL CULTURE MEDIUM DEVELOPMENT

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P-419 NOVEL AT-LINE SENSOR DESIGNS FOR LIVE CELL DENSITY

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P-420 DEVELOPMENT OF A SMALL ONLINE BIOMASS MONITORING TOOL FOR MICROPLATES

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P-421 OXYGEN UPTAKE RATE SOFT-SENSING FOR BIOMASS AND METABOLIC TRANSITIONS

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P-422 ONLINE BIOPROCESS MONITORING BASED ON 2D-FLUORESCENCE SPECTROSCOPY

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P-423 IMPACT OF PROCESS IMPURITIES ON THE DETERMINATION OF HARVEST YIELD

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P-424 HT QUANTITATION OF IGG BY FLUORESCENCE POLARISATION SPECTROSCOPY

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P-425 SCALE UP, SCALE DOWN: CHARACTERIZATION OF REDUCED SCALE MODELS

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P-426 CLONE STABILITY ASSESSMENT USING CHEMSTRESS® FUNCTION PROFILING ARRAYS

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P-427 STABILITY OF PARA-AMINOBENZOIC ACID IN CELL CULTURE MEDIA

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P-428 IMPACT OF WHEAT HYDROLYSATE VARIABILITY IN CELL CULTURE PERFORMANCE

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P-429 AUTOMATION OF HIGH-THROUGHPUT TITER ASSAYS FOR CELL LINE DEVELOPMENT

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P-430 IGG GLYCAN SCREENING ASSAYS IN CRUDE CELL CULTURE SUPERNATANTS

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P-431 ONLINE MONITORING OF VIABLE CELL CONCENTRATIONS IN SMALL BIOREACTORS.

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P-432 DEFINE THE UNDEFINED – TOWARDS REALLY CHEMICALLY DEFINED MEDIA

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P-433 AUTOMATING AT-LINE METABOLITE ANALYSIS FOR HIGH THROUGHPUT BIOREACTORS

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P-434 IN SITU FLUORESCENCE MONITORING IN INSECT CELL BIOPROCESSES

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P-435 PROCESS-INDUCED CELL-CYCLE SYNCHRONIZATION

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P-436 STRATEGIES TO CONTROL A PROCESS USING CELL DENSITY ONLINE MEASUREMENT

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P-437 IN SILICO CHO MODEL GUIDES CELL CULTURE PROCESS DEVELOPMENT

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P-438 DATA RICH CELL LINE SCREENING: COMBINING AMBR15 WITH BIOPROFILE FLEX2

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P-439 IDENTIFICATION OF AN EXTRA BAND IN TLC TEST OF YEAST EXTRACT

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P-440 ENHANCED METHOD TO MONITOR CELL CULTURES BY DIELECTRIC SPECTROSCOPY

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P-441 SUFFER YOUR MEDIA FROM BURN-OUT? – ANALYZING STRESSED MEDIA

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P-442 MIMICKING INDUSTRIAL SCALE CO2 PROFILES IN CHO SMALL SCALE PROCESSES

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P-443 COMPARING DIFFERENT AT-LINE ANALYTICS FOR ONLINE RAMAN SPECTROSCOPY

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P-444 A MICROFLUIDIC APPROACH TO INFECTIVITY ANALYSIS OF LENTIVIRAL VECTORS

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P-445 EXPLORING THE CELL CULTURE DESIGN SPACE BY PREDICTIVE DIGITAL TWINS

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P-446 DEVELOPING AN AMBIC CHO REFERENCE PLATFORM FOR THE BIOTECH COMMUNITY

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P-447 CASE STUDY: UNEXPECTED IMPACT OF SHEAR STRESS ON INTENSIFIED PROCESS

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P-448 HIGH THROUGHPUT GLYCOSYLATION ASSAYS FOR GLYCOPROTEINS USING LECTINS

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P-449 NEW: HIGH THROUGHPUT AUTOMATION FOR ASSESSMENT OF CLONE ATTRIBUTES

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P-450 POTATO: APPLICATION FOR CELL CULTURE PROCESS DEVELOPMENT,AND CONTROL

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P-451 INTEGRATED SAMPLE AND DATA MANAGEMENT FOR MICRO-BIOREACTOR EXPERIMENTS

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P-452 A PLATFORM APPROACH TO ASSESS DEVELOPABILITY RISKS OF BIOLOGICS

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P-453 OFF-GAS METABOLITE ANALYSIS FOR QUALITY CONTROL AND PROCESS CONTROL OF MAMMALIAN CELL CULTURE

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CELL CULTURE PROCESS ENGINEERING, PRODUCT QUALITY AND INTEGRATION WITH DOWNSTREAM PROCESSING

