

Preliminary Program
(March 20, 2023)

Cell Culture Engineering XVIII

April 23-28, 2023

**Grand Fiesta Americana Coral Beach Hotel
Cancun, Mexico**

Conference Chairs

Chetan Goudar
Amgen, USA

Laura A. Palomares
UNAM, Mexico

Tongtong Wang
Genentech, USA



Engineering Conferences International
369 Lexington Avenue, 3rd Floor #389 - New York, NY 10017, USA
www.engconfintl.org – info@engconfintl.org

We would like to acknowledge the contributions from CCE XVII Chairs who built a strong program

Saturday, April 22, 2023

17:00 Early career preconference registration

Sunday, April 23, 2023

10:00 – 13:00 Preconference International Biomanufacturing omics workshop

12:30 – 17:30 Poster set-up

14:00 – 16:45 Conference Check-In

14:30 – 15:30 Early Career Preconference Flash talks (8 x 5-min talks)

15:30 – 16:15 Early Career Pre Conference Icebreaker/ Networking

16:15 – 16:45 Coffee break

16:45 – 17:00 Welcome remarks
ECI Liaison (Michael Betenbaugh, Johns Hopkins University, USA)
CCE Chairs

17:00 – 17:45 **Keynote 1**
Alison Moore, Allogene Therapeutics, USA
“Cell Culture Engineering” and what this means for the future of medicine

18:00 – 19:30 Dinner

19:30 – 21:30 **Poster Session (even-numbered posters)**
Chairs: **Karthik Jayapal, Merck & Co., USA**
Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA
Olivier Henry, Polytechnique Montreal, Canada
Yao-Ming Huang, Eli Lilly & Co., USA

We would like to acknowledge the contributions from CCE XVII Chairs who built a strong program

Monday, April 24, 2023

- 06:30 – 08:00 **Breakfast**
- 08:00 – 08:45 **Keynote 2**
Guangping Gao, University of Massachusetts Medical School, USA
Human gene therapy – Principles, history, state of the art, challenges and approaches
- Session 1: Multispecific Modalities: Commercialization Successes & Future Trends**
Chairs: **Inn Yuk, Genentech, USA**
Alan Dickson, University of Manchester, United Kingdom
- 08:45 – 08:50 **Session introduction**
- 08:50 – 09:10 **Invited Commercialization Experience**
Latonia Harris, Janssen R&D, Johnson & Johnson, USA
Insights into bispecific antibody development, characterization, and manufacture
- 09:10 – 09:30 **Invited Commercialization Experience**
Jessica Wu, Genentech, USA
Continuous improvement in bispecifics manufacturing: Advantages and disadvantages of 2-cell vs. 1-cell culture process
- 09:30 – 09:50 **Invited Process Experience**
Shawn Lawrence, Regeneron Pharmaceuticals, USA
Regeneron bispecific molecule structure begets platform production process compatibility
- 09:50 – 10:10 **Invited Process Experience**
Weichang Zhou, WuXi Biologics, China
Challenges and successes in developing and manufacturing multiple formats of bispecific antibodies
- 10:10 – 10:40 Coffee Break
- 10:40 – 10:55 **Protein engineering: Computing tools**
Neeraj Agrawal, Amgen, USA
Transforming molecule selection and process development through attribute focus and the deployment of high-performance computing tools
- 10:55 – 11:00 **Poster Talk: Vector/CLD Design**
Anett Ritter, Novartis Institutes for BioMedical Research, Switzerland
Fine-tuning of plasmid design and glycoengineering strategies to generate tailored CHO cell lines
- 11:00 – 11:05 **Poster Talk: Cocultivation**
Dawn Eriksen-Stapleton, Pfizer, USA
Co-culturing cell lines for efficient manufacture of multispecifics
- 11:05 – 11:10 **Poster Talk: Cellular Bottlenecks**
Tobias Jerabek, University of Applied Sciences Biberach, Germany
Analysis of production bottlenecks in BiTE molecules producing CHO Cells

We would like to acknowledge the contributions from CCE XVII Chairs who built a strong program

