25TH ESACT MEETING

WWW.ESACT2017.COM LAUSANNE 2017 MAY, 14-17

CELL TECHNOLOGIES FOR INNOVATIVE THERAPIES

ESACT

European Society for Animal Cell Technology

PROGRAMME BOOK

CONTENTS

NOTES

WELCOME FROM THE MEETING CHAIRMAN

On behalf of the European Society for Animal Cell Technology (ESACT) and the local Organising Committee, I wish to welcome you to the 25th ESACT Meeting. It all started in 2013, shortly after the ESACT Meeting in Lille, when I proposed to host the 2017 Meeting in the recently built Swiss Tech Convention Centre in Lausanne. This venue was somehow designed for such an event and I am convinced that we will enjoy the convenience of the facility as well as the great location.

Such an event would not take place without the support of dedicated colleagues from the different committees, i.e. the Executive Committee, the Scientific Committee and the Organising Committee. Hence, I wish to sincerely thank all who worked hard to make this happen. I also would like to address my gratitude to the team at MCI who provided support to all organisational aspects and to our many sponsors who generously contributed to this event. Finally, a note to acknowledge the fantastic support received from the ESACT Frontiers group. This group of early career scientists was only recently created and what they did for this meeting simply exceeded all our expectations!

ESACT meetings offer a great opportunity to access the latest advances in the field of animal cell technology. This time again, we will benefit from highly informative contributions from both academia and industry. The Scientific Programme contains five sessions which cover the different activities in our field. 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 as well as for the pre-selection of the top 100 posters which are eligible for the poster prize. In addition and before the meeting even officially starts, we will have the opportunity to experience insightful pre-conference symposium sessions. I would like to address my special thanks to all the individuals and companies who made this happen. Thanks to them, I am convinced that we established a highly informative programme based on the most innovative contributions in our field.

The networking opportunities are certainly another highlight of ESACT meetings. This will be possible throughout the conference and I encourage you to reach out to your colleagues in the field and interact as much as possible. And there is more! Many of us remember discussions we had during networking events organized during the meeting. Therefore, I encourage you to use the many networking opportunities we created for you during this meeting.

On Sunday evening, make sure to experience the exhibitor's reception. The reception is planned after the opening sessions on Sunday May 14. The exhibition is one of the highlights of ESACT meetings and once again delegates will have the opportunity to discover the latest tools, technologies and services provided in the field of animal cell technology. The reception will take place in the exhibition hall and will be the official opening of the exhibition.

On Tuesday afternoon, we will experience a private visit of The Olympic Museum followed by a cocktail dinner. A boat trip on Lac Léman will take us from the Swiss Tech Convention Centre to the museum located in Ouchy, Lausanne. The museum is one of the highlights of any visit to Lausanne, not only because of the outstanding and recently modernised exhibition but also because of the great location.

Finally, a special event is planned for the closing of the meeting on Wednesday evening, at the Swiss Tech Convention Centre. Indeed, we celebrate the 25th time this meeting takes place. Note that the poster prize and the 2nd ESACT video contest prize will be awarded during the dinner. So make sure to attend this event which will provide one more opportunity to interact and celebrate!

On behalf of the Organising Committee, I wish you a very successful 25th ESACT Meeting.

Matthieu Stettler

Chairman of the 25th ESACT Meeting

WELCOME FROM THE EXECUTIVE COMMITTEE

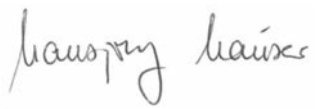
ESACT is celebrating the 25th meeting, 41 years after the first one. With pride we can state that the ESACT meetings are, not only well established and leading in the field within Europe, but are also an opportunity for participants/attendees/scientists from around the whole world to participate and contribute to the scientific programme, the poster session or the trade exhibition. We are convinced that this meeting will again fulfil your expectations, not only with regard to science and business but as well as for the networking programme.

It is a long-lasting tradition that the execution of the meeting is in the hand of a local chairman. For this meeting we delegated the task to an exceptional person. Matthieu Stettler lives close to Lausanne, his working place in Vevey (Merck) is close-by and he is a prototype of a cosmopolitan Swiss citizen from the Lake Geneva region. He is rather young for such a task, probably the youngest chairman we ever had in our history. Matthieu got a perfect background education in bioengineering at the EPFL in Lausanne and works in industry. The latter deserves a special note. Since such kind of chairmanship is highly demanding, it definitively affects the capacity of the person as an employee. We are thus very grateful to Merck for giving Matthieu enough room for this task.

Bringing such a meeting to fly needs many efforts from different organizations and individuals. We thank the scientific committee for setting up an excellent programme, the organizing committee for assembling all different activities, the speakers and poster presenters for their preparations, the exhibitors for setting up their booths and the sponsors for their generous support and last but not least MCI for the organization.

Our main thanks and congratulations go to Matthieu Stettler who developed this meeting in a highly structured and organized way and for his personal commitment and the time devoted to this event. We wish all of you a meeting that meets your expectations, success for the presentations, new impulses and lots of interactions amongst the participants.

On behalf of the ESACT Executive Committee



Hansjörg Hauser
Chairman

Paula Alves
Vice Chairwoman

MEETING ORGANISATION AND ESACT COMMITTEES

MEETING CHAIRMAN

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- Merck, Switzerland

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- UAB, Spain

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- UCB Pharma, Belgium

Martin Jordan
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Isabelle Knott
- GSK Vaccines, Belgium

ESACT Office: **Els van den Berg**

ESACT FRONTIERS

ESACT Frontiers Program (EFP) is an initiative within ESACT focused on promoting career progression and active engagement of young generations to ESACT and to the field of Animal Cell Technology. With this, the next generation of ESACT scientists gets a platform to influence the development of the society and can give the young generation of scientists a voice in our community.

Current members:

Mercedes Segura
- Bluebird bio, USA

Simon Ausländer
- ETH Zurich, Switzerland

Emma Petiot
- CPE Lyon, France

Ana Filipa Rodrigues
- iBET, Portugal

Christopher Sellick
- MedImmune, UK

Verena Lohr
- Sanofi, Germany

Paulo Fernandes
- Autolus, UK

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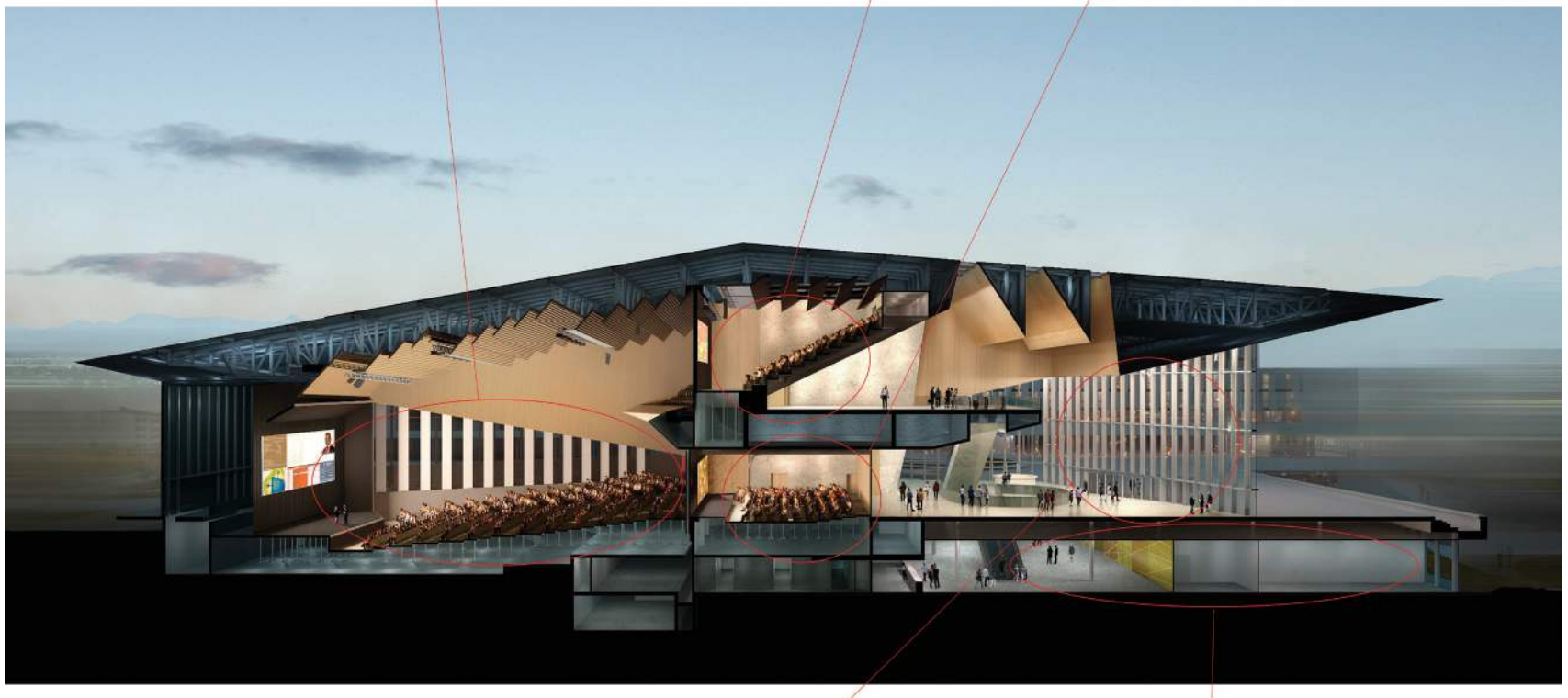
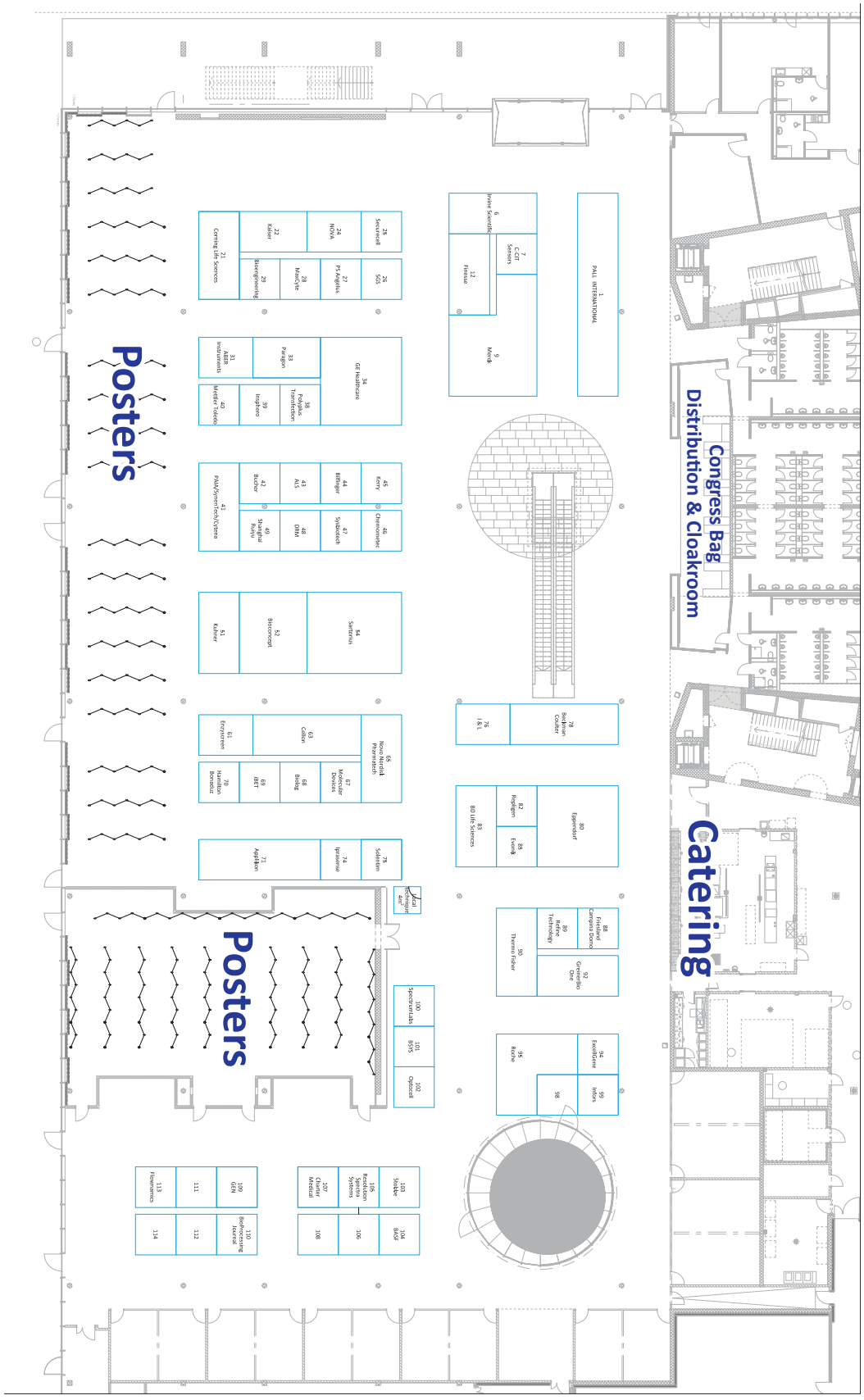
VENUE MAP


Plenary Hall
Auditorium A
Auditorium C
Auditorium B
Registration
Lunches
Foyer Campus
Catering
Exhibition & Posters
Foyer Garden

EXHIBITION MAP



EXHIBITOR LIST

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Learn more at **Kerry.com**

NETWORKING EVENTS

Sunday 19:00 - 21:00

EXHIBITOR'S RECEPTION

The reception is planned after the opening session of the 25th ESACT Meeting on Sunday. The exhibition is one of the highlights of ESACT meetings and once again delegates will have the opportunity to discover the latest tools, technologies and services provided in the field of animal cell technology. The reception will take place in the exhibition hall and will be the official opening of the exhibition.

Tuesday 16:00 - 21:00

OUTING TO THE OLYMPIC MUSEUM

A private visit of the museum and a cocktail dinner are planned on Tuesday after the end of the poster session. A boat trip on Lac Léman will take the delegates from the Swiss Tech Convention Centre to the museum in Ouchy, Lausanne. The museum is one of the highlights of any visit to Lausanne, not only because of the outstanding and recently modernised exhibition but also because of the great location.

Wednesday 19:30 - 00:00

25TH ESACT MEETING CELEBRATION

A special event is planned for the closing of the meeting on Wednesday evening, at the Swiss Tech Convention Centre. Indeed, we celebrate the 25th time this meeting takes place. Note that the poster prize and the 2nd ESACT video contest prize will be awarded during the dinner. So make sure to attend this event which will provide one more opportunity to interact and celebrate!

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IMPORTANT INFORMATION

VENUE

SwissTech Convention Center
Quartier Nord de l'EPFL
Route Louis-Favre 2
CH - 1024 Ecublens

TECHNICAL SECRETERIAT

ESACT 2017, c/o MCI
9, Rue du Pré-Bouvier
1247 Satigny, Geneva
Switzerland

T +41 22 33 99 729
F +41 22 33 99 631
esact2017@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 2017 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.

OPENING HOURS

Saturday	13th of May	16:00 - 19:00
Sunday	14th of May	09:00 - 21:00
Monday	15th of May	08:30 - 21:00
Tuesday	16th of May	08:30 - 15:30
Wednesday	17th of May	08:30 - 17:00

SPEAKERS PREVIEW ROOM

Speakers have to provide their presentations in the Business Center AB located on the Exhibition level (-1). This has to be done no later than two hours before the scheduled time of the session.

Speaker's room opening hours:

Saturday	13th of May	16:00 - 19:00
Sunday	14th of May	09:00 - 21:00
Monday	15th of May	08:30 - 21:00
Tuesday	16th of May	08:30 - 15:30
Wednesday	17th of May	08:30 - 17:00

WIFI ACCESS

User ID: 2779426012
Password: 7457

ACCESS TO THE MEETING

The delegate fee gives access to the following:

- Access to all the sessions of the ESACT Meeting
- Lunches
- Exhibitor's Reception on Sunday, May 14th
- Networking Events

Accompanying person fee give access to:

- Lunches
- Networking Events

NOTES

Call for Applications for ACTIP Fellowships 2017-2018

ACTIP (the Animal Cell Technology Industrial Platform) is a scientific and informal European forum of companies employing animal cell technology (**www.actip.org**). Twice a year the representatives of the member companies meet to discuss scientific research, development, technology and regulatory topics of mutual interest. Besides the representatives of the member companies, invited speakers and observer companies (SMEs working on the themes covered by the meeting) meet together and participate to these meetings that take place in the home towns (and sometimes on the premises) of ACTIP member companies. The meetings are characterized by a friendly atmosphere and very collaborative discussions.

We want to open 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, test development… ACTIP wants to offer you the floor to present your project and personal expertise to our community; not only an excellent opportunity for you to present your project to experts 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 meeting of ACTIP. 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 2017 to spring 2019. In order to be selected for such an opportunity, ACTIP invites you to send in an application to us for the ACTIP Fellowship.

How to apply?

Applicants should be younger than 35 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. A recent *Curriculum Vitae* with full contact details should accompany the application.
Both the project description and recent CV should be sent to:
Dr. Chantra Eskes, Executive Secretary ACTIP, email: **actip@secam-ce.eu**

Timeline

Applications can be sent from 29 May until 7 August 2017. Evaluations by ACTIP experts will take place from 10 August to 30 September 2017. Experts will be assigned by the ACTIP Steering Committee. Selected Fellows will be notified by 13 October 2017 at the latest. 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 2017 to June 2019.

We look forward to receiving your applications!

ACTIP Animal Cell Technology Industrial Platform

ESACT
MEDALS 2017

Dr. Elisabeth Fraune

Sartorius Stedim Systems GmbH

The ESACT medal is being awarded to Dr. Elisabeth Fraune for her activities to promote ESACT over many years and her contributions in manufacturing systems engineering for bioprocesses.

Elisabeth Fraune studied bioprocess engineering at the Technical University of Berlin, Germany. In 1986, she received her Ph. D. (Dr. rer. nat.) in Chemistry from the University of Hannover, Institute Prof. Karl Schügerl for her research on the production and purification of human β-Interferon in Mouse-L-cells supervised by Prof. Jürgen Lehmann.

She joined BRAUN BIOTECH in Melsungen, Germany, and established an industrial R&D Bioprocess Laboratory in which she led research projects into animal cell cultivation. One of these focused on the development of animal cell culture bioreactors coupled with perfusion technology (internal and external spin filters).

Within the Sartorius Stedim Systems Company (now located in Guxhagen, Germany) Elisabeth Fraune is focuses on process engineering projects for predominantly industrial customers. Her fields of expertise include upstream and downstream process design, development of perfusion processes and the implementation of single-use technologies in upstream, downstream as well as freeze & thaw applications.

Elisabeth Fraune has been a frequent and active member of the ESACT International Organizing Committee since 1992. In 1993, she was also member of the Organizing Committee of the ESACT meeting in Würzburg, Germany.

Dr. Yves-Jacques Schneider

Université Catholique de Louvain, Belgium

The ESACT medal is awarded to Professor Yves-Jacques Schneider for his activities to promote ESACT towards a society that merges academic achievements with industrial development for the creation and production of new biological tools through animal cell engineering.

Yves-Jacques, a Belgian citizen, started his career with a PhD (1977) in cell biochemistry biology and an Agrégation de l'Enseignement supérieur in cell pharmacology in 1983, under the supervision of Professors C. de Duve and A. Trouet at the Medical School of the Université Catholique de Louvain. He moved to the Faculty of Sciences in Louvain-la-Neuve, in 1988.

As a researcher and later on as a professor at the Université Catholique de Louvain, he focused his interest in cell membranes and transport. For example, he developed a special track etched membrane for optimal cultivation of mammalian epithelial cells. He also developed cell culture systems as in vitro tools for pharmaco-toxico studies.

As a full professor since 1993, he is in charge of lectures in biochemistry, biotechnology and pharmaco-toxicology. Since 1988, he is the director of a research laboratory of cellular, nutritional and toxicological biochemistry and since 2013, the chairman of the Life Science Institute. Besides academic activities, he is a member of the board of directors of it4ip and of the board of directors of the Certech. Yves-Jacques combines a deep interest for research with a high enthusiasm for teaching and a strong willingness to sustain industrial projects.

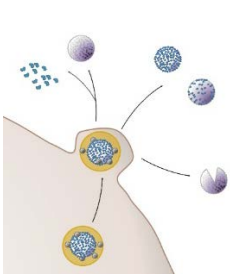
Yves-Jacques was a member of the ESACT Executive Committee (2011-2013). He was Chairman of the local organizing committee of the ESACT Meeting in Lille in 2013. Yves-Jacques is also the Chairman of BELACT (Belgian Animal Cell Technology Society).

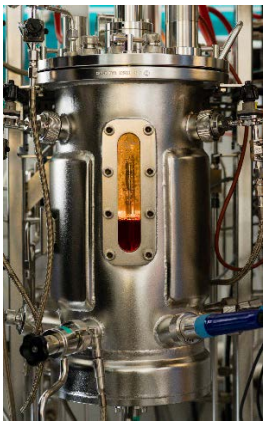
CELL CULTURE-BASED VIRAL VACCINES 2017

SECOND EDITION

September 19th – 22nd, 2017

Llafranc, Costa Brava / Spain





Photos: Ehl & MPI, Magdeburg

The main topics: (1) Principles of immunology and virology, (2) Cell lines for vaccines production, (3) Upstream process development and intensification, (4) Analytical and potency assays, (5) Downstream processing of viral vaccines, (6) Vaccine formulation and delivery systems, (7) QbD and PAT in vaccine development, (8) Regulatory issues, (9) Vaccine traditional markets, immunization policies, and supply solutions, (10) Several case studies for vaccine development and manufacturing will be presented by international experts.

Confirmed lecturers include Amine Kamen (McGill, Canada), Reingard Grabherr (Boku, Austria), Isabelle Knott (GSK, Belgium), Leo van der Pol (IntraVac, The Netherlands), Yvonne Genzel (MPI, Germany), Francesc Godia (UAB, Spain), Cristina Peixoto (iBET, Portugal), Emma Petiot (CPE-Lyon Engineer School, France), Patricia Leung-Tack (Sanofi-Pasteur, France), Erin Sparrow (WHO, Switzerland) and Ray Prasad (Bill and Melinda Gates Foundation, USA). Other information can be found at www.esact.org.

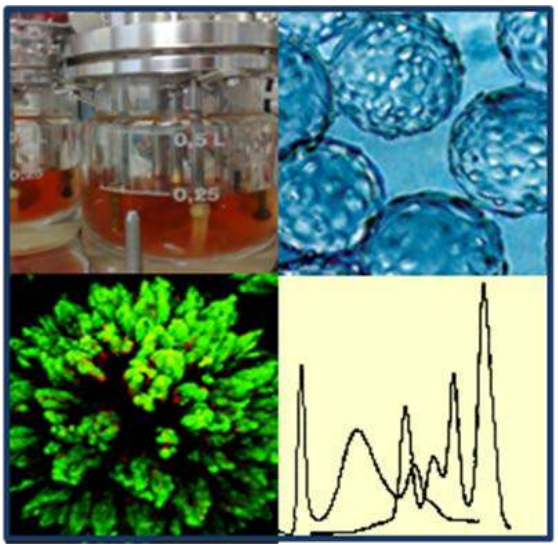
Application possible until 30th of June!

