

***Preliminary Program***  
(March 31, 2020)

# **Cell Culture Engineering XVII**

**November 1 – 6, 2020**

**JW Marriott Starr Pass Tucson Resort  
Tucson, Arizona, USA**

**Conference Chairs**

**Timothy Charlebois**  
Pfizer, Inc., USA

**Jamey Young**  
Vanderbilt University, USA

**Gargi Maheshwari**



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**Sunday, November 1, 2020**

- 12:30 – 17:30           Poster set-up
- 14:00 – 16:45           Conference Check-In
- 14:30 – 15:30           Early Career Preconference Flash talks (10 x 5-min talks)
- 15:30 – 16:15           Early Career Preconference Icebreaker/ Networking
- 16:15 – 16:45           Coffee break
- 16:45 – 17:00           Welcome remarks  
CCE Chairs and ECI Liaison
- 17:00 – 17:45           **Keynote 1**  
**How Technology, Big Data, and Systems Approaches are Transforming  
21<sup>st</sup> Century Healthcare**  
**Leroy Hood**, SVP and Chief Scientific Officer, Providence St. Joseph Health;  
Chief Strategy Officer, Co-founder and Professor, Institute for Systems Biology
- 18:00 – 19:30           Dinner
- 19:30 – 21:30           **Poster Session (even-numbered posters)**  
Chairs: Karthik Jayapal, Janssen, USA  
          Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA  
          Olivier Henry, Polytechnique Montreal, Canada  
          Yao-Ming Huang, Eli Lilly & Co., USA

**Monday, November 2, 2020**

**Breakfast on own**

08:00 – 08:45

**Keynote 2**

**TBD**

**Michael Kamarck**, Ph.D., Chief Technology Officer, Vir Technology

**Session 1: Systems and Synthetic Biology for Improved Cell Culture Performance**

Chairs: **Bhanu Mulukutla**, Pfizer, USA

**Nicole Borth**, University of Natural Resources and Life Sciences, Vienna

08:45 – 08:50

Session introduction

08:50 – 09:15

**HCP proteomics identifies difficult to remove HCPs as a function of cell age**

**Kelvin Lee**, University of Delaware, USA

09:15 – 09:40

**Solving the problem of clonal diversity through pathway mediated design approaches**

**Paul E. Gulde**, Thermo Fisher Scientific, USA

09:40 – 09:45

**Maximizing mAb galactosylation: Simultaneous removal of metabolic and cellular machinery bottlenecks**

**Itzcoatl Gomez**, University College Dublin, Ireland

09:45 – 10:10

**Systems design of virus production through synthetic biology**

**Wei-Shou Hu**, University of Minnesota, USA

10:10 – 10:40

Coffee Break

10:40 – 11:05

**Amino acid metabolism in CHO cells**

**Maciek Antoniewicz**, University of Delaware, USA

11:05 – 11:30

**Glycoengineering: A multidimensional challenge across different eukaryotic hosts**

**Michael Betenbaugh**, Johns Hopkins University, USA

11:30 – 11:35

**Mechanistic insights into N-glycosylation of recombinant proteins produced in CHO cell fed-batch cultures through systems biology and computational modeling**