Monday, April 24, 2023 (continued)

11:10 – 11:25 **Platform Improvements from Systems Biology**
Johan Rockberg, KTH, Sweden
Cellular demands of secreted protein products – systems and synthetic biology improve quality and titer

11:25 – 11:40 **Cell-Free Platform Experience**
Marcella Yu, Sutro Biopharma, USA
Building one block at a time toward complex biologics using cell-free protein synthesis process

12:00 – 13:30 Lunch

13:30 - 15:00 Workshops (4 concurrent workshops)
Chairs: Margarida Serra, iBET, Portugal
Anurag Khetan, Bristol-Myers Squibb, USA

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

Workshop 3: Opportunities and Challenges to Bring Clinical and Commercial Cell and Gene Therapies to More Patients

Chairs: Andy Snowden, Janssen, USA
Sean Palecek, University of Wisconsin, USA
Mercedes Seguar, ElevateBio, USA

Workshop 4: Acceleration to the Clinic and Market in the Post-COVID Era

Chairs: Nick Abu-Absi, Abbvie, USA
Weichang Zhou, WuXi Biologics, China
Shailen Singh, Merck, USA

Workshop 5: Advances in Cell Engineering and Alternate Expression Systems

Chairs: Christina Alves, Takeda, USA
Susan Sharfstein, SUNY Polytechnic Institute, USA
Ana Coroadinha, iBET/ITQB-NOVA, Portugal

15:00 – 15:30 Coffee Break

Session 2: Cell Line Development: Current State and Future Directions

Chairs: **Zhimei Du, Landmark Bio, USA**
Mark Smales, University of Kent, United Kingdom
Jamey Young, Vanderbilt University, USA

15:30 – 15:35 Session Chair opening remarks: Zhimei Du and Jamey Young

15:35 – 15:55 **Gang Chen, Regeneron Pharmaceuticals, Inc., USA**
Cell line technologies for speed-to-clinic and commercial production of biologics

15:55 – 16:15 **Takeshi Omasa, Osaka University, Japan**
Newly-established Chinese hamster-derived cell line for protein production

We would like to acknowledge the contributions from CCE XVII Chairs who built a strong program

Monday, April 24, 2023 (continued)

- 16:15 – 16:35 **James Budge, University of Kent, United Kingdom**
Engineering of Chinese hamster ovary cell lipid metabolism results in an expanded ER and enhanced recombinant biotherapeutic protein production
- 16:35 – 16:55 **Meiping Chang, Merck Research Lab, USA**
Chromosomal instability drives convergent and divergent evolution toward advantageous inherited traits in mammalian CHO bioproduction lineages
- 16:55 – 17:15 **Nicole Borth, BOKU University and Austrian Center of Industrial Biotechnology, Austria**
What's in a Phenotype?
- 17:15 – 17:20 **Poster Talk, Kim Le, Upside Foods, USA**
Rebuilding CHO again and again: Development of a species agnostic modular cell line development platform for cultivated meat
- 17:20 – 18:00 Free time
- 18:00 – 19:30 Dinner
- 19:30 – 21:30 **Poster session (odd-numbered posters)**
Chairs: **Karthik Jayapal, Merck & Co., USA**
Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA
Olivier Henry, Polytechnique Montreal, Canada
Yao-Ming Huang, Eli Lilly & Co., USA