ANIMAL CELL TECHNOLOGY COURSE 2017

SEVENTH EDITION

September 24th - 28th, 2017

Llafranc, Costa Brava / Spain



Photos: www.ibet.pt

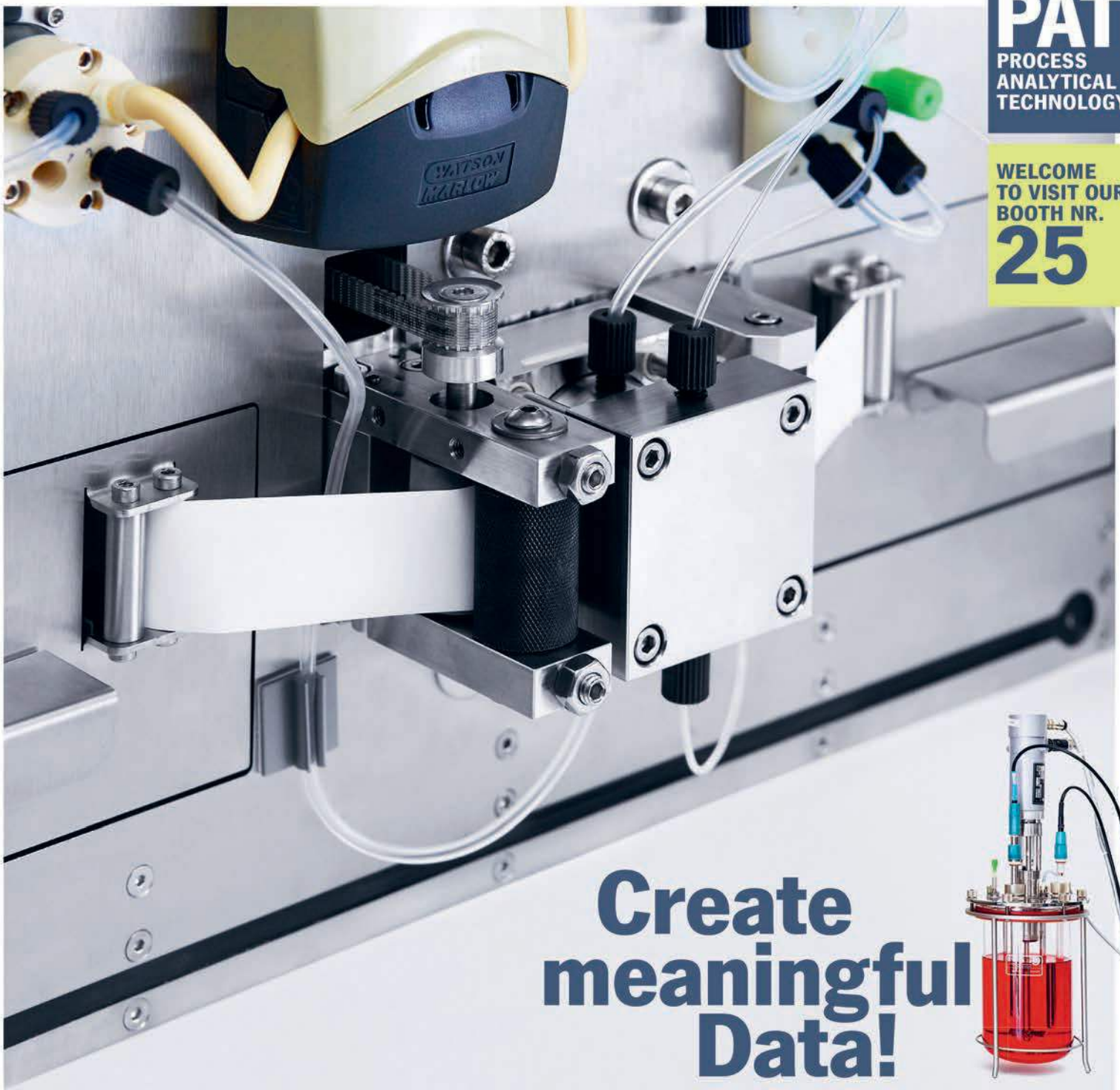
The main topics: (1) Cell line development, (2) Cellular mechanisms, (3) Genomics and proteomics, (4) Post-translational modifications, (5) Bioreactor scale-up, scale-down and single use bioreactors, (6) Downstream processing, (7) Integrated bioprocess for cell based vaccines, (8) Economical aspects of ACT bioprocesses, (9) Integrated bioprocess for protein production, (10) Integrated bioprocess for stem cells, (11) Industrial perspectives of ACT.

Confirmed lecturers include Terry Papoutsakis (University Delaware, USA), Manuel Carrondo and Paula Alves (iBET, Portugal), Nicole Borth (Boku, Austria), Francesc Gòdia (UAB, Spain), Stefanos Grammatikos (UCB Pharma SA, Belgium) and Anne Tolstrup (Biogen, Denmark). Other information can be found at www.esact.org.

Application possible until 30th of June!

PAT
PROCESS ANALYTICAL TECHNOLOGY

WELCOME TO VISIT OUR BOOTH NR. 25



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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

TIME	SUNDAY 14 MAY	TIME	MONDAY 15 MAY	TIME	TUESDAY 16 MAY	TIME	WEDNESDAY 17 MAY
09.00-09.30		09.00-09.30	Session 2 : Cell Engineering & Analytics	09.00-09.30	Session 6 : Enabling Cell Based Technologies (continued)	09.00-09.30	Session 8 : Cell Cultue Based Process Engineering and Product Quality (continued)
09.30-10.00		09.30-10.00		09.30-10.00		09.30-10.00	
10.00-10.30	Symposium Sessions	10.00-10.30		10.00-10.30		10.00-10.30	
10.30-11.00		10.30-11.00	Coffee Break	10.30-11.00	Coffee Break	10.30-11.00	Coffee Break
11.00-11.30		11.00-11.30	Session 3 : Cell Engineering & Analytics	11.00-11.30	Session 7 : Cell Culture Based Process Engineering and Product Quality	11.00-11.30	Session 9 : Cell Cultue Based Process Engineering and Product Quality (continued)
11.30-12.00		11.30-12.00		11.30-12.00		11.30-12.00	
12.00-12.30	Symposium Sessions	12.00-12.30		12.00-12.30		12.00-12.30	
12.30-13.00		12.30-13.00	Lunch	12.30-13.00	Lunch and ESACT General Assembly	12.30-13.00	Lunch
13.00-13.30		13.00-13.30		13.00-13.30		13.00-13.30	
13.30-14.00		13.30-14.00		13.30-14.00		13.30-14.00	
14.00-14.30	Symposium Sessions	14.00-14.30	Poster Session & Coffee	14.00-14.30	Poster Session & Coffee	14.00-14.30	Session 10 : Emerging Cell Based Therapeutic Approaches
14.30-15.00		14.30-15.00		14.30-15.00		14.30-15.00	
15.00-15.30		15.00-15.30		15.00-15.30		15.00-15.30	
15.30-16.00	Coffee Break	15.30-16.00	Session 4 : Cell Culture Based Vaccines	15.30-16.00	Outing to Lausanne Olympic Museum	15.30-16.00	Closing Ceremony and Keynote 2
16.00-16.30	Opening Session and Keynote 1	16.00-16.30		16.00-16.30		16.00-16.30	
16.30-17.00		16.30-17.00		16.30-17.00		16.30-17.00	
17.00-17.30		17.00-17.30	Coffee Break	17.00-17.30		17.00-17.30	
17.30-18.00	Session 1 : Cell Engineering & Analytics	17.30-18.00	Session 5 : Enabling Cell Based Technologies	17.30-18.00		17.30-18.00	
18.00-18.30		18.00-18.30		18.00-18.30		18.00-00.00	Celebration of the 25th ESACT Meeting
18.30-19.00		18.30-19.00		18.30-19.00			
19.00-19.30	Exhibitors Reception	19.00-19.30	Workshop Session	19.00-19.30			
19.30-20.00		19.30-20.00		19.30-20.00			
20.00-20.30		20.00-20.30		20.00-20.30			
20.30-21.00				20.30-21.00		00.00	

SYMPOSIUM AND WORKSHOP SESSIONS

TOPICAL SYMPOSIUM SESSION
MAY 14, 10:00-11:30, AUDITORIUM B

Data-driven approaches for cell culture process development

Alessandro Butté (ETH) and Christoph Freiberg (Genedata)

The development of production cell lines and optimal upstream processes has enormously been accelerated, amongst others, by introducing automation and parallelization such as the usage of scale-down bioreactor models and by applying more and more clone and product analytics methods. This symposium provides insights by experts from the biopharmaceutical industry about their ways of keeping track and analyzing the vast amounts of analytics data and process parameters and how their concepts look like to make data-driven decisions in the area of cell line and upstream process development. The presenters will illustrate their concepts with example case studies and will discuss about future outlooks and challenges on the use of data-driven approaches.

Presentations:

- Claudia Goetzberger-Schad (Bayer) - Integration of diverse data across the cell line development process
- Michael D. Hoffman (Sanofi) - Sanofi cell line development: data-driven approaches for cell line generation and clone selection
- Patrick Sagmaister (Exputec) - Process data management and analysis
- Moritz von Stosch (GSK) - Development of hybrid models for bioprocess development

TOPICAL SYMPOSIUM SESSION
MAY 14, 10:00-11:30, AUDITORIUM C

ESACT Frontiers session:
Turning great ideas to commercial success: pathways, funding and….luck?

Verena Lohr (Sanofi) and Emma Petiot (CPE Lyon)

This symposium will focus on approaches and strategies which can bring ideas to successful commercialisation, covering:

- The value of networks (as through the UK-based BioProNet) to define ideas, make connections and build confidence in concept.
- Translation of idea or initial product specification towards the basis for a commercial venture (licensed product, new company, product pipeline).
- Large company perspective and approaches in the processes of drug discovery, development and commercialization.

The session will build on case study experiences from experts, followed by a Q&A discussion session for active audience participation.

Presentations:

- Alan Dickson (Professor University of Manchester / co-director BioProNET)
- Geoffrey Esteban (CEO IPRASENSE)
- Jean Delaveau (CEO LYOPHITECH / former industrialization director at MERIAL)

TOPICAL SYMPOSIUM SESSION
MAY 14, 12:00-13:30, AUDITORIUM B

ACTIP/ESACT joint session: Advanced therapy medicinal products (ATMPs) – manufacturing, safety and regulatory aspects – examples from the industry

Luc Kupers (Sanofi) and Otto Merten (Genethon)

Viral vectors are extensively used as delivery systems for gene and cell therapies, oncotherapies and vectors for display or expression of antigens in different vaccination strategies. Developments and optimisations in vectorology and cell culture technologies performed over many years have conducted to medium-large scale production of viral vectors allowing pre-clinical and clinical trials for therapeutic applications and finally to the arrival of the first gene therapy products on the market.

However, often animal cell culture technologists are not always informed on these advances and achievements because they are essentially presented and communicated at specialized scientific meetings or in specialized journals. The purpose of this symposium is to present an overview on mass production of viral vectors as well as on special achievements with respect to the use of AAV (adeno-associated viral) and retroviral vectors in clinical applications. Since the regulatory framework and safety aspects are of particular importance for the use of ATMPs, this issue will also be dealt with. The audience is invited to participate in the discussion on remaining challenges in the manufacturing, safety and regulatory aspects of ATMPs.

Presentations:

- Amine Kamen (McGill University) - Process intensification to address the challenges of viral vectors manufacturing for gene and cell therapies
- Peter Ulrich (Novartis) - Safety considerations for genetically engineered T cell therapies
- Laurence Guianvarc'h (Généthon) - Production process of AAV vectors by transfection in suspension cells: scale up and transfer to a CMO
- Martin Wisher (Merck) - The regulatory framework of ATMs

MERCK SPONSORED SYMPOSIUM SESSION
MAY 14, 12:00-13:30, AUDITORIUM C

Cell culture media designed for intensified perfusion processes

Delia Lyons (Merck) and Kevin Kollel (Merck)

Current market needs are driving the interest of the industry towards the application of intensified processes and continuous manufacturing. Most commonly intensified processes include the application of perfusion technology, which facilitates the accumulation of very high cell densities (>50 mio cells/mL) in the bioreactor. The accumulation of biomass can be applied as a scale up bioreactor or to increase volumetric productivity in the production bioreactor. The increased volumetric productivity allows using smaller bioreactors and consequently decreases the capital investment in a plant. However, in order to maintain high cell densities, cell culture media needs to be exchanged continuously and it is currently considered the highest expenditure in an upstream continuous process. Optimization of cell culture media that results in lower perfusion rates will drive the cost of the upstream process significantly down.

In this work, we applied an integrated design approach that includes nutritional fundamentals, design of experiments and multivariate analysis to formulate a new chemically defined perfusion medium. This perfusion medium was developed using multiple CHO cell lines and proteins to ensure broad spectrum applicability. In addition, this perfusion medium has been evaluated for several perfusion applications that include seed train bioreactor, steady state perfusion and other protein production modalities.

Presentations:

- Techniques used to develop perfusion medium
- Small scale modelling limitations and alternatives
- Case studies with newly developed catalogue perfusion medium
- Analysis of product quality attributes in perfusion and flexibility to modify it

GE HEALTHCARE SPONSORED SYMPOSIUM SESSION
MAY 14, 14:00-15:30, AUDITORIUM B

From research to clinic: intensify your cell culture process

Andreas Castan (GE Healthcare)

The journey from molecule discovery to manufacturing can be challenging and market success is heavily dependent on the swift creation of a high performing cell culture process. Cell culture scientists drive this success by striving for scalable, robust processes that reach target titres and deliver consistent protein profiles. They must also keep pace with accelerated development timelines, delivering a cost-effective solution to support a viable business case. During this session, seasoned experts will present case studies and share their insights into overcoming obstacles. We look forward to welcoming you to this interactive session and to share thoughts and experiences on your own journey from research to clinic.

Presentations:

- Clare Lovelady (Medimune) - Medimmune will describe approaches to cell line development including transferring from gene to a production cell line.
- Kurt Russ (Rentschler Biotechnologie) - Rentschler will present their proven scale up and scale down approach for stirred tank bioreactors (STR's) and discuss implementation across different cell culture processes.
- Véronique Chotteau (KTH, Royal Institute of Technology) - Continuous processing remains an important industry topic and the KTH Royal Institute of Technology will describe opportunities to intensify seed train and production operations in order to reduce costs and improve process efficiency.
- Mats Lundgren (GE Healthcare) - GE will discuss regulatory considerations with particular focus on the increasing use of single use technologies in cell culture processes.

SARTORIUS STEDIM BIOTECH SPONSORED SYMPOSIUM SESSION
MAY 14, 14:00-15:30, AUDITORIUM C

Speed to clinic accelerating biopharmaceutical development

Miriam Monge and Joerg Weyand (Sartorius Stedim Biotech)

Bringing life-saving biopharmaceuticals to market as quickly as possible is the priority for many companies. The Sartorius Integrated Solutions team has assembled leading industry experts from the likes of Roche, Novartis and mAbXience to describe state-of-the-art methods for accelerating biopharmaceutical development and increasing speed to clinic. These presentations will be supplemented with customer case studies presented by Sartorius speakers.

During this symposium, you will learn how process characterization can be performed in micro-scale and benchtop bioreactors. We will describe practical tips for developing and implementing continuous and intensified bioprocesses platforms and we will illustrate this talk with a case study from Novartis describing how the firm implemented a perfusion process in 1000-L single-use bioreactors. Finally, you will see how working with a CRO can expedite the development of biosimilars ensuring they reach the clinic in the shortest time possible.

Presentations:

- Gerben Zijlstra (Sartorius Stedim Biotech) - Continuous and intensified bioprocessing: a practical guide - The development, implementation and control of intensified and continuous bioprocesses
- Annette Beattie (mAbxience) - Interactions with a CRO during a biosimilar drug development cycle
- Benjamin Neunstoecklin (Novartis) - Productivity and robustness increase of process characterization studies through the use of automated high throughput bioreactors
- David Garcia (Novartis) - Scaling continuous processes: from 1L to 1000L single use

TOPICAL WORKSHOP SESSION
MAY 15, 19:00-20:30, AUDITORIUM C

CHO genome workshop

Nicole Borth (BOKU University), Mike Betenbaugh (Johns Hopkins University) and Kelvin H Lee (University of Delaware)

Over the last few years, a surge of community efforts have generated significant amounts of publicly available genome scale information for scientists and industrialists working with Chinese Hamster Ovary cells. There are now two Chinese Hamster genomes available and more than 10 genome sequences for a variety of CHO cell lines. Both the CHO-K1 sequence and the Chinese Hamster genome are part of the RefSeq program and receive regular annotation updates. Tools available for systems biology research include www.CHOgenome.org as the single direct entry point to all CHO related information, a genome browser, a proteome database, a community generated consensus genome scale metabolic reconstruction and a CHOmine. In addition, with contributions from the scientific community and industry, a new reference genome of the Chinese Hamster was generated using PacBio sequencing, to overcome the drawbacks of the available, Illumina-based reference draft genomes (large number of contigs and scaffolds, high percentage of NNNs, some genes split across scaffolds/ contigs, difficult to assemble repetitive sequences). The recently completed reference genome based on both the PacBio and the Illumina sequences is of much better quality than the previous version and boasts an N90 of 122 scaffolds and less than 0.2% NNNs. To celebrate its completion we plan to present in this workshop presentations on all systems biology applications and tools that will enhance our understanding and control of CHO cells as production vehicles for biopharmaceutics.

Presentations:

- New Chinese Hamster genome and assembly based on combined Illumina-Pacbio sequencing data
- Alan Dickson (University of Manchester) - Genome Editing to create enhanced mammalian biomanufacturing platforms
- Pierre-Alain Girod (Selexis) - Whole genome sequencing to survey genetic changes in stable CHO cell lines
- Gerald Klanert (Austrian Center of Industrial Biotechnology) - Epigenetic regulation and gene expression – how a phenotypic switch is turned
- Colin Clarke (NIBRT) - Widespread heteroplasmy of the mitochondrial genome in CHO cells
- Paula Meleady (Dublin City University) - Quantitative phosphoproteomic analysis of CHO cells
- Deniz Baycin (Turgut Ilaclari Biotechnology Center, Turkey) - Lipidomics of CHO cells

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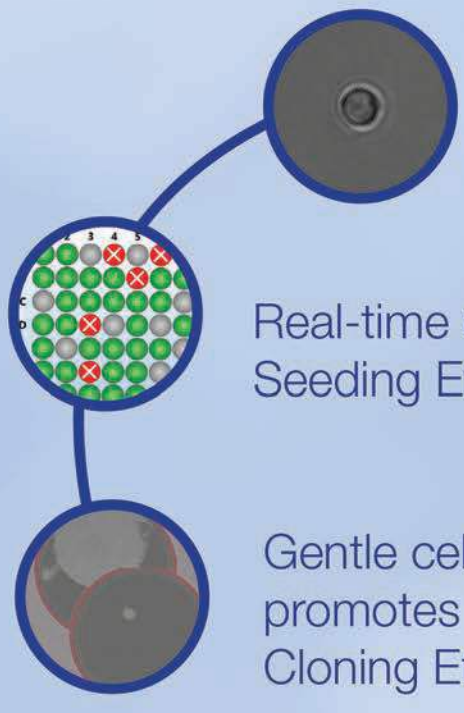

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SUNDAY 14 MAY, 2017

16.00 – 17.30 **OPENING AND KEYNOTE**
Chairpersons: Matthieu Stettler and Hansjörg Hauser

16.45 – 17.30 **SP001** CELL THERAPY AND CELL CHOICES IN THE SWISS TRANSPLANTATION PROGRAM- FROM THE LABORATORY TO CLINICAL RESEARCH AND USE
Lee Ann Laurent-Applegate – CHUV, Switzerland

17.30 – 19.00 **SESSION 1: CELL ENGINEERING AND ANALYTICS**
Chairpersons: Anne Tolstrup and Christopher Sellick

17.30 – 18.00 **SP002** ENGINEERING CELL METABOLISM TO ENHANCE PROTEIN PRODUCTION
Nathan Lewis - University of California, San Diego, United States

18.00 – 18.20 **OR001** CRISPR-CAS BASED SYNTHETIC TRANSCRIPTION FACTORS: A STRATEGY FOR IMPROVING BIOPRODUCTION IN CHO CELLS
Si Nga (Susie) Sou [1,], Dirk-Jan Kleinjan [1], Caroline Wardrope [1], Susan Rosser [1]*
[1]Institute of Quantitative Biology, Biochemistry, and Biotechnology, School of Biological Sciences, University of Edinburgh, Edinburgh, United Kingdom

18.20 – 18.40 **OR002** DEGRADATION OF RECOMBINANT PROTEINS OF DIVERSE FORMATS BY CHO HOST CELL PROTEASES IS CIRCUMVENTED VIA KNOCK-OUT OF CHO MATRIPTASE
Holger Laux [1,], Sandrine Romand [1], Ursula Bodendorf [2]*
[1]BTDM, [2]ATI, Novartis, Basel, Switzerland

18.40 – 19.00 **OR003** TRANSPOSON-MEDIATED GENE INTEGRATION – THE FUTURE OF STABLE CHO CELL LINE DEVELOPMENT?
Gavin Barnard [1,]*
[1]Biotechnology Discovery Research, Eli Lilly, INDIANAPOLIS, United States

19:00 – 21.00 **EXHIBITOR'S RECEPTION**

** Presenting Author*

MONDAY 15 MAY, 2017

09.00 – 10.30 **SESSION 2: CELL ENGINEERING AND ANALYTICS** (CONTINUED)
Chairpersons: Alan Dickson and Anne Tolstrup

09.00 – 09.30 **SP003** POPULATION DYNAMICS OF MONOCLONAL CHO CELL LINES
Karin Anderson – Pfizer, United States

09.30 – 09.50 **OR004** SMALL RNA - BIG IMPACT: USING MICRORNAS TO ENHANCE MANUFACTURABILITY OF DIFFICULT-TO-EXPRESS PROTEINS IN CHO CELLS
Martin Gamer [1,], Simon Fischer [2], Lisa Pieper [3], Jürgen Fieder [1], Patrick Schulz [2], Harald Bradl [2], Ingo Gorr [1]*
[1]Early Stage Bioprocess Development, [2]Cell Culture Development CMB, Boehringer Ingelheim, Biberach, [3]Institute of Cell Biology and Immunology, University of Stuttgart, Stuttgart, Germany

09.50 – 10.00 **SP004** MAMMALIAN CELL LINE DEVELOPMENT, MINIATURIZATION, AUTOMATION, AND ANALYSIS USING THE BERKELEY LIGHTS PLATFORM
Kim Le – Amgen, United States

10.00 – 10.10 **OR006** A NOVEL SITE-SPECIFIC INTEGRATION SYSTEM FOR CELL LINE DEVELOPMENT
Mara Christine Inniss [1,], Lin Zhang [1]*
[1]Cell Line Development, Pfizer, Andover, United States

10.10 – 10.15 **Poster Spotlight - PO266** IDENTIFYING OPPORTUNITIES IN CELL ENGINEERING FOR THE PRODUCTION OF 'DIFFICULT TO EXPRESS' RECOMBINANT PROTEINS
Hirra Hussain [1,], David Fisher [2], Robert Roth [3], Alan J Dickson [1]*
[1]University of Manchester, Manchester, [2]AstraZeneca, Cambridge, United Kingdom, [3]AstraZeneca, Molndal, Sweden

10.15 – 10.20 **Poster Spotlight - PO234** OPTIMIZATION OF THE CLC FOR MANUFACTURING PURPOSES USING A NOVEL SINGLE CELL PRINTING TECHNOLOGY
Amélie Mahé [1,], Pierre-Alexis Cayatte [1], Alix Lecomte [1], Keith Wilson [1], Adrian Haines [1]*
[1]Bioprocess R&D, Novimmune SA, Plan-les-Ouates, Switzerland

10.20 – 10.25 **Poster Spotlight - PO236** A NOVEL SIRNA AIDED METHOD FOR CHO CELL LINE SELECTION
Andreas Bernhard Diendorfer [1,], Vaibhav Jadhav [1], Zach Wurz [2], Frank Doyle [3], Ted Eveleth [2], Scott Tenenbaum [3], Nicole Borth [1 4]*
[1]Austrian Center of Industrial Biotechnology, Vienna, Austria, [2]HocusLocus LLC, [3]State University of New York Polytechnic Institute, Albany, United States, [4]University of Natural Resources and Life Sciences, Vienna, Austria

10.25 – 10.30 **Poster Spotlight - PO308** EVALUATION OF MICRORNA-BASED GENETIC SWITCHES AS TRANSGENE EXPRESSION MODULATORS IN CHO CELLS
Ricardo Valdés-Bango Curell [1,], Craig Monger [1 2], Krishna Motheramgari [1 2], Justine Meiller [1], Alan Costello [1], Nicole Borth [3], Martin Clynes [1], Colin Clarke [2], Niall Barron [1]*
[1]National Institute for Cellular Biotechnology, Dublin City University, [2]National Institute for Bioprocessing Research and Training, Dublin, Ireland, [3]Department of Biotechnology, BOKU University of Natural Resources and Life Sciences, Vienna, Austria

10.30 – 11.00 Coffee break

11.00 – 12.30 **SESSION 3: CELL ENGINEERING AND ANALYTICS** (CONTINUED)
Chairpersons: Terry Papoutsakis and Alan Dickson

11.00 – 11.30 **OR007** DIRECTED EVOLUTION OF CHO CELLS WITH INCREASED SYNTHETIC CAPACITY
David James [1,], Katie Syddall [1], Alejandro Fernandez-Martell [1]*
[1]Chemical and Biological Engineering, University of Sheffield, Sheffield, United Kingdom

11.30 – 11.50 **OR008** VITAMIN B5 TRANSPORT AS A METABOLIC SELECTION FOR HIGHLY EFFICIENT RECOMBINANT PROTEIN EXPRESSION BY MAMMALIAN CELLS
Lucille Pourcel [1,], Valérie Le Fourn [2], Pierre-Alain Girod [3], Nicolas Mermod [1]*
[1]University of Lausanne, Lausanne, [2]SELEXIS SA, Genève, [3]SELEXIS SA, Gevève, Switzerland

11.50 – 12.10 **OR009** GLYCOENGINEERING IN A HUMAN CELL LINE FOR IMPROVEMENT OF BIOPHARMACEUTICALS HALF LIFE
Karina Nawrath [1,]*
[1]Platformdevelopment, Glycotope GmbH, Berlin, Germany

12.10 – 12.30 **OR010** LIPIDOMICS FOR ROBUST HIGH PERFORMANCE PROCESS DEVELOPMENT
Andréa Mc Cann [1], Grégory Mathy [1,], Laetitia Malphettes [1]*
[1]Upstream Process Sciences, UCB Pharma S.A., Braine l'Alleud, Belgium

12.30 – 14.00 Lunch

14.00 – 15.30 **POSTER SESSION AND COFFEE**

PRESENTATION OF UNEVEN POSTER NUMBERS
Presenting authors must be at their poster for discussion.