**Madhuresh Sumit**, Pfizer Inc., USA

11:35 – 12:00

**Next-generation, feedback responsive cell factories for recombinant protein manufacturing**

**Laura Segatori**, Rice University, USA

12:00 – 13:30

Lunch

**Workshops (4 concurrent workshops)**

Chairs: **Laura Palomares**, IBT UNAM, Mexico

**Anurag Khetan**, Bristol-Myers Squibb, USA

**Monday, November 2, 2020 (continued)**

- 13:30 – 14:00      **Workshop 1**  
**Advances and challenges with tech transfer, scale up and comparability**  
Chairs:    Diana Ritz, GSK, USA  
              Claudia Berdugo, Catalent, USA  
              Kelly Wiltberger, Biogen, USA
- 14:00 – 14:20      **Workshop 2**  
**Actionable 'omics in cell culture and bioprocessing: Best practices and opportunities**  
Chairs:    Henry Lin, Merck, USA  
              Paula Meleady, Dublin City University, Ireland  
              Nathan Lewis, University of California San Diego, USA
- 14:20 – 14:40      **Workshop 3**  
**What does process and product characterization and biosimilar development mean for process development of biologics?**  
Chairs:    Thomas Ryll, Immunogen, USA  
              Arti Narayanan, Genentech, USA  
              Jeff Yant, Amgen, USA
- 14:40 – 15:00      **Workshop 4**  
**Opportunities and challenges bringing cell and gene therapies to patients (and to market)**  
Chairs:    Andy Snowden, Kite, USA  
              Margarida Serra, IBET, Portugal  
              Liz Practico, Bluebird bio, USA
- 15:00 – 15:30      Coffee Break
- Session 2: Cell Line Development: Current State and Future Directions**  
Chairs:    Zhimei Du, Merck, USA  
              Mark Smales, University of Kent, United Kingdom
- 15:30 – 15:35      Session introduction
- 15:35 – 16:00      **What is in a phenotype?**  
Nicole Borth, BOKU University of Natural Resources and Applied Life Sciences, Austria
- 16:00 – 16:25      **Chromosome instability and engineering for CHO and newly established Chinese hamster-derived cell line**  
Takeshi Omasa, Osaka University, Japan
- 16:25 – 16:30      **Engineering of Chinese hamster ovary cell lipid metabolism results in an expanded ER and enhanced recombinant biotherapeutic protein production**  
James Budge, University of Kent, United Kingdom
- 16:30 – 16:55      **Enhancing CHO cell performance via high-throughput screening and genetic engineering**  
David Razafsky, MilliporeSigma, USA

**Monday, November 2, 2020 (continued)**

- 16:55 – 17:00      **Whole Genome CRISPR screening of CHO cells to improve bioproduction capabilities**  
Bruno Fievet, Horizon Discovery, UK
- 17:00 – 17:25      **Integrated CHO cell line technologies for drug discovery, clinical development, and commercialization**  
Gang Chen, Regeneron Pharmaceuticals, Inc., USA
- 17:30 – 18:00      Transition
- 18:00 – 19:30      Dinner
- 19:30 – 21:30      **Poster session (odd-numbered posters)**  
Chairs: Karthik Jayapal, Janssen, USA  
Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA  
Olivier Henry, Polytechnique Montreal, Canada  
Yao-Ming Huang, Eli Lilly & Co., USA

**Tuesday, November 3, 2020**

**Breakfast on own**

**Session 3: Analysis and Control of Cell Culture-based Manufacturing**

Chairs: Marcella Yu, Boehringer Ingelheim, USA

Sarika Mehra, IIT Bombay, India

- 08:00 – 08:05      Session Introduction
- 08:05 – 08:30      **Nested control and advanced sensing for robust mAb glycan quality**  
Anne Skaja Robinson, Carnegie Mellon University, USA
- 08:30 – 08:55      **Transforming molecule selection and process development through attribute focus and the deployment of high-performance computing tools**  
Neeraj J. Agrawal, Amgen, USA
- 08:55 – 09:20      **Loss of cell viability is tracked by decreased cytoplasmic conductivity**  
Michael Butler, NIBRT, Ireland
- 09:20 – 09:25      **Hybrid mechanistic-empirical modeling for biomanufacturing process optimization**  
Conor O'Brien, University of Minnesota, USA
- 09:25 – 09:50      **Utilizing a web-based empirical modeling application to optimize amino acid concentrations in chemically-defined CHO cell culture media**  
Taha Salim, Merck & Co., Inc., USA
- 09:50 – 10:20      Coffee Break
- 10:20 – 10:45      **Implementing PAT into manufacturing: Novel method to ensure pH comparability across sites and scales**  
Christian Klinger, Roche Diagnostics GmbH, Germany
- 10:45 – 11:10      **Multi-omics BTI-MODEL platform aids QBD and incorporates automated glycan analysis**  
Pauline M. Rudd, University College, Dublin, Ireland
- 11:10 – 11:35      **Debottlenecking mAb production by integrated systems biology approach of transcriptomics and genome-scale metabolic based metabolomics**  
Seongkyu Yoon, University of Massachusetts Lowell, USA
- 11:35 – 11:40      **Achieving active control of cell culture performance with the aid of machine learning techniques**  
John M. Schmitt, Lonza, USA
- 11:40 – 12:05      **Machine learning and advanced data analytics automating the exploitation of Raman spectroscopy: From micro-scale to large-scale operation**  
Stephen Goldrick, University College London, United Kingdom
- 12:05 – 13:30      Lunch

**Tuesday, November 3, 2020 (continued)**

**Session 4: CCE for Cell-based Therapies**

Chairs: Chris Ramsborg, Bristol-Myers Squibb, USA  
Krishnendu Roy, Georgia Institute of Technology, USA