Tuesday, April 25, 2023

- 07:30 – 08:30 Optional breakfast conversation for diversity, equity, and inclusion
- 06:30 – 08:45 **Breakfast**
- Session 3: Systems and Synthetic Biology for Improved Cell Culture Performance**
Chairs: **Bhanu Mulukutla, Pfizer, USA**
Nicole Borth, BOKU University and Austrian Center of Industrial Biotechnology, Austria
- 08:45 – 08:50 Session introduction
- 08:50 – 09:10 **Jack Scarcelli, Pfizer Inc., USA**
Systems and synthetic biology approaches towards optimization of N-glycan sialylation
- 09:10 – 09:30 **Nathan Lewis, University of California, USA**
What does a cell need for efficient protein secretion: Deciphering, modeling, and augmenting the CHO machinery
- 09:30 – 09:50 **Ioscani Jiménez del Val, College Dublin, Ireland**
GalMAX: Model-inspired glycoengineering for biopharmaceutical quality assurance
- 09:50 – 10:10 **Wei-Shou Hu, University of Minnesota, USA**
Synthetic cell lines for recombinant AAV production
- 10:10 – 11:00 Coffee Break
- 11:00 – 11:20 **Laura Segatori, Rice University, USA**
Feedback-responsive cell factories for biomanufacturing
- 11:20 – 11:30 **Eleftherios Papoutsakis, University of Delaware, USA**
The microRNA landscape of the extracellular vesicles generated by Chinese hamster ovary cells under normal and stressed conditions
- 11:30 – 11:40 **Jamey Young, Vanderbilt University, USA**
Metabolic engineering of high-productivity CHO host lines for biomanufacturing
- 11:40 – 11:50 **Lars Nielsen, University of Queensland, Australia**
Biologics 4.0: Emergence of the CHO Biofoundry
- 11:50 – 12:00 **Veronique Chotteau, KTH, Sweden**
Transcriptomics guided mechanistic metabolic model for perfusion culture process
- 12:00 – 13:30 Lunch
- Session 4: Analysis and Control of Cell Culture-based Manufacturing**
Chairs: **Marcella Yu, Sutro Bio, USA**
Sarika Mehra, IIT Bombay, India
- 13:30 – 13:35 Session Introduction

We would like to acknowledge the contributions from CCE XVII Chairs who built a strong program

Tuesday, April 25, 2023 (continued)

- 13:35 – 13:55 **Christian Klinger, Roche, Germany**
Effective cell culture operations by implementing accurate, non-invasive determination of the critical process parameter pH in Roche's Drug Substance Network
- 13:55 – 14:15 **Dong-Yup Lee, Sungkyunkwan University, South Korea**
Real-time data-driven and multi-scale model-guided system for bioprocess digital twin platform
- 14:15 – 14:35 **Jianlin Xu, Bristol-Myers Squibb, USA**
Upstream control strategy development for afucosylated species in mAb biomanufacturing
- 14:35 – 14:55 **Shanta Boddapati, Seattle Genetics, USA**
Bioreactor scale induced alteration in cell metabolic state can impact amino acid misincorporations in recombinant proteins produced in CHO cells
- 14:55 – 15:15 **Stephen Goldrick, University College London, United Kingdom**
Machine learning and advanced data analytics automating the exploitation of Raman spectroscopy: from micro-scale to large-scale operation
- 15:15 – 15:35 **Anne Robinson, Carnegie Mellon University, USA**
Advanced control of glycosylation and titer in fed-batch monoclonal antibody production
- 15:35 – 15:40 **Poster Talk, Ryan Graham, Genentech, Inc., USA**
Achieving product quality targets while maintaining high titer in CHO cell culture processes
- 15:40 – 15:45 **Poster Talk, Cameron Harrington, Pfizer, USA**
Short chain fatty acids produced by CHO cells enhance their specific productivity in fed-batch cultures
- 15:45 – 17:00 **Poster Session (even-numbered posters) / Coffee**
Chairs: **Karthik Jayapal, Merck & Co., USA**
Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA
Olivier Henry, Polytechnique Montreal, Canada
Yao-Ming Huang, Eli Lilly & Co., USA

We would like to acknowledge the contributions from CCE XVII Chairs who built a strong program

Wednesday, April 26, 2023

06:30 – 08:00 **Breakfast**

08:00 – 12:00 Networking time

12:00 – 13:30 **Workshops (4 concurrent workshops)**
Chairs: Margarida Serra, iBET, Portugal
Anurag Khetan, Bristol-Myers Squibb, USA

Workshop 2: How Can We Leverage Learnings from Standard Biologics and Biosimilars to Develop and Characterize New Biologic and Cell/Gene Therapies?