** Presenting Author*

15.30 – 17.00 SESSION 4: CELL CULTURE BASED VACCINES

Chairpersons: Paula Alves and Rino Rappuoli

15.30 – 16.00 **SP005** THE PER.C6 CELL LINE: FROM A PROMISING VACCINE MANUFACTURING PLATFORM TO PROVEN REAL WORLD PERFORMANCE

Dirk Redlich – Janssen, Belgium

16.00 – 16.20 **OR011** A CONTINUOUS TUBULAR BIOREACTOR FOR STABLE PRODUCTION OF CELL CULTURE-DERIVED INFLUENZA VIRUS VACCINES

Felipe Tapia [1,2,], Yvonne Genzel [2], Volker Sandig [3], Udo Reichl [2,4]*

[1]International Max Planck Research School for Advanced Methods in Process and Systems Engineering, Max Plank Institute, [2]Bioprocess Engineering, Max Plank Institute for Dynamics of Complex Technical Systems, Magdeburg, [3]ProBioGen AG, Berlin, [4]Chair of Bioprocess Engineering, Otto von Guericke University Magdeburg, Magdeburg, Germany

16.20 – 16.40 **OR012** PRODUCTION AND PURIFICATION OF ZIKA AND YELLOW FEVER VIRUS-LIKE PARTICLES (VLPS) EXPRESSED IN MAMMALIAN CELLS

Leda Castilho [1,2,], Renata Alvim [1], Marcos Pinho [1], Tania Pato [3], Adrian Creanga [2], Sung-Youl Ko [2], Wing-Pui Kong [2], Barney Graham [2]*

[1]Cell Culture Engineering Lab., COPPE, Federal University of Rio de Janeiro, Rio de Janeiro, Brazil, [2]VRC, National Institutes of Health (NIH), Bethesda, MD, United States, [3]Biomanguinhos, FIOCRUZ, Rio de Janeiro, Brazil

16.40 – 16.50 **OR013** OPTIMIZATION OF A BIOPROCESS FOR THE DEVELOPMENT OF A WHOLE VIRUS INACTIVATED HEPATITIS C VIRUS VACCINE

Anne F. Pihl [1,2,], Christian K. Mathiesen [1,2], Tanja B. Jensen [1,2], Garazi P. Alzua [1,2], Anna Offersgaard [1,2], Ulrik Fahnøe [1,2], Jan P. Christensen [2], Jens Bukh [1,2], Judith M. Gottwein [1,2]*

[1]Copenhagen Hepatitis C Program (CO-HEP), Department of Infectious Diseases and Clinical Research Centre, Hvidovre Hospital, Hvidovre, [2]Department of Immunology and Microbiology, University of Copenhagen, Copenhagen, Denmark

16.50 – 16.55 **Poster Spotlight - PO221** VAXARRAY SEASONAL INFLUENZA ASSESSMENT OF CELL-DERIVED INFLUENZA VACCINE POTENCY

Rose Nash [1,], Kathy Rowlen [1], Erica Dawson [1], Laura Kuck [1]*

[1]INDEVR, Boulder, United States

16.55 – 17.00 **Poster Spotlight - PO166** ON-LINE MONITORING OF DIELECTRIC CELL PROPERTIES FOR THE ANALYSIS OF VIRUS-LIKE PARTICLE PRODUCTION BY CAP CELLS

Sonia Gutiérrez [1,], Kerstin Hein [2], Núria Civit [1], Francesc Gòdia [1]*

[1]Chemical, Biological and Environmental Engineering, Universitat Autònoma de Barcelona, Cerdanyola del Vallès, Spain, [2]Cevec Pharmaceuticals, GmbH, Cologne, Germany

17.00 – 17.30 Coffee break

17.30 – 18.30 SESSION 5: ENABLING CELL BASED TECHNOLOGIES

Chairpersons: Michael Betenbaugh and Martin Fussenegger

17.30 – 18.00 **SP006** SOLVING THE ENVIRONMENTAL ISSUES FOR CELLS: TOWARDS PRECISE REGULATION OF STEM CELL FUNCTIONS

Ken-Ichiro Kamei - Kyoto University, Japan

18.00 – 18.15 **OR014** A NOVEL IN VITRO PANCREATIC ISLET MODEL SYSTEM FOR DIABETES RESEARCH

Aparna Neelakandhan [1], Adelinn Biernath [1], Olivier Frey [1], Burcak Yesildag [1,]*

[1]InSphero AG, Schlieren, Switzerland

18.15 – 18.20 **Poster Spotlight - PO354** DEVELOPMENT OF A WOUND HEALING ASSAY USING INCLUSION BODIES

Anne Stamm [1,], Sarah Strauß [2], Peter Vogt [2], Thomas Scheper [1], Iliyana Pepelanova [1]*

[1]Institute of Technical Chemistry, Leibniz University Hannover, [2]Department of Plastic, Aesthetic, Hand and Reconstructive Surgery, Hannover Medical School, Hannover, Germany

18.20 – 18.25 **Poster Spotlight - PO363** 3D-PRINTED MICROFLUIDIC CHANNEL AND CULTIVATION MOLD FOR QUANTITATIVE EVALUATION OF CELL MIGRATION PROPERTY

Ko-Ichiro Miyamoto [1,], Torsten Wagner [2], Michael Schöning [2], Tatsuo Yoshinobu [1]*

[1]Department of Electronic Engineering, Tohoku University, Sendai, Japan, [2]Institute of Nano- and Biotechnologies, Aachen University of Applied Sciences, Jülich, Germany

18.25 – 18.30 **Poster Spotlight - PO369** FLUORESCENT CELL-BASED BIOSENSORS FOR DETECTION AND QUANTIFICATION OF LABEL-FREE VIRUS AND VIRAL VECTORS

Miguel Ricardo Guerreiro [1,2,], Paula Marques Alves [1,2], Ana Sofia Coroadinha [1,2]*

[1]iBET - Instituto de Biologia Experimental e Tecnológica, [2]Instituto de Tecnologia Química e Biológica António Xavier, Oeiras, Portugal

** Presenting Author*

TUESDAY 16 MAY, 2017

09.00 – 10.30 **SESSION 6: ENABLING CELL BASED TECHNOLOGIES** (CONTINUED)
Chairpersons: Martin Fussenegger and Michael Betenbaugh

09.00 – 09.30 **SP007** HUMAN STEM CELL BASED IN VITRO MODELING OF PARKINSON'S DISEASE.
Jens Schwamborn - University of Luxembourg, Luxembourg

09.30 – 09.55 **OR015** DYNAMIC REMODELING OF NEURAL CELLULAR AND EXTRACELLULAR SIGNATURES DEPICTED IN 3D IN VITRO DIFFERENTIATION OF HUMAN IPSC-DERIVED NSC
Daniel Simão [1,2,], Ana Paula Terrasso [1,2], Marta M Silva [1,2], Francisca Arez [1,3], Marcos F Sousa [1,2], Nuno Raimundo [4], Patrícia Gomes-Alves [1,2], Eric J Kremer [5,6], Paula Alves [1,2], Catarina Brito [1,2]*
[1]iBET, Instituto de Biologia Experimental e Tecnológica, [2]Instituto de Tecnologia Química e Biológica, Oeiras, Portugal, [3]Instituto de Tecnologia Química e Biológica, Oeiras, France, [4]Universitätsmedizin Göttingen, Institut für Zellbiochemie, Göttingen, Germany, [5]Institut de Génétique Moléculaire de Montpellier, CNRS UMR [5535], [6]Université de Montpellier, Montpellier, France

09.55 – 10.20 **OR016** MIMICKING METABOLIC LIVER ZONATION RESTORES FUNCTIONAL HETEROGENEITY IN CULTURED HEPATOCYTES
Tom Wahlicht [1,2,], Christoph Lipps [1,2], Dagmar Wirth [1,2]*
[1]Model Systems for Infection and Immunity, Helmholtz Centre for Infection Research, Braunschweig, [2]REBIRTH Cluster of Excellence, Hannover, Germany

10.20 – 10.25 **Poster Spotlight - PO366** DEVELOPMENT OF ALTERNATIVE ANIMAL CELL TECHNOLOGY PLATFORMS: CHO BASED CELL-FREE PROTEIN SYNTHESIS SYSTEMS FOR THE PRODUCTION OF "DIFFICULT-TO-EXPRESS" PROTEINS
Lena Thoring [1,], Srujan Dondapati [1], Marlitt Stech [1], Doreen Wüstenhagen [1], Stefan Kubick [1]*
[1]Cell-free and Cell based Bioproduction, Fraunhofer Institute for Cell therapy and Immunology, Potsdam, Germany

10.25 – 10.30 **Poster Spotlight - PO371** AUTOMATION-COMPATIBLE MICROFLUIDIC SYSTEM FOR MULTI-TISSUE INTEGRATION
Olivier Frey [1,], David Fluri [1], Jin-young Kim [2], Kasper Renggli [3], Andreas Hierlemann [3], Jens Kelm [1]*
[1]InSphero AG, Schlieren, Switzerland, [2]DGIST, Daegu, Korea, Republic Of, [3]BSSE, ETH Zurich, Basel, Switzerland

10.30 – 11.00 Coffee break

11.00 – 12.30 **SESSION 7: CELL CULTURE BASED PROCESS ENGINEERING AND PRODUCT QUALITY**
Chairpersons: Chetan Goudar and Paulo Fernandes

11.00 – 11.30 **SP008** Title TBA
Thomas Ryll – Immunogen, United States

11.30 – 11.45 **OR019** USE OF BIOCAPACITANCE PROBES FOR OPTIMIZED PROCESS CONTROL AT LARGE-SCALE MANUFACTURING
Christoffer Bro [1,], Chris Kwiatkowski [2], Joshua Goldstein [3], Eugene Schaefer [3], Anne Tolstrup [1]*
[1]Manufacturing Sciences, Biogen, Hillerod, Denmark, [2]Technical Development, Biogen, Cambridge, [3]Janssen Research & Development, Janssen, Malvern, United States

11.45 – 12.00 **OR020** HIGH THROUGHPUT ANALYSIS OF ANTIBODY GLYCOSYLATION IN CELL CULTURE SAMPLES
Sebastian Giehring [1,], Christine Wosnitza [1], Christian Meissner [1]*
[1]PAIA Biotech GmbH, Köln, Germany

12.00 – 12.05 **Poster Spotlight - PO128** SEED TRAIN CULTURE CONDITIONS CAN AFFECT PRODUCTION CULTURE PERFORMANCE: A CASE STUDY FOR A CHO CELL CULTURE PROCESS
Martin Gawlitzek [1,], Meg Tung [1], Szu-han Wang [1], Shahram Misaghi [2], Robert Kiss [1]*
[1]Late Stage Cell Culture, [2]Early Stage Cell Culture, Genentech, South San Francisco, United States

12.05 – 12.10 **Poster Spotlight - PO059** DIAMINE OXIDASE N-GLYCOSYLATION SITE ASN110 IS HIGHLY CONSERVED IN EVOLUTION AND ESSENTIAL FOR SECRETION
Elisabeth Gludovacz [1,2,], Daniel Maresch [1], Clemens Grünwald-Gruber [1], Verena Puxbaum [1], Laurenz J. Baier [1], Leonor Lopes de Carvalho [3], Friedrich Altmann [1], Tiina A. Salminen [3], Barbara Ulm [2], Sophie Pils [2], Thomas Boehm [2], Bernd Jilma [2], Nicole Borth [1]*
[1]University of Natural Resources and Life Sciences, [2]Medical University of Vienna, Vienna, Austria, [3]Åbo Akademi University, Turku, Finland

12.10 – 12.15 **Poster Spotlight - PO145** LEACHABLES FROM SINGLE-USE DISPOSABLE BIOREACTORS – MAKING BETTER BAGS WORSE
Paul S Kelly [1,], Samantha Pare [1], Niall Barron [1], Orla Coleman [1], Paula Meleady [1], Martin Clynes [1], Shane McSweeney [1], Jonathon Bones [2], Sara Carillo [2], Noemi Dorival Garcia [2]*
[1]National Institute for Cellular Biotechnology, Dublin City University, [2]National Institute for Bioprocessing Research and Training , Dublin, Ireland

** Presenting Author*

12.15- 12.20 **Poster Spotlight - PO174** USE OF AN ANTIOXIDANT TO IMPROVE MONOCLONAL ANTIBODY PRODUCTION AND QUALITY IN CHO CELLS

Tae Kwang Ha [1,], Helene Faustrup Kildegaard [1], Gyun Min Lee [2]*

[1]Novo Nordisk Foundation Center for Biosustainability, Technical University of Denmark, Kgs.Lyngby, Denmark, [2]Department of Biological Sciences, Korea Advanced Institute of Science and Technology, Daejeon, Korea, Republic Of

12.20 – 12.25 **Poster Spotlight - PO030** INTEGRATED MEDIA BLENDING INCREASES EFFICIENCY OF CLONE SELECTION

Caroline Desmurget [1,], Jean-Marc Bielser [1], Martin Jordan [1], David Brühlmann [1], Marc Nater [1], Jonathan Souquet [1], Herve Broly [1]*

[1]MERCK, Corsier sur Vevey, Switzerland

12.25 – 12.30 **Poster Spotlight - PO065** DEVELOPMENT OF AN ANALYTICAL APPROACH FOR ON-LINE MONITORING AND CONTROL OF MONOCLONAL ANTIBODIES QUALITY

Florian Cambay [1,], Gregory De Crescenzo [1], Olivier Henry [1], Yves Durocher [2]*

[1]Chemical engineering, Ecole Polytechnique de Montréal, [2]Human Health Therapeutics Portfolio, National Research Council Canada, Montréal, Canada

12.30 – 14.00 Lunch and ESACT General Assembly (Auditorium C)

14.00 – 15.30 POSTER SESSION AND COFFEE

PRESENTATION OF EVEN POSTER NUMBERS

Presenting authors must be at their poster for discussion.

16.00 – 21.00 OUTING TO THE LAUSANNE OLYMPIC MUSEUM

** Presenting Author*

WEDNESDAY 17 MAY, 2017

09.00 – 10.30 **SESSION 8: CELL CULTURE BASED PROCESS ENGINEERING AND PRODUCT QUALITY** (CONTINUED)
Chairpersons: Alain Bernard and Chetan Goudar

09.00 – 09.30 **SP009** INTENSIFICATION OF A MULTI-PRODUCT PERFUSION PLATFORM THROUGH MEDIUM AND PROCESS DEVELOPMENT
Shawn Barrett – Sanofi, United States

09.30 – 09.45 **SP010** OPTIMIZATION OF A MAMMALIAN CELL PERFUSION CULTURE IN PRODUCTIVITY AND PRODUCT QUALITY
Moritz Wolf – ETH, Switzerland

09.45 – 10.00 **OR021** CONFIRMING SIALYLATION BIOMARKERS IN A CHO BIOPROCESS USING OMICS
Amanda Lewis [1,], Timothy Erlandson [2], Alison Lee [2], Nelly Aranibar [3], Bethanne Warrack [3], Angela Au [4], Michael Borys [2], Michael Reily [3]*
[1]MS&T, [2]PD, BMS, Devens, [3]R&D, BMS, Lawrenceville, [4]MS&T, BMS, Syracuse, United States

10.00 – 10.30 **SP011** SUCCESSES AND CHALLENGES OF CELL CULTURE FOR THERAPEUTIC MAB PRODUCTION
Thierry Ziegler – Sanofi, France

10.30 – 11.00 Coffee break

11.00 – 12.30 **SESSION 9: CELL CULTURE BASED PROCESS ENGINEERING AND PRODUCT QUALITY** (CONTINUED)
Chairpersons: Florian Wurm and Alain Bernard

11.00 – 11.30 **SP012** ANOTHER ARROW IN THE QUIVER – CELL RETENTION/PERFUSION – HOW, WHEN AND WHY - JUDICIOUS USE OF A BRUTE-FORCE TECHNOLOGY
Gregory Hiller – Pfizer, United States

11.30 – 11.50 **OR022** THE DEVELOPMENT OF NOVEL SURFACTANTS AND THEIR ROLE IN DEFINED MEDIA
Tanja Bus [1,], Meike N. Leiske [1], Anne-Kristin Truetzschler [1], Ekaterina Rudiseva [2], Sandra Klausing [3], Christoph Heinrich [3], Anja Traeger [1], Ulrich S. Schubert [1]*
[1]Laboratory of Organic and Macromolecular Chemistry (IOMC), Jena Center for Soft Matter (JCSM), Friedrich Schiller University, Jena, [2]Institute of Cell Culture Technology, Bielefeld University, [3]XELL AG, Bielefeld, Germany

11.50 – 12.10 **OR023** SMALL PROCESS CHANGES DO MATTER- MATCHING SCALE DOWN AND AT SCALE CELL CULTURE PERFORMANCE FOR A THERAPEUTIC ANTIBODY
Veronica Carvalhal [1,], Thomas DiRocco [1], Brian Horvath [1], Jessica Wuu [1], Steve Meier [1], Bob Kiss [1]*
[1]LSCC, Genentech, South San Francisco, United States

12.10 – 12.30 **OR024** BIOCHEMICAL CHARACTERIZATION OF REDOX ACTIVE SUBSTANCES TO IMPROVE HARVEST ROBUSTNESS DURING MONOCLONAL ANTIBODY PRODUCTION
Sven Loebrich [1,], Wesley Chen [1], Thomas Ryll [1], Seth Kitchener [1]*
[1]Cell Line and Upstream Process Engineering, ImmunoGen, Waltham, United States

12.30 – 14.00 Lunch

14.00 – 15.30 **SESSION 10: EMERGING CELL BASED THERAPEUTIC APPROACHES**
Chairpersons: Nicolas Mermod and Hansjörg Hauser

14.00 – 14.30 **SP013** DESIGNER MATRICES FOR STEM CELL-BASED ORGANOID CULTURE
Matthias Lutolf – EPFL, Switzerland

14.30 – 14.50 **OR025** IMPROVING MATURATION OF CARDIOMYOCYTES DERIVED FROM HUMAN PLURIPOTENT STEM CELLS: AN "-OMICS" DRIVEN APPROACH
Cláudia Correia [1], Alexey Koshkin [1], Patrícia Duarte [1], Dongjian Hu [2], Ana Teixeira [1], Ibrahim Domian [2], Margarida Serra [1,], Paula M. Alves [1]*
[1]iBET/ITQB-NOVA, Oeiras, Portugal, [2]Massachusetts General Hospital/Harvard Medical School, Boston, MA, United States

14.50 – 15.10 **OR026** ASSESSMENT OF A CELL THERAPY APPROACH FOR DUCHENNE MUSCULAR DYSTROPHY USING MESOANGIOBLASTS AND TRANSPOSABLE VECTORS
Pavithra Iyer [1,], Lionel Mavoungou [1], Flavio Ronzoni [2], Joanna Zemla [3], Marisa Jaconi [2], Malgorzata Lekka [3], Nicolas Mermod [1]*
[1]Institute of Biotechnology, UNIVERSITY OF LAUSANNE, Lausanne, [2]Department of Pathology and Immunology, Faculty of Medicine, University of Geneva, Geneva, Switzerland, [3]Institute of Nuclear Physics, Polish Academy of Sciences, Krakow, Poland

** Presenting Author*

15.10 – 15.30 **OR027** BETA-CELL-MIMETIC DESIGNER CELLS PROVIDE CLOSED-LOOP GLYCEMIC CONTROL

Mingqi Xie [1,], Haifeng Ye [2], Martin Fussenegger [1]*
[1]ETH ZURICH D-BSSE, Basel, Switzerland, [2]East China Normal University, Shanghai, China

15.30 – 17.00 KEYNOTE AND CLOSING

Chairpersons: Chetan Goudar and Matthieu Stettler

15.30 – 16.15 **SP014** TECHNOLOGIES TAILORED FOR CELLULAR THERAPY MANUFACTURING

Jamie Piret - University of British Columbia, Canada

19.00 – 00.00 25TH ESACT MEETING CELEBRATION AT THE SWISSTECH CONVENTION CENTER

** Presenting Author*

ESACT
SPEAKER ABSTRACTS
ORAL COMMUNICATIONS

SP001 Cell Therapy and Cell Choices in the Swiss Transplantation Program-From the laboratory to clinical research and use

Lee Ann Laurent-Applegate – CHUV, Switzerland

The cellular therapies and transplantation programs began in the University Hospital (CHUV) focusing on oxidative stress and aging with special interest of cells from tissue of all ages from fetal to aged skin. In the late1990's, orientation was on cellular and molecular mechanisms of wound healing and tissue repair in fetal skin of different gestation periods. Much of the research was oriented for cell selection techniques and procedures for potential use of cell sources in the clinic. First clinical trials using novel cell sources and "biological bandages" for pediatric burn patients and chronic wounds in adults began in 2000 with clinical studies published in 2005-2006 (The Lancet, Cell Transplantation & Experimental Gerontology). Further work has advanced parallel to new Regulatory structure adopted in Europe and Switzerland in 2007. A new program of Transplantation for Musculoskeletal Tissues was organized along with the formal registration within the regulatory framework along with an associated Biobank Program. Extensive cell banks have been produced in the laboratory over the last 25 years consisting of different human bone, cartilage, disc, muscle, tendon and skin sources (fetal, child, young adult, adult, old adult). Continued research in studying the fundamental mechanisms of progenitor cells has helped to identify their virtues in tissue repair and particularly for burn patients. New techniques have been brought from the bench-top (with the development of characterized, consistent, clinical-grade progenitor cell banks) to clinical use for acute and chronic wounds in humans. The "biological bandages" were used as a base for the Project Platform SwissTransMed to associate antimicrobial factors for the treatment of burn patients. This National Platform includes partners in Geneva (Uni and HUG), Zurich (Uni and Vet Swiss Zurich), Lausanne (CHUV and EPFL) and Bern (Uni) and this Platform has developed two candidate formulations for anti-microbial biological bandages.

Conflict of interest: Prof. Laurent-Applegate is a co-founder of a spin-off company from the University Hospital for cellular therapies.

SP002 Engineering cell metabolism to enhance protein production

Nathan Lewis – University of California, San Diego, United States

Over the past 3 decades, mammalian cells have become the predominant production hosts for biotherapeutics, and now produce 6 of the top 10 grossing pharmaceuticals. However, the complexity of the protein-based drugs and the host cells pose major challenges that must be controlled to improve the safety, efficacy, and affordability of these pharmaceuticals. The connection of metabolism to these attributes has been long appreciated, but a comprehensive view of CHO metabolism has been lacking. To address this need, we have identified >1700 metabolic genes in the Chinese hamster genome and mapped out thousands of active metabolic reactions in CHO cells. In this talk I will demonstrate how these models provide insights into the protein-production capacity of CHO cells, and how it influences the metabolic needs differ across products. We further explore how these resources allow us to control the production of toxic by-products, such as lactic acid and thereby improve bioprocess phenotypes.

Conflict of interest: None Declared

OR001 CRISPR-CAS BASED SYNTHETIC TRANSCRIPTION FACTORS: A STRATEGY FOR IMPROVING BIOPRODUCTION IN CHO CELLS

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[1]Institute of Quantitative Biology, Biochemistry, and Biotechnology, School of Biological Sciences, University of Edinburgh, Edinburgh, United Kingdom

Background and novelty: Despite advances in Chinese hamster ovary (CHO) cell bioprocess optimisation, production of large complex proteins remains costly and high degree of variability among final products is problematic. Novel strategies that target molecular pathways for high product yield and consistency are vital. To overcome this bottleneck, we developed CRISPR-Cas based synthetic transcription factors (sTF) that modulate expression of endogenous mRNA and miRNA targets involved in protein trafficking and glycosylation.

Experimental approach: sTF utilises two forms of Cas9 proteins: Endonuclease inactive 'dead' Cas9 (dCas9) with activator attached and native cutting Cas9. In EGFP and Herceptin® expressing CHO-K1, we transiently expressed dCas9 with sgRNAs against upstream of protein transport-related gene promoters (Rab5A & Aprc1b) for transcriptional activation, or against their promoter regions for suppression. To lower galactosyltransferase (GalT)-associated miRNA expression (miR-181d-5p, miR500 & miR501), cells were co-expressed with dCas9 and sgRNAs against miRNA promoters; or with native Cas9 and sgRNAs against mature miRNA sequences[1]. mRNA and miRNA levels of target genes were quantified by q-rt-PCR, protein level of GalTs, EGFP and IgG by western blot, EGFP fluorescence and IgG-ELISA, respectively.

Results and discussion: The dCas9 approach receives up to 30% increase in EGFP and IgG expression, along with 2 to 5-fold rise in Rab5A and Aprc1b mRNA levels. Our results show positive correlation between protein trafficking and rProtein yield.

Both Cas9 and dCas9 approaches reduce miR-181d-5p, miR500 & miR501 by around 35%, this simultaneously enhances GalT1 & 4 expression by up to 2-fold and improves protein galactosylation. This system allows concurrent manipulation of multiple mRNA and miRNA with dCas9, where dCas9 expression can be further controlled via AID- or ecDFR-Degron technology.

Bibliography, Acknowledgements: [1]Chang H et al.2016. Sci. Rep.**6**:22312

Disclosure of Interest: None declared

OR002 DEGRADATION OF RECOMBINANT PROTEINS OF DIVERSE FORMATS BY CHO HOST CELL PROTEASES IS CIRCUMVENTED VIA KNOCK-OUT OF CHO MATRIPTASE

H. Laux[1],, S. Romand[1], U. Bodendorf[2]*
[1]BTDM, [2]ATI, Novartis, Basel, Switzerland

Background and novelty: CHO cells are the preferred production host for recombinant therapeutic proteins. Recently, an increasing number of non-antibody format proteins are entering the pipeline of pharmaceutical companies. However one of the major hurdles for the production of non-antibody glycoproteins is host cell-related proteolytic degradation which can drastically impact developability and timelines of pipeline projects.

We have surprisingly identified, out of the ca. 700 proteases, matriptase as the major protease involved in degradation of recombinant proteins using CHO-K1 cell line. Subsequently matriptase was knocked-out. This resulted in a superior matriptase knockout cell line with strongly reduced or no proteolytic degradation activity towards recombinantly expressed proteins.

Experimental approach: Using a variety of tools and techniques such as applying different protease class specific inhibitors, transcriptomics and siRNA mediated knock-down we were able to identify that the serine protease “matriptase”, is the major protease involved in degradation of recombinant proteins expressed in CHO-K1 cell lines. Subsequently, we generated a matriptase gene knockout cell line applying TALEN technology.

Results and discussion: Protein candidates of diverse formats, which were highly degraded using wildtype CHO-K1 cells were not or significantly less degraded using the matriptase KO cells. Notably also cell growth, cell viability and productivity levels were comparable between the wildtype cells and the matriptase KO cells. The KO genotype and phenotype is stable over at least a period of 6 month. Especially the highly sophisticated combination of the published Chinese hamster genome with several screening methods and cell line engineering tools has enabled the development of this superior CHO cell line suitable for the expression of recombinant proteins prone to proteolytic clipping.

Bibliography, Acknowledgements: Thanks to E. Oakeley!

Disclosure of Interest: None declared

OR003 TRANSPOSON-MEDIATED GENE INTEGRATION – THE FUTURE OF STABLE CHO CELL LINE DEVELOPMENT?

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Background and novelty: Therapeutic proteins (e.g. mAbs, bispecific mAbs and Fc-fusions) are typically produced using CHO cell culture. Unfortunately, stable CHO cell line development is a laborious process. Technologies that speed up cell line development while simultaneously yielding higher final product titers will greatly improve drug discovery and development. We describe the development a transposon-mediated gene integration system (TMI) to create stable CHO pools and clonally derived cell lines (CDCLs).

Experimental approach: Expression studies were conducted in shake flasks and bioreactors. Protein A purification was performed on laboratory scale FPLC units (e.g. AKTAs).

Results and discussion: CHO pools yielding mAb titers up to 7.6 g/L were generated using TMI. This represented a 3- to 10-fold increase relative to random gene integration (RI) for a panel of molecules. The TMI CHO pools (that required only 2 weeks to create) yielded similar titers relative to high titer stable CHO CDCLs obtained from RI (that required approximately 4-6 months to create). We performed detailed DNA and RNA analysis to understand why titers were higher. High titers for TMI CHO pools were attributed to a combination of increased gene copy number, much higher messenger RNA levels and increased homogeneity of the actively expressing cell population. These results are consistent with previous findings that transposes integrate genes into transcriptionally active regions of the genome. Extensive protein product quality analysis

was performed to validate this new method. Despite large differences in titer between TMI and RI CHO pools, protein product quality was similar. Finally, we demonstrated that TMI yielded high titer CDCLs from screening only a small number of CDCLs. Reduced screening reduces the time required to identify stable CHO cell lines. Taken together, these results demonstrate the superiority of TMI relative to RI.

Bibliography, Acknowledgements: Eli Lilly and Company

Disclosure of Interest: None declared

SP003 Population Dynamics of Monoclonal CHO Cell Lines

Karin Anderson
Pfizer, United States

The majority of complex biologicals such as monoclonal antibodies (mAbs) are generated in Chinese hamster ovary (CHO) host cells. CHO cells readily express these complex proteins in suspension, can be grown at large scale in chemically defined medium, and can be easily genetically modified if so desired. While CHO cells are well-suited for the production of biotherapeutics, it is also well established that these cells can demonstrate genetic and/or phenotypic drift over extended cultivation. Currently, single cell cloning is one of many process development steps implemented to increase process robustness with the ultimate goal of reliably delivering safe and efficacious products to patients. Additionally, comprehensive process characterization and in-process controls as well as thorough understanding of product quality attributes by highly improved and advanced analytical methods provide necessary confidence that the product is safe, and efficacious and that the manufacturing process is robust.

The genetic heterogeneity exhibited by CHO cells can be exploited to understand the population dynamics of cloned cell lines. Understanding the interplay between cell line heterogeneity, cell culture conditions, and cell age will be important in advancing our understanding of the impact of population dynamics on process outcomes. Using genetic markers as a tool to characterize and understand sub-populations of cloned cell lines and how they change over time will be presented. Industry view on the relative importance of clonality will be discussed.

Conflict of interest: None Declared

OR004 SMALL RNA - BIG IMPACT: USING MICRORNAS TO ENHANCE MANUFACTURABILITY OF DIFFICULT-TO-EXPRESS PROTEINS IN CHO CELLS

M. Gamer[1,], S. Fischer[2], L. Pieper[3], J. Fieder[1], P. Schulz[2], H. Bradl[3], I. Gorr[1]*
[1]Early Stage Bioprocess Development, [2]Cell Culture Development CMB, Boehringer Ingelheim, Biberach, [3]Institute of Cell Biology and Immunology, University of Stuttgart, Stuttgart, Germany

Background and novelty: The number of complex and thus difficult-to-express (DTE) protein formats has grown considerably and will increasingly challenge cell line development (CLD). MicroRNAs (miRNAs) have become a recognized cell engineering tool to enhance bioprocess performance of CHO cells. However, in previous reports, beneficial miRNAs were introduced into cell lines already producing a recombinant protein. In addition, there is still a lack of evidence whether miRNAs are capable of enhancing production of DTE proteins. We generated engineered CHO host cells overexpressing a pro-productive or control miRNA. Both host cell lines were evaluated in two independent CLD campaigns to determine if miRNA engineering can also boost production of challenging proteins.

Experimental approach: 2 different CHO host cells stably expressing either miR-557 or a control miRNA were established. Both engineered host cell lines were tested in two entire CLD campaigns using 2 different mAb candidates (easy- and difficult-to-express mAbs). Cell performance was tested at various stages throughout the CLD process as well as in controlled fed-batch processes. Product quality attributes of mAbs produced by either miR-557 overexpressing or control cell lines were additionally analyzed.

Results and discussion: Clonal cell lines derived from miR-557 expressing CHO host cells clearly outperformed control cells and exhibited substantially increased product titers without compromising product quality. The pro-productive effects were more pronounced with regard to the selected DTE antibody. For this antibody, several miR-557 expressing cell lines achieved product titers of 1 g/L, while the best control cell lines only reached a maximum of 0.5 g/L. Hence, our results demonstrate that host cell engineering using miRNAs represents a promising tool to overcome limitations in bioprocess development especially regarding challenging proteins.

Disclosure of Interest: None declared

SP004 Mammalian Cell Line Development, Miniaturization, Automation, and Analysis using the Berkeley Lights Platform

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Background and novelty: The biologic manufacturing process begins with establishing a clonally derived, stable production cell line. Generating a highly productive cell line is resource intensive and typically involves long timelines due to screening of large numbers of candidates and time required to adapt cell lines to suboptimal conditions. Often, miniaturization and automation strategies are employed to allow for reductions in resources and higher throughputs. However, we are beginning to reach the physical limitations of this approach. New nanofludic technologies offer solutions to move past these limits. One integrated platform is now being offered from Berkeley Lights Inc. The approach miniaturizes cell culture volumes (105 times smaller) through growing cells on custom nanofluidic chips. Cells are manipulated on a single cell level though use of OptoElectronic Positioning (OEP) technology, which utilizes projected light patterns to activate photoconductors that gently, repels cells. Common cell culture tasks can be programmed though software, and allow for thousands of cell lines to maintained at once. Finally, cultures can be interrogated for productivity and growth characteristics while on the chip.

Experimental approach: In this communication, we attempted to assess whether it was feasible to perform key cell line development work on this platform.

Results and Discussion: We demonstrate that commercial production CHO cell lines can cultured on this environment. We next show that sub clone isolation, recovery, and selection can be achieved with very high efficiency. Finally, we demonstrate the ability to load transfected populations into the instrument and extract out viable clonally-derived production lines. Overall, this technology has potential to dramatically alter current cell line development workflows through the replacement of laborious manual processes with nanofludics, software and automation. Potential future applications can be focused toward increasing capacity, decreasing resource requirements, improving cell line quality, and decreasing cycle times.

Conflict of interest: None Declared

OR006 A NOVEL SITE-SPECIFIC INTEGRATION SYSTEM FOR CELL LINE DEVELOPMENT

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Background and novelty: RMCE (recombinase-mediated cassette exchange) has been used in the research community to enable reproducible site-specific genomic integration with high efficiency. Recently, similar systems have been adopted in the biopharmaceutical field to allow more predictable generation of stable cell lines expressing therapeutic proteins. We built a novel RMCE system using Bxb1 recombinase – a serine recombinase shown to have high efficiency in mammalian cells1 – and compare this system with the industry-standard Flp/FRT system.

Experimental approach: RMCE landing pads were integrated in the CHO genome using CRISPR/Cas9 coupled with homology-directed repair2 and characterized the integration using whole genome resequencing. We then introduced monoclonal antibody targeting vectors into these cell lines to compare the efficiency and accuracy of Bxb1 and Flp/FRT RMCE systems.

Results and discussion: We demonstrated that RMCE landing pads can be efficiently integrated into the CHO genome by CRISPR/Cas9 mediated homologous recombination. We showed that the Bxb1 RMCE system has significantly higher recombination efficiency than the Flp/FRT system and the clonal cell lines generated with Bxb1 RMCE had a higher rate of correct integration. Bxb1-based RMCE can be used to integrate mAb genes in a site-specific manner with high efficiency and high accuracy compared with the Flp/FRT RMCE system. This novel RMCE system will add to our ability to predictably engineer cell lines for biopharmaceutical production.

Bibliography, Acknowledgements: 1 Xu, Z. et al. Accuracy and efficiency define Bxb1 integrase as the best of fifteen candidate serine recombinases for the integration of DNA into the human genome. BMC biotechnology **13**, 87, doi:10.1186/1472-6750-13-87 (2013).

2 Lee, J. S., Kallehauge, T. B., Pedersen, L. E. & Kildegaard, H. F. Site-specific integration in CHO cells mediated by CRISPR/Cas9 and homology-directed DNA repair pathway. Scientific reports **5**, 8572, doi:10.1038/srep08572 (2015).

Disclosure of Interest: None declared

OR007 DIRECTED EVOLUTION OF CHO CELLS WITH INCREASED SYNTHETIC CAPACITY

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Background and novelty: We report a simple and effective means to significantly increase the biosynthetic capacity of host CHO cells – permanent culture at reduced temperature.

Experimental approach: CHO cells were maintained in suspension culture in chemically defined medium at 32°C for over 200 days (>150 generations).

Results and discussion: CHO cells gradually acquired a specific proliferation rate equivalent to that of control cells grown at 37°C (>0.03h-1). However, the mean volume and biomass content (protein, RNA) of cells maintained at 32°C also increased, reaching double that of control parental cells. Relative to control CHO cells at 37°C, evolved cells maintained at 32°C exhibited significantly increased transfection efficiency, and both transient and stable production of recombinant proteins (MAb, Enbrel). N-glycan processing was unaffected. As evolved cells exhibited no change in ploidy, we hypothesised that evolved CHO cells achieved increased biomass accumulation rate at 32°C via adaptive thermogenesis (metabolic heat generation), which is typically observed in the brown fat tissue of hibernating animals such as hamsters. In accord with this hypothesis, evolved cells exhibited a significantly increased mitochondrial function (basal and maximal oxygen consumption rates) with a significant reduction in the cellular content of reactive oxygen species. Our data indicates that this phenotypic transformation of host CHO cells to an inherently more biomass intensive and productive state likely requires multiple, coordinated changes in host cell gene expression that would be difficult to attain with current genome editing technologies.

Bibliography, Acknowledgements: BBSRC, Lonza Biologics

Disclosure of Interest: None declared

OR008 VITAMIN B5 TRANSPORT AS A METABOLIC SELECTION FOR HIGHLY EFFICIENT RECOMBINANT PROTEIN EXPRESSION BY MAMMALIAN CELLS

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Background and novelty: Vitamins are essential micronutrients required to support the growth and propagation of any living cell. Indeed, mammalian cells cannot synthesize them, and the lack of vitamins in the diet is directly linked to severe cellular defects [1-3]. The multivitamin sodium-transporter SLC5A6 participates in the uptake of vitamin B5 (pantothenate) in mammalian cells and thereby in promoting an efficient energetic metabolism [4, 5]. Recent studies determining changes in central metabolism that may limit growth and recombinant protein expression highlighted a regulatory link between cell metabolism, metabolite consumption and accumulation and cell growth [6].

Experimental approach: We designed an improved selection method based on the co-expression of SLC5A6, relying on mammalian cell dependence on this vitamin for energy production.

Results and discussion: This method yields polyclonal cell populations producing recombinant proteins at homogeneous and high level, using the selective advantage of improved cell metabolism, growth and viability. This selection is also efficient to select variant cells synthesizing difficult-to-express chimerical proteins at elevated levels, unlike state-of-the-art methods.

Altogether, the SLC5A6/vitamin B5 selection is a new and powerful metabolic selection method to specifically recover mammalian cells stably expressing a gene of interest at the highest levels.

Bibliography, Acknowledgements: 1. Ghosal, A., et al., Am J Physiol Gastrointest Liver Physiol, 2013. 304(1): p. G64-71. **2**. Brunetti, D., et al., Hum Mol Genet, 2012. 21(24): p. 5294-305. **3**. Garcia, M., et al., PLoS One, 2012. 7(7): p. e40871. **4**. Prasad, P.D., et al., J Biol Chem, 1998. 273(13): p. 7501-6. **5**. Quick, M. and L. Shi, Vitam Horm, 2015. 98: p. 63-100. **6**. Dean, J. and P. Reddy, Biotechnol Bioeng, 2013. 110(6): p. 1735-47.

Disclosure of Interest: None declared

OR009 GLYCOENGINEERING IN A HUMAN CELL LINE FOR IMPROVEMENT OF BIOPHARMACEUTICALS HALF LIFE

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Background and novelty: Glycosylation is a critical attribute which can influence the biopharmaceuticals activity. Gene

editing technologies like ZFN, TALEN and CRISPR/Cas are efficient tools to gear up the glycosylation machinery for specific needs of biopharmaceuticals. Glycooptimization can target the amount of e.g. fucose, galactose and sialic-acid. As case study we show on a glycoprotein expressed in a portfolio of glycoengineered human GlycoExpress cells the specific improvement of the glycosylation profile especially with regards to the potential reduction of liver receptor binding properties and thereby a prolonged half-life.

Experimental approach: Applying gene editing the N-Acetylgalactosamin (GalNAc) moiety located on N-glycans which exhibit high affinity towards the asialoglycoprotein receptor was removed by knockout of two GalNAc transferases GalNTA and B simultaneously. The expressed glycoprotein was purified by HILIC-UPLC-ESI-QTOF-MSMS to elucidate the amount of GalNAc structures. Briefly, the glycoprotein was denatured, deglycosylated and resulting free N-glycans were fluorescence-tagged followed by HILIC-UPLC separation with fluorescence detection coupled to an ESI-QTOF mass spectrometer used to record MS and CID-MSMS data.

Results and discussion: Gene editing enabled the opportunity to knockout two GalNAc transferases simultaneously with high efficiency resulting in a glycoprotein lacking GalNAc residues and leading to unexpected changes in other N-glycan features like an increased amount of high-antennary structures. By additional sialyltransferase overexpression the N-glycan pattern was significantly improved with regard to sialylation degree. Here a glycoprotein was generated which shows high similarity for the main glycospecies to the plasma derived product.

Bibliography, Acknowledgements: Dr. in Biology, Associate Director for Platformdevelopment at Glycotope GmbH, multiple years of experience in mammalian cell cultivation, development and engineering.

Disclosure of Interest: None declared

OR010 LIPIDOMICS FOR ROBUST HIGH PERFORMANCE PROCESS DEVELOPMENT

A. Mc Cann[1], G. Mathy[1,], L. Malphettes[1]*
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Background and novelty: Over the last decades, major improvements in cell engineering and culture processes enabled to reach high titer but generated also increasing impurities levels raising new challenges for harvest and protein purification. Thanks to recent advances in analytical tools especially mass spectrometry, the advent of lipidomics offers now the capacity to study thousands of lipid species, unravelling the possibility to understand and potentially control the interactions between high performance cell cutlure, harvest and purification.

Experimental approach: A new method was developed to analyze and quantify lipids. Lipids were first extracted with Methyl tert-butyl ether (MTBE) method (1), then separated by liquid chromatography and finally detected by mass spectrometry. Finally we applied this method to analyze the lipid content of four different cell lines each expressing a different recombinant protein, during a fed batch process.

Results and discussion: Lipid from CHO cells were extracted with a yield between 80% and 95%. Interestingly, in some cell lines/experimental conditions, we highlighted an overproduction of triglycerides and cholesterol leading to the accumulation of lipid droplets known as energy storage sink. From a process development perspective these findings can be considered as a resource waste since the stored energy is not used for protein/biomass biosynthesis but also as potential process issues during the harvest and the first capture steps given the hydrophobic nature of these molecules. Additional analysis will be required to fully understand the link existing between lipids metabolism, cell line and process development conditions. We believe that these investigations will open the door to many applications such as clone selection, process, and harvest development.

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Disclosure of Interest: None declared

SP005 The Per.C6 cell line: From a promising vaccine manufacturing platform to proven real world performance

Dirk Redlich – Janssen, Belgium

Vaccines play a crucial role in the global fight against infectious diseases. The unique position of vaccines is, for example, demonstrated by the fact that no other modality, not even antibiotics, has had such a major effect on childhood mortality reduction (WHO, World Bank, UNICEF, 2009). Establishing platforms, which can support flexible and fast approaches throughout the discovery and development process of vaccines, is pivotal to ensure appropriate response times in outbreak situations of infectious diseases like Ebola and Zika. Equally important are the robustness, reliability, and low cost of those

platforms for the manufacturing of large quantities of vaccine doses.

The PER.C6® cell line is an adenovirus E1 immortalized human cell substrate which has been used for more than two decades and has proven clinically to be safe and to be a successful platform for the development and manufacturing of vaccines.

The PER.C6® cell line technology has been shown to be a suitable substrate to a wide range of applications like whole inactivated virus vaccines, attenuated virus (including adenovirus) vaccines, monoclonal antibodies, and recombinant proteins.

Advantages of the PER.C6® cell line range from being highly permissive to human and animal viruses, to superior manufacturing characteristics like enabling cell growth in suspension under animal-free conditions and culturing at high cell densities.

This presentation will discuss the general advantages of cell line applications in the field of vaccine development and manufacturing. The PER.C6® cell line and real world applications will be discussed.

A focus will be on the overcome and still existing regulatory and technical challenges introducing the PER.C6® cell line as a future platform for marketed products.

Conflict of interest: None Declared

OR011 A CONTINUOUS TUBULAR BIOREACTOR FOR STABLE PRODUCTION OF CELL CULTURE-DERIVED INFLUENZA VIRUS VACCINES

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Background and novelty: Continuous virus production is a promising approach to reduce the cost of manufacture and availability of viral vaccines. Cell culture-based influenza vaccines are currently produced in batch mode and a continuous production approach based in stirred tank bioreactors (CSTRs) was recently reported [1]. Nevertheless, virus productivity levels in this system were low due to the accumulation of defective interfering particles (DIPs) [1]. In addition, the high virus passage numbers in stirred tanks involve the risk of unwanted antigenic mutations. This work describes the development of a plug-flow tubular bioreactor (PFBR) system for continuous production of influenza virus that solve boths limitations.

Experimental approach: The PFBR system [2] consisted of a CSTR connected to the PFBR (silicon tubing, 105 m, 37°C) with a nominal production rate of 12 mL/h. Either MDCK suspension cells or AGE1.CR.pIX cells (pIX, ProBioGen) were continuously produced in the CSTR and transferred to the PFBR where air was injected. MDCK- or pIX-adapted influenza virus strain A/PR/8/34 (RKI) was used to prepare a virus stock that was continuously pumped to the entry of the PFBR to infect the cells. Samples were taken to determine cell, virus, and DIPs replication dynamics using a PCR method previously described [1].

Results and discussion: The PFBR was mantained stable for weeks, and stable influenza virus titers were obtained ranging between 1.5 and 2.5 log10(HA Units/100µL) for pIX and MDCK cells, respectively. DIPs replication dynamic was stable and at low levels over three weeks of production. Overall, it was demonstrated that avoiding the accumulation of defective interfering particles is possible using the PFBR system, and this bioreactor is a promising novel platform that could equally be used for continuous production of other viruses.

Bibliography, Acknowledgements: [1] Frensing et al. **2013**, PLOS ONE 8(9):e72288, [2] Tapia et al. **2016**, PCT/EP2016/060150.

Disclosure of Interest: None declared

OR012 PRODUCTION AND PURIFICATION OF ZIKA AND YELLOW FEVER VIRUS-LIKE PARTICLES (VLPS) EXPRESSED IN MAMMALIAN CELLS

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Background and novelty: The year 2016 has shown the health threats posed by zika (ZIKV) and yellow fever (YFV) viruses, both mosquito-borne viruses belonging to the family Flaviviridae, genus Flavivirus. ZIKV spread to approximately 60 countries around the globe, and its association with serious congenital malformations was confirmed, making clear the need for a ZIKV vaccine. Concurrently, a major YFV outbreak in Angola and Congo demanded 29 million doses of the existing egg-derived vaccine, causing depletion of the WHO stockpile and leading to the emergency use of a fractional (1/5) vaccine dose. This made clear the urgent need for developing a new, non-egg derived YFV vaccine. Virus-like particles (VLPs) are important tools that can be used to develop diagnostic tools, therapeutics for passive immunization and vaccines for

prevention of infectious diseases.

Experimental approach: In this work, production of ZIKV and YFV VLPs was investigated in suspension-adapted mammalian cell lines (HEK293, CHO.K1, BHK-21 and MDCK) by transient and stable lipofection. Different transfection and cell culture conditions were evaluated, and the supernatants were purified by chromatographic techniques including ion-exchange membrane adsorbers and multimodal resins. VLPs were detected by ELISA and immunoblot assays.

Results and discussion: HEK293 cells had the most favorable host cell line properties among those evaluated. Based on the pI of the envelope protein of ZIKV and YFV, membrane-based anion-exchange chromatography was used as a first purification step and allowed for a high degree of concentration and removal of host-cell DNA. The subsequent step using a multimodal resin in flow-through mode allowed for separation of host-cell proteins. Purified particles analyzed by electron microscopy were 30-50 nm in size, as expected for flaviviruses. Mouse immunogenicity studies are ongoing.

Bibliography, Acknowledgements: Financial support from CNPq, Capes and FAPERJ.

Disclosure of Interest: None declared

OR013 OPTIMIZATION OF A BIOPROCESS FOR THE DEVELOPMENT OF A WHOLE VIRUS INACTIVATED HEPATITIS C VIRUS VACCINE

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Background and novelty: There is no vaccine against hepatitis C virus (HCV), a pathogen causing chronic liver disease and >700.000 deaths per year. Recently established infectious HCV cell culture systems enable the development of a whole virus HCV vaccine.

Experimental approach: Previously developed genotype 1-6 HCV recombinants [1] were further cell culture adapted by serial passage in Huh 7.5 hepatoma cells. Putative adaptive mutations were identified by Sanger and Next Generation Sequencing. Serum-free HCV [2] was produced in 10-layer cell factories or hollow fiber bioreactors and purified/ concentrated by cross flow filtration, ultracentrifugation and chromatography. BALB/c mice were immunized with UV-inactivated HCV equivalent to ~8 log10 focus forming units (FFU), formulated with Alum+MPLA. Purified serum IgG was tested in an in vitro neutralization assay [1].

Results and discussion: Serial passage yielded polyclonal virus stocks with peak infectivity titers of ~6 log10 FFU/mL and putative adaptive mutations. Using a further adapted genotype 5 recombinant [4], cell factories allowed for 5 harvests of 800 mL supernatant with ~6 log10 FFU/mL, while bioreactors allowed for 12 harvests of 20 mL supernatant with up to 7.6 log10 FFU/mL. Purification of up to 20 L culture supernatant yielded up to 2000-fold concentrated highly-pure HCV antigen with up to 25 % overall recovery. Immunogenicity testing resulted in induction of neutralizing antibodies against a homologous genotype 5 recombinant without hypervariable region 1 [3].

We have developed a bioprocess allowing demonstration of immunogenicity of cell culture derived HCV in mice. Future optimization aims at increasing HCV yield to facilitate development of a vaccine for human use.

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Disclosure of Interest: None declared

SP006 Solving the environmental issues for cells: Towards precise regulation of stem cell functions

Ken-Ichiro Kamei – Kyoto University, Japan

Cells are well-organized their functions within tissues as well as a body. To control cell functions as we desired, we need to learn how our body can regulate their functions. The key is “niche”. Cellular “niche”, or in vivo cellular microenvironments, consisted with soluble factors, extracellular matrices (ECMs) and cell-cell interactions, have critical roles for determining functions, such as self-renewal, differentiation, survival and apoptosis. Conventional macro-scale techniques can only provide limited controls of microenvironments over cells, therefore, there is a current lack of tools to perform accurate and effective procedures. To meet this urgent need, we propose to develop micro/nanofabrication technology to create artificial niche within a microfluidic device for a better control of cell function, including human pluripotent stem cells (hPSCs).

In my presentation, I will introduce two on-going research as listed below.
1) High-throughput microfluidic device to obtain functional microtissues
2) Nanofiber matrices for scaled-up culture of stem cells

Conflict of interest: None Declared

OR014 A NOVEL IN VITRO PANCREATIC ISLET MODEL SYSTEM FOR DIABETES RESEARCH

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Background and novelty: Anti-diabetic drug research depends largely on isolated islets as an in vitro model system due to their central role in regulation of blood glucose homeostasis and metabolism. However, inherent heterogeneity in islet size, cellular composition and function as well as the short in vitro lifespan of both native and dispersed islets pose a significant challenge to their use.

Experimental approach: To address this issue, we developed a standardized 3D islet model by reaggregating dispersed primary islet cells in a multiwell hanging-drop platform to generate islets homogenous in size, cellular content, and tissue architecture. The resulting uniform islets, cultured in 96-well-plates in a single islet per well format, enables high-throughput data acquisition with low intra-assay variability.

Results and discussion: Reaggregated islets displayed highly reproducible and robust glucose-regulated insulin and glucagon secretion across donors and stable viability for more than 28 days in culture. In perifusion systems, the step from 2.8 to 16.7 mM glucose induced biphasic insulin secretion with a prominent first phase (~35-fold increase) and a sustained, pulsatile second phase (~8-fold increase) potentiated by glucagon-like peptide 1 (GLP-1), closely mimicking dynamic in vivo insulin secretion. Basal β-cell proliferation observed in reaggregated islets from multiple donors was comparable to previously described rates and was successfully increased with various stimulators, including glycogen synthase kinase inhibitors, glucokinase activators and GLP-1 agonists. Long-term exposure to β-cell stress inducers, such as diabetogenic drugs, increased glucose or cytokine concentrations, impaired β-cell function and viability. This impairment was partially restored upon stress inducer removal or anti-diabetogenic compound addition. Our results demonstrate that our model is suitable for high throughput study of islet function and regeneration in health and disease.

Disclosure of Interest: None declared

SP007 Human stem cell based in vitro modeling of Parkinson's disease

Jens Schwamborn – University of Luxembourg, Luxembourg

Research on human brain development and neurological diseases is limited by the lack of advanced experimental in vitro models that truly recapitulate the complexity of the human brain. Furthermore, animal models of human neurodegenerative diseases have failed dramatically, and the success rate of clinical trials based on these models has been disappointing. Here, we describe a novel and robust human brain organoid system, which is highly specific to the midbrain, derived from regionally patterned neuroepithelial stem cells. These human midbrain organoids contain spatially organized groups of dopaminergic neurons, which make them an attractive model to study Parkinson's disease. Midbrain organoids are characterized in detail for neuronal, astroglial, and oligodendrocyte differentiation. Furthermore, we show the presence of synaptic connections and electrophysiological activity. The complexity of this model is further highlighted by the myelination of neurites. The present midbrain organoid system has the potential to be used for advanced in vitro disease modeling and therapy development.

Conflict of interest: Co-founder and share-holder of the biotech company Braingineering Technologies (BTech). BTech is using models that will be discussed in this presentation.

OR015 DYNAMIC REMODELING OF NEURAL CELLULAR AND EXTRACELLULAR SIGNATURES DEPICTED IN 3D IN VITRO DIFFERENTIATION OF HUMAN IPSC-DERIVED NSC

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Background and novelty: Brain microenvironment plays an important role in development and function. Disruption of its homeostasis is often related to pathological conditions, as the lysosomal storage disease mucopolysaccharidosis type VII (MPS VII), caused by deficient β-glucuronidase activity. We hypothesized that 3D differentiation of human neural stem cells (hNSC) neurospheres in perfusion stirred-tank bioreactors could sustain microenvironment remodeling, recapitulating key cell-ECM interactions.

Experimental approach: Differentiation of hNSC derived from induced pluripotent stem cells (hiPSC-NSC), both from healthy donors and a MPS VII patient, were shown to recapitulate neurogenic developmental pathways, generating tissue-like 3D structures with neuronal, astroglial and oligodendroglial cells. Changes in neural microenvironment during differentiation, namely at cell membrane and ECM composition, were addressed using quantitative transcriptomic (NGS) and proteomic data (SWATH-MS).

Results and discussion: Data revealed a significant enrichment in structural proteoglycans, such as neurocan, versican, brevican and tenascin C, along with downregulation of basement membrane constituents (e.g., laminins, collagens and fibrillins). In MPS VII cells, important disease hallmarks were recapitulated, as the accumulation of glycosaminoglycans. Glial differentiation was increase and alterations in neuronal activity and connectivity were observed.

In summary, we demonstrated that neural cellular and extracellular developmental features are recapitulated in hiPSC-NSC-derived neural microtissues. These can be valuable in vitro models to address molecular defects associated with neurological disorders that affect the microenvironment homeostasis, as MPS VII.

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Disclosure of Interest: None declared

OR016 MIMICKING METABOLIC LIVER ZONATION RESTORES FUNCTIONAL HETEROGENEITY IN CULTURED HEPATOCYTES

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Background and novelty: Liver toxicity is one of the leading causes for high drug attrition rates. Consequently, more thorough in vitro assessment of emerging compounds using hepatocytes is now regarded crucial in pre-clinical drug screening. However, currently available culture systems fail to reflect the two spatially separated and distinct metabolic phenotypes, pericentral or periportal, that hepatocytes display in vivo. This so called metabolic zonation is formed as a consequence of Wnt-signalling gradients within the liver microarchitecture. Upon in vitro culture of hepatocytes the pericentral phenotype is lost, which is responsible for most of the phase I drug metabolism. We therefore aimed to restore hepatic functional heterogeneity by creating a long-term stable in vitro system of liver zonation that mimics liver Wnt-signalling.

Experimental approach: Immortalised human and murine hepatic cell lines were genetically engineered to allow controlled induction of Wnt-signalling based on a Doxycycline-dependent synthetic expression unit. While Wnt-signalling activation was analysed using a fluorescent reporter, phenotypic changes were assessed by marker gene expression.

Results and discussion: Depending on the inducer concentration, any ratio of pericentral versus periportal hepatocytes could be established in vitro within 4 days. The Wnt-signalling state was distributed mosaic-like resembling liver zonation in vivo and was preserved in 3D culture conditions. The establishment of the pericentral phenotype was verified by increased expression of pericentral markers with simultaneous down-regulation of periportal markers. The change in phenotype was stable over 2 weeks compared to small-molecule-driven activation of Wnt-signalling which was prone to negative feedback regulation and therefore only transient. Of note, expression of phase I metabolic genes including CYP1A1, CYP2A1 and AhR was increased in the Wnt-signalling active population.

Disclosure of Interest: None declared

SP008 Title TBA

Thomas Ryll – Immunogen, United States

OR019 USE OF BIOCAPACITANCE PROBES FOR OPTIMIZED PROCESS CONTROL AT LARGE-SCALE MANUFACTURING

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Background and novelty: Monoclonal antibody production is moving towards high-titer fed-batch processes. Development of such processes often requires pushing cell densities much higher which can amplify sensitivity to nutrient feed addition amounts per cell both with regards to titer and to product quality. Such processes require tightly controlled nutrient feed

addition during the process to balance nutrient consumption. Legacy manufacturing processes have typically applied fixed-volume bolus feeds, which in combination with small variations in seed density and/or growth rates can result in significant variation in feed amount added per cell. Therefore, for high titer processes Biogen has moved to variable-volume feeding via dynamic biomass dependent nutrient feed control and this strategy has enabled us to generate robust processes with titers in the 7-10g/L range.

Experimental approach: Biocapacitance based nutrient feeding was applied for a high-cell density, high titer monoclonal antibody process, which was developed as part of the strategic partnership between Janssen and Biogen. The process is sensitive to nutrient feed amounts, and was successfully scaled to 15,000L scale manufacturing bioreactors using a feed control strategy based on integral biocapacitance. Furthermore, biocapacitance was used to control and determine the inoculum transfer volumes between bioreactors in order to further streamline the process.

Results and discussion: Data will be presented from the application of biocapacitance based feed amount strategy at manufacturing scale for a high titer process, where the feed amount per cell is important to tightly control product quality. The biocapacitance based transfer volume determinations as well as the feed addition strategies resulted in consistent process performance and product quality control. Furthermore, the use of automated inline measurements minimized operator interactions and errors compared to offline measurements.

Disclosure of Interest: None declared

OR020 HIGH THROUGHPUT ANALYSIS OF ANTIBODY GLYCOSYLATION IN CELL CULTURE SAMPLES

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Background and novelty: The glycosylation of glycoproteins is a critical quality attribute (CQA) and thus needs to be analyzed during the cell line and bioprocess development. The current analytical methods for measuring glycosylation demand rather high amounts of purified protein and use sophisticated protocols and equipment. In addition, they only offer limited throughput, which makes these methods not very well suited for cell line development work.

In this study we evaluated a PAIA bead-based immunoassay with ProteinA capture beads in combination with fluorescence labeled plant lectins to detect carbohydrates (fucose, galactose, mannose and sialic acid) in a high throughput 384-well plate format. The sample preparation protocol is simple and does not require purified protein. One lectin can be assayed per well offering the possibility to compare several lectins and multiple samples with each microtiter plate.

Experimental approach: Several IgGs were spiked into CHO cell culture supernatants and treated with a mild denaturation solution. 5-10 µL of this solution, corresponding to only few µg of IgG, were used for each well in the assay. Cetuximab (Erbitux, Merck) was measured without denaturation.

Results and discussion: A mild denaturation treatment was necessary to expose and detect the Fc glycosylation sites on IgGs. The Fab glycosylation of cetuximab was measured without treatment, indicating that glycans that are not buried in the Fc region are easily accessible. The lectin binding signals were compared with known glycan patterns of the different antibodies obtained with orthogonal methods. The results suggest that this approach will be a powerful screening tool for early process development to ensure critical quality attributes.

Disclosure of Interest: None declared

SP009 Intensification of a Multi-Product Perfusion Platform through Medium and Process Development

Shawn Barrett – Sanofi, United States

Integrated Continuous Biomanufacturing (ICB) provides many important strategic advantages for therapeutic protein production through process intensification, simplification and integration. The success of this technology will be significantly enhanced by the platform's ability to push towards high productivity in conjunction with minimizing the associated perfusion rate, resulting in dramatic reductions in cost of good manufactured. We have previously demonstrated that an in-house chemically defined medium can support cell densities exceeding 100 million viable cells/mL in 10L perfusion bioreactors with an average productivity of 2 g/L/day. Further optimization utilizing high throughput technology specifically tailored to improve cell specific productivity (SPR) resulted in an intensified medium that is capable of achieving greater than 2X increase in SPR while maintaining low cell specific perfusion rate (CSPR). When combined with process knowledge and efforts to improve shear protection in a high oxygen demand environment, we were able to achieve 4 g/L/day volumetric productivity of an IgG for over 30 days in a state of control. In this talk, recent case studies on the application of this intensified perfusion platform to cell lines producing different classes of biologics will be described, effects on product quality will be illustrated, and engineering and economic considerations for commercial scale will be discussed.

Conflict of interest: None Declared

SP010 Optimization of a mammalian cell perfusion culture in productivity and product quality

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Background & Novelty: Continuous production of biopharmaceuticals expressed in mammalian cells combines several advantages compared to traditional batch-wise processing. In particular higher volumetric productivities and an enhanced product quality are pathing the way to a more general application of continuous mammalian cell perfusion cultures. The goal of this study is the optimization of a mammalian cell perfusion culture by tuning key cell culture variables aiming for superior performances compared to established fed-batch process.

Experimental Approach: Suitable operating conditions were determined by the application of small-scale experiments in SpinTube bioreactors. Identified process parameters were tested in a previously developed stirred tank perfusion bioreactor setup employing an external alternating flow filtration device for cell retention [1]. The effect of key process parameters was evaluated in a sequential screening approach. Varying one parameter at a time, measurements of extra- and intracellular metabolites, product concentration as well as product quality attributes were used to investigate their effect on cellular growth, productivity and product quality at steady state.

Results & Discussion: The tuning of key cell culture parameters led to a superior performance of the perfusion culture. Especially, the decrease of the cell specific perfusion rate resulted in the decrease of product loss in the bleed due to slower cell growth. The variation of cell specific perfusion rates strongly effected the N-linked glycosylation pattern of produced antibodies and could be thus employed to tune towards a desired product quality. Overall, this study underlines the high potential of the perfusion mode for the production of therapeutic proteins.

Literature: [1] D. J. Karst, E. Serra, T. K. Villiger, M. Soos, and M. Morbidelli, "Characterization and comparison of ATF and TFF in stirred bioreactors for continuous mammalian cell culture processes," Biochem. Eng. J., vol. 110, pp. 17–26, 2016.

OR021 CONFIRMING SIALYLATION BIOMARKERS IN A CHO BIOPROCESS USING OMICS

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Background and novelty: Biologics represent an increasingly important class of therapeutics. The glycosylation distribution of these proteins is an important characteristic impacting activity, half-life, & immunogenicity. Despite its importance, limited information is available linking process to glycosylation distribution. The low-throughput glycosylation methods require significant time & material to generate meaningful data. Alternatively, biomarkers, genes or metabolites whose levels are linked with glycosylation, can be monitored across scales & conditions [1].

Previously we studied a protein where sialylation variation resulted from an oxidative stress response causing metabolic changes & reduced sialylation [2]. We identified proposed biomarkers for sialylation.

Experimental approach: We validate proposed sialylation biomarkers using Omics techniques. Fed-batch bioprocesses are carried out at manufacturing & lab scale under conditions known to increase sialylation through the addition of Mn & a modified process control strategy. Cell culture pellets & supernatant were analyzed using transcriptomics & metabolomics.

Results and discussion: Biomarker levels were compared to the control & found to be consistently correlated with sialylation level. With increasing sialylation we measured reduced extracellular mannose, increased intracellular GlcNAc & GalNAc, & reduced expression of PDK, PFK, & G6PD. 11 of 13 previously identified intracellular metabolites, & 10 of 40 previously identified gene expression biomarkers were again significantly correlated with sialylation. Finally we compare the Omics profiles from three control strategies which shows the modified process control strategy is more effective than Mn addition in mitigating the impact of oxidative stress on process performance. This work is a novel contribution to the field & refines our understanding of CHO sialylation biomarkers.

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[2]Lewis, AM et al, PLOS ONE, 2016.

Disclosure of Interest: None declared

SP011 Successes and challenges of cell culture for therapeutic mAb production

Thierry Ziegler – Sanofi, France

Last 3 decades have seen strong transformation of Therapeutic Biologics world with around fifty monoclonal antibody products approved today covering various therapeutic indications. It is anticipated that 50% more monoclonal antibody products will be on the market by 2020, with potential world-wide sales will be nearly $125 billion.

In order to support increasing product needs, significant progresses have been made in cell culture for therapeutic mAb production. Drivers such cost of goods, process simplification and scaleability combined with innovation in cell line engineering and metabolomics has led to 100-fold improvement in product titer using simple fed-batch cultures. In parallel, improved bioreactor design and development of single-use technologies has led to significant simplification of bioreactor process. These tremendous improvements has successfully led to reduced cost of cell culture and also moved the majority of cost and bottleneck to downstream.

Today, with increasing regulatory burden and arrival of biosimilars, cell culture is facing new challenges linked to increasing need to control and modify product characteristics as well as level of specific protein contaminants. In one sanofi development project where changes in process led to modified mAb characteristics, original product quality could be recovered through media/feed customization. In another example, it was shown that consistent mAb quality can be produced using continuous manufacturing.

After providing a summary of the key drivers and progress made in cell culture in the past years, the presentation will focus on approaches used to customize product quality highlighting challenges and successes through examples.

Conflict of interest: None Declared

SP012 Another Arrow in the Quiver – Cell Retention/Perfusion – How, When and Why - Judicious Use of a Brute-Force Technology

Gregory Hiller – Pfizer, United States

Animal cell culture has always suffered from the simple fact that the cells we culture are no longer IN an animal. They require full life support – perfect temperature, ample oxygen, nutrients, and trace elements, but most problematically, they require protection from the accumulation of toxic metabolites. The accumulation of toxic metabolites slows growth, suppresses achievable cell densities, and also can decrease the per cell, or specific productivity. Over the past decade our research group has attempted to devise innovative strategies to resolve this problem. Cell metabolism can be controlled in many ways to minimize the production of toxic metabolites, but these techniques often have the downside of slowing cell growth, limiting peak cell density, and thereby limiting overall productivity of a culture. Perfusion of course can flush the metabolites from the cell culture system and allow for continued growth, but it is a somewhat 'brute-force' technique that requires large volumes of cell culture medium and can be difficult to implement at the largest scales currently used in production of biopharmaceuticals. Through the use of metabolomics techniques our group has identified and quantified previously unreported specific metabolites that accumulate in CHO fed-batch cultures. Using this understanding, our techniques of lactate suppression, and judicious use of cell-controlled perfusion, we can significantly increase the productivity of classical fed-batch, hybrid perfusion fed-batch, and high-intensity low-volume perfusion processes while simultaneously minimizing the difficulty of scale-up.

Conflict of interest: None Declared

OR022 THE DEVELOPMENT OF NOVEL SURFACTANTS AND THEIR ROLE IN DEFINED MEDIA

T. Bus[1],[*], M. N. Leiske[1], A.-K. Truetzschler[1], E. Rudiseva[2], S. Klausing[3], C. Heinrich[3], A. Traeger[1], U. S. Schubert[1]

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Background and novelty: High-titer cell lines and high-quality products are in the spotlight of biotechnological production. Hence, the selection of the cell culture media is one of the main criteria to reach high standards. This fact is mirrored through the fast growing sector of media engineering and the increasing number of new formulations with different ingredients and compositions sold for customized use. In this study we developed novel synthetic additives for the utilization as anti-shear force and anti-foaming agent in chemically defined media for suspension cell culture.

Experimental approach: A series of novel tailor-made polymeric compounds were synthesized and investigated regarding their utilization in chemically defined media in comparison to e.g. Pluronic and other common surfactants. Cell growth and viability of HEK cells were monitored during subcultivation and final batch processes using shaking flasks with and without baffled bottom. To assess the influence of surfactants on cells as well as on the cellular uptake of nanocarriers in more detail, confocal microscopy and flow cytometry were performed using fluorescently labeled surfactants.

Results and discussion: The presented compounds revealed excellent cell viabilities and competitive growth rates in

dynamic cell culture compared to established surfactants. Based on live cell imaging, an increased intracellular localization of surfactants rather than membrane accumulations was detected. This could correlate with differences in particle uptake efficiencies. Thus, a follow-up study assessing the interaction of surfactants and various charged particles was performed. Taken together, these compounds represent promising alternatives for the use as supplements in chemically defined cell culture media since they exhibit a simple synthesis route.

Bibliography, Acknowledgements: We would like to thank the German Federal Ministry of Education & Research (BMBF # 031A518B Vectura) for funding.

Disclosure of Interest: None declared

OR023 SMALL PROCESS CHANGES DO MATTER- MATCHING SCALE DOWN AND AT SCALE CELL CULTURE PERFORMANCE FOR A THERAPEUTIC ANTIBODY

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Background and novelty: During a large-scale production campaign using CHO cells producing a therapeutic antibody, growth and productivity were lower than expected. A 20% lower titer was obtained as compared with the scale down model results. Cell culture process troubleshooting and understanding showed an unexpected high sensitivity to initial pCO2 and pH in the cell culture process.

Experimental approach: CHO cells expressing a therapeutic antibody were cultured in chemically-defined media at 2 L and 12,000 L scales. Differences in initial pCO2 were observed and led to the investigation of process sensitivity at different pCO2 and pH conditions. CO2 is used to lower and control pH during cell culture. Cell culture medium bicarbonate concentrations were adjusted to create different pH and pCO2 conditions. Additionally, a scale-down model was developed to mimic pCO2 profiles at 12,000 L by changing both sparger design and operating sparging strategies.

Results and discussion: This cell culture process is sensitive to small differences in initial pCO2 and pH. Scale-up differences were able to be minimized by process changes with successful applicability at the 12,000 L scale. A subsequent large-scale campaign using these process changes showed comparable performance between the 12,000 L and the scale-down model.

Disclosure of Interest: None declared

OR024 BIOCHEMICAL CHARACTERIZATION OF REDOX ACTIVE SUBSTANCES TO IMPROVE HARVEST ROBUSTNESS DURING MONOCLONAL ANTIBODY PRODUCTION

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Background and novelty: Bio-manufacturing of monoclonal antibodies in mammalian cells harbors the risk of antibody interchain disulfide bond reduction upon harvest. Depending on the harvest method and physiological state of the culture at the end of the production run, cell lysis and concomitant release of intracellular reducing agents can occur to variable degrees and may profoundly compromise structural integrity of the product. Due to engineering constraints, the development of accurate and predictable small scale models for both filtration based and centrifugation harvest procedures remains a challenge. Hence, great emphasis has been put on auxiliary engineering controls to prevent antibody reduction, including supplementation of cell culture media with redox active substances.

Experimental approach: Here, we report an integrated approach encompassing biochemical characterization of lysates from CHO cells of varying viabilities from a small scale bioreactor model, in conjunction with numerous organic or inorganic redox active substances.

Results and discussion: We find that several additives protect structural integrity when subjecting purified antibody to both chemical reduction by DTT and biological reduction using cell lysate in vitro. Using this approach we can model at-scale harvest scenarios, assess occurring lysis, and mitigate against antibody disulfide bond reduction using media additives.

Disclosure of Interest: None declared

SP013 Designer matrices for stem cell-based organoid culture

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Animal cell culture has always suffered from the simple fact that the cells we culture are no longer IN an animal. They require full life support – perfect temperature, ample oxygen, nutrients, and trace elements, but most problematically, they require protection from the accumulation of toxic metabolites. The accumulation of toxic metabolites slows growth, suppresses achievable cell densities, and also can decrease the per cell, or specific productivity. Over the past decade our research group has attempted to devise innovative strategies to resolve this problem. Cell metabolism can be controlled in many ways to minimize the production of toxic metabolites, but these techniques often have the downside of slowing cell growth, limiting peak cell density, and thereby limiting overall productivity of a culture. Perfusion of course can flush the metabolites from the cell culture system and allow for continued growth, but it is a somewhat 'brute-force' technique that requires large volumes of cell culture medium and can be difficult to implement at the largest scales currently used in production of biopharmaceuticals. Through the use of metabolomics techniques our group has identified and quantified previously unreported specific metabolites that accumulate in CHO fed-batch cultures. Using this understanding, our techniques of lactate suppression, and judicious use of cell-controlled perfusion, we can significantly increase the productivity of classical fed-batch, hybrid perfusion fed-batch, and high-intensity low-volume perfusion processes while simultaneously minimizing the difficulty of scale-up.

Conflict of interest: None Declared.

OR025 IMPROVING MATURATION OF CARDIOMYOCYTES DERIVED FROM HUMAN PLURIPOTENT STEM CELLS: AN "-OMICS" DRIVEN APPROACH

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Background and novelty: The immature phenotype of human pluripotent stem cell derived cardiomyocytes (hPSC-CMs) constrains their potential in cell therapy and drug testing. In this study we aim to overcome this hurdle by devising a novel scalable strategy for maturation of functional hPSC-CM.

Experimental approach: We assessed if alteration of hPSC-CM culture medium composition to mimic in vivo substrate usage during cardiac development induces hPSC-CM maturation in vitro. Specifically, we selected multiple conditions based on the fact that during cardiac development CMs start to use first lactate and then fatty acids as a major source of energy. hPSC-CMs cultured in different media were characterised using a set of "-omics" tools (metabolomics, fluxomics and transcriptomics), structural, morphological and functional analyses.

Results and discussion: We demonstrated that hiPSC-CM cultured in glucose depleted medium supplemented with fatty acids and galactose display features that resemble more mature CM, than hiPSC-CM cultured in standard glucose rich medium, namely: energetically efficient oxidative metabolism, transcriptional signatures closer to ventricular CM; more elongated morphologies; organized sarcomeric structures; higher myofibril alignment; improved calcium handling, contractility and action potential kinetics.

Also, we revealed that addition of galactose to culture medium improves total oxidative capacity of the cells, avoiding the lipotoxicity.

In sum, this work provides an important link between substrate utilisation and functional maturation of hPSC-CMs and facilitates the application of this promising cell type to clinical and preclinal applications.

Bibliography, Acknowledgements: This work was supported by FP7 European Union Project Cardio Repair European Multidisciplinary Initiative (HEALTH-2009_242038); Fundação para a Ciência e Tecnologia funded projects CardioRegen (HMSP-ICT/0039/2013) and CARDIOSTEM (MITPTB/ECE/0013/2013).

Disclosure of Interest: None declared

OR026 ASSESSMENT OF A CELL THERAPY APPROACH FOR DUCHENNE MUSCULAR DYSTROPHY USING MESOANGIOBLASTS AND TRANSPOSABLE VECTORS

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Background and novelty: Duchenne muscular dystrophy (DMD) is a lethal X-linked disease affecting 1 in 5000 boys, in which dysfunctional dystrophin leads to muscle wasting. Autologous transplantation of genetically modified myogenic stem cells would be an attractive therapeutic option for this lethal disease. However, cell therapy of DMD met modest success,

possibly due to the large size of the dystrophin coding sequence and transgene silencing. Mesoangioblasts (MABs) are muscle progenitor cells with an ability to fuse with myofibers. The present study investigates use of PiggyBac transposon-mediated gene transfer in MABs for a cell therapy approach in a dystrophin-deficient mouse model (mdxSCID).

Experimental approach: Dystrophic MABs were transfected with transposable vectors containing full-length dystrophin and GFP/nlacZ, and transplanted intra-muscularly or intra-arterially into mdxSCID mice.

Results and discussion: Intra-arterial delivery indicated that MABs retained their ability to cross the vessel walls and migrate to regenerating muscles. By intra-muscular delivery, expression of dystrophin and dystrophin-associated proteins was restored in 18-45% of myofibers in murine muscles and was stable for the assessed period of five months. Dystrophin protein levels in transplanted muscles were found to be between 10-30% of wild type. Furthermore, approximately 3% of the satellite-like cell population comprised mesoangioblast derived cells, implying that transplanted MABs retained their ability to colonize the satellite cell niche. Functional restoration was assessed by atomic force microscopy assays of transplanted muscles, which indicated that almost 80% of fibers had similar elasticity properties as wild type muscles. These findings provide a proof-of-principle that the PiggyBac transposon system has the potential to express full-length dystrophin in muscles, and thereby possibly improve cell-based therapies of DMD.

Disclosure of Interest: None declared

OR027 BETA-CELL-MIMETIC DESIGNER CELLS PROVIDE CLOSED-LOOP GLYCEMIC CONTROL

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Background and novelty: Chronically deregulated blood-glucose levels (hyperglycemia) in diabetes mellitus result from a loss of pancreatic insulin-producing β-cells (type-1 diabetes, T1D) or from impaired insulin sensitivity of body cells and glucose-stimulated insulin release (type-2 diabetes, T2D). Unless treated in time, sustained hyperglycemia can initiate pathologic cascades that result in more severe disorders such as cardiovascular diseases, renal failures, the metabolic syndrome, or hormone dysfunctions. Therefore, therapeutic strategies that precisely coordinate early diagnosis with effective treatment are urgently needed to contain and reverse the Diabetes Mellitus pandemic in the 21st century.

Experimental approach: Here, we show that therapeutically applicable β-cell-mimetic designer cells can be established by minimal engineering of human cells. We achieved glucose responsiveness by a synthetic circuit that couples glycolysis-mediated calcium entry to an excitation-transcription system controlling therapeutic transgene expression. These systems may enable a combination of diagnosis and treatment for diabetes mellitus therapy.

Results and discussion: Coupling of CaV1.3-based glucose sensing to insulin production and secretion resulted in the β-cell-mimetic HEK-β that provided increased 3-week insulin secretion profiles compared to the pancreatic cell line 1.1E7 and human islets in vitro. Control of postprandial glucose metabolism was similar between HEK-β and 1.1E7, but only HEK-β reached the blood glucose levels of healthy mice.

Similarly, implanting Cav1.3-transgenic HEK-293 cells engineered for glucose-stimulated GLP-1 production into type-2 diabetic mice resulted in self-sufficient GLP-1 expression and substantially improved glucose-stimulated insulin secretion and glucose tolerance.

Bibliography, Acknowledgements: Xie et al. Science (2016) 354, 1296-1301

Disclosure of Interest: None declared

SP014 Technologies Tailored for Cellular Therapy Manufacturing

Jamie Piret – University of British Columbia, Canada

A major wave of promising cellular therapies is progressing through clinical trials, such that many bioprocess engineers and scientists are confronting the challenges of economically manufacturing safe and efficacious cell products. These production processes often depend on devices and methods that were developed for related applications, such as blood cell processing or vaccine manufacturing. Thus, we have a unique window of opportunity to tailor innovative technologies in order to better address the emerging specialized needs of cell therapy manufacturing. This presentation will describe advances ranging from microfluidic technologies to patient-scale culture processing, and novel methods for monitoring the quality and safety of complex populations of cells. The development of reliable, high-performance and economical means of mammalian cell manufacturing is on the critical path to ensuring that promising new health care technologies become widely available to innumerable patients in dire need.

Conflict of interest: None Declared

NOTES

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NOTES

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POSTER PRESENTATIONS

- Uneven poster numbers will be presented on Monday May 15 from 14:00 to 15:30.
- Even poster numbers will be presented on Tuesday May 16 from 14:00 to 15:30

* Presenting author

Posters selected for the ESACT poster prize

CELL CULTURE BASED PROCESS ENGINEERING AND PRODUCT QUALITY

PO001 UNDERSTANDING THE IMPACT OF CELL CULTURE PROCESS MANIPULATIONS ON MONOCLONAL ANTIBODY CRITICAL QUALITY ATTRIBUTES AND FUNCTIONAL RESPONSE

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PO002 FAST AND STREAMLINED TECHNOLOGY TRANSFER TO CONTRACT MANUFACTURING ORGANIZATION FOR EARLY-STAGE CLINICAL MONOCLONAL ANTIBODY PRODUCTION

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PO003 DIELECTRIC IMPEDANCE SPECTROSCOPY FOR NON-DESTRUCTIVE QUALITY ASSESSMENT OF 3D CELLULAR CONSTRUCTS

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PO004 OPTIMIZED PEI-BASED TRANSFECTION REAGENTS FOR PRODUCTION OF CLINICAL GRADE VIRAL VECTORS

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PO005 EFFECTS OF REAL-TIME BIOPROCESS CONTROL USING RAMAN SPECTROSCOPY

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PO006 A MACHINE LEARNING APPROACH FOR NON-INVASIVE CELL DENSITY DETERMINATION IN ADHERENT CELL CULTURES

Alexandre Super[1,], Nicolas Jaccard[2], Thibault Asselborn[1], Shuchang Liu[1], David De Silva Thompson[1], Gerardo Santiago Toledo[1], Ana De Sousa Valinhas[1], Yuhong Zhou[1], Ivan Wall[1], Lewis D. Griffin[2], Nicolas Szita[1]*
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PO007 INVESTIGATION OF THE APPLICABILITY OF ATR-IR FOR THE ANALYSIS OF MONOCLONAL ANTIBODY AGGREGATION IN BIOPROCESSES

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PO008 DEVELOPMENT OF MEASUREMENT, MONITORING, MODELLING AND CONTROL STRATEGIES IN PRODUCTION PROCESSES WITH CHO CELL CULTURES

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PO009 HIGH-THROUGHPUT SAMPLE PROCESSING AND ANALYTICS OF SAMPLES DERIVED FROM HIGH-THROUGHPUT DOWN SCALE BIOREACTOR SYSTEMS

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PO010 IMPROVEMENT OF CHO SPECIFIC PRODUCTIVITY USING TYROSINE AND CYSTEINE DERIVATIVES

Caroline Hecklau[1], Sascha Pering[1], Alisa Schnellbaecher[1], Thomas Eichhorn[1], Aline Zimmer[1,]*
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PO011 MIXING AND TEMPERATURE CHARACTERIZATION OF SINGLE-USE MIXER SYSTEMS

Andreas Andersson[1,], Karin Sjöberg Gällnö[1], Annika Morrison[1], Andreas Castan[1], Jakob Liderfelt[1]*
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PO012 DEVELOPMENT OF A CHO CELL CULTURE PLATFORM FOR MONOCLONAL ANTIBODY PRODUCTION: FROM CLONE GENERATION TO PILOT PLANT SCALE-UP

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PO013 ON THE ROAD TOWARDS THE PRODUCTION OF NANOPARTICLES FOR UTILIZATION IN DEFINED MEDIA

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PO014 INOCULUM PERFORMANCE UNDER DIFFERENT CULTURE CONDITIONS: ONE CLONE, MULTIPLE BEHAVIOR

Ankur Bhatnagar[1,], Dinesh Baskar[1], Saravanan Desan[1], Chandrashekhar K.N.[1], Janani K[1], Shilpa Bhat[1], Sohini Jana[1], Ritika Lakhotia[1], Kumaran S.V.[1]*
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PO015 ADVANTAGES AND CHALLENGES OF A CONTINUOUS UPSTREAM PROCESS

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PO018 ANALYSIS OF PRODUCT QUALITY ATTRIBUTES BY MIR SPECTROSCOPY

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PO019 INFLUENCE OF MEDIA SUPPLEMENTS ON NANOPARTICLE PERFORMANCE

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PO020 HIGHTHROUGHPUT SCREENING AND MULTIVARIATE ANALYSIS IDENTIFY CRITICAL COMPONENTS DURING CHO MEDIA AND FEED DEVELOPMENT

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PO021 BIOPROCESS ENGINEERING STRATEGIES FOR ENHANCED GAG-VLPS PRODUCTION IN STABLE INSECT CELLS

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PO022 BIOPROCESS INTENSIFICATION AND OPTIMIZATION USING MACROSCOPIC PREDICTIVE MODELS OF CELL CULTURE PROCESSES

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PO023 DIFFERENTIAL ANALYSIS OF IGG PRODUCT QUALITY BY INTACT MASS ANALYSIS FOR FED-BATCH-CULTIVATED CHO CELLS UNDER GLUCOSE LIMITATION

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PO024 BROAD ANALYTICAL PLATFORM DEVELOPMENT FOR ADVANCED PROCESS MONITORING AND CONTROL IMPLEMENTATION

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PO025 OPTIMISATION OF TRANSIENT EXPRESSION PLATFORM TO INCREASE TITRE AND THROUGHPUT

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PO026 NEW SOLUTIONS FOR VIRUS RISK MITIGATION IN CELL CULTURE MEDIA

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PO027 OBSERVATIONS OF CELL CULTURE PERFORMANCE AND PRODUCT QUALITY UPON SUBCLONING OF CHO PRODUCTION CELL LINES

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PO028 HYDRODYNAMICS OPTIMIZATION IN HUMAN CELL PERFUSION CULTURE

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PO029 CONTROLLING TERMINAL SIALYLATION OF MAB THROUGH CULTURE CONDITION

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PO030 INTEGRATED MEDIA BLENDING INCREASES EFFICIENCY OF CLONE SELECTION

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PO031 HOW CELL CULTURE AUTOMATION BENEFITS UPSTREAM PROCESS DEVELOPMENT

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PO032 IMPACT OF PROCESS AND CHO CELL ENGINEERING ON ANTIBODY YIELD AND QUALITY

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PO033 NEW MODELS FOR PREDICTING MICROCARRIER JUST-SUSPENDED STATE IN BIOREACTORS

Céline Loubière[1,2,], Eric Olmos[1,2], Emmanuel Guedon[1,2], Isabelle Chevalot[1,2], Dominique Toye[3], Angélique Delafosse[1,2,3]*

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PO034 BIOSIMILARS DEVELOPMENT CASE STUDY: HOW TO MATCH BOTH GLYCOPROFILE AND CHARGE PROFILE?

Céline RAYMOND[1,], Charlène FRANCOIS[1], Sandra GONZALEZ[2], Armelle GILLETTA DE SAINT JOSEPH[2], Sonia BEAUDEAN[2], Dominique BUTEUX[1]*

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PO035 CASCADING EFFECTS IN BIOPROCESSING: THE IMPACT OF CELL CULTURE ENVIRONMENT ON MAMMALIAN CELL BEHAVIOUR AND HOST CELL PROTEIN SPECIES

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PO036 DEVELOPMENT OF A NOVEL POLOXAMER [188] SHEAR PROTECTANT

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PO037 EXPERIENCES WITH A PARALLELIZED AND AUTOMATED SMALL SCALE FERMENTATION SYSTEM REGARDING SCALABILITY OF RESULTS IN PROCESS DEVELOPMENT

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PO038 A NOVEL PLATFORM FOR HIGH THROUGHPUT CELL LINE SCREENING & DEVELOPMENT

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PO039 INCREASE THROUGHPUT IN DESIGN AND PRODUCTION OF NON-ANTIBODY TOOL PROTEINS AND CELL LINES

Christoph Freiberg[1,], Gian Andrea Signorell[1], Lukas Flueck-Kabay[1], Amanda Fitzgerald[2], Maria Wendt[1], Yang-Chieh Chou[3], Hans Peter Fischer[1]*

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PO040 CASE STUDY OF HIGH CELL DENSITY CELL CULTURE AND CLARIFICATION POST-FLOCCULATION WITH TOTAL SINGLE USE SOLUTIONS AT A 1800L SCALE

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PO041 APPLICATION OF DIELECTRIC SPECTROSCOPY TO DETERMINE BIOMASS AND METABOLIC STATUS IN A CELL CULTURE PROCESS

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PO042 VALIDATION OF A GMP COMPLIANT PROCESS TO PRODUCE RECOMBINANT ADENO-ASSOCIATED VIRUS VECTORS IN HEK 293 SUSPENSION CELLS

Daniel Blessing[1,2,], Gabriel Vachey[2], Mergim Ramosaj[2], Catherine Pythoud[2], Bernard Schneider[1], Florian Wurm[3], Nicole Déglon[2]*

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PO043 INVESTIGATION OF A DOWNSTREAM PROCESSING FOR THE APPLICATION OF ONCOLYTIC MEASLES VIRUSES IN THE GENE THERAPY

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PO044 INVESTIGATING THE WARBURG EFFECT: HOW HIGH EXTRACELLULAR LACTATE AFFECTS INDUCED PLURIPOTENT STEM CELL METABOLISM AND PLURIPOTENCY

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PO045 MONITORING THE PRODUCTION OF AAV VECTORS IN INSECT CELLS BY FLUORESCENCE SPECTROSCOPY

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PO046 TAILORING N-GLYCOSYLATION BY RATIONAL CELL CULTURE MEDIUM DESIGN

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PO047 DEVELOPMENT OF DOE BASED FED-BATCH STRATEGIES FOR HIGH-PRODUCING CHO CELL CULTURES

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PO048 TRANSCRIPTOME ANALYSIS IN HIGH-PRODUCING CHO CELL CULTURES: STRATEGIES TO DESIGN HIGH-PERFORMING CELL CULTURE MEDIA

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PO049 COUPLING SE-UPLC WITH LC-MS / MS FOR UNDERSTANDING AGGREGATE AND SHOULDERS ELUTING WITH MONOCLONAL ANTIBODIES PRODUCED IN CHO CELLS

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PO050 HOW TO EFFICIENTLY SCALE UP CLINICAL MANUFACTURING OF THE ONCOLYTIC VIRUS VSV-GP AND MOVE QUICKLY FROM BENCH TO BEDSIDE

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PO052 A PAT APPLICATION FOR THE MONITORING OF VIABLE CELL DENSITY AND AUTOMATING FEEDING STRATEGIES IN MAMMALIAN CELL CULTURES FOR IMPROVED PERFORMANCE

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PO053 IMPROVEMENT OF A PLATFORM MEDIA AND FEED SCREEN FOR MASTER CELL BANK CANDIDATES

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PO054 PERFUSION MEDIA DEVELOPMENT USING CELL SETTLING IN AUTOMATED CELL CULTURE SYSTEM

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PO055 CHARACTERIZATION AND OPTIMIZATION OF DIFFERENT APPROACHES FOR VLP PRODUCTION IN INSECT CELLS

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PO056 DEVELOPMENT OF AN IN-LINE NANOFILTRATION STEP FOR VIRUS REMOVAL IN A CONTINUOUS CELL CULTURE PROCESS

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PO057 TRANSFER OF GMP-COMPLIANT MANUFACTURING OF NATIVE AND GENETICALLY MODIFIED HUMAN MESENCHYMAL STEM CELLS TO A MULTIPLATE BIOREACTOR TECHNOLOGY

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PO058 MICROCARRIER-BASED CULTIVATION OF HUMAN MESENCHYMAL STEM CELLS IN THREE DIFFERENT SUSPENSION BIOREACTOR SYSTEMS

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PO059 DIAMINE OXIDASE N-GLYCOSYLATION SITE ASN110 IS HIGHLY CONSERVED IN EVOLUTION AND ESSENTIAL FOR SECRETION

Elisabeth Gludovacz[1,2,], Daniel Maresch[2], Clemens Grünwald-Gruber[2], Verena Puxbaum[2], Laurenz J. Baier[2], Leonor Lopes de Carvalho[3], Friedrich Altmann[2], Tiina A. Salminen[3], Barbara Ulm[1], Sophie Pils[1], Thomas Boehm[1], Bernd Jilma[1], Nicole Borth[2]*

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PO060 IMPROVEMENTS ON A SCALABLE BIOPROCESS FOR THE 2KL PRODUCTION OF AN ANTIBODY WITH THE SINGLE-USE TECHNOLOGY

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PO061 AN 'INDUSTRY FIRST' 500L BIOREACTOR CHO TRANSIENT CULTURE: DEVELOPMENT OF LARGE SCALE TRANSIENT EXPRESSION CAPABILITIES

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PO062 COMBINING METABOLIC AND PROCESS ENGINEERING STRATEGIES TO IMPROVE RECOMBINANT GLYCOPROTEIN PRODUCTION AND QUALITY

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PO063 ESTABLISHMENT OF AN AUTOMATIZATION SYSTEM FOR A CONTINUOUS INTEGRATED BIOPHARMACEUTICAL MANUFACTURING PROCESS

Fabian Feidl[1,], Michael Sokolov[1], Moritz Wolf[1], Sebastian Vogg[1], Jean-Marc Bielser[2], Jonathan Souquet[2], Hervé Broly[2], Massimo Morbidelli[1], Alessandro Butté[3]*

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PO064 COMPREHENSIVE ANALYSIS OF THE IMPACT OF TRACE ELEMENTS IN MEDIA ON CLONE DEPENDENT PROCESS PERFORMANCE AND PRODUCT QUALITY

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PO065 DEVELOPMENT OF AN ANALYTICAL APPROACH FOR ON-LINE MONITORING AND CONTROL OF MONOCLONAL ANTIBODIES QUALITY

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PO066 DEVELOPMENT AND ASSESSMENT OF A ROBOTIC HIGHTHROUGHPUT PLATFORM FOR ANTIBODY PURIFICATION MINIPURIFICATION

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PO067 VIABLE CELL DENSITY MONITORING IN BIOREACTOR WITH LENSLESS IMAGING

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PO068 TIME-DEPENDENT PRODUCT HETEROGENEITY IN MAMMALIAN CELL FERMENTATION PROCESSES

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PO069 ACOUSTIC WAVE SEPARATION – A SCALABLE DISRUPTIVE TECHNOLOGY FOR CONTINUOUS CLARIFICATION OF FED BATCH CELL CULTURE PRIOR TO CAPTURE CHROMATOGRAPHY

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PO070 UNDERSTANDING THE EFFECT OF HIGH GAS ENTRANCE VELOCITY ON CHINESE HAMSTER OVARY (CHO) CELL CULTURE PERFORMANCE AND ITS IMPLICATIONS ON BIOREACTOR SCALE-UP

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PO071 EFFICIENT PROTEIN PRODUCTION BY TRANSIENT GENE EXPRESSION USING INSECT CELLS

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PO072 IMPLEMENTATION OF DIFFERENT CULTURE STRATEGIES FOR INCREASING CELL DENSITY IN HEK293 CULTIVATIONS IN BIOREACTOR

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PO073 PROCESS INTENSIFICATION FOR THE PRODUCTION OF ANTIMICROBIAL PEPTIDES WITH STABLY TRANSFORMED DROSOPHILA MELANOGASTER S2 CELLS

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PO074 APPROACH TO OUTSOURCE THE MANUFACTURING OF A CELL CULTURE MEDIUM

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ESACT European Society for Animal Cell Technology

PO075 MEASURING AND MANIPULATING THE HYDRODYNAMIC ENVIRONMENT OF AN IPSC-DERIVED CARDIOMYOCYTE DIFFERENTIATION PROCESS

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PO076 STRATEGIES FOR MICROCARRIER-BASED STEM CELL PRODUCTION: NEW HARVEST ENZYMES AND DEFINED MEDIA FOR HMSC

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PO077 EXTENDED GENE EXPRESSION AT BIOREACTOR SCALE

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PO078 A NOVEL APPROACH OF HIGH THROUGHPUT CELL LINE SCREENING SPECIFIC FOR PERFUSION PROCESSES

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PO079 MODULATING ANTIBODY GALACTOSYLATION THROUGH CELL CULTURE MEDIUM FOR IMPROVED FUNCTION AND PRODUCT QUALITY

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PO080 MULTIMODAL SPECTROSCOPIC BIOPROCESS MONITORING FOR IN-LINE DETECTION OF CHO CELL VIABILITY

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PO081 DEVELOPMENT OF A SCALABLE PROCESS FOR MANUFACTURING CGMP GRADE RECOMBINANT HUMAN LAMININ 521 BASED ON THE CAP-GO EXPRESSION SYSTEM

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PO082 DEVELOPMENT OF A HIGH-THROUGHPUT PLATFORM TO SUPPORT CELL CULTURE MEDIA AND FEED SCREENING

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PO083 "DE NOVO" HIGH DENSITY PERFUSION MEDIUM: INCREASED PRODUCTIVITY AND REDUCED PERFUSION RATES

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PO084 CONTINUOUS SUSPENSION CELL CULTURE MONITORING IN BIOREACTORS USING QUANTITATIVE PHASE IMAGING.

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PO085 METTLER TOLEDO PCO2 PROBE EVALUATION/IMPLEMENTATION FOR A PERFUSION BASED CELL CULTURE SYSTEM

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PO086 ONLINE CAPACITANCE MEASUREMENT FOR BIOMASS MONITORING OVER CULTIVATION SCALES AND PLATFORMS

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PO087 IMPROVING MAMMALIAN CELL CULTURE PROCESS DEVELOPMENT BY MODEL-BASED DESIGN OF EXPERIMENT

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PO088 USING RADIO-FREQUENCY IMPEDANCE TO CONTROL CONTINUOUS HIGH DENSITY PERFUSION CULTURE WITH THE ALTERNATING TANGENTIAL FLOW SYSTEM

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PO089 OVERCOMING CHALLENGES IN SCALING DOWN A PERFUSION CELL CULTURE MANUFACTURING PROCESS

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PO090 A TECHNOLOGY ROADMAPPING PROCESS TO TRANSFORM THE BIOPHARMACEUTICAL MANUFACTURING INDUSTRY

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PO091 LATEST DEVELOPMENTS IN SCALABLE, HIGH-TITER TRANSIENT PROTEIN EXPRESSION IN THE EXPICHO EXPRESSION SYSTEM

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PO092 UNDERSTANDING OF DECREASED SIALYLATION OF FC-FUSION PROTEIN IN HYPEROSMOTIC RECOMBINANT CHINESE HAMSTER OVARY CELL CULTURE: N-GLYCOSYLATION GENE EXPRESSION AND N-LINKED GLYCAN ANTENNARY PROFILE

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PO093 DISRUPTIVE COST-EFFECTIVE ANTIBODY MANUFACTURING PLATFORM BASED ON CUTTING-EDGE PURIFICATION PROCESS

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PO094 SCIENTIFIC STRATEGY FOR RESIN SELECTION AND SINGLE-USE FILM ARCHITECTURAL DESIGN FOR CELL CULTURE SYSTEMS

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PO095 SCALE-UP OF HIGH AREA FILTERS FOR MICROFILTRATION OF CELL CULTURE MEDIA

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PO096 ANALYSES OF PRODUCT QUALITY OF COMPLEX POLYMERIC IGM PRODUCED BY CHO CELLS

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PO097 DEVELOPMENT OF A HIGH THROUGHPUT SCALE DOWN MODEL FOR A HIGH CELL DENSITY PER.C6®-BASED ADENOVIRUS PERFUSION PRODUCTION PROCESS

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PO098 CHO SINGLE CELL SUBCLONING AND STABILITY OVER PROLONGED PASSAGING IN THE PRESENCE AND ABSENCE OF SELECTION PRESSURE

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PO099 EVALUATION OF SIGNAL PEPTIDES FOR ENHANCED PRODUCTION LEVELS IN CHO DG44 CELLS

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PO100 INVESTIGATING THE CHANGE IN A CHARGE VARIANT PROFILE OF A MONOCLONAL ANTIBODY FROM A COMMERCIAL MAMMALIAN CELL CULTURE PROCESS

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PO101 EVALUATION OF THE GLYCOSYLATION PROFILE OF A MONOCLONAL ANTIBODY PRODUCED IN PERFUSION MODE BY CHO CELLS USING HILIC-HPLC AND MALDI-TOF/TOF MASS SPECTROMETRY

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PO102 STRATEGIES FOR OPTIMIZED CELL CULTURE MEDIA: EFFICIENT DESIGN TO IMPROVE TITER AND INFLUENCE PRODUCT QUALITY

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PO103 NEW PLATFORM FOR THE INTEGRATED ANALYSIS OF BIOREACTOR ONLINE AND OFFLINE DATA

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PO104 ACCELERATED PLATFORM PROCESS FOR DEVELOPMENT OF BISPECIFIC ANTIBODY PRODUCTION

Karsten Winkler[1,], Stefan Iarusso[2], Julia Waldschmitt[2], Susanne Seitz[1], Andrea Franke[1], Anne Furthmann[1], Judith Seidemann[1], Daniel Rehm[1], Anja Magritz[1], Silke Rieck[2], Markus Laukel[2], Thomas Rose[1], Volker Sandig[1]*

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PO105 A NOVEL APPROACH TO SETUP HYBRID-MODELS IN MAMMALIAN CELL CULTURE

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PO106 ENGINEERING CHARACTERIZATION OF THE ALLEGRO STIRRED TANK REACTORS FOR SUCCESSFUL CELL CULTURE SCALE-UP

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PO108 IMPLEMENTATION OF A VIRUS BARRIER MEDIA FILTER INTO FED-BATCH BIOPROCESSES

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PO109 HYBRID MODELING OF MAMMALIAN CELL CULTURE BIOPROCESSES

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PO110 EXPANDING PROCESS KNOWLEDGE THROUGH DOE PRINCIPLES: A NOVEL APPROACH TO LATE STAGE CHO CELL CULTURE PROCESS CHARACTERIZATION

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PO111 BISPECIFIC ANTIBODY – CHALLENGES IN PROCESS DEVELOPMENT

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PO112 DEVELOPMENT AND UPSCALE OF HEK293 TRIPLE TRANSFECTION PROCESS IN SINGLE-USE BIOREACTORS FOR INDUSTRIAL MANUFACTURE OF AAV VECTORS

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PO113 IDENTIFICATION OF PROCESS PARAMETERS WHICH UNDERPIN ROBUST PLATFORM PRODUCTION PROCESSES

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PO114 PROCESS INTENSIFICATION TO IMPROVE LENTIVIRAL VECTOR PRODUCTION FROM STABLE CELL LINES

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PO115 STRATEGIES TO OPTIMIZE CELL GROWTH AND SCALE UP THE PROCESS USING A NEW SINGLE USE BIOREACTOR SYSTEM, AMBR 250

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PO116 FLUID DYNAMICS OF THE FLOW FIELD IN A DISPOSABLE 600-ML ORBITALLY SHAKEN BIOREACTOR

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PO117 OPTIMIZATION OF DISSOLVED CARBON DIOXIDE LEVEL IN CELL CULTURE TO MAXIMIZE CHO CELL GROWTH AND PRODUCTIVITY

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PO118 REPURPOSING FED-BATCH MEDIA AND FEEDS FOR HIGHLY PRODUCTIVE CHO PERFUSION PROCESSES

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PO119 A NOVEL PEPTIDE-BASED PLATFORM FOR THE PRODUCTION OF O-GLYCOSYLATED THERAPEUTIC PROTEINS

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PO120 IMPACT OF BIOREACTOR DESIGN ON PERFORMANCE OF MICROCARRIER-BASED CELL CULTURE PROCESSES

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PO122 HIGH YIELD PROCESS FOR THE PRODUCTION OF ACTIVE HUMAN ALPHA-GALACTOSIDASE A IN SUSPENSION CHO K1 CELLS

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PO123 DESIGN AND EVALUATION OF NEXT-GENERATION BIOLOGICS FOR CANCER IMMUNO THERAPY

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PO124 CONTINUOUS GLUCOSE MONITORING AND CONTROL IN BIOREACTORS WITH A DISPOSABLE OPTICAL BIOSENSOR, A NEW APPLICATION FOR AN OLD CONCEPT

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PO125 DEVELOPMENT OF SIMPLE AND EFFICIENT CELL HARVEST METHODS FOR MICROCARRIER CULTURES

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PO126 SCALABLE STEM CELL EXPANSION BIOPROCESS USING SINGLE-USE, FED-BATCH REACTOR ENGINEERED FOR HIGH PRODUCTIVITY

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PO127 GLYCOSYLATED HUMAN CCBE1 PROTEIN: FROM RECOMBINANT PROTEIN PRODUCTION TO PROTEOMIC CHARACTERIZATION

Marta Marques Silva[1,], Sara Rosa[1], Marcos F.Q. Sousa[1], José Inácio[2], Cristina Peixoto[1], Margarida Serra[1], José Belo[2], Patrícia Gomes-Alves[1], Paula M. Alves[1]*
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PO128 SEED TRAIN CULTURE CONDITIONS CAN AFFECT PRODUCTION CULTURE PERFORMANCE: A CASE STUDY FOR A CHO CELL CULTURE PROCESS

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PO129 A METHODICAL AND SYSTEMATIC INTEGRATION OF UPSTREAM AND DOWNSTREAM PROCESSING OF BIOPHARMACEUTICAL PROTEINS

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PO130 OPTIMAL SELECTION OF THERAPEUTIC ANTIBODIES AND PRODUCTION CELL LINES BY ASSESSMENT OF CRITICAL QUALITY ATTRIBUTES AND DEVELOPABILITY CRITERIA

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PO131 COST MODELLING OF UPSTREAM PRODUCTION PROCESS OF LENTIVIRAL VECTORS IN HEK-293 CELLS COMPARING MULTI-TRAY 10 STACKS AND FIXED-BED BIOREACTOR

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PO132 HIGH GLUCOSE CONCENTRATION AND LOW SPECIFIC CELL GROWTH RATE IMPROVE SPECIFIC R-TPA PRODUCTIVITY IN CHEMOSTAT CULTURE OF CHO CELLS

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PO133 UNDERSTANDING GLYCOSYLATION VARIABILITY IN CHO CELL CULTURES

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PO134 ONLINE AND REAL-TIME CONTROL OF CHO CELL SPECIFIC GROWTH RATE THROUGHOUT CULTURES IN BIOREACTOR

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PO135 SOLID PHASE ENZYMIC RE-MODELLING TO PRODUCE SINGLE GLYCOFORM ANTIBODIES

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PO136 EFFICIENT AND INTENSIFIED BIOPROCESS DEVELOPMENT BASED ON HIGH THROUGHPUT AND HIGH AUTOMATION TOOLS COUPLED WITH MULTIVARIATE DATA ANALYSIS

Michael Sokolov[1,], Fabian Feidl[1], David Brühlmann[2], Jean-Marc Bielser[2], Jonathan Souquet[2], Hervé Broly[2], Massimo Morbidelli[2], Alessandro Butté[1]*
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PO137 ULTRA SCALE-DOWN MIMICS FOR PERFUSION CULTURE: EXPERIMENTAL AND MODELELING OPTIMISATION STUDY FOR RAPID BIOPHARMACEUTICAL PROCESS DEVELOPMENT

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PO138 DESIGNING A CAMELID/HUMAN HEAVY-CHAIN ANTIBODY WITH ENHANCED ANTITUMOUR ACTIVITY

Natalie Krahn[1,], Cal D'Eall[2], Rob Pon[2], Martin Rossotti[2], Greg Hussack[2], Maureen Spearman[3], Debbie Callaghan[2], Jörg Stetefeld[1], Michael Butler[3], Yves Durocher[4], Jamshid Tanha[2]*
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PO139 IDENTIFICATION OF PARAMETERS INFLUENCING ANTIBODY HEAVY CHAIN DIMER FORMATION IN MAMMALIAN CELL CULTURE.

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PO140 DATA MANAGEMENT IMPLEMENTATION TO SUPPORT HIGH THROUGHPUT MAMMALIAN CELL PROCESS DEVELOPMENT

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PO141 IMPACT OF MICROVESICLES OVER CELL GROWTH AND RECOMBINANT PROTEIN PRODUCTION FROM CHO CELLS

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PO142 AUTOMATED HIGH THROUGHPUT CELL CULTURE METHODS FOR THE DEVELOPMENT AND INVESTIGATION OF LARGE SCALE PERFUSION PROCESSES

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PO143 KINETIC STUDIES OF CO-INFECTION OF SF9 CELLS BY RECOMBINANT BACULOVIRUSES AT LOW MOI – IMPLICATIONS FOR VLP AND AAV VECTOR PRODUCTION

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PO144 GENERIC WORKFLOW FOR THE SETUP OF SUBSTANTIAL TARGET-ORIENTED MECHANISTIC PROCESS MODELS FOR MAMMALIAN PROCESSES

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PO145 LEACHABLES FROM SINGLE-USE DISPOSABLE BIOREACTORS – MAKING BETTER BAGS WORSE

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PO146 PERFORMANCE EVALUATION OF A CHEMICALLY DEFINED FEED IN TERMS OF CELL GROWTH AND PRODUCTIVITY IN CHO DG44 DHFR- CELLS

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PO147 A PH CONTROLLED HIGH-THROUGHPUT SYSTEM FOR CELL CULTURE PROCESS DEVELOPMENT

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PO148 OVERCOMING THE CHALLENGES IN DEVELOPING A HIGH CELL DENSITY PERFUSION CELL CULTURE PROCESS FOR A RECOMBINANT ENZYME

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PO149 PROCESS INTENSIFICATION GUIDED BY SYSTEMS BIOTECHNOLOGY: ANALYSIS OF A CHO FED BATCH PROCESS WITH ULTRA-HIGH SEEDING AFTER PERFUSION PRESTAGE FOR THE PRODUCTION OF MONOCLONAL ANTIBODIES

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PO150 SELECTION, OPTIMISATION AND RAW MATERIAL VARIABILITY PREDICTION FOR HYDROLYSATE-BASED BIOLOGICAL ADDITIVES USED TO SUPPLEMENT BIOPHARMACEUTICAL GROWTH MEDIA

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PO151 UNDERSTANDING THE EFFECTS OF UTILIZING A COMPLETE FEEDING SUPPLEMENT TO MODULATE GLYCOSYLATION PROFILES

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PO152 EVALUATION OF A CHEMICALLY DEFINED MEDIA DESIGNED FOR BATCH, FED-BATCH AND PERFUSION PROCESSES WITH CHO CELLS

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PO153 SURFACTANTS IN CELL CULTURE MEDIA: IMPACT ON HEK AND CHO CELLS IN CULTIVATION AND TRANSFECTION

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PO154 OVERCOMING THE MEDIA DESIGN CHALLENGES IN TRANSIENT GENE EXPRESSION WITH CHO CELL LINES

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PO155 IMPACT OF PH ON MONOCLONAL ANTIBODY PRODUCTIVITY AND PRODUCT QUALITY OF A BIOSIMILAR CLONE IN A MICRO BIOREACTOR SYSTEM

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PO156 ANTIOXIDANT EFFECT OF THIAZOLIDINE MOLECULES IN CELL CULTURE MEDIA IMPROVES STABILITY AND PERFORMANCE

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PO157 SILK PROTEIN SERICIN PEPTIDE AS GROWTH FACTOR IN MAMMALIAN CELL CULTURE

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PO158 DISACCHARIDES AS ENERGY SOURCE IN PROTEIN-FREE MAMMALIAN CELL CULTURES

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PO159 DEVELOPMENT OF A CHEMICALLY DEFINED MEDIUM FOR OPTIMAL GROWTH AND RECOMBINANT PROTEIN EXPRESSION IN HEK293 CELLS

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PO160 IDENTIFICATION OF CELL CULTURE MEDIA COMPONENTS THAT PREVENT AGGREGATION OF AN FC-FUSION PROTEIN

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PO161 BIOREACTOR SCALING THOUGHT NEW – FROM 0.25 TO 2000 L WITH UTILITY FUNCTIONS

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PO162 SCALE-UP OF A STIRRED SINGLE-USE BIOREACTOR FAMILY

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PO163 STRATEGIES FOR OPTIMIZING UPSTREAM PROCESSES

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PO164 COMPARISON OF BOLUS AND CONTINUOUS FEED STRATEGIES FOR A CHO-K1 CELL LINE

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PO165 INLINE SENSORS AND A PREDICTIVE CONTROLLER TO OPTIMALLY CONTROL CHO CELL CULTURE PROCESSES

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PO166 ON-LINE MONITORING OF DIELECTRIC CELL PROPERTIES FOR THE ANALYSIS OF VIRUS-LIKE PARTICLE PRODUCTION BY CAP CELLS

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PO167 SCALE-UP AND PROCESS TRANSFER IN BIOPHARMACEUTICAL MANUFACTURING: THE PATH TO INTELLIGENT BIOREACTOR CONTROL SOFTWARE

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PO168 UP AND DOWN SCALE CONSIDERATIONS FOR THE CONTINUOUS PRODUCTION OF GLYCOOPTIMIZED BIOPHARMACEUTICALS

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PO169 EVALUATION OF FIXED-BED, DISPOSABLE BIOREACTOR FOR VIRAL PRODUCTION IN REPLACEMENT OF ROLLER BOTTLES

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PO170 APPLICATION OF NEXT GENERATION ANALYTICAL TECHNIQUES TO SCALE DOWN MAMMALIAN PROCESSES

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PO171 PROCESS CHARACTERIZATION OF A CHO CELL CULTURE FOR PRODUCING THERAPEUTIC PROTEINS USING A QUALIFIED SCALE-DOWN MODEL

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PO172 COMPREHENSIVE ANALYSIS OF GLYCOSYLATION MODULATING MEDIA ADDITIVES FOR CELL LINE SELECTION

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PO173 FROM OBSERVATION TO CONTROL: USING CELL CULTURE AUTOMATION FOR ENHANCED PRODUCT QUALITY OPTIMIZATION

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PO174 USE OF AN ANTIOXIDANT TO IMPROVE MONOCLONAL ANTIBODY PRODUCTION AND QUALITY IN CHO CELLS

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PO175 MODEL-BASED CELL CULTURE CONTROL – UNSTRUCTURED, UNSEGREGATED MODELS AS A KEY ELEMENT FOR ADAPTIVE SEED TRAIN AND FED-BATCH OPTIMIZATION

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PO176 A NOVEL SINGLE-USE DEVICE FOR EFFICIENT LARGE-SCALE MEDIA PREPARATION

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PO177 MODULATING GALACTOSYLATION BY CELL CULTURE FEED OPTIMIZATION

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PO178 NEW APPROACH FOR CROSS FUNCTIONAL RISK MANAGEMENT FOR RAW MATERIALS USED IN A MULTISITE BIOTECH COMPANY

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PO179 COMPARISON OF TWO HIGH-THROUGHPUT BIOREACTOR SYSTEMS WITH 2L GLASS BIOREACTORS FOR CLONE SELECTION

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PO180 IMPACT OF METABOLISM CHANGES ON PRODUCT QUALITY IN HIGH PERFORMING MAMMALIAN CELL CULTURES

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PO181 CONTROL OF ANTIBODY'S GALACTOSYLATION: APPLICATION OF A HIGH-THROUGHPUT PLATFORM

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PO182 QUALITY BY DESIGN APPROACH USED IN THE CHARACTERIZATION OF A COMMERCIAL CELL CULTURE MANUFACTURING PROCESS OF TWO RECOMBINANT PROTEINS: VON WILLEBR AND FACTOR AND HUMAN FACTOR VIII

Valérie Duret[1,], Véronique Ducros[1], Edwige Dormond[1], Caroline Mialon[1], Makram Abou Arraj[1], Yves Stauffer[1], Florentina Vallez-Chetreanu[1], Sébastien Bourgeois[1], Philippe Baumgartner[1]*

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PO183 CREATING A SUITABLE MICROENVIRONMENT FOR GROWING HUMAN PRIMARY T CELLS TO HIGH CELL DENSITIES

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PO184 NOVEL BIFUNCTIONAL PEPTIDE TAG FOR THE PRODUCTION OF O-GLYCOSYLATED HUMAN BIOTHERAPEUTICS

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PO185 POLY-PATHWAY MODELLING APPROACH SIMULATING MULTIPLE METABOLIC STATES BY LARGE KINETICS MODEL

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PO186 HIGH CAPACITY PROTEIN A- MAGNETIC BEAD FOR CELL CLARIFICATION AND ANTIBODY CAPTURE IN ONE STEP FOR MANUFACTURING PROCESS

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PO187 USING AMBR AS SCALE DOWN MODELS IN CELL CULTURE

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PO188 INVESTIGATION OF PROTEIN RETENTION IN FILTER BASED HIGH DENSITY PERFUSION PROCESS

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PO189 ACCELERATING TIMELINE TO IND BY USING POOL FOR TOX STRATEGY

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PO190 THE NEW AGE OF DIGITAL BIOMANUFACTURING

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PO191 SOFT SENSORS: NEW INNOVATIVE APPROACH FOR PROCESS MONITORING OF CELL GROWTH IN SMALL SCALE FERMENTATION SYSTEMS

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PO192 MONITORING BETWEEN-BATCH BEHAVIOR OF REAL-TIME ADJUSTED CELL-CULTURE PARAMETERS

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PO192-A OPTIMIZING THE AMINO ACID METABOLISM OF CHINESE HAMSTER OVARY CELLS TOWARDS ENHANCED FED-BATCH PROCESS PERFORMANCE

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PO192-B EXPANSION OF 3D HUMAN INDUCED PLURIPOTENT STEM CELL AGGREGATES IN BIOREACTORS: BIOPROCESS INTENSIFICATION AND SCALING-UP APPROACHES

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PO193 TOWARDS A PREDICTIVE MANUFACTURABILITY ASSESSMENT PLATFORM FOR THERAPEUTIC KL BODIES

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PO193-A ENHANCING AUTOMATED SAMPLING, PROCESS MONITORING, AND NUTRIENT FEEDBACK CONTROL FOR A SYSTEM OF 3-L BIOREACTORS

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CELL CULTURE BASED VACCINES

PO194 DEVELOPOMENT OF SUSPENSION MDCK CELLS CULTURED IN CHEMICALLY-DEFINED MEDIUM FOR INFLUENZA VIRUS PRODUCTION

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PO195 PROCESS INTENSIFICATION OF YELLOW FEVER VIRUS AND ZIKA VIRUS PRODUCTION IN PERFUSION BIOREACTORS

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PO196 "THE ALPHAVIRUS STRUCTURAL PROTEIN EXPRESSING USING PICHIA PASTORIS AND BACULOVIRUS"

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PO197 PROCESS DEVELOPMENT OF INFLUENZA GAG VIRUS-LIKE PARTICLES PRODUCTION IN HEK-293 SUSPENSION CULTURE

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PO198 VIRUS PRODUCTION IN SINGLE-USE BIOREACTOR SYSTEMS USING PRE-STERILIZED MICROCARRIERS

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PO199 EFFECT OF INSULIN ON INFLUENZA PRODUCTION IN HEK293 CELLS

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PO200 DEVELOPMENT OF VIRTUAL EXPERIMENTATION OF MAMMALIAN CELLS PROCESS IN BIOREACTORS

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PO201 EVALUATION OF THE XPANSION BIOREACTOR SYSTEM FOR CELL & VIRAL CULTURE

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PO202 DEVELOPMENT OF HIGH CELL DENSITY HEK293 FED-BATCH PROCESS FOR HIGH YIELD PRODUCTION OF ADENOVIRUSES

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PO203 A MODULAR STRATEGY FOR MULTI-HA INFLUENZA VLPS PRODUCTION: COMBINING STABLE AND BACULOVIRUS-MEDIATED EXPRESSION IN INSECT CELLS

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PO204 OPTIMIZATION OF THE PRODUCTION PROCESS FOR A VLP-BASED RABIES VACCINE

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PO205 NOVEL AVIAN DUCKCELT-T17 CELL LINE FOR PRODUCTION OF VIRAL VACCINES : APPLICATION TO INFLUENZA VIRUSES PRODUCTION

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PO206 PRODUCTION OF INFLUENZA VIRUS-LIKE PARTICLES USING MAMMALIAN (HEK293) AND INSECT (SF9) CELL PLATFORMS

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PO207 GENERATION OF INFLUENZA VIRUS SEED STOCKS IN HEK-293 SUSPENSION CELL CULTURES BY REVERSE GENETICS

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PO208 HIGH-THROUGHPUT PROCESS VACCINE DEVELOPMENT USING FULLY INTEGRATED ROBOTIC PLATFORM (AMBR & NOVAFLEX)

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PO209 ADENOVIRUS PRODUCTION IN A SINGLE USE STIRRED-TANK BIOREACTOR SYSTEM

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PO210 INTRANASAL VACCINATION OF MICE AGAINST HEPATITIS E VIRUS USING ADENO-ASSOCIATED VECTORED VACCINE

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PO211 APPLICATION OF NANOTECHNOLOGY TECHNIQUES TO THE CHARACTERIZATION OF BIOPROCESSES: OBTENTION OF HIV-1 BASED VLPS BY PEI-MEDIATED TRANSIENT TRANSFECTION IN THE HEK 293 CELL LINE

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PO212 DEVELOPMENT OF A CHEMICALLY DEFINED MEDIUM FOR VIRUS VACCINE PRODUCTION IN A DUCK SUSPENSION CELL LINE

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PO213 DISRUPTIVE VACCINE MANUFACTURING PLATFORM AIMING TO REACH EXTRA LOW PRODUCTION COST

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PO214 AVIAN AGE1.CR CELL LINES FOR THE PRODUCTION OF AN ATTENUATED STRAIN OF RABIES VIRUS

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PO215 PROCESS ECONOMICAL EFFECTS OF IMPLEMENTATION OF READY-TO-USE MICROCARRIERS IN CELL-BASED VIRUS VACCINE PRODUCTION

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PO216 NOVEL AND SCALABLE PRODUCTION PROCESS FOR A PESTE DES PETITES RUMINANTS VIRUS VACCINE

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PO216-A EVALUATION OF BATCH AND SEMI-BATCH BIOREACTORS FOR SABIN BASED INACTIVATED POLIO VACCINE PRODUCTION USING AN ANIMAL COMPONENT FREE MEDIA

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PO217 PROCESS ECONOMY MODELING FOR VIRAL VECTOR PRODUCTION

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PO218 CELL CULTURE-BASED PRODUCTION OF SPECIFIC DEFECTIVE INTERFERING PARTICLES FOR INFLUENZA ANTIVIRAL THERAPY

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PO219 ADAPTIVE EVOLUTIONARY ENGINEERING OF INSECT CELLS FOR IMPROVED INFLUENZA HA VLPS PRODUCTION

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PO220 CYPHER ONE: AUTOMATED INTERPRETATION OF HEMAGGLUTINATION INHIBITION (HAI) ASSAYS

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PO221 VAXARRAY SEASONAL INFLUENZA ASSESSMENT OF CELL-DERIVED INFLUENZA VACCINE POTENCY

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PO222 FOOT AND MOUTH DISEASE VACCINE PRODUCTION IN CELL CULTURE

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PO223 DYNAMICS OF INTRACELLULAR METABOLITE POOLS DURING MDCK SUSPENSION GROWTH AND INFLUENZA VIRUS REPLICATION

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PO224 SELECTION OF STABLY PRODUCING DROSOPHILA S2 CELLS FOR INCREASED DENGUE VLP PRODUCTION

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PO225 EXTENSIVE REARRANGEMENTS BUT HIGH GENOMIC STABILITY IN A BIOTECHNOLOGICALLY ADVANTAGEOUS DERIVATIVE OF MODIFIED VACCINIA VIRUS ANKARA

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PO226 ON-LINE MONITORING OF MVA AND INFLUENZA VIRUS REPLICATION AT HIGH-CELL-DENSITIES

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CELL ENGINEERING AND ANALYTICS

PO227 OPTIMIZED TRANSFECTION EFFICIENCY FOR CHO-K1 SUSPENSION CELLS THROUGH COMBINATION OF TRANSFECTION AND CULTURE MEDIA

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PO228 REGULATION OF RECOMBINANT PROTEIN EXPRESSION DURING CHOBRI/RCTA POOLS GENERATION INCREASES PRODUCTIVITY AND STABILITY

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PO229 HYPER N-GLYCOSYLATED HUMAN INTERFERON-ALPHA2B PRODUCED IN HEK293 CELLS PRESENTS HIGHER ANTITUMOR ACTIVITY THAN THE CHO-K1-DERIVED PROTEIN

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PO230 PROCESS DEVELOPMENT BY CONDITIONAL MANIPULATION OF ENDOGENOUS CHO CELL MIRNA

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PO231 GENERATING MONOCLONAL PRODUCTION CELL LINES WITH ≥ 99.9 % PROBABILITY

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PO232 LEGACY CLONING METHODS IN THE MODERN WORLD PART 1: REASSESSING THE CAPILLARY AIDED CELL CLONING TECHNIQUE

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PO233 IMPROVED VECTOR DESIGN EASES CELL LINE DEVELOPMENT WORKFLOW IN THE CHOZN GS-/- EXPRESSION SYSTEM

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PO234 OPTIMIZATION OF THE CLC FOR MANUFACTURING PURPOSES USING A NOVEL SINGLE CELL PRINTING TECHNOLOGY

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PO235 ANTI-TETANUS NEUTRALIZING HUMAN MONOCLONAL ANTIBODIES

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PO236 A NOVEL SIRNA AIDED METHOD FOR CHO CELL LINE SELECTION

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PO237 LEGACY CLONING METHODS IN THE MODERN WORLD PART 2: VALIDATING THE STATISTICAL MODEL FOR CAPILLARY AIDED CELL CLONING

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PO238 NEW SINGLE CELL DEPOSITION TECHNOLOGIES WITH INTEGRATED IMAGE ANALYSIS FOR CELL LINE DEVELOPMENT OF PRODUCTION CELL LINES

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PO239 DESIGN OF A PLATFORM FOR THE EXPRESSION, PURIFICATION AND IN VITRO ASSESSMENT OF SOLUBLE GLYCOSYLATED RECOMBINANT HUMAN STEM CELL FACTOR PRODUCED IN HEK293 CELLS

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PO240 STUDYING MITOCHONDRIAL METABOLISM IN CHO CELL LINES CONTAINING DIFFERENT HETEROPLASMY VARIANTS

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PO241 APPLICATION OF LARGE SCALE MODELLING OF THE PROTEIN BIOMASS OBJECTIVE IN CHO CELLS USING ENHANCED PULSE SILAC AND PROTEOMIC RULER APPROACH

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PO242 CHO CELL CLONE STABILITY ASSESSMENT USING FUNCTIONAL PHENOTYPE ARRAY PROFILING

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PO243 CHO CELL CLONE IDENTIFICATION AND TRACKING USING FUNCTIONAL PHENOTYPE ARRAY PROFILING

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PO244 HIGH-THROUGHPUT QUANTITATION OF FC CONTAINING RECOMBINANT PROTEINS IN CELL CULTURE SUPERNATANT BY FLUORESCENCE POLARIZATION SPECTROSCOPY

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PO245 CELL LINE ENGINEERING USING MIRNAS IN A NOVEL HUMAN PRODUCTION CELL LINE

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PO246 DEVELOPING ALTERNATIVES TO CHINESE HAMSTER OVARY (CHO) MEDIA FOR SINGLE CELL CLONING

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PO247 EXPEDITING UPSTREAM STAGES OF PROTEIN BIOMANUFACTURE THROUGH THE USE OF UBIQUITOUS CHROMATIN OPENING ELEMENTS - UCOES

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PO248 NEW POOL GENERATION PROCESS CLD 2.0

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PO249 LEVERAGING THE CHO CELL TOOLKIT TO ACCELERATE BIOTHERAPEUTICS INTO THE CLINIC

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PO250 HIGH-THROUGHPUT PLATFORM FOR DESIGN OF MULTI-COMPONENT SYNTHETIC DNA ASSEMBLIES FOR CHO CELL ENGINEERING

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PO251 GENOME EDITING TO CREATE ENHANCED MAMMALIAN BIOMANUFACTURING PLATFORMS

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PO252 CELL PRINTING: A FLUIDICS APPROACH TO SINGLE CELL CLONING FOR MANUFACTURING CELL LINES.

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PO253 ULTRA-DEEP NEXT GENERATION MITOCHONDRIAL GENOME SEQUENCING REVEALS WIDESPREAD HETEROPLASMY IN CHINESE HAMSTER OVARY CELLS

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PO254 NEXT GENERATION RNA SEQUENCING REVEALS EXTENSIVE ALTERNATIVE SPLICING OF THE CHO CELL TRANSCRIPTOME FOLLOWING TEMPERATURE SHIFT

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PO255 GENOME-SCALE MODELING APPROACH FOR IN SILICO ANALYSIS OF CHO CELL METABOLIC NETWORK

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PO256 IDENTIFICATION OF INTEGRATION SITES OF CHO GENOME FOR THE GENERATION OF HIGH PRODUCER CELLS BY CRISPR/CAS9 MEDIATED TARGET INTEGRATION

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PO257 SYNTHESIS OF THE CHO CELL PROTEOME

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PO258 METABOLIC PROGRAMMING OF CHO CELLS VARYING IN CELLULAR BIOMASS ACCUMULATION DURING FED-BATCH CULTURE

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PO259 CHO MEDIA PLATFORM FACILITATES INTEGRATED CELL LINE DEVELOPMENT AND MEDIA OPTIMIZATION

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PO260 HIGH-TROUGHPUT LIPIDOMIC AND TRANSCRIPTOMIC ANALYSIS TO COMPARE SP2/0, CHO, AND HEK-293 MAMMALIAN CELL LINES

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PO261 THE DEVELOPMENT OF A TARGETED INTEGRATION CHO HOST FOR CLINICAL & COMMERCIAL CELL LINE DEVELOPMENT

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PO262 MODEL-DRIVEN STRAIN DESIGN OF CHO CELLS FOR BIOTHERAPEUTIC PROTEIN PRODUCTION

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PO263 SINGLE CELL CHARACTERISATION OF CHINESE HAMSTER OVARY CELLS

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PO264 A CROSS-SPECIES HIGH-THROUGHPUT SIRNA SCREEN FOR SUSPENSION CHO CELLS

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PO265 USE OF AN AUTOMATED CELL SCREENING SYSTEM FOR THE GENERATION OF STABLE HIV-1 PACKAGING CELL LINES FOR THE MANUFACTURE OF LENTIVIRAL VECTORS

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PO266 IDENTIFYING OPPORTUNITIES IN CELL ENGINEERING FOR THE PRODUCTION OF 'DIFFICULT TO EXPRESS' RECOMBINANT PROTEINS

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PO267 COMPLETE KNOCKOUT OF LACTATE DEHYDROGENASE IN CHINESE HAMSTER OVARY (CHO) CELLS

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PO268 DEVELOPMENT OF A TRANSPOSON-MEDIATED INTEGRATION SYSTEM TO GENERATE HIGH YIELD PRODUCING CELLS WITH LOW COPY NUMBER OF INTEGRATED TARGET ANTIBODY GENE

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PO269 A NEW CELL LINE DEVELOPMENT PLATFORM FOR HIGH EFFICIENCY SINGLE CELL DEPOSITION WITH IN-SITU IMAGE VERIFICATION

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PO270 CELL CYCLE AND TRANSCRIPTOME ANALYSIS USING RNA-SEQ FOR BETTER UNDERSTANDING OF CHO-K1 SUSPENSION CELL LINE BIOPROCESSING

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PO271 A FLUX MODEL THAT QUANTIFIES THE PARTITION OF METABOLIC RESOURCES BETWEEN CELLULAR AND MAB GLYCOSYLATION IN GS-CHO CELLS

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PO272 COMPARISON OF GLUCOSE-LACTATE METABOLISM OF THREE DIFFERENT MAMMALIAN CELL LINES USING FLUX BALANCE ANALYSIS

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PO273 FECTOPRO®: A POWERFUL HIGH YIELD TRANSFECTION SOLUTION FOR TRANSIENT CHO AND HEK-293 EXPRESSION SYSTEMS

Geraldine Guerin-Peyrou[1], Jelena Vjetrovic[1,], Patrick Erbacher[1], Mathieu Porte[1]*

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PO274 ROBUST AND RELIABLE TRANSIENT PROTEIN PRODUCTION WITH PEIPRO®, A WELL CHARACTERIZED PEI OPTIMIZED FOR TRANSFECTION

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PO275 IDENTIFICATION AND CHARACTERIZATION OF POTENTIAL MICRO-RNAS AS PHENOTYPE ENGINEERING TARGETS TO DELAY THE ONSET OF CELL DEATH.

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PO276 COMPARISON OF BICISTRONIC AND TRICISTONIC EXPRESSION STRATEGIES FOR TRASTUZUMAB AND TRASTUZUMAB-INTERFERON-A2B PRODUCTION IN CHO AND HEK293 CELLS

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PO277 SIALIC ACID AND BEYOND: ENGINEERING VIRAL RESISTANCE IN CHO CELLS

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PO278 IMPROVED PLATFORMS FOR CHO CELL LINE DEVELOPMENT

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PO279 PRODUCTION OF THERAPEUTICALLY RELEVANT LENTIVIRAL VECTORS FOR CLINICAL STUDIES

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PO280 PURSUING IMPROVED CONDITIONS FOR GENETIC MODIFICATION OF HUMAN CELLS FOR REPO PRODUCTION UNDER SUSPENSION SERUM-FREE CONDITIONS

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PO281 MOLECULAR IMPACT OF THE MIRNA 23 CLUSTER ON BIOPROCESS ATTRIBUTES OF CHO CELLS

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PO282 INTRACELLULAR SECRETION ANALYSIS OF RECOMBINANT THERAPEUTIC ANTIBODIES IN ENGINEERED CHO CELLS AIMING TO ESTABLISH HIGH PRODUCER

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PO283 DIFFERENTIAL LONG NON-CODING RNA EXPRESSION INDUCED BY HYPOTHERMIC SHOCK IN CHINESE HAMSTER OVARY CELLS

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PO284 EVALUATION OF DIFFERENT GENOMIC SITES AND INTEGRATION APPROACHES FOR RECOMBINANT GENE EXPRESSION

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PO285 ZIKA MONOCLONAL ANTIBODY DISCOVERY BY HIGH-THROUGHPUT SEQUENCING OF PAIRED HEAVY AND LIGHT CHAINS FROM SINGLE B CELLS

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PO286 RATIONAL ANTIBODY HUMANIZATION ASSISTED BY MOLECULAR DYNAMICS SIMULATIONS

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PO287 ACCELERATED HOMOLOGY-DIRECTED TARGETED INTEGRATION OF TRANSGENES IN CHO CELLS VIA CRISPR/CAS9 AND FLUORESCENT ENRICHMENT

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PO288 MS-SILAC APPROACH FOR PHOSPHO PROTEOMICS OF IGF SIGNALING IN PRODUCER CHO CELLS

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PO289 SK-HEP-1 AS PLATFORM FOR EXPRESSION OF NOVEL RECOMBINANT HUMAN FACTOR IX WITH AUGMENTED CLOTTING ACTIVITY

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PO290 NEW RED-SHIFTED FLUORESCENT BIOSENSOR FOR MONITORING INTRACELLULAR REDOX CHANGES IN MAMMALIAN CELL LINES

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PO291 INCREASING CHO FED BATCH PRODUCTIVITY THROUGH SMALL MOLECULE TARGETING OF EPIGENETIC MACHINERY

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PO292 ASSESSMENT OF GENOMIC REARRANGEMENTS IN CHINESE HAMSTER OVARY (CHO) CELLS

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PO293 CONSTRUCTION OF A SYSTEM FOR RAPID EVALUATION OF PRODUCTION ENHANCER GENE IN CHO ANTIBODY PRODUCTION

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PO294 GS SYSTEM FOR INCREASED EXPRESSION OF DIFFICULT-TO-EXPRESS PROTEINS

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PO295 STRENGTHENING THE UTILITY OF FACS WHEN CLONING CELLS

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PO296 MAMMALIAN SYSTEMS BIOTECHNOLOGY REVEALS GLOBAL CELLULAR ADAPTATIONS IN A RECOMBINANT CHO CELL LINE

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PO297 LAB-AUTOMATION & DATABASE INTEGRATION: STREAMLINING THE CELL LINE DEVELOPMENT PROCESS

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PO298 EXPEDITING PROTEIN BIOMANUFACTURING THROUGH THE UCOE® GENE EXPRESSION PLATFORM

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PO299 TARGETED EPIGENETIC MODULATION OF EXPRESSION CASSETTES REVERTS SILENCING OF TRANSGENE EXPRESSION

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PO300 CRISPR-BASED TARGETED EPIGENETIC EDITING IN CHO CELLS

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PO301 GENERATING HIGH PRODUCING SINGLE CELL CLONES BY UTILIZING AN OPTIMIZED SELECTION STRATEGY

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PO302 CHARACTERIZATION OF ANTIBODY-PRODUCING CHO CELLS WITH CHROMOSOME ANEUPLOIDY

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PO303 QUANTITATIVE PHOSPHOPROTEOMIC ANALYSIS OF RECOMBINANT CHINESE HAMSTER OVARY CELLS IN RESPONSE TO REDUCED CULTURE TEMPERATURE

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PO304 PROCESS DEVELOPMENT AND OPTIMIZATION FOR THE PRODUCTION OF CLINICAL GRADE HIV-1 ENVELOPE GLYCOPROTEIN VARIANTS

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PO305 WHOLE GENOME SEQUENCING TO SURVEY GENETIC CHANGES IN STABLE CHO CELL LINES

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PO306 DYNAMIC CHANGES TO THE PHOSPHOPROTEOME OF RECOMBINANT CHINESE HAMSTER OVARY CELLS DURING GROWTH IN SUSPENSION CULTURE.

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PO307 ECHO SYSTEMS – ENHANCING THE CHO CELL FACTORY THROUGH SYSTEMS BIOLOGY

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PO308 EVALUATION OF MICRORNA-BASED GENETIC SWITCHES AS TRANSGENE EXPRESSION MODULATORS IN CHO CELLS

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PO309 THE GENERATION OF A PROPRIETARY NEW CHO HOST CELL LINE WITH ENHANCED BIOMANUFACTURING QUALITY ATTRIBUTES

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PO310 GENETIC ELEMENT COMBINATIONS TO IMPROVE EXPRESSION LEVEL OF CELL LINES FOR MONOCLONAL ANTIBODY PRODUCTION IN CHO CELLS

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PO311 SIALYLATION OF O-LINKED GLYCANS IS CRUCIAL FOR SIGNIFICANT PROLONGED PLASMA HALF-LIFE OF RECOMBINANT C1 INHIBITOR.

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PO312 WHAT NGS CAN TELL US: SPONTANEOUS EXPRESSION OF A SLEEPING GENE IN CHO CELLS LEADS TO CRITICAL CHANGES IN PRODUCT QUALITY

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PO313 MIRNA KNOCKOUT USING CRISPR/CAS9 TO ENHANCE CHO CELL BIOPHARMA PHENOTYPE

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PO314 DEFINITION AND REMOVAL OF BOTTLENECKS IN CURRENT CHO PRODUCTION CELL LINES WITH REGARD TO COMPLEX BIOLOGICAL FORMATS

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PO315 CHO-GLYCO-ENGINEERING USING CRISPR/CAS9 MULTIPLEXING TO DEVELOP CELL LINES WITH HOMOGENEOUS N-GLYCAN PROFILES FOR PHARMACEUTICAL DRUG PRODUCTION

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PO316 PATHWAY MODULATOR BOOSTS YIELDS FOR THERAPEUTIC PROTEIN PRODUCTION

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PO317 INVESTIGATION OF FACTORS INFLUENCING RECOMBINANT HUMAN BMP2 EXPRESSION IN MAMMALIAN CELLS

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PO318 SYSTEMATIC INVESTIGATION OF PDMAEMA-FUNCTIONALIZED MAGNETIC NANOPARTICLES FOR THEIR UTILIZATION IN BIOTECHNOLOGY

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PO319 INTEGRATED 'OMICS STUDY OF A CONTINUOUS MANUFACTURING CHO PRODUCTION PROCESS FOR MONOCLONAL ANTIBODIES

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PO320 UNRAVELLING THE LACTATE METABOLISM OF CHO CELLS ENGINEERED TO GROW IN GALACTOSE

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PO321 DOING MORE WITH LESS: HIGHER PRODUCTIVITY IN CHO CELLS WITH LOWER SELECTION PRESSURE

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PO322 BIOMANUFACTURING OF HEPARAN SULFATE GLYCOSAMINOGLYCANS USING ENGINEERED CHO CELLS

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PO323 UPR-MEDIATED INCREASE IN IGG PRODUCTIVITY IN RCHO CELLS ADAPTED UNDER MILD TUNICAMYCIN STRESS

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PO324 COMPARISON BETWEEN FACS-SINGLE CELL SORTING AND LIMITING DILUTION TO OBTAIN CLONAL CHO CELL LINES: VALIDATION OF SINGLE CELL CLONING BY FACS AND HIGH-RESOLUTION IMAGING

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PO325 ENHANCEMENT OF ANTIBODY PRODUCTIVITY IN RECOMBINANT CHO CELLS CONSTRUCTED BY TARGETING THE IGG1 GENE TO THE STABLE CHROMOSOME

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PO326 EFFICIENT TRANSIENT EXPRESSION OF HUMAN MATURE BONE MORPHOGENETIC PROTEINS BY PRO-PEPTIDE ENGINEERING

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PO327 DEVELOPMENT OF RETROVIRAL VECTORS CAPABLE OF SITE-SPECIFIC GENE INSERTION TOGETHER WITH PROTEIN DELIVERY

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PO328 CRISPR/CAS9 BASED MIRNA ENGINEERING OF N-GLYCOSYLATION IN CHO CELLS

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PO329 ELIMINATING ANTIBODY HEAVY CHAIN C-TERMINAL LYSINE HETEROGENEITY BY KNOCKING OUT CARBOXYPEPTIDASE D USING CRISPR TECHNOLOGY IN CHO CELLS

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PO329-A CELL GENOME EDITING AND ENVELOPE GLYCOPROTEIN RE-DESIGN FOR THE ESTABLISHMENT OF NOVEL CELL LINES FOR STABLE PRODUCTION OF LENTIVIRAL VECTORS

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PO330-B LIPIDOMICS: CHALLENGE, TECHNIQUES, AND FUTUR POSSIBILITIES FOR MAMMALIAN CELL CULTURE

Andréa McCann, Grégory Mathy, Laetitia Malphettes

EMERGING CELL BASED THERAPEUTIC APPROACHES

PO330 ANTI-CD19 CHIMERIC ANTIGEN RECEPTORS ARE ACTIVE IN T CELLS AFTER LENTIVIRAL TRANSDUCTION

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PO331 MANUFACTURE OF CAR-T CELLS FOR ADOPTIVE CELL THERAPY

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PO332 DEVELOPMENT OF A THERAPEUTIC RECOMBINANT RETROVIRUS PRODUCER CELL LINE USING THE SINGLE-STEP CLONING-SCREENING METHOD

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PO333 IVECTOR: A BRAIN AND SPINE INSTITUTE'S CORE FACILITY FOR BIOPRODUCTION OF VIRAL GENE TRANSFER VECTORS (LENTIVIRUS; AAV2, 8, 9, RH10; CAV-2 CANINE ADENOVIRUS).

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PO335 IMPACT OF AGGREGATE CULTURE ON CARDIOMYOCYTE DIFFERENTIATION AND HYPOTHERMIC STORAGE

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PO337 IMPROVEMENTS IN POST-FREEZE STABILITY OF CLINICAL GRADE HMSC TO SOLVE LOGISTICAL CHALLENGES OF CELL THERAPIES

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PO338 DEVELOPMENT OF EXTRACELLULAR VESICLES PRODUCTION WITH A SCALABLE SINGLE USE PLATFORM

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PO339 USING BACULOVIRUS AS A GENE SHUTTLE IN HMSC: OPTIMIZATION OF TRANSDUCTION EFFICACY

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PO340 GENERATION OF A FUNCTION BLOCKING ANTIBODY AGAINST NOTCH LIGAND DELTA-LIKE-1 WITH THERAPEUTIC EFFICACY AGAINST BREAST CANCER

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PO341 VALIDATION OF A NEW SOURCE OF RECOMBINANT BASIC FIBROBLAST GROWTH FACTOR FOR THE CULTIVATION OF MESENCHYMAL STEM CELLS

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PO342 APTAMER-MODIFIED POLYCAPROLACTONE NANOPARTICLES FOR TARGETED DRUG DELIVERY

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PO343 SOLUTIONS FOR ROBUST CELL THERAPY PRODUCTION

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PO344 OPTIMIZATION OF ADENO-ASSOCIATED VIRAL VECTOR PRODUCTION USING A NE W SCALABLE SUSPENSION PLATFORM

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PO345 TESTING APPROACHES FOR CELL BASED THERAPEUTICS: RAPID TESTING AND REGULATORY EXPECTATIONS

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PO346 NOVEL BIOTECHNOLOGICAL STRATEGY TO OBTAIN IN VITRO ERYTHROID CELLS

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PO347 APPLYING PROTEOMIC TOOLS TO UNVEIL HUMAN CARDIAC STEM CELLS ROLE IN MYOCARDIAL ISCHEMIA-REPERFUSION INJURY

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PO348 A NOVEL SCALABLE PRODUCTION PLATFORM FOR LENTIVIRAL VECTORS BASED ON HUMAN SUSPENSION CELL LINES

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PO349 AAV PRODUCTION IN SUSPENSION: EVALUATION OF DIFFERENT CELL CULTURE MEDIA AND SCALE-UP POTENTIAL

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PO350 DEVELOPMENT OF A COST-EFFICIENT SCALABLE PRODUCTION PROCESS FOR RAAV-8 BASED GENE THERAPY BY TRANSFECTION OF HEK-293 CELLS

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PO351 QUANTITATIVE MAPPING OF THE IMMUNE-REGULATORY PROPERTIES OF HUMAN MESENCHYMAL STEM CELL AGGREGATES ON A CHIP

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PO352 IMPACT OF HYDRODYNAMIC STRESS ON CELL GROWTH AND MICROCARRIER-CELL-AGGLOMERATE FORMATION IN MICROCARRIER-BASED CULTIVATIONS OF ADIPOSE TISSUE-DERIVED STROMAL/STEM CELLS

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ENABLING CELL BASED TECHNOLOGIES

PO353 IPSC DERIVED CARDIOMYOCYTES DEVELOPMENT FOR MULTI-ORGAN-CHIP CULTIVATION

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PO354 DEVELOPMENT OF A WOUND HEALING ASSAY USING INCLUSION BODIES

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PO355 COMPUTATIONAL DESIGN OF RAW MATERIALS, PRODUCTS, EQUIPMENT AND PEOPLE FLOWS TO OPTIMIZE THE ERGONOMICS OF CELL THERAPY PRODUCTION ENVIRONMENT

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PO356 STANDARDISATION OF HIGH THROUGHPUT SPHEROID ENGINEERING USING THE LABCYTE ECHO ACOUSTIC DISPENSER

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PO357 SERUM-FREE SUSPENSION LIVER CELL LINES - THE USAGE IN (ECO-)TOXICOLOGICAL EVALUATION

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PO358 MODELLING TUMOR-STROMA INTERACTIONS TO ADDRESS DISEASE PROGRESSION AND DRUG RESPONSE MECHANISMS IN VITRO

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PO359 A METHOD TO SIMULATE DIFFUSION AND METABOLIC ACTIVITY IN A MULTI-ORGAN-CHIP

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PO360 DEVELOPMENT OF A PERFUSED ORGANOTYPIC KIDNEY MODEL USING DECELLULARIZED RAT KIDNEYS

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PO361 INTEGRATING AN IN VITRO-BASED THERAPEUTIC INDEX INTO PHENOTYPIC DRUG DISCOVERY APPROACHES

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PO362 VASCSKIN-ON-A-CHIP: INTEGRATION OF A PERFUSED VASCULATURE TO HUMAN SKIN-EQUIVALENTS.

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PO363 3D-PRINTED MICROFLUIDIC CHANNEL AND CULTIVATION MOLD FOR QUANTITATIVE EVALUATION OF CELL MIGRATION PROPERTY

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PO364 CHARACTERIZATION OF SKOV-3 SPHEROIDS OBTAINED BY ULTRA-LOW ATTACHMENT AND HANGING-DROP METHODS FOR DRUG SCREENING ASSAYS

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PO365 LAB AS A SERVICE - AUTOMATED CELL-BASED ASSAYS

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PO366 DEVELOPMENT OF ALTERNATIVE ANIMAL CELL TECHNOLOGY PLATFORMS: CHO BASED CELL-FREE PROTEIN SYNTHESIS SYSTEMS FOR THE PRODUCTION OF "DIFFICULT-TO-EXPRESS" PROTEINS

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PO367 A HIGH-THROUGHPUT CELL PROLIFERATION ASSAY FOR SCREENING SINGLE-USE MATERIALS FOR CELL CULTURE COMPATABILITY

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PO368 PRODUCTION OF RECOMBINANT FACTOR VII IN SK-HEP-1 HUMAN CELL LINE

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PO369 FLUORESCENT CELL-BASED BIOSENSORS FOR DETECTION AND QUANTIFICATION OF LABEL-FREE VIRUS AND VIRAL VECTORS

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PO370 DEVELOPMENT OF HIGH THROUGHPUT METHODS TO CHARACTERIZE RAW MATERIAL IMPACT TO PROCESS PERFORMANCE

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PO371 AUTOMATION-COMPATIBLE MICROFLUIDIC SYSTEM FOR MULTI-TISSUE INTEGRATION

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PO372 CHARACTERIZATION AND APPLICATION OF 3D MULTI-DONOR HUMAN LIVER MICROTISSUES FOR PREDICTIVE DILI TESTING AND MECHANISTIC INVESTIGATIONS

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PO373 DRUG TOXICITY ON LIVER SPHEROIDS IN A MICROFLUIDIC DROPLET ARRAY

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PO374 ESTABLISHMENT AND CHARACTERIZATION OF 3-D TUMOUR SPHEROIDS USING FORCED FLOATING AND HANGING DROP METHODS

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PO375 ALTERNATIVES TO THE USE OF ANIMALS DURING DEVELOPMENT OF BIOTECHNOLOGICAL MEDICINAL PRODUCTS: REFINE, REDUCE, REPLACE

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PO376 SOFT BIOCOMPATIBLE MICROCARRIERS FOR ADIPOSE-DERIVED MESENCHYMAL STEM CELLS EXPANSION

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PO377 ASSESSMENT OF MITOCHONDRIAL ACTIVITY IN 3D HUMAN LIVER MICROTISSUES AS A TOOL FOR MECHANISTIC INVESTIGATIONS OF ADVERSE DRUG EFFECTS

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PO378 BONE MARROW-ON-A-CHIP: LONG-TERM CULTURE OF HUMAN HEMATOPOIETIC STEM CELLS IN A 3D MICROFLUIDIC ENVIRONMENT

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PO379 INFLUENCE OF TACROLIMUS TREATMENT ON ENDOTHELIAL CELLS

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PO380 IN-VITRO VASCULOGENESIS TO INTERCONNECT ORGANOIDS IN A MULTI-ORGAN-CHIP PLATFORM

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PO381 CELLULAR BIOASSAYS DEVELOPED WITH FUNCTIONALLY IMMORTALIZED CELL LINES

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PO382 THE CHOICE OF TUMOR-STROMA CELL PAIR FOR CANCER CELL MODEL DESIGN HAS AN IMPACT ON TUMOR CELL GROWTH AND DRUG RESPONSE

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