- 13:30 – 13:35      Session Introduction
- 13:35 – 13:40      **Impact of heparin/collagen nanolayers on the expansion and immunophenotype of Mesenchymal stem cells**  
Said Cifuentes, University of Puerto Rico, USA
- 13:40 – 13:45      **Functionalized microcarriers for enhanced CAR T cell manufacturing**  
Nathan Dwarshuis, Georgia Institute of Technology, USA
- 13:45 – 14:10      **Development and implementation of an allogeneic cell therapy process platform**  
Andrew Snowden, Kite Pharma Inc., USA
- 14:10 – 14:35      **Addressing bioprocess challenges for regulatory T-cell manufacturing**  
James M. Piret, University of British Columbia, Canada
- 14:35 – 15:00      **Characterization of natural killer cell expansion through chronic stimulation with K562 cells for developing an off-the-shelf cellular therapy**  
Samira Azarin, University of Minnesota, USA
- 15:00 – 15:25      **Process development and manufacturing for hematopoietic stem cell gene therapies**  
Susan Abu-Absi, bluebird bio, USA
- 15:30 – 17:00      **Poster Session (even-numbered posters) / Coffee**  
Chairs: Karthik Jayapal, Janssen, USA  
Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA  
Olivier Henry, Polytechnique Montreal, Canada  
Yao-Ming Huang, Eli Lilly & Co., USA
- 17:00                Evening out with dinner at Old Tucson Studios

**Wednesday, November 4, 2020**

**Breakfast on own**

08:00 – 12:00      Networking time / Grab 'n Go lunches

12:00 – 13:30

**Workshops (4 concurrent workshops)**

Chairs: Laura Palomares, IBT UNAM, Mexico  
Anurag Khetan, Bristol-Myers Squibb, USA

**Workshop 5**

**Enable acceleration to the clinic and market**

Chairs: Nick Abu-Absi, Abbvie, USA  
Shailendra Singh, Merck, USA  
Ravali Raju, Pfizer, USA

**Workshop 6**

**Advances in cell engineering and alternate expression systems**

Chairs: Christina Alves, Biogen, USA  
Susan Sharfstein, SUNY Polytechnic Institute, USA  
Lasse Pedersen, Technical University of Denmark, Denmark

**Workshop 7**

**Industry 4.0: Big data, machine learning and artificial intelligence in cell culture**

Chairs: Seongkyu Yoon, University of Massachusetts, Lowell, USA  
Madhuresh Sumit, Pfizer, USA  
Kara Calhoun, Genentech, USA

**Workshop 8**

**Perfusion technologies: Challenges and opportunities**

Chairs: Leda Castilho, Federal University of Rio De Janeiro, Brazil  
Jason Walther, Sanofi, USA  
Sen Xu, Bristol-Myers Squibb Co., USA

13:45 – 14:30

**Martin Sinacore Award Lecture**

**Session 5: Continuing Challenges and Solutions in Biopharmaceutical Manufacturing: Scale-up, Scale-out, and Tech Transfer**

Chairs: Inn Yuk, Genentech, Inc., USA  
Raghu Shivappa, Takeda, USA

14:30 – 14:35

Session Introduction

14:35 – 15:00

**Ensuring successful manufacturing scale-up via a comprehensive development and process transfer approach**

Kelly Wiltberger, Biogen, USA

15:00 – 15:25

**Challenges of an accelerated technology transfer and representative cell culture case studies**

Jonathan Cacciatore, Merck & Co., Inc., USA

15:25 – 15:50

**Making large scale processes transparent – Unraveling the impact of shear forces for scale-up and transfer**

Thomas Wucherpfennig, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

**Wednesday, November 4, 2020 (continued)**

- 15:50 – 16:15      **Ensuring comparability of drug substance through targeted process variation and media fingerprinting**  
Kathryn Aron, Bristol-Myers Squibb, USA
- 16:15 – 16:20      **Characterization and improvement of shear related challenges in large-scale manufacturing TFF N-1 perfusion**  
Alex Vaca, Biogen, USA
- 16:20 – 16:50      Coffee Break
- 16:50 – 17:15      **Off-gas analysis to enhance process monitoring, transfer and control**  
Amy Nehring, Amgen, USA
- 17:15 – 17:40      **“Still or Sparkling?” - Scale-up and transfer of a process based on a particularly pCO<sub>2</sub> sensitive cell line**  
Sven Markert, Roche Diagnostics GmbH, Germany
- 17:40 – 18:05      **Understanding the impact of high gas entrance velocity on CHO cell culture processes to improve process scale up**  
Robin Luo, Boehringer Ingelheim Fremont Inc., USA
- 18:05 – 18:30      **Bioreactor controller modeling and metabolic flux analysis to ensure comparable biopharmaceutical processes during scale-up and intensification**  
Robert Balcarcel, Bayer U.S. LLC, USA
- 18:30 – 18:35      **Every patient, every time --- even for industry-neglected diseases**  
Matthew Croughan, Tahoe Biotechnology Institute, USA
- 18:35 – 20:00      Dinner
- 20:00 – 21:30      **Poster Session (odd-numbered posters) / Social Hour**  
Chairs: Karthik Jayapal, Janssen, USA  
Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA  
Olivier Henry, Polytechnique Montreal, Canada  
Yao-Ming Huang, Eli Lilly & Co., USA

