Program

Cell Culture Engineering XVI
An ECI Conference Series

May 6 – May 11, 2018
Saddlebrook Resort, Tampa, Florida, USA

Chairs
Anne Skaja Robinson
Tulane University, USA
Raghavan Venkat
MedImmune, USA
Gene Schaefer
Janssen, USA
Saddlebrook Resort
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Cell Culture Engineering Series History

Cell Culture Engineering I (1988)
Anthony Sinskey and Wei-Shou Hu
Palm Coast, Florida

Cell Culture Engineering II (1990)
Anthony Sinskey and Wei-Shou Hu
Santa Barbara, California

Cell Culture Engineering III (1992)
Michael Flickinger
Palm Coast, Florida

Cell Culture Engineering IV (1994)
Barry Buckland, Theodora Bibila, Wei-Shou Hu
San Diego, California

Cell Culture Engineering V (1996)
Barry Buckland, Theodora Bibila
San Diego, California

Cell Culture Engineering VI (1998)
Jeff Chalmers, Rob Arathoon
San Diego, California

Cell Culture Engineering VII (2000)
Bill Miller, Richard Schoenfeld
Santa Fe, New Mexico

Cell Culture Engineering VIII (2002)
Mike Betenbaugh and John Aunins
Snowmass, Colorado

Cell Culture Engineering IX (2004)
Octavio Ramirez and Lynne Krummen
Riviera Maya Cancun, Mexico

Cell Culture Engineering X (2006)
James Piret and Konstantin Konstantinov
Whistler, British Columbia, Canada

Cell Culture Engineering XI (2008)
Peter Gray and Carole Heath
Coolum, Queensland, Australia

Cell Culture Engineering XII (2010)
Kelvin Lee and Dana Andersen
Banff, Alberta, Canada
Cell Culture Engineering Series History
(continued)

Cell Culture Engineering XIII (2012)
Matt Croughan and Mark Leonard
Scottsdale, Arizona

Cell Culture Engineering XIV (2014)
Amine Kamen and Weichang Zhou
Quebec City, Quebec, Canada

Cell Culture Engineering XV (2016)
Robert Kiss, Sarah Harcum and Jeff Chalmers
La Quinta, California
CCE Steering Committee

Dana Andersen (Genentech, USA)
John Aunins (Seres Therapeutics, Inc., USA)
Mike Betenbaugh (Johns Hopkins University, USA)
Barry Buckland (BiologicB LLC, USA)
Jeff Chalmers (The Ohio State University, USA)
Matt Croughan (Keck Graduate Institute, USA)
Peter Gray (University of Queensland, Australia)
Sarah Harcum (Clemson University, USA)
Carole Heath (Amgen, USA)
Wei-Shou Hu (University of Minnesota, USA)
Amine Kamen (McGill University, Canada)
Robert Kiss (Sutro Biopharma, Inc.)
Konstantin Konstantinov (Codiak Biosciences, USA)
Lynne Krummen (Vir, USA)
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Mark Leonard (Pfizer, USA)
William Miller (Northwestern University, USA)
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Rashmi Kshirsagar (Biogen, USA)
Josh Leonard (Northwestern University, USA)
Amanda Lewis (Bristol-Myers Squibb, USA)
Gary Lye (University College London, UK)
Arthi Narayanan (Genentech, USA)
Eleftherios T Papoutsakis (University of Delaware, USA)
Devesh Radhakrishnan (BioMarin, USA)
Pranhitha Reddy (Gene to BLA, USA)
Organizing Committee (continued)

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Marcella Yu (Boehringer Ingelheim, USA)
Weichang Zhou (WuXi Biologics, China)
2018 Cell Culture Engineering Award Winner
William M. Miller
Northwestern University

Bill has served the cell culture community for 30+ years through pioneering contributions, leadership, and training. Common themes in his research are (1) cell plasticity and the importance of the culture environment for modulating cell responses and (2) taking inspiration from the in vivo environment to develop more effective culture systems for cell-based therapies and tissue engineering. Bill’s most significant contributions include:

- **Biotherapeutic protein production**: Bill’s PhD and independent research played a leading role in exploring environmental effects on cell growth, metabolism, and protein production, and helped provide the foundation for efficient biotherapeutic protein production. His papers on dilution rate, pH, and the levels of nutrients and metabolic byproducts have been highly cited and generated substantial interest in the biotechnology industry. Subsequent research elucidated the mechanisms responsible for cell inhibition by elevated pCO2.