Chairs: Arthi Narayanan, Genentech, USA
Octavio T. Ramirez, Universidad Nacional Autonoma de Mexico, Mexico
Yao-Ming Huang, Eli-Lilly, USA

Workshop 6: Industry 4.0: Big Data, Machine Learning and Artificial Intelligence in Cell Culture

Chairs: Seongkyu Yoon, University of Massachusetts, Lowell, USA
Madhuresh Sumit, Sanofi, USA
Ravali Raju, Amgen, USA

Workshop 7: Perfusion Technology: Challenges and Future Strategies

Chairs: Leda Castilho, Federal University of Rio de Janeiro, Brazil
Michael Borys, Bristol-Myers Squibb, USA
Veronique Chotteau, KTH Royal Institute of Technology, Sweden

Workshop 8: Actionable ‘omics in Cell Culture and Bioprocessing: Best Practices and Opportunities

Chairs: Nathan Lewis, University of California, San Diego, USA
Paula Meleady, Dublin City University, Ireland
Henry Lin, Sanofi, USA

13:45 – 14:30 **Martin Sinacore Award Lectures**
Pooja Jambunathan, Merck, USA

Accelerated process development and commercialization - Bringing life-saving drugs to market

Madhuresh Sumit, Pfizer, Inc., USA
TBD

14:30 – 15:30 Break

Session 5: CCE for Cell-based Therapies

Chairs: **Krishnendu Roy, Georgia Institute of Technology, USA**
John Moscariello, Bristol-Myers Squibb, USA

15:30 – 15:35 Session Introduction

15:35 – 15:55 **Madhusudan V. Peshwa, Tessera Therapeutics, USA**
Rapid, scalable, cost-effective process for generation of stably integrated chimeric antigen receptor (CAR) engineered T-cells by “Gene Writing”: An all RNA approach, without need for use of viral vectors or nucleases

We would like to acknowledge the contributions from CCE XVII Chairs who built a strong program

Wednesday, April 26, 2023 (continued)

- 15:55 – 16:15 **Stephen Balakirsky, Georgia Institute of Technology, USA**
AI-enabled biomanufacturing
- 16:15 – 16:35 **Ivie Aifuwa, Bristol-Myers Squibb, USA**
Adaptive T cell processing through integrated process analytical technologies
- 16:35 – 16:45 **Zhimei Du, Landmark Bio, USA**
Differential effects on natural killer cell production by membrane-bound cytokine stimulations
- 16:45 – 16:55 **Joseph Egan, University College London, United Kingdom**
A soft sensor of cell concentration in a perfusion bioreactor via a digital twin
- 16:55 – 17:05 **Margarida Serra, iBET, Portugal**
Advancing manufacture of hiPSC-derived hepatocytes with improved functionality: A nature-inspired protocol
- 17:05 – 17:15 **James Piret, University of British Columbia, Canada**
Process Analytical Utility of Raman Spectroscopy for Cell Therapy Manufacturing
- 17:15 – 17:25 **Susan Abu-Absi, 2seventy bio, USA**
Engineered T-cell therapy: State of the science
- 18:00 – 19:30 Dinner
- 19:30 – 21:30 **Poster session (odd-numbered posters)**
Chairs: **Karthik Jayapal, Merck & Co., USA**
Shawn Lawrence, Regeneron Pharmaceuticals, Inc., USA
Olivier Henry, Polytechnique Montreal, Canada
Yao-Ming Huang, Eli Lilly & Co., USA