P-500 HYDROCYLONE FOR MAB PRODUCTION IN A PERFUSION SINGLE-USE BIOREACTOR

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P-501 STABLE TRANSFECTION OF SF9 CELLS FOR THE CONTINUOUS PRODUCTION OF AMPS

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P-502 APPLICATION OF 2-COMPARTMENT SYSTEM TO STUDY LARGE-SCALE HETEROGENEITY

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P-503 POST-LAUNCH REMOVAL OF ASM IN AN NS0-PROCESS

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P-504 HIGH CELL DENSITY CULTIVATION TO IMPROVE INFLUENZA A VIRUS PRODUCTION

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P-505 ACOUSTIC BIOPROCESSING FOR PERFUSION APPLICATIONS

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P-506 DOE PROCESS OPTIMIZATION TO REDUCE IL-2 FRAGMENTATION

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P-507 BIOREACTOR PRODUCTION CONDITIONS ON GLYCOSYLATION

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P-508 HIGH CELL DENSITY CLARIFICATION USING SINGLE-USE TECHNOLOGIES

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P-509 HIGH ZINC SUPPLEMENTATION IN CHO CELLS INCREASES MAB AND EPO TITER

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P-510 EFFECTS OF ALTERNATIVE SUGARS AND LACTATE ON THE GLYCOPROFILE OF IGG

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P-511 GREBA: A NOVEL MODEL FOR THE GLYCOSYLATION OF IGG PRODUCED BY CHO CELLS

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P-512 MEDIA ADDITIVES AFFECT ANTIBODY QUALITY PROFILES IN PERFUSION CULTURE

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P-513 EXPRESSION OF FULL-LENGTH SHARK-DERIVED ANTIBODY BY CHO CELL

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P-514 DISPOSABLE HARVEST STRATEGIES FOR TOMORROW'S INTENSIFIED PROCESSES

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P-515 CONTROL OF PROTEIN SIALYLATION IN CHO CELL CULTURE PROCESS

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P-516 CO2 ISSUES INDUCE METABOLIC DYSFUNCTION IN CHO CELL CULTURE PROCESSES

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P-517 ACCOUNTING ENZYME REGULATION IN PROTEIN GLYCOSYLATION MODELS

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P-518 COMPARISON OF ENZYMATIC IGG DEFUCOSYLATION IN SOLID AND LIQUID PHASE

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P-519 CFD MODELLING FOR CHARACTERIZATION OF GROWTH AND PRODUCTION PARAMETERS

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P-520 DESIGN OF EXPANSION PROCESSES USING A COMPUTER-AIDED METHOD

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P-521 BIOACTIVE COMPONENTS FROM HYDROLYSATES FOR MEDIA SUPPLEMENTS

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P-522 UNDERSTANDING CHO CELL CULTURE PROGRESSION THROUGH PHOSPHOPROTEOMICS

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P-523 CHANGES IN FATTY ACID CONTENT OF CHO CELLS SWITCHING GROWTH CONDITIONS

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P-524 DE-RISKING SCALE UP THROUGH EFFECTIVE BIOREACTOR CHARACTERISATION

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P-525 INTENSIFICATION OF A PLATFORM FED-BATCH PROCESS- A CDMO PERSPECTIVE

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P-526 AUTOMATION AND DIGITALIZATION IN CELL LINE AND UPSTREAM DEVELOPMENT

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P-527 VARIABILITY IN TRACE METAL LEVELS AND ITS IMPACT ON PRODUCT QUALITY

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P-528 DEVELOPING A GLUCOSE-LIMITED GALACTOSE-SUPPLEMENTED FED-BATCH STRATEGY

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P-529 DEMONSTRATING PROCESS SCALABILITY WITH A COMPLETE UPSTREAM PLATFORM

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P-530 EVALUATION OF CELL CULTURE PROCESS ROBUSTNESS AND CELL LINE STABILITY

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P-531 SCALE-UP AND SCALE-DOWN OF FED-BATCH CELL CULTURE PROCESS: CASE STUDY

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P-532 A CHO HIGH CELL DENSITY PERFUSION PROCESS WITH IMPROVED GLYCAN PROFILE

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P-533 HIV ENVELOPE GLYCOPROTEINS AS IMMUNOGENS – EXPRESSION AND MANUFACTURE

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P-534 NEW CELL CULTURE MEDIUM COMPONENT TO REDUCE PRODUCT MICROHETEROGENEITY

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P-535 IMPACT OF SINGLE-USE BIOREACTOR AERATION ON CELL CULTURE PERFORMANCE

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P-536 DRY COMPACTION OF SINGLE CHEMICALS AND CELL CULTURE MEDIA

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P-537 BIP INDUCER X: AN ER STRESS INHIBITOR FOR ENHANCING MAB PRODUCTION