- **Blood stem cells and megakaryocytes**: Bill and collaborator Terry Papoutsakis were the first to show that low pO2 greatly enhanced stem and progenitor cell expansion, which has since been reported for a wide variety of stem cells. They developed mathematical models of the bone marrow O2 distribution and confirmed that stem and primitive progenitor cells likely reside at low pO2 in vivo. Bill’s team discovered that differentiation of megakaryocytic and erythroid cells, which must reach the bone marrow sinuses before they fully mature into non-motile platelets and red blood cells, is greatly enhanced at higher pO2 and pH. These findings facilitated development of an efficient multi-stage culture process for megakaryocytic cells and platelets.

- **Bioreactors for blood cells and tissue engineering**: Bill and collaborators were among the first to develop bioreactors for blood stem and progenitor cells. They demonstrated the benefits of continuous perfusion for progenitor cell expansion, and showed that blood cells could be more effectively cultured in controlled, stirred-tank suspension bioreactors than in static flasks. More recently, Bill’s team used computational fluid dynamics to design a uniform-shear-rate microbioreactor to study platelet production, and developed well-characterized and controlled bioreactors to support renal cell expansion and differentiation in decellularized kidney scaffolds.

- **Mentorship and Service**: Bill has directed Northwestern’s MS in Biotechnology Program for 10 years, directed the NIH Predoctoral Biotechnology Training Program since 2014, and co-directed a postdoctoral NIH training program at the intersection of engineering/data science and pediatrics since 2015. He has trained 39 PhD students, 7 postdoctoral fellows, and many MS and undergraduate students. His former trainees work and play leadership roles in a wide range of (bio)pharmaceutical and biotechnology companies. He has also been an active member of the cell culture engineering community, having chaired CCE VII with Richard Schoenfeld in Santa Fe, NM and the Scale-up and Manufacturing of Cell-Based Therapies V conference with Tom Brieva.

Amanda Lewis is a Senior Engineer in Manufacturing Sciences & Technology at Bristol-Myers Squibb, where she leads a team of scientists and engineers responsible for supporting new and existing commercial biologics processes. She first joined BMS in 2013 in Biologics Development, and since then has held positions with increasing levels of responsibility. In her time at BMS, she has developed expertise in ‘Omics tools for monitoring and characterization of biologics processes, and has led several studies using metabolomics and transcriptomics to increase understanding and control of product glycosylation. She currently leads a cross-functional and cross-site initiative to integrate metabolomics testing into commercial programs to increase process understanding and robustness. She also leads a white paper exercise to understand key relationships between critical quality attributes and process control from an end to end biologics design, development, and commercialization perspective. She received her B.S. from MIT in 2008, and her PhD from the University of Texas at Austin in 2013, both in Chemical Engineering.

Amanda continues to engage in the broader scientific community. She has co-authored 18 peer-reviewed publications, including 7 since joining BMS, and presented her work at 7 scientific conferences in the past 5 years. She also serves as a guest editor for Current Opinion in Biotechnology's Pharmaceutical Technology issue, and was recently invited to serve on the scientific advisory board for a PhD training program in Systems Biology.

Amanda has consistently demonstrated an interest in mentorship and STEM education. Since 2011, she serves as an alumni interviewer for MIT, volunteering her free time to meet with high school students to answer questions about MIT and share her experience as an alumna. She serves on the BMS University Relations team where she has championed a new initiative to partner with faculty across the country and build relationships with schools outside of the Northeast region. She also developed and led a program called “BMS Women in ChemE Exploration Day”. This annual event brings female chemical engineering undergraduate students from neighboring universities on-site for a day to learn about careers in BioPharma. The program is intended to inspire more female engineering talent to consider long term careers in the Bioprocessing field.

Previous winners of this award are Colin Clarke (Dublin City University, Ireland), Corinne Hoesli (McGill University, Canada), and Huong Le (Amgen).
Welcome from the CCE XVI Chairs

Welcome everyone to Saddlebrook, the legendary resort in Tampa, FL, for the 16th Cell Culture Engineering (CCE) conference! As we celebrate the 30th anniversary of our meeting it is exciting that our meeting continues to be the premiere cell culture engineering conference and continues to shape the direction of cell culture technologies and growth of the biotechnology industry. Throughout this time, the CCE series has also been the main forum where industry and academia meet to assess the science and technology progress in the field and to guide trends and establish good practices.

With over 400 participants from 24 countries on 5 continents, this year’s meeting is certainly one of the largest ECI conferences ever, and one of the most diverse to date involving many students, academics, government, and industry representatives to invest in the future and sustain the growth of the cell culture engineering industry. We will have the largest number of academics and students ever to attend the meeting and this is made possible by the generous sponsorship from our industry partners. To welcome new members of our community and to increase interactions with our community early in their career, whether in academia or industry, we are introducing a new opening segment to the conference on Sunday afternoon. This opening segment will include short presentations followed by a networking session. The conference program includes more than 50 oral presentations, four keynote addresses and two award lectures. In addition, we have eight thematic workshops and ~ 200 posters. As has been the tradition and a key success factor of this conference series, a significant amount of time has been allocated to poster sessions. You are invited and strongly encouraged to take full advantage of this opportunity to explore and discuss the large body of interesting and excellent work that will be presented in these sessions.