Thursday, April 27, 2023

- 06:30 – 08:00 **Breakfast**
- 08:00 – 08:45 **Keynote 3 (Multispecifics: Title TBD)**
Ray Deshaies, Head of Global Research, Amgen
- Session 6: Production of Viral Vectors and Other Emerging Therapeutic Modalities**
Chairs: **Scott Estes, Codiak Biosciences, USA**
Paula Alves, iBET, Portugal
- 08:45 – 08:50 Session Introduction
- 08:50 – 09:10 **Jenny Shupe, Biogen, USA**
Advancing the productivity, robustness, and scalability of AAV production process by transient transfection in suspension cell culture
- 09:10 – 09:25 **David McNally, University of Massachusetts Chan Medical School, USA**
Advanced manufacturing platform for AAV-mediated gene therapeutic production
- 09:25 – 09:45 **Saurabh Sen, Sanofi, USA**
Development of a Subclonal host cell line for AAV production
- 09:45 – 09:50 **Poster Talk, Sandra Klausing, Sartorius, Germany**
On the AAVenue to success: Advances in technologies for AAV production
- 09:50 – 09:55 **Poster Talk, Jean-Simon Diallo, Virica Biotech, Canada**
Overcoming barriers in viral vector manufacturing: Small molecule targeting of antiviral defences
- 09:55 – 10:45 Coffee Break
- 10:45 – 11:05 **Ashley Baltes, Bristol-Myers Squibb, USA**
Development of a second-generation lentiviral vector to reduce COGM while meeting both vector and CAR T cell CQAs
- 11:05 – 11:25 **Kerstin Otte, University of Applied Sciences Biberach, Germany**
A hot new bioprocess strategy to improve small EV production
- 11:25 – 11:45 **James Wagner, Merck, USA**
Scalable, serum-free cell culture platform for improved production of diverse live virus and viral vector vaccine candidates
- 11:45 – 11:50 **Poster Talk, Ana Meliciano, iBET/ITQB-NOVA, Portugal**
Towards large-scale production of human-induced pluripotent stem cell-derived extracellular vesicles in stirred-tank bioreactors
- 11:50 – 11:55 **Poster Talk, Charlotte Piard, Codiak BioSciences, USA**
Making bionanoparticles at the 500L scale: The evolution of a perfusion cell culture to increase supply of exosomes
- 11:55 – 12:00 **Poster Talk, Lars Pelz, Max-Planck Institute Magdeburg, Germany**
Influenza A virus OP7 defective interfering particles: Cell culture-based production and antiviral efficacy in vivo

We would like to acknowledge the contributions from CCE XVII Chairs who built a strong program

Thursday, April 27, 2023 (continued)

- 12:00 – 13:30 Lunch
- Session 7: Cell Culture for Integrated and Continuous Bioprocessing**
Chairs: **Massimo Morbidelli, Politecnico di Milano, Italy**
Henry Lin, Sanofi, USA
Jason Walther, Sanofi, USA
- 13:30 – 13:35 Session Introduction
- 13:35 – 13:55 **Paul Gramlich, Amgen, USA**
Maintaining productivity over extended durations for perfusion processes
- 13:55 – 14:15 **María del Carme Pons Royo, BOKU University and Austrian Center of Industrial Biotechnology, Austria**
Scaleable microscale perfusion systems for yeast and mammalian cells to accelerate process development of bioproducts
- 14:15 – 14:35 **Susan Essilfie, Just Biotherapeutics, USA**
Implementation of high productivity perfusion cell culture at-scale in an integrated continuous manufacturing platform
- 14:35 – 14:55 **Ricardo Suárez-Heredia, Sanofi, USA**
On digital bioprocessing for manufacturing intelligence: Application of process analytical technology (PAT) and process data analytics (PDA) for upstream process development and intensification
- 14:55 – 15:05 **Mona Bausch, Merck KGaA, Germany**
Development of a highly concentrated perfusion medium supplement to decrease media demand leveraging a newly designed 250 mL single use perfusion bioreactor
- 15:05 – 15:15 **Jun Tian, WuXi Biologics, China**
Ultra-intensified intermittent-perfusion fed-batch (UIIPFB) process quadrupled productivity of a bispecific antibody
- 15:15 – 16:00 Coffee Break
- 16:00 – 17:00 **CCE Award Lecture**
Manuel Carrondo, IBET - Instituto de Biologia Experimental e Tecnológica, Portugal
Cell Culture and Social Engineering
- 17:00 – 18:30 Break
- 18:30 – 19:30 Reception
- 19:30 – 21:30 Banquet

Friday, April 28, 2023

- 06:30 Breakfast & Departures

We would like to acknowledge the contributions from CCE XVII Chairs who built a strong program