**Thursday, November 5, 2020**

**Breakfast on own**

08:00 – 08:45

**Keynote 3**

**Human Gene Therapy – Principles, History, State of the Art, Challenges and Approaches**

**Guangping Gao**, Ph.D., Professor, Department of Microbiology and Physiological Systems; Director Gene Therapy Center & Viral Vector Core, University of Massachusetts Medical School

**Session 6: CCE for Gene therapy and emerging modalities**

Chairs: Scott Estes, Codiak Biosciences, USA

Jennifer Maynard, University of Texas-Austin, USA

08:45 – 08:50

Session Introduction

08:50 – 08:55

**Development of high cell density fed-batch culture for production of lentiviral vectors at high titer**

Chun Fang Shen, National Research Council of Canada, Canada

08:55 – 09:00

**The development and scale-up of an upstream process for manufacturing exosomes**

Joon Chong Yee, Codiak Bioscience, USA

09:00 – 09:25

**Intensified viral vaccine production: Towards a cell culture-based platform for perfusion mode cultivation**

Udo Reichl, MPI Magdeburg, Germany

09:25 – 09:50

**Process development for a red cell therapy: Producing a cell therapy without a nucleus**

Alan Gilbert, Rubius Therapeutics, USA

09:50 – 10:15

**Exosomes as delivery vehicles for RNA based therapeutics**

Kerstin Otte, University of Applied Sciences Biberach, Germany

10:15 – 10:45

Coffee Break

10:45 – 11:10

**Cell culture strategies to elevate recombinant adeno-associated virus production capacity in HEK293 cells**

Chia Chu, Pfizer, USA

11:10 – 11:35

**Dialing-in potency and high productivity for AAV production**

Peter Slade, Voyager Therapeutics, USA

11:35 – 12:00

**A novel AAV production process using suspension PCL cultivation**

Jenny Shupe, Biogen, USA

12:00 – 13:30

Lunch

**Thursday, November 5, 2020 (continued)**

**Session 7: Cell Culture for Integrated and Continuous Bioprocessing**

Chairs: Massimo Morbidelli, ETH Zurich, Switzerland  
Chetan T. Goudar, Amgen, USA

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|---------------|--|
| 13:30 – 13:35 | Session Introduction   |
| 13:35 – 13:40 | <b>Assessment of Ebri Breez biosystem microfluidic device as a scale down model for dynamic high-intensity, low-volume perfusion process (HILVOP)</b><br>Ana Maria Ovalle, Pfizer Inc., USA        |
| 13:40 – 13:45 | <b>Commercial scale N-1 perfusion: Opportunities and challenges,</b><br>Daniel Karst, Biogen, Switzerland  |
| 13:45 – 14:10 | <b>Marching toward implementation of an integrated continuous biomanufacturing process: Turning fun into reality</b><br>Marcella Yu, Boehringer Ingelheim Inc., USA                                |
| 14:10 – 14:35 | <b>Seed train intensification by smart high cell density cryopreservation and N-1 perfusion processes using specialized expansion media</b><br>Mona Bausch, Merck KGaA, Germany                    |
| 14:35 – 15:00 | <b>Characterization of steady state and non-steady state perfusion cultures for leveraging these two different perfusion platforms for biologics manufacturing</b><br>Jack Huang, Merck & Co., USA |
| 15:00 – 15:25 | <b>Development and implementation of the next generation intensified monoclonal antibody manufacturing process</b><br>Jianlin Xu, BMS, USA   |
| 15:30 – 16:00 | Coffee Break   |
| 16:00 – 17:00 | <b>CCE Award Lecture</b>   |
| 17:00 – 18:00 | Panel Discussion   |
| 18:00 – 18:30 | Break  |
| 18:30 – 19:30 | Reception  |
| 19:30 – 21:30 | Banquet  |

**Friday, November 6, 2020**

Departures