Cell culture technologies continue to fuel the growth of biologics based medicines and 2017 was a banner year with more than 15 new products being approved in the US. Last year was particularly significant, as our industry also contributed to two new classes of medicines, being hailed as “cures”. The US FDA approved two medicines in the field of adoptive cell therapy and another in gene therapy that will no doubt spur significant new innovation in the field of cell culture technologies. In addition, five biosimilars were approved and the technological innovation needed to increase global access for our life changing medicines is more urgent than ever. In 2017 we also saw cancer patients beginning to realize the true potential of immunotherapies and the regulators are challenging the biotechnology industry to speed up the development of these life-changing medicines. In addition, medicines with novel modalities and formats are continuing to advance through clinical development and it is clear that current mammalian cell technologies need to be adapted and new discoveries are needed to enable successful commercialization of these medicines. With this in mind, we’ve put together a program that will showcase new directions, challenges, and successes in the cell culture engineering arena, as shared by leading academic and industrial experts. We have introduced a new oral session, “Towards other cell lines and systems – Opportunities and Challenges Beyond CHO” that will highlight advances that could prove transformative for mammalian cell culture. Additionally, we have introduced a new session focused on cell and gene therapies, that will highlight the opportunities for cell culture engineers in this emerging field. We will also continue with the oral session on “Current Concerns and Regulatory Strategies”, with which we aim to highlight the most current challenges facing our community, be they derived from accelerated programs, the entry of biosimilars, or novel therapies. We have also introduced a workshop session that will challenge cell culture engineers to innovate to increase global access of biologics. Finally, as a celebration of 30th Anniversary of Cell Culture Engineering conference, we are honored to have Wei-Shou Hu, the chair of CCE I and II, teaming up with Weichang Zhou, the chair of CCE XIV, to host a plenary session titled “30 years of Cell Culture Engineering”. We strongly encourage each one of you to engage in the
dialogue that is enabled by this conference venue, sharing your thoughts and expertise with others as we collectively shape the future of cell culture engineering.

We also invite you to enjoy the warmth of the Tampa area and the Saddlebrook resort, especially those of you that are waiting for winter to end in 2018. The resort is located on 480 acres of rolling terrain surrounded by lagoons and cypress trees. Saddlebrook was purposely planned as a car-free “walking village” ensuring guests can easily walk throughout the entire resort. The resort’s 540 suites showcase an inviting rich tropical design and are clustered around nine serene courtyards complete with gardens, stone benches, stone paver walkways, and native lush Florida landscaping. In listening to the feedback from prior conferences, we have arranged the schedule to provide you with free time on Wednesday morning, and we hope you will take advantage of the many opportunities at the resort that include two Arnold Palmer signature golf courses and a championship tennis complex that features 45 courts including four Grand Slam surfaces. The Sports Village features two adjacent fitness centers, one sand and two grass volleyball courts, a regulation-size basketball court, and three swimming pools including the Superpool, a half-million gallon free-form pool. We look forward to having you all at a memorable gala dinner where we will recognize the next winner of the Cell Culture Engineering award, recognize some of the outstanding posters presented here, learn of the chairs for the next CCE to be held in 2020, and enjoy our last opportunity together to network and enjoy the camaraderie of our incredible cell culture community.

We would like to thank all the oral session chairs, workshop program and session chairs, and poster session chairs, all of whom have worked with remarkable dedication to put together a balanced and high-quality program. And, once again, thanks to the generous contributions from our corporate sponsors for enabling our outstanding academic attendance.

We would also like to convey to our cell culture community a message of regret at not having been able to accept many colleagues from Academia and Industry who were interested in participating in this event. Clearly, this conference continues to be in high demand. But, the implicit working principle of keeping the conference with a size of participants that would maximize interactions among scientists and engineers while still allowing efficient cross-fertilization between different sectors makes it difficult to accommodate all requests to attend.

Finally, special thanks to Barbara Hickemell and her dedicated team at ECI, particularly Kathy Chan, Kevin Korpics, and Tressa D’Ottavio for their tireless help and enormous assistance with the logistics and details. Certainly, many of you received personalized emails from Kathy in managing the invitation and registration process. We hope that this conference will live up to the high standard that has been set for the CCE series by preceding Chairs. We also want to thank the many student volunteers, and Saddlebrook resort staff, for helping make this meeting a success.

Once again, welcome to Saddlebrook and the beautiful Tampa Bay area, and a warm welcome to Cell Culture Engineering XVI. We look forward to meeting each of you personally.

Anne Skaja Robinson, Gene Schaefer, and Raghavan Venkat
Chairs, Cell Culture