

Cell Culture Engineering XV

An ECI Conference Series Volume 16AC

Palm Springs, California, USA
8-13 May 2016

Editors:

Robert Kiss
Jeff Chalmers

Sarah Harcum

ISBN: 978-1-5108-2749-3

Printed from e-media with permission by:

Curran Associates, Inc.
57 Morehouse Lane
Red Hook, NY 12571



Some format issues inherent in the e-media version may also appear in this print version.

Copyright© (2016) by Engineering Conferences International
All rights reserved.

Printed by Curran Associates, Inc. (2016)

For permission requests, please contact Engineering Conferences International
at the address below.

Engineering Conferences International
32 Broadway, Suite 314
New York, NY 10004
USA

Phone: (212) 514-6760
Fax: (212) 514-6030

info@engconfintl.org

Additional copies of this publication are available from:

Curran Associates, Inc.
57 Morehouse Lane
Red Hook, NY 12571 USA
Phone: 845-758-0400
Fax: 845-758-2633
Email: curran@proceedings.com
Web: www.proceedings.com

Sunday, May 8, 2016

1:00 PM – 5:00 PM

Conference Check-in (Flores Foyer)

3:00 PM – 4:30 PM

Workshops (3 in parallel)

Workshop 1: Advances in cell line engineering and protein expression strategies (Flores 6, 7, 8)

Facilitators: Trent Munro (Amgen) and Richard Schwartz (NIH)

Sponsored by UCB Pharma SA

Workshop 2: Increasing speed to the clinic while ensuring future manufacturability (Fiesta 10, 13, 14)

Facilitators: Suzanne Farid (UCL) and Steven Lang (Janssen Biotherapeutics)

Sponsored by Gilead Sciences

Workshop 3: Advances in analytical methods and their use for process characterization (Fiesta 9, 11, 12)

Facilitators: Claudia Buser (Sanofi) and Rao Kandula (Celgene)

Sponsored by Biomarin

4:45 PM – 5:30 PM

Opening Remarks (Fiesta)

Conference Chairs: Robert Kiss, Sarah Harcum, Jeff Chalmers

ECI Technical Liaison: Mike Betenbaugh

Native American Dance Performance – Eric Runningpath

5:30 PM – 6:30 PM

Keynote – Ira Mellman (Genentech)

The renaissance of cancer immunotherapy is a revolution for patients¹

6:45 pm - 8:15 pm

Dinner (La Casa)

8:30 PM – 10:30 PM

Poster Session (Authors of even-numbered posters are asked to stay with their posters)

Sponsored by Applikon Biotechnology, Inc. and Celgene

Monday, May 9, 2016

6:30 AM – 8:00 AM

Breakfast Buffet

Organizing Committee Breakfast Meeting (The Studios)

8:00 AM – 9:55 AM

Session 1: Novel Protein Formats & Technologies

Sponsored by Genentech

8:00 AM – 8:05 AM

Introduction – Session Chairs

John Joly (*Genentech*)

Jennifer Maynard (University of Texas, Austin)

8:05 AM – 8:15 AM

Poster Highlights

8:05 AM Poster Highlight for Novel Protein Formats (Session 1):

Alyssa Powell (Ambrx)

Antibody production with site-specific non-natural amino acid incorporation for generation of antibody drug conjugates

8:10 AM Poster Highlight for Non-Protein Products (Session 9):

Suzanne S. Farid (University College London)

Cell therapy manufacturing strategies: Impact on cost of goods, cost of development and commercialization

8:15 AM – 8:40 AM

Talk 1: Steven Lang (Janssen R&D)

Building quality novel formats and development processes.....3

8:40 AM – 9:05 AM

Talk 2: Jennitte Stevens (Amgen)

Engineering, expression screening, and production cell line development of hetero Ig molecules using charge pair mutations.....5

9:05 AM – 9:30 AM

Talk 3: Christoph Spiess (Genentech)

Bispecific antibodies: Strategies, considerations and challenges.....7

9:30 AM – 9:55 AM

Talk 4: Pierre Moretti (Glenmark Pharma)

A novel bispecific antibody for HER2⁺ breast cancer: The BEAT GBR 1302.....9

10:00 AM – 10:30 AM

Coffee Break / Networking

10:30 AM – 11:15 AM

Keynote – Stephen Hadley (Gates Foundation)

Challenges developing biologics for the prevention and treatment of infectious diseases impacting global health.....12

11:15 AM – 12:20 PM

Session 2a: Cell Line Development Advances

11:15 AM – 11:20 AM

Introduction – Session Chairs

Scott Estes (Codiak Biosciences)

Alan Dickson (University of Manchester)

Monday, May 9, 2016 (continued)

11:20 AM – 11:30 AM

Poster Highlights

11:20 AM Poster Highlight for Cell Line Development Advances (Session 2)

Jae Seong Lee (Technical University of Denmark)
Accelerated homology-directed targeted integration of transgenes in CHO cells via CRISPR/Cas9 and fluorescent enrichment

11:25 AM Poster Highlight for Application of 'Omics (Session 8):

Hooman Hefzi (UCSD)
A community genome-scale model of Chinese hamster ovary cell metabolism identifies differences in the efficiency of resource utilization for various bioprocesses

11:30 AM – 11:55 AM

Talk 5: Wei-Shou Hu (University of Minnesota)
Systems engineering of a CHO cell line for enhanced process robustness.....14

11:55 AM – 12:20 PM

Talk 6: Wei-Kuang Chi (Development Center for Biotechnology of Taiwan)
Omics approach for generating a high-yield CHO cell line producing monoclonal antibodies.....17

12:20 PM – 1:45 PM

Lunch

1:45 PM – 3:30 PM

Session 2b: Cell Line Development Advances (continued)

1:45 PM – 1:50 PM

Introduction – Session Chairs
Scott Estes (Biogen)
Alan Dickson (University of Manchester)

1:50 PM – 2:15 PM

Talk 7: Nathan E. Lewis (University of California, San Diego)
Predictive engineering of CHO cells using systems biology models.....20

2:15 PM – 2:40 PM

Talk 8: Helene Fastrup Kildegaard (Technical University of Denmark)
Generation of desirable CHO cell factories with predictive culture performance using CRISPR/Cas9-mediated genome engineering.....22

2:40 PM – 3:05 PM

Talk 9: Kerstin Otte (Biberach University of Applied Sciences)
Effective microRNAs for cell line engineering and cellular mechanisms of action.....24

3:05 PM – 3:30 PM

Talk 10: Yongping Crawford (Genentech)
Developing the host for targeted integration cell line development.....26

3:30 PM – 4:00 PM

Coffee Break / Networking

4:00 PM – 6:20 PM

Session 3: Integrated Continuous Processing for Biologics

4:00 PM – 4:05 PM

Introduction – Session Chairs
Oscar Lara-Velasco (GSK)
Laura Palomares (UNAM)

Monday, May 9, 2016 (continued)

4:05 PM – 4:15 PM

Poster Highlights

4:05 PM Poster Highlight for Integrated Continuous Processing (Session 3)

Daniel Vázquez (Max Planck Institute)

Process optimization for semi-continuous virus production at high cell densities

4:10 PM Poster Highlight for Applications of QbD & PAT (Session 10)

Gene Schaefer (Janssen)

Moving from a bioreactor scale-up/scale-down approach to a more holistic operational design space view

4:15 PM – 4:40 PM

Talk 11: Udo Reichl (Max Planck Institute)

Process optimization for semi-continuous virus production at high cell densities.....29

4:40 PM – 5:05 PM

Talk 12: Zhimei Du (Merck)

Evolution of an integrated continuous antibody manufacturing process.....32

5:05 PM – 5:30 PM

Talk 13: Jason Walther (Sanofi)

Overcoming process intensification challenges to deliver a manufacturable and competitive integrated continuous biomanufacturing platform.....34

5:30 PM – 5:55 PM

Talk 14: Gregory W. Hiller (Pfizer)

Cell-controlled high-intensity perfusion and hybrid fed-batch systems that drastically reduce perfusion rates and harmonize with continuous downstream processing.....37

5:55 PM – 6:20 PM

Talk 15: Ricardo Silva (iBET)

Purification of a hepatitis C vaccine candidate: Comparison between multi- column chromatographic processes operated in positive and negative mode.....40

6:30 PM – 8:30 PM

Dinner (Tennis Courtside)

8:30 PM – 10:30 PM

Poster Session (Authors of odd-numbered posters are asked to stay with their posters)

Sponsored by GE Healthcare, Irvine Scientific and Kerry

Tuesday, May 10, 2016

6:30 AM – 8:00 AM

Breakfast Buffet

8:00 AM – 10:15 AM

Session 4a: Current Concerns

8:00 AM – 8:05 AM

Introduction – Session Chairs
Tongtong Wong (Lilly)
Jamey Young (Vanderbilt University)

8:05 AM – 8:10 AM

Poster Highlight for Current Concerns (Session 4):
Kelvin Lee (University of Delaware)
A host cell protein that may impact polysorbate degradation

8:10 AM – 8:35 AM

Talk 16: Beth Junker (Merck)
Life in the fast lane: Developing and commercializing KEYTRUDA®, a novel breakthrough therapy designation oncology therapy, in three years from first patient dosed to US approval.....42

8:35 AM – 9:00 AM

Talk 17: Nicole Borth (BOKU University of Natural Resources and Applied Life Sciences)
To clone or not to clone? – Wrong question! An investigation on genome heterogeneity and stability and on what controls cell behavior.....45

9:00 AM – 9:25 AM

Talk 18: Brian E. Mickus (Gilead Sciences)
Targeted sequencing for comprehensive genetic characterization of a recombinant CHO cell line.....47

9:25 AM – 9:50 AM

Talk 19: Christopher C. Frye (Eli Lilly)
Polysorbate 20 and 80 degradation by Group XV lysosomal phospholipase A2 Isomer X1 in monoclonal antibody formulations.....49

9:50 AM – 10:15 AM

Talk 20: Kevin Kayser (SAFC)
Genetic engineering of MMV virus resistance into CHO cells: Probing the role of various CHO sialyltransferases in virus binding and internalization.....51

10:15 AM – 10:45 AM

Coffee Break / Networking

10:45 AM – 12:45 PM

Session 5: Scale-up and Scale-down Challenges

10:45 AM – 10:50 AM

Introduction – Session Chairs
Anurag Khetan (Bristol-Myers Squibb)
Frank Chaplen (Oregon State University)

10:50 AM – 10:55 AM

Poster Highlight for Scale-up and Scale-down Challenges (Session 5):
Jin Yin (Sanofi)
A holistic approach to the scale-up of a microcarrier-based perfusion cell culture process for the production of a therapeutic enzyme

10:55 AM – 11:20 AM

Talk 21: Alex Doane (Biogen)
Implementation of a recirculating TFF N-1 perfusion system at manufacturing scale: Conquering process hurdles and scaling challenges.....53

Tuesday, May 10, 2016 (continued)

11:20 AM – 11:45 AM

Talk 22: Weili Wang (MaxCyte)
Seamless scalability, consistency and quality of transient protein production in CHO Cells by using MaxCyte flow electroporation technology.....55

11:45 AM – 12:10 PM

Talk 23: Zizhuo Xing (Bristol- Myers Squibb)
A carbon dioxide stripping model for mammalian cell culture in manufacturing scale bioreactors.....58

12:10 AM – 12:35 PM

Talk 24: Weichang Zhou (WuXi AppTec)
Scale-up and scale-down challenges for a high density long-term perfusion suspension cell culture in large-scale single use bioreactors.....60

12:35 PM – 1:30 PM**Pick-up Box Lunches****1:30 PM – 5:30 PM****Networking / Free Time****5:30 PM – 7:00 PM****Workshops (3 in parallel)**

Workshop 4: Next generation manufacturing design: Batch to continuous (Fiesta 9, 11, 12)
Facilitators: Chetan Goudar (Amgen) and Rashmi Kshirsagar (Biogen)
Sponsored by Genzyme

Workshop 5: Empowering the next generation of cell culture scientists and engineers: Training and funding (Fiesta 10, 13, 14)
Facilitators: Matt Croughan (KGI), Anne Robinson (Tulane University) and Gene Schaefer (Janssen R&D)
Sponsored by Eppendorf, Inc.

Workshop 6: Lessons learned on quality by design approach through process development and characterization (Flores 6, 7, 8)
Facilitators: Thomas Link (Roche) and Vijay Janakiraman (Merck)
Sponsored by Bristol-Myers Squibb

7:00 PM – 9:00 PM**Dinner (All Grass Area)****9:00 PM – 10:30 PM**

Poster Session (Authors of even-numbered posters are asked to stay with their posters)
Sponsored by Lonza Biologics plc, Novo Nordisk A/S and MilliporeSigma

Wednesday, May 11, 2016

6:30 AM – 8:00 AM

Breakfast Buffet

8:00 AM – 9:50 AM

Session 6a: Impact of Process Conditions on Product Quality
Sponsored by Thermo Fisher Scientific

8:00 AM – 8:05 AM

Introduction – Session Chairs
Thomas Ryll (Immunogen)
Susan Sharfstein (SUNY Polytechnic Institute)

8:05 AM – 8:10 AM

Poster Highlight for Impact of process conditions on product Quality (Session 6)
Karin Anderson (Pfizer)
Impact of culture conditions and cell age on sequence variant levels in monoclonal antibody biotherapeutics

8:10 AM – 8:35 AM

Talk 25: Jose C. Menezes (Lisbon University)
Bioanalytical comparability of biotechnology products subject to changes in their manufacturing process.....62

8:35 AM – 9:00 AM

Talk 26: David Bruehlmann (Merck Serono SA and University of Würzburg)
The potential of small molecules to modulate glycosylation by media design.....64

9:00 AM – 9:25 AM

Talk 27: Gyun Min Lee (KAIST)
Factors affecting the sialylation of Fc- fusion protein in recombinant CHO cell culture.....66

9:25 AM – 9:50 AM

Talk 28: Sigma S. Mostafa (KBI BioPharma)
Optimization of glycosylation and charge distribution through culture parameters and supplements.....68

9:50 AM – 10:20 AM

Coffee Break / Networking

10:20 AM – 11:15 AM

Session 6b: Impact of Process Conditions on Product Quality

10:20 AM – 10:25 AM

Continuation – Session Chairs
Thomas Ryll (Immunogen)
Susan Sharfstein (SUNY Polytechnic Institute)

10:25 AM – 10:50 AM

Talk 29: Masaru Shiratori (Genentech)
Identification of cell culture levers to lower trisulfide modifications in monoclonal antibodies produced in CHO cell culture.....71

10:50 AM – 11:15 AM

Talk 30: Sven Markert (Roche Diagnostics GmbH)
From observation to control: Using cell culture automation for enhanced product quality optimization.....73

11:15 AM – 12:15 PM

Keynote – Jan Hillson (Momenta Pharmaceuticals)
Cell culture engineering and biosimilars: The physician's perspective.....75

Wednesday, May 11, 2016 (continued)

12:15 PM – 1:45 PM

Lunch

1:45 PM – 2:15 PM

Sinacore Award – Huoug Le (Amgen)
Evaluation of public genome references for RNA-seq data analysis in Chinese hamster ovary cells.....77

2:15 PM – 3:15 PM

Session 7a: Advanced Cell Culture Process Control

2:15 PM – 2:20 PM

Introduction – Session Chairs
Raghavan Venkat (MedImmune)
Mike Butler (University of Manitoba)

2:20 PM – 2:25 PM

Poster Highlight for Advanced Cell Culture Process Control (Session 7)
Sha Sha (University of Massachusetts Lowell)
Real time prediction and control of glycoform profile of mammalian cell cultures using in silicoglycosylation model coupled with extracellular metabolites

2:25 PM – 2:50 PM

Talk 31: Bhanu Chandra Mulukutla (Pfizer)
Systems Analysis of CHO cell metabolism for enhanced fed-batch process performance: Identification of novel growth inhibitors and their control.....79

2:50 PM – 3:15 PM

Talk 32: Catarina Brito (iBET)
3D tumor models with defined cellular and physico- chemical components: Impact of recapitulative tumor microenvironment on disease progression.....81

3:15 PM – 3:45 PM

Coffee Break / Networking

3:45 PM – 5:25 PM

Session 7b: Advanced Cell Culture Process Control

3:45 PM – 4:10 PM

Talk 33: Veronique Chotteau (KTH Royal Institute of Technology)
Poly-pathway model approach: Simulation of multiple metabolic states.....84

4:10 PM – 4:35 PM

Talk 34: Seongkyu Yoon (University of Massachusetts Lowell)
Real time prediction and control of glycoform profile of mammalian cell cultures using in silico glycosylation model coupled with extracellular metabolites.....86

4:35 PM – 5:00 PM

Talk 35: Stephen Goldrick (UCL/MedImmune)
Application of multivariate data analysis in the monitoring and control of mammalian cell processes.....88

5:00 PM – 5:25 PM

Talk 36: John Smelko (Biogen)
Implementation of Raman spectroscopy at manufacturing scale: Overcoming modeling challenges while implementing advanced process control.....91

5:25 PM – 6:30 PM

Networking / Free Time

Wednesday, May 11, 2016 (continued)

6:30 PM – 9:00 PM

Dine-Around Town (transportation provided)

9:00 PM – 10:30 PM

Poster Session (Authors of odd-numbered posters are asked to stay with their posters)

Sponsored by Solentim Ltd. and Takeda

Thursday, May 12, 2016

6:30 AM – 8:00 AM

Breakfast Buffet

Organizing Committee Breakfast Meeting (Diego Rivera Room)

8:00 AM – 9:45 AM

Session 8a: Application of 'Omics and other Technologies for Accelerating and Enhancing Bioprocess Development

8:00 AM – 8:05 AM

Introduction – Session Chairs
Chetan Goudar (Amgen)
Hal Alper (University of Texas, Austin)

8:05 AM – 8:30 AM

Talk 37: Jamey D. Young (Vanderbilt University)
Application of ^{13}C flux analysis to identify high-productivity CHO metabolic phenotypes.....93

8:30 AM – 8:55 AM

Talk 38: Amanda Lewis (Bristol-Myers Squibb)
Understanding and controlling sialylation in a CHO fusion protein at lab and manufacturing scale using targeted omics techniques.....95

8:55 AM – 9:20 AM

Talk 39: Markus Michael Mueller (Boehringer Ingelheim Pharma GmbH)
Targeting product quality: Where systems biotechnology and process design meet.....98

9:20 AM – 9:45 AM

Talk 40: Neil Templeton (Merck)
Fluxomics: The integration of metabolic flux analysis (MFA) with multivariate data analysis (MVDA) to identify key process parameters for CHO cell culture.....100

9:45 AM – 10:15 AM

Coffee Break / Networking

10:15 AM – 12:05 AM

Session 8b: 'Omics Applications

10:15 AM – 10:40 AM

Talk 41: Chapman Wright (Biogen)
Biotherapeutic development in the 'Omics Age: The CHO genome and beyond.....102

10:40 AM – 11:05 AM

Talk 42: Dong-Yup Lee (National University of Singapore)
Mammalian systems biotechnology: An integrative framework for combining *in silico* modeling and multi-Omics datasets in different CHO parental cell lines.....104

11:05 AM – 12:05 PM

Keynote – Michael Jensen (Juno Therapeutics)
Next Gen CAR T-cells.....107

12:05 PM – 1:45 PM

Lunch

Thursday, May 12, 2016 (continued)

Two Parallel Oral Sessions

1:45 PM – 3:30 PM	<u>Session 9: Non-Protein Products (Fiesta 1-8)</u>
1:45 PM – 1:50 PM	Introduction — Session Chairs Chris Ramsborg (Juno Therapeutics) Bill Miller (Northwestern University)
1:50 PM – 2:15 PM	Talk 43: Alvin W. Nienow (University of Loughborough) Agitation strategies for the culture and detachment of human mesenchymal stem cells (hMSCs) from microcarriers in multiple bioreactor platforms.....109
2:15 PM – 2:40 PM	Talk 44: E. Terry Papoutsakis (University of Delaware) Cell-derived microparticles for cell therapy, cargo delivery, and applications in CHO-cell biotechnology.....111
2:40 PM – 3:05 PM	Talk 45: Francesc Gòdia (Universitat Autònoma de Barcelona) Intracellular characterization of Gag-GFP VLP production upon PEI-mediated transient transfection of HEK 293 cells.....113
3:05 PM – 3:30 PM	Talk 46: Rachel Legmann (Pall Life Sciences) Industrialization of adenoviral vector production in fixed bed bioreactor and amplification of primary liver cells in Xpansion® bioreactor: Autologous insulin producing cells for the treatment of diabetes, from bench to clinical scale.....115
1:45 PM – 3:30 PM	<u>Session 10: Applications of QbD & PAT for Cell Culture (Fiesta 9-13)</u> <i>Sponsored by Regeneron Pharmaceuticals, Inc.</i>
1:45 PM – 1:50 PM	Introduction — Session Chairs Ashraf Amanullah (aTyr Pharma) Rob Thomas (Loughborough University)
1:50 PM – 2:15 PM	Talk 47: Melissa S. Mun (Genentech) A quality by design (QbD) approach to cell culture process characterization.....117
2:15 PM – 2:40 PM	Talk 48: Michael Borys (Bristol- Myers Squibb) Incorporation of QbD elements into the development and characterization of a second generation process.....119
2:40 PM – 3:05 PM	Talk 49: Mathieu Streefland (Merck) Development of a process analytical technology (PAT) infrastructure for future biologics upstream processing.....121
3:05 PM – 3:30 PM	Talk 50: Girish J Pendse (Eli Lilly) Use of quality by design principles for development of upstream process control strategy.....123
3:30 PM – 4:00 PM	Coffee Break / Networking

Thursday, May 12, 2016 (continued)

4:00 PM – 5:30 PM

Workshops (3 in parallel)

Workshop 7: Applications of omics technologies

Facilitators: Erdmann Rapp (Max Planck Institute) & Manuel Carrondo (iBET) (Fiesta 9-13)

Sponsored by Amgen

Workshop 8: Modulating product quality through cell culture process

Facilitators: Kara Calhoun (Genentech) and Shyamsundar Subramanian (Teva) (Fiesta 1-8)

Sponsored by Lilly

Workshop 9: Opportunities for and challenges of process transfer and Scale-up (Flores 1, 2, 3)

Facilitators: Gayle Derfus (Gilead) and Arthi Narayanan (Genentech)

Sponsored by MilliporeSigma

5:30 PM – 6:00 PM

Coffee Break / Networking

6:00 PM – 7:00 PM

CCE Award Lecture — Jeff Chalmers (Ohio State University)

7:00 PM – 7:30 PM

Reception (Flores Foyer and Veranda)

7:30 PM – 10:30 PM

Banquet (Flores 4-8)

Sponsored by Genentech

- Presentation of Poster Awards
- Presentation of Cell Culture Engineering Award
- Roast of CCE Award Winner – Konstantin Konstantinov (Codiak Biosciences)
- Announcement of Chairs for CCE XVI
- Announcement of Upcoming ECI Conferences
- Closing Remarks by Conference Chairs

Friday, May 13, 2016

6:30 AM – 8:30 AM

Breakfast Buffet

8:30 AM – 9:30 AM

Departures

Poster Presentations

Session I: Cell Line Development Advances

1. **Automated, high throughput imaging during cell line development to increase the assurance of clonality.....125**
David Shaw, Genentech, Inc., USA
2. **Establishing a robust two-step cloning strategy for the generation of cell lines with a high probability of monoclonality.....127**
Alison Young, Fujifilm Diosynth Biotechnologies, United Kingdom
3. **Proof that can travel - documented clonality report for regulatory submission.....130**
Paul Miller, Solentim Inc, United Kingdom
4. **Insight into single cell cloning in serum-free media.....132**
Tsuyoshi Yamaguchi, Kyowa Hakko Kirin Co., Ltd., Japan
5. **Karyotype-based analysis of cell line instability and clonality in CHO cells.....135**
Jong Youn Baik, University of Delaware, USA
6. **Assessment of genomic instability in Chinese Hamster ovary (CHO) cells.....137**
Sabine Vcelar, ACIB GmbH, Austria
7. **Identifying low-Level sequence variants via next generation sequencing to aid stable CHO cell line screening.....139**
Sheng Zhang, AbbVie, USA
8. **Time course of transcription and chromatin states during batch culture in Chinese Hamster ovary cells.....141**
Inmaculada Hernandez, Austrian Center of Industrial Biotechnology, Austria
9. **Prediction of stable and transient expression of recombinant proteins from CHO cells based upon translational reprogramming.....143**
Charlotte Godfrey, University of Kent, United Kingdom
10. **Generation of a stable pluripotent cell line from Chinese Hamster embryonic fibroblasts.....145**
Dong Seong Cho, University of Minnesota, USA
11. **Microfluidic accelerated evaluation of CHO cell clones by perfusion of fed-batch conditioned media.....147**
Darek Sikorski, University of British Columbia, Canada
12. **Genome-wide RNAi screen for improved functional expression of recombinant proteins from HEK 293 cells.....149**
Joseph Shiloach, NIDDK, USA
13. **Bridging the gap of screening and scale up in CHO, hybridoma, HEK293 and other cell lines: Single use optimum growth flasks 30mL-5L flasks with transfer caps, and ports.....151**
Sam Ellis, Thomson Instrument Company, USA

14. **Sub-physiological culture temperature boosts expression levels of membrane proteins in CHO cells.....153**
Sampath Kumar, Adimab LLC, USA
15. **Varied productivity according to the differences between targeted locations of antibody expression vectors in Chinese Hamster ovary cells.....155**
Noriko Yamano, Tokushima University, Japan
16. **Targeted integration of multiple active sites in CHO genome for rapid generation of stable and high monoclonal antibody producing cell lines.....157**
Yuansheng Yang, Bioprocessing Technology Institute, Singapore
17. **Identifying opportunities in cell engineering for the production of 'difficult to express' recombinant proteins.....159**
Hirra Hussain, The University of Manchester, United Kingdom
18. **CHO-K1 host cell engineering strategy enabling the establishment of strains producing higher yields of recycling antibodies.....161**
Hisahiro Tabuchi, Chugai Pharmaceutical, Japan
19. **Flow cytometry screening strategy for the enrichment of high-producing Chinese Hamster ovary cells for monoclonal antibody manufacturing.....163**
Takeshi Okumura, Daiichi Sankyo Co., Ltd., Japan
20. **Reduction of metabolic waste products, ammonia and lactate, through the coupling of GS selection and LDH-A down-regulation in CHO cells.....165**
Soo Min Noh, KAIST, South Korea
21. **Cre-loxP-controlled cell-cycle checkpoint engineering in Chinese Hamster ovary cells.....167**
Takeshi Omasa, Osaka University, Japan
22. **Expression of glycoproteins with excellent pharmacokinetic properties on the novel CAP-Go expression platform.....170**
Silke Wissing, CEVEC Pharmaceuticals, Germany
23. **An integrated cell line development platform for generation of high yielding CHO stable cell lines expressing a stabilized trimeric pre-fusion RSV F recombinant viral glycoprotein.....172**
Richard Schwartz, Vaccine Research Center, NIAID, NIH, USA
24. **Development of hyper osmotic resistant CHO host cells.....174**
Yasuharu Kamachi, Takeda Pharmaceutical Company Limited, Japan
25. **Genetic engineering of CHO cells for viral resistance to MMV: Targeting virus binding, internalization, intracellular trafficking and transport to nucleus.....176**
Joaquina Mascarenhas, SAFC, USA
26. **Accelerated homology-directed targeted integration of transgenes in CHO cells via CRISPR/Cas9 and fluorescent enrichment.....178**
Jae Seong Lee, Technical University of Denmark, Denmark
27. **CRISPR-CAS9 knockout library for CHO.....180**
Lasse E. Pedersen, Technical University of Denmark, Denmark

28. **Glycoengineering of Chinese Hamster ovary cell for modulating glycoprotein N-linked sialylation.....183**
Chengyu Chung, Johns Hopkins University, USA
29. **Re-programming CHO cell metabolism using miR-23 tips the balance towards a highly productive phenotype.....185**
Niall Barron, Dublin City University, Ireland
30. **A novel platform for high throughput cell line screening & development.....187**
Maria Wendt, Genedata AG, Switzerland
31. **Cell Express 100TM - A robust, simple and cost effective alternative to high-throughput automated platforms for cell line development.....189**
Raj Kumar Kunaparaju, USHA Bio-tech, India

Session II: Impact of Process Conditions on Product Quality

32. **Changes in product quality – what is comparable “enough” and what is “similar enough?”.....191**
David K. Robinson, Robinson Vaccines and Biologics LLC, USA
33. **Improving the productivity and product quality of antibodies expressed from a CHO transient system.....193**
Athena Wong, Genentech, Inc., USA
34. **A systematic development approach to optimize and control biopharmaceutical product quality.....195**
Min Zhang, Fujifilm Diosynth Biotechnologies, USA
35. **Strategies for optimizing a cell culture platform to achieve high recombinant protein titer without impacting product quality.....197**
Natarajan Vijayasankaran, Genentech, Inc., USA
36. **Impact of harvest conditions on the glycosylation profile of a therapeutic antibody.....199**
Raghavan Venkat, MedImmune LLC, USA
37. **Investigating the impact of process optimization on productivity, product quality, cell metabolism, and intracellular environment.....201**
Shailendra Singh, MedImmune, USA
38. **Enhancing enveloped viral particles production by targeted supplementation design: Releasing bottlenecks in IC-BEVS.....203**
António Roldão, iBET, Portugal
39. **Efforts to reduce impact of media variability on product quality for a commercial perfusion process.....205**
Nirel Rillera, BioMarin Pharmaceutical Inc., USA
40. **Bioreactor perfusion via single-use centrifugation has fewer product quality implications than tangential flow filtration.....208**
Rustin Shenkman, Shire, USA
41. **Impact of culture conditions and cell age on sequence variant levels in monoclonal antibody biotherapeutics.....210**
Karin Anderson, Pfizer, Inc., USA

42. **Evaluation of product antibody (mAb) heterogeneity in non-clonal cell pools for early pre-clinical development.....212**
Gabi Tremml, Bristol-Myers Squibb, USA
43. **A biphasic cultivation strategy to optimize protein expression and minimize aggregation of the final product.....214**
Andreas Castan, GE Healthcare, Ireland
44. **Adjusting product quality attributes of a biosimilar using process levers.....216**
Brett Belongia, Momenta Pharmaceuticals, USA
45. **Improving the metabolic efficiency of mammalian cells and its impact on glycoproteins quality.....218**
Eric Karengera, École Polytechnique de Montréal, Canada
46. **CHO cell culture process impacts monoclonal antibody trisulfide modification and sulfhydryl-drug conjugation.....220**
Michael Hippach, Agensys, Inc, USA
47. **Critical process parameter identification using the ambr15(tm) for process characterization.....222**
Matthew Zustiak, Patheon Biologics, USA
48. **Influence of cultivation parameters or supplement on product qualities and culture performances during perfusion.....225**
Kyu-Yong Kim, LG Life Sciences, Ltd., South Korea

Session III: Advanced Cell Culture Process Controls and Modeling

49. **Reduction of N-glycan profile variation by using capacitance probes for optimized process control.....228**
Christoffer Bro, Biogen, Denmark
50. **Advanced process monitoring and feedback control to enhance cell culture process production and robustness.....230**
An Zhang, Biogen, USA
51. **Monitoring live stem cells in suspension and attached to carriers in conventional and single use bioreactors.....233**
John Carvell, Aber Instruments Ltd., United Kingdom
52. **Monitoring live biomass in disposable bioreactors in range of vessel formats.....235**
Dan Kopec, Sartorius Stedim Biotech, Germany
53. **Use of an automated, integrated laboratory environment to enable predictive modeling approaches for identifying critical process parameters and controlling key quality attributes.....237**
Brandon J. Downey, Bend Research, Inc., USA
54. **Softsensors: New approach for process monitoring cell growth in small scale fermentation systems.....240**
Wolfgang Paul, Roche Innovation Center, Germany

55. **Advancement of cell culture process understanding and control through real-time multivariate process monitoring, use of statistical process modes and deployment of process analytical technologies.....242**
Patrick O. Gammell, Amgen, USA
56. **Agent-based model predictive framework to control cell culture bioreactors.....245**
Elif S. Bayrak, Amgen Inc., USA
57. **Kinetic physico-chemical model for cell culture processes – applications and opportunities.....247**
Natraj Ram, AbbVie, USA
58. **Accelerate cell culture development using the modular automated sampling technology (MASTTM) platform in an integrated bioprocess lab environment.....249**
Clinton B. Pepper, Bend Research, USA
59. **Development of bioreactor auto-sampling system for real time product quality monitoring in mammalian cell culture.....251**
Meena George, Boehringer Ingelheim Fremont Inc, USA
60. **Lensless imaging for continuous CHO viable cell density monitoring in bioreactors.....253**
Geoffrey Esteban, IPRASENSE, France
61. **Continuous suspension cell culture monitoring in bioreactors using quantitative imaging.....255**
Ann D'Ambruoso, Applikon, USA
62. **Investigating the reverse Warburg effect: How high extracellular lactate alters breast cancer metabolism.....257**
Daniel C. Odenwelder, Clemson University, USA
63. **Real time prediction and control of glycoform profile of mammalian cell cultures using in silicoglycosylation model coupled with extracellular metabolites.....259**
Sha Sha, University of Massachusetts Lowell, USA
64. **A stochastic model to study genetic and metabolic effects on N-linked protein glycosylation.....261**
Philipp N. Spahn, University of California, San Diego, USA
65. **CHO-specific recombinant protein glycosylation reaction network.....264**
Benjamin G. Kremkow, University of Delaware, USA
66. **Controller design for effective glycosylation control in mAbs.....266**
Devesh Radhakrishnan, University of Delaware, USA
67. **Elucidating glycosylation pattern of protein produced in mammalian cells.....268**
Tung S. Le, University of Minnesota, USA
68. **Poly-pathway model approach: Simulation of multiple metabolic states.....270**
Erika Hagrot, KTH Royal Institute of Technology, Sweden

Session IV: Scale-Up and Scale-Down Challenges for Cell Culture Based Manufacturing

69. **Improved scale-down model development case study for raw materials screening.....272**
Angela Au, Bristol-Myers Squibb, USA

70. **Characterization of TAP Ambr250 disposable bioreactors as a reliable scale-down model for biologics process development.....274**
Ping Xu, Bristol-Myers Squibb, USA
71. **Metabolomic analysis for scale-down model improvement.....276**
Eric Garr, Bristol-Myers Squibb, USA
72. **Demonstrating process performance comparability of the Keytruda® upstream process after transfer and scale-up to different manufacturing sites.....278**
Jürgen van de Lagemaat, MSD, Netherlands
73. **Challenges in the use of scale-down models for understanding and mitigating process variations of a monoclonal antibody production process.....280**
A. Peter Russo, Merck & Co., Inc., USA
74. **Scale-up in the single use age: Does geometry matter?.....282**
Colin Jaques, Lonza Biologics, United Kingdom
75. **A rapid approach for basal and feed media optimization in ambr® 15 bioreactors.....284**
Michael Gillmeister, Lonza, USA
76. **Tubespins as a suitable scale-down model of 2L high cell density bioreactors for CHO cell culture.....286**
Natalia Gomez, Amgen , USA
77. **Process scale-up issues: Relics of the past or continues to cause major headaches.....288**
Sadettin Ozturk, MassBiologics, USA
78. **Novel, efficient scale-up of inclined settlers for perfusion bioreactor cultures.....290**
Dhinakar S. Kompala, Sudhin Biopharma Company, USA
79. **Bioreactor scale-up harmonization - From process development to manufacturing.....292**
Claudia Berdugo-Davis, Cook Pharmica LLC, USA
80. **Scale-up and scale-down topics facing the industry.....295**
Markus M. Mueller, Boehringer Ingelheim Pharma GmbH & Co.KG, Germany
81. **Case study for improved process robustness at manufacturing scale for a mammalian cell culture process: Troubleshooting medium preparation and gas entrance velocity effects.....297**
Robin Luo, Boehringer Ingelheim, USA
82. **Performance consistency of fed-batch cultures across multiple systems used in upstream process development.....299**
Matthieu Stettler, Merck Serono, Switzerland
83. **Overcoming scale-up challenges with a non-robust cell line.....301**
Sigma Mostafa, KBI Biopharma, USA
84. **Application of online CO₂ monitoring to enable a better understanding of cell culture performance variation between GMP-scale and scaled-down bioreactors.....303**
Ting-Kuo Huang, Genentech Inc., USA
85. **Establishing a pH measurement reference method for site/process transfer purposes.....305**
Meg Tung, Genentech Inc., USA

86. **Case study: Lessons learned during tech transfer at a multi-product legacy launch facility.....307**
Arthi Narayanan, Genentech Inc., USA
87. **Scale down model in industrial cell culture processes – A powerful tool to ensure reliable production.....309**
Marco Jenzsch, Roche Pharma Biotech, Germany
88. **Advances in bioreactor scale-down modeling using Process Analytical Technology (PAT).....311**
Liyang Yang, Astrazeneca, USA
89. **Challenges of scale down model for disposable bioreactors: Case studies on growth & product quality impacts.....313**
Jincai Li, WuXi AppTec, China
90. **A holistic approach to the scale-up of a microcarrier-based perfusion cell culture process for the production of a therapeutic enzyme.....315**
Jin Yin, Genzyme, A Sanofi Company, USA
91. **Bioreactor process improvements in a legacy perfusion-based process.....317**
Mustafa Hanif, Genzyme, A Sanofi Company, USA
92. **Preferentially selecting cellular metabolism and improving productivity by controlling do and Pco2.....319**
Sofie Goetschalckx, Genzyme, A Sanofi Company, USA
93. **Challenges and their resolutions during process development and tech transfer of a late stage bispecific antibody product.....321**
Marcella Yu, Sanofi, USA
94. **Scalability of the Mobius® single-use bioreactor from bench to clinical scale: Examination of key engineering parameters and robustness.....323**
Lee Madrid, EMD Millipore, USA
95. **Single-step flask to 250 L cell culture with a hybrid mixing single-use bioreactor.....325**
Nephi Jones, Thermo Fisher Scientific, USA

Session V: Integrated Continuous Process Development for Cell Culture

96. **Rapid development of a perfusion process with high productivity.....327**
Sen Xu, Merck Research Laboratories, USA
97. **Integrated continuous bioprocessing - a gold mine for cell culture process understanding?.....329**
Mats Akesson, Novo Nordisk A/S, Denmark
98. **Perfusion media development and evaluation with spin tube and ambr15 high-throughput small-scale models.....331**
Yang Wang, Thermo Fisher Scientific, Inc., USA
99. **Process intensification through integration of upstream perfusion cell culture with downstream continuous chromatography in monoclonal antibody production.....333**
Andreas Castan, GE Healthcare, Sweden

100. **Modeling perfusion for medium component optimization using ambr15TM.....336**
Delia Lyons, SAFC, USA
101. **Small-scale comparison of pseudoperfusion feeding strategies using basal and concentrated feed media.....338**
Leda R. Castilho, Federal University of Rio de Janeiro, Brazil
102. **Towards integrated continuous viral vaccines production using two-stage bioreactor systems.....340**
Felipe Tapia, Max Planck Institute Magdeburg, Germany
103. **Development of a quality driven integrated continuous biomanufacturing process.....342**
Daniel Karst, ETH Zurich, Switzerland
104. **mAb product consistency in long duration microfiltration-based CHO perfusion process.....344**
Douglas Rank, EMD Millipore, USA
105. **Toward development of continuous bioprocesses: Comparison of fed-batch and perfusion upstream production processes in early development.....346**
B. Jean McLarty, Sanofi, USA
106. **Process intensification of perfusion: To steady-state, or unsteady-state, that is the question.....348**
Henry Lin, Boehringer Ingelheim, USA
107. **Size matters: Assessment of a larger pore hollow fiber to reduce product retention in perfusion.....350**
Samantha B. Wang, Boehringer Ingelheim, USA
108. **Process robustness and cell line variation in N-1 high density perfusion system.....352**
Haofan Peng, Biogen, USA
109. **Process optimization for semi-continuous virus production at high cell densities.....354**
Daniel Vázquez, Max Planck Institute for Dynamics of Complex Technical Systems, Germany
110. **Non-invasive real-time monitoring of glucose and lactate by NIR-spectroscopy during perfusion CHO culture.....356**
Jean-Francois P Hamel, Massachusetts Institute of Technology, USA

Session VI: Application of 'Omics and other Technologies for Accelerating and Enhancing Bioprocess Development

111. **Understanding and overcoming process insults through application of 'omics technologies.....358**
Alan Gilbert, Biogen, USA
112. **Technical evaluation of RNA-Seq and microarray approaches in comparative transcriptomics analysis of CHO cells.....361**
Chun Chen, Amgen Inc., USA
113. **Evaluation of public genome references for RNA-Seq data analysis in Chinese Hamster ovary cells.....363**
Huong Le, Amgen Inc, USA

114. **Increasing diversity of production cell lines through miniaturization, automation, and high-throughput analytics.....365**
Kim Le, Amgen Inc., USA
115. **Utilizing RNA-Seq technique to improve molecular understanding of Chinese Hamster ovary (CHO) cell bioprocessing.....367**
Yogender Kumar Gowtham, Clemson University, USA
116. **Manipulation and exploitation of MicroRNAs for enhanced recombinant protein production in CHO cells.....369**
Tulshi Patel, University of Kent, United Kingdom
117. **Implementation and evaluation of a high-throughput siRNA screening system for suspension CHO cells.....371**
Gerald Klanert, University of Natural Resources and Life Sciences, Vienna, Austria
118. **Lipidomic analysis to enhance the understanding of Chinese Hamster ovary cells.....373**
Yue Zhang, Johns Hopkins University, USA
119. **Lipidomics for robust high performance process development.....375**
Laetitia Malphettes, UCB Pharma SA, Belgium
120. **High titer transient gene expression platform based on GS CHO cell line – rapid protein expression tool for preclinical drug development.....377**
Yashas Rajendra, Eli Lilly & Company, USA
121. **Improving biologics development by high performance glycoanalysis.....379**
Erdmann Rapp, Max Planck Institute for Dynamics of Complex Technical Systems, Germany
122. **Genomics based methodology of cell-culture media formulation for improved bio-therapeutic productivity and quality consistency.....381**
Hemlata Bhatia, University of Massachusetts Lowell, USA
123. **Multi-omic profiling of EPO producing CHO cell panel reveals metabolic adaptation to heterologous protein production.....383**
Daniel Ley, Technical University of Denmark, Denmark
124. **A multi-omic approach to understanding recombinant protein degradation in Chinese Hamster ovary cells.....385**
Ronan M. Kelly, Eli Lilly & Company, USA
125. **Multi-omic modeling of translational efficiency for synthetic gene design.....387**
Joseph Longworth, University of Sheffield, United Kingdom
126. **Enhancing site-specific CHO produced antibody through media optimization using metabolomics approach.....389**
Ching-Jen Yang, Development Center for Biotechnology, Taiwan
127. **A correction method for systematic error in metabolomic time-course data.....391**
Stanislav Sokolenko, University of Waterloo, Canada
128. **Integration of transcriptomic data with a genome-scale model reveals key metabolic features of high producer CHO cell lines.....393**
Ziomara P. Gerdtsen, CeBiB, Universidad de Chile, Chile

129. **Development of plate-based sialic acid assays to support clone screening and early Stage upstream process development.....395**
Julie Gardin, BioMarin Pharmaceutical, Inc., USA
130. **Site-specific glycan analysis of proteins in cell culture conditioned media and sub-cellular fractions by LC-MS/MS for understanding the impact of process conditions on N-glycosylation.....397**
Karina Bora de Oliveira, MedImmune, USA
131. **A community genome-scale model of Chinese Hamster ovary cell metabolism identifies differences in the efficiency of resource utilization for various bioprocesses.....399**
Hooman Hefzi, University of California, San Diego, USA
132. **A bioinformatic pipeline for studying ribosome occupancy in CHO cells.....401**
Shangzhong Li, University of California San Diego, USA
133. **¹³C flux analysis in industrial CHO cell culture applications.....403**
Allison G. McAtee, Vanderbilt University, USA
134. **Elucidating cell line and tissue differences derived from cricetus griseus by transcriptomics and proteomics.....405**
Kelley Heffner, Johns Hopkins University, USA

Session VII: Non-Protein Products of Cell Culture

135. **Scale-down and initial characterization studies of an allogeneic cell therapy manufacturing process.....407**
John Gaut, Celgene Cellular Therapeutics, USA
136. ***Poster Withdrawn***
137. **Expansion and differentiation of T cells under defined xeno-free culture conditions.....409**
Jessie H.T. Ni, Irvine Scientific, USA
138. **Cell therapy manufacturing strategies: Impact on cost of goods, cost of development and commercialisation.....411**
Suzanne S. Farid, University College London, United Kingdom
139. **An innovative protein delivery system for therapeutic cells.....413**
Jean-Pascal Lepetit-Stoffaes, Université Laval, Canada
140. **Effect of cell-surface interactions on monocyte-derived immunotherapy products.....415**
Corinne A. Hoesli, McGill University, Canada
141. **Optimization of a defined serum-free medium for the production of therapeutic human myoblasts.....417**
Jean-Pascal Lepetit-Stoffaes, Université Laval, Canada
142. **Biological relevance of YAP regulation by Wnt signaling during neural tissue patterning of human induced pluripotent stem cells.....419**
Yan Li, Florida State University, USA
143. **PCL-PDMS-PCL copolymer-based microspheres mediate cardiovascular differentiation from embryonic stem cells.....421**
Yan Li, Florida State University, USA

144. **Neural patterning of human induced pluripotent stem cells for studying neurotoxicity.....423**
Yuanwei Yan, Florida State University, USA
145. **Human cardiac stem cells for allogeneic cell therapies: integrating bioprocess development and 'omics characterization tools.....426**
Paula Alves, iBET/NOVA-ITQB, Portugal
146. **Integrated strategies for the production, maturation and storage of functional cardiomyocytes derived from human pluripotent stem cells.....428**
Margarida Serra, iBET, Portugal
147. **Integration of bioprocess design with transcriptomic and metabolomic characterization for the expansion of human pluripotent stem cells.....430**
Margarida Serra, iBET, Portugal
148. **Scalable production of mesenchymal stem/stromal cells from different human sources in microcarrier-based stirred culture systems.....432**
Ana Fernandes-Platzgummer, Universidade de Lisboa, Portugal
149. **Development of an adherent cell based virus production process in Mobius® single-use bioreactor.....434**
Michael Cunningham, EMD Millipore, USA
150. **Scaling microcarrier-based cell expansion processes.....436**
Mark Szczypka, Pall Life Sciences, USA
151. **Transient production of VLPs in HEK 293 cells and the evaluation of parameters influencing transfection and expression.....438**
Daniel Blackstock, NIH, USA
152. **Production of stable, immunogenic foot-and-mouth disease vaccine in a chemically-defined, serum-free medium optimized for BHK-21 Cells.....440**
Paul Gulde, Thermo Fisher Scientific, USA
153. **Development of chemically-defined, animal component-free medium for suspension MDCK cell-based influenza vaccine production.....442**
Jenny Bang, Irvine Scientific, USA
154. **Fluorescent influenza-like particles and control over their composition.....444**
Marc G. Aucoin, University of Waterloo, Canada
155. **HEK293 suspension cell culture platform for production of viruses and viral vectors.....446**
Sven Ansorge, National Research Council of Canada, Canada
156. **Efficient production of influenza virus-like particles in HEK-293SF cells.....448**
Alina Venereo-Sanchez, Ecole Polytechnique de Montreal/National Research Council Canada, Canada
157. **A flow cytometric granularity assay for the quantification of infectious virus.....450**
Megan Logan, University of Waterloo, Canada

Session VIII: Current Concerns and Emerging Trends in Cell Culture Bioprocessing

158. **Impact of Poloxamer 188 variability on biologics manufacturing: Mitigations and causal investigation.....452**
Salim Charaniya, Roche Pharma Technical Development, USA
159. **Evaluating sugar-based detergents as a potential alternative to poloxamer bubble protectant.....454**
Jessica Wu, Genentech, Inc., USA
160. **A host cell protein that may impact polysorbate degradation.....456**
Kelvin Lee, University of Delaware, USA
161. **Troubleshooting the recovery of master cell bank for a commercial product.....458**
Mei Shao, Alexion Pharmaceuticals, USA
162. **Adapting an in-licensed/acquired cell culture process to platform conditions.....460**
Raghu Shivappa, Johnson & Johnson, USA
163. **Challenges in the development and adaptation of platform process to existing pipeline.....462**
Edmund Scarfo, Takeda Pharmaceutical Co Ltd, USA
164. **A holistic approach to facility protection from adventitious agents – A case study.....464**
Matthew D. Osborne, Eli Lilly and Co., Ireland
165. **Nanofiltration as an effective means to prevent virus contamination of cell culture processes.....466**
Kimberly Mann, EMD Millipore, USA
166. **The oxygen binding protein, HEMOXCell(R), increases CHO cell growth and extends viability by enhancing oxygen delivery.....468**
Katrin Braasch, University of Manitoba, Canada
167. **The differential polarizability of CHO cells can be used to monitor changes in metabolism.....470**
Katrin Braasch, University of Manitoba, Canada
168. **Development of antibody detection methods for active product at the cell culture stage.....472**
Gregory Walsh, Genzyme, A Sanofi Company, USA
169. **Development and application of glycosyltransferases for in vitro glycoengineering.....474**
Alfred Michael Engel, Roche Diagnostics GmbH, Germany
170. **Improvement of CHO specific productivity using amino acid derivatives.....476**
Aline Zimmer, Merck KGaA, Germany
171. **Deepening Knowledge on CHO cells metabolism using multiple tracer substrates.....478**
Manuel Carrondo, iBET, Portugal
172. **NMR-based design of chemically-defined protein-free feed medium for the CHO expression system.....480**
Marina Goldfeld, Merck & Co., Inc., USA

173. **How to select the most suitable media for your cells.....482**
Marcella CF Dalm, Synthon Biopharmaceuticals BV, Netherlands
174. **Comparison of commercial CHO cell media formulations using material-oriented recurrent spectral libraries.....484**
Kelly H. Telu, NIST, USA
175. **Using definitive screening design to effectively assess the combinatorial impacts of media supplements on monoclonal antibody production in mammalian cells.....486**
Aaron Chen, Seattle Genetics, USA
176. **Integrating emerging trends in upstream process development: Autosampling, nutrient feedback control, and single use tanks.....488**
T. Craig Seamans, Merck Research Labs, USA
177. **Implementation activities for a chemically-defined media platform to minimize media variability impact to cell culture performance and product quality.....490**
Martin Gawlitzek, Genentech, Inc., USA
178. **Development of a chemically defined media and a chemically defined feeding strategy for extended growth and enhanced productivity in CHO-K1 and CHO DG44 cultures.....492**
Sagar Kokal, Kerry, USA
179. **Evaluation of performance enhancing effects of supplementation with complex feed system and supplements with Sheff-CHO CD complete media in CHO-K1 and CHO DG44 cultures.....494**
John F. Menton, Kerry, USA
180. **Incidence and potential implications of methylglyoxal in industrial cell culture revisited.....496**
Frank Chaplen, Oregon State University, USA
181. **An addition of lithium chloride improves the transient gene expression yield in CHO cells498**
Che Lin Kim, KAIST, South Korea
182. **Anti-oxidant addition to CD-CHO media to prevent damage induced by UV disinfection.....500**
Emma V. Dare, University of Waterloo, Canada
183. **Development of an enriched CHO feed media for quality therapeutic antibody production from high performing clones.....502**
David T. Ho, Irvine Scientific, USA
184. **Fed-batch process development using metabolically efficient CHO cells.....504**
Cecile Toussaint, Universite de Montréal, Canada
185. **Adaptation of CHO metabolism to long term phosphate limitation.....506**
Mugdha Gadgil, National Chemical Laboratory, India
186. **Separation of IgG glycoforms for biosimilars development using Fc gamma receptors as affinity-based chromatography ligands.....508**
Austin Boesch, Dartmouth College, USA

Session IX: Quality by Design and Scale-down Model Qualification

- 187. **Building QbD frameworks retrospectively for commercial products and the use of scale-down model qualification strategies to support continuous improvement.....510**
Jose C. Menezes, Lisbon University, Portugal

- 188. **Moving from a bioreactor scale-up/scale-down approach to a more holistic operational design space view.....512**
Gene Schaefer, Janssen R&D, USA

- 189. **Retrospective implementation of quality by design for legacy commercialized enzyme replacement therapies.....514**
Anup Agarwal, Shire, USA

- 190. **Accelerated bioprocess characterization by data enrichment in scale-down models.....516**
Viktor Konakovsky, Fujifilm Diosynth Biotechnologies, United Kingdom

Session X: Novel Protein Formats

- 191. **Antibody production with site-specific non-natural amino acid incorporation for generation of antibody drug conjugates.....518**
Alyssa Powell, Ambrx, Inc., USA