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P-538 IMPACT OF ACETYLATED AND NON-ACETYLATED FUCOSE ANALOGUES

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P-539 CHO BASED ANTIBODY PRODUCTION IN 200L CUBICAL STIRRED SU BIOREACTOR

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ESACT **P-540 DEBOTTLENECKING YOUR TIMELINE USING AN INTENSIFIED PERFUSION PROCESS**

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P-541 FED-BATCH PROCESS OPTIMIZATION FOR ANTIBODY PRODUCTION AT 2000 L SCALE

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ESACT **P-542 DEVELOPMENT OF GIBCO™ QP-CHO™ MEDIUM THROUGH MULTI-OMIC ANALYSIS**

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ESACT **P-543 CELL CULTURE PROCESS PARAMETERS FOR MODULATING MAB AFUCOSYLATION**

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ESACT **P-544 ATPS PHASE SEPARATION FOR INTEGRATED CLARIFICATION AND PURIFICATION**

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P-545 IMPACT OF CELL CULTURE MEDIA ADDITIVES ON IGG GLYCOSYLATION

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P-546 SCALE-DOWN PERFUSION METHODOLOGIES FOR RAPID BIOPROCESS DEVELOPMENT

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P-547 IMPACT OF MEDIUM FILTRATION ON CELL GROWTH AND CHARGE VARIANT PROFILE

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P-548 PROCESS OPTIMIZATION FOR FAB PRODUCTION IN EXPICHO-S™ CELLS

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P-549 OPTIMIZATION OF FAB PRODUCTION IN CHO-S CELLS: THE IMPACT OF FEEDINGS

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P-550 PROCESS INTENSIFICATION STRATEGIES FOR AN INDUCIBLE CHO CELL LINE

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P-551 RAPID FED-BATCH DEVELOPMENT USING MODELING AND HIGH THROUGHPUT TOOLS

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P-552 TEMPERATURE IMPACT ON MABS CHARGE IN FOUR INDUSTRIAL PROCESSES

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P-553 HI-INTENSITY LOW-VOLUME PERFUSION – OPTIMIZATION, BENCHMARK, SCALE-UP

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P-554 A VERSATILE TOOLBOX FOR RAPID DEVELOPMENT OF INTENSIFIED CHO PROCESSES

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P-555 SYSTEMATIC EVALUATION OF HIGH-THROUGHPUT SCALE-DOWN MODELS

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P-556 OPTIMISATION OF FEED AND TEMPERATURE IMPROVED EPO-FC PRODUCTION

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P-557 SERICIN, CULTURE SUPPLEMENT IMPROVING CELL CULTURE

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P-558 OPTIMIZING QUALITY AND PRODUCTIVITY OF A FC-FGF21 FUSION PROTEIN

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P-559 REDUCTION OF UNIT OPERATIONS IN ANIMAL CELL CULTURE PROCESSE

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P-560 THE RELEVANCE OF CELL SIZE IN A CHO CELL FED- BATCH PROCESS

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P-561 PERFUSION MEDIA DEVELOPMENT FOR SCALABLE PROCESSES

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P-562 A ROAD MAP TO LICENSURE FOR MULTICOLUMN CAPTURE IN A MAB PROCESS

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P-563 INTENSIFIED SEED EXPANSION & SIMPLIFIED CLARIFICATION OF FED-BATCH

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P-564 DEVELOPMENT OF AN AUTOMATED PERFUSION BIOREACTOR 'AMBR® 250 PERFUSION'

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P-565 MEDIA SUPPLEMENT INDUCED SIGNALING IN CHO CELLS VIA TRIPLE SILAC-MS

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P-566 A SMALL-SCALE MAB PLATFORM WITH A CONTINUOUS AND INTEGRATED DESIGN

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P-567 MEDIA & FEED SUPPLEMENTS ENABLE FINE-TUNING OF HIGH MANNOSE GLYCANS

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P-568 CHO SEED CULTURE INTENSIFICATION AND ITS CELLULAR EFFECTS ON N-STAGE

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P-569 SEED TRAIN INTENSIFICATION IN ROCKED 2D-BIOREACTORS AFFECTING CQAS

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P-570 HIGH-PERFORMANCE PERFUSION PROCESSES USING PREDICTIVE DIGITAL TWINS

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P-571 CONSIDERATIONS FOR ACCELERATING READINESS TO PROCESS QUALIFICATION

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P-572 ALTERNATE SUGARS AS ENERGY SOURCE IN CELL CULTURE PROCESS

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P-573 DEVELOPMENT OF A CD MEDIUM FOR RECOMBINANT CHO-GS CLONES

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P-574 LEVERAGING MEDIA AND SUPPLEMENTS FOR DESIRED PROTEIN GLYCOSYLATION

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P-575 DEVELOPMENT OF A CHEMICALLY DEFINED FEED FOR CHO GS CELLS

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P-576 DEVELOPMENT OF SERUM-FREE MEDIUM FOR RECOMBINANT PROTEIN IN CHO CELLS

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P-577 TEMPERATURE DOWNSHIFT AFFECTS SIALYLATION GENE EXPRESSION IN CHO CELLS

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P-578 STRATEGIES TO IMPROVE SCALE UP AND SCALE DOWN OF UPSTREAM PROCESSES

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P-579 LIQUID ENGINEERING: THE OPTIMUM MEDIA ENVIRONMENT FOR BIOPROCESSING

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P-580 NOVEL DIPEPTIDES FOR CELL CULTURE MEDIA AND THEIR CELLULAR RESPONSE

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P-581 SCALE-UP MODEL OF A MAB PROCESS FROM MICOBIOREACTOR TO XDR-1000

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P-582 DEVELOPMENT OF CHEMICALLY DEFINED MEDIUM FOR VERO CELLS

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P-583 MEDIA DEVELOPMENT FOR SEED TRAIN INTENSIFICATION AND CRYOPRESERVATION

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P-584 CONTROLLING FAB TERMINAL SIALYLATION OF ANTIBODIES

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P-585 TROUBLE SHOOTING CASE STUDY: REDUCTION OF COPPER DURING SCALE-UP

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P-586 ACHIEVING OPERATIONAL EFFICIENCY IN BIOPROCESS DEVELOPMENT

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P-587 MEDIA REFORMULATION; CHALLENGES FOR PROCESS DEVELOPMENT AND SCALE UP

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P-588 EARLY STAGE PROCESS DEVELOPMENT AND SCALE UP USING HTP BIOREACTORS

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P-589 A CFD BASED KLA MODEL IN MICROTITER PLATES FOR CELL CULTURE SCALE-UP

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P-590 HIGH DENSITY PERFUSION OF HUMAN/ANIMAL CELLS IN SMALL-SCALE BIOREACTOR

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P-591 BAC VS PLASMID – EXPRESSION OF THE "DIFFICULT-TO-EXPRESS" PROTEIN CD19

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P-592 MITIGATE ADVENTITIOUS AGENT CONTAMINATION RISKS IN CELL CULTURE MEDIA

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P-593 A SOFTWARE IMPLEMENTING QUALITY BY CONTROL TO BIOPROCESSES

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P-594 USE OF A 24-WELL MICROBIOREACTOR AS PROCESS DEVELOPMENT TOOL

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P-595 INCREASING HD-BIOP3 SEEDING EFFICIENCIES USING VIPS

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P-596 HIGH-THROUGHPUT DOWNSTREAM PLATFORM FOR BIOSIMILAR MAB DEVELOPMENT

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P-597 ADVANCING N-1 PERFUSION PROCESS DEVELOPMENT

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P-598 CELL GROWTH RATE DETERMINES THE QUALITY OF A MONOCLONAL ANTIBODY

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P-599 ADDRESSING CHO CLONAL DIVERSITY USING MULTI-OMICS ANALYSIS

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P-600 CONTROL OF LIPIDS IN MAMMALIAN CELL BIOPROCESS BY SYNTHETIC BIOLOGY

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P-601 DEVELOPMENT OF A >10 G/L HIGH-TITER FED-BATCH CHO PLATFORM PROCESS

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P-602 ARE YOU FEEDING MORE CELLS THAN YOU THINK?

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P-603 SIMULATING LARGE-SCALE BIOREACTOR HETEROGENEITIES IN MINI-BIOREACTORS

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P-604 INSECT CELL PROTEIN PRODUCTION: NOVEL HIGH VOLUME SHAKER FLASK TECHNOLOGY

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P-605 A MULTI-SCALE APPROACH TO CHO MEDIA BENCHMARKING

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P-606 AN END-TO-END CELL CULTURE PROCESS DEVELOPMENT PLATFORM AND ITS APPLICATION TO BIOSIMILAR PRODUCT DEVELOPMENT

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P-607 VALIDATION OF CHEMICALLY DEFINED MEDIA FOR VACCINE AND GENE THERAPY PRODUCTION

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P-608 AN EASY-TO-USE MEDIA SUPPLEMENT FOR INCREASED BIOMOLECULE GALACTOSYLATION

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Connecting with **patients**

" I'm so proud to be part of the UCB panel. It has given me the chance to help others with the same condition and to have a voice. It's tough living with a skin condition but talking about new ideas to improve treatment and sharing experiences has helped me both mentally and physically. "
Victoria, living with psoriasis

UCB has a passionate, long-term commitment to help patients and families living with severe diseases lead normal, everyday lives.

Our ambition is to offer them innovative new medicines and ground-breaking solutions in two main therapeutic areas: neurology and immunology. We foster cutting-edge scientific research that is guided by patients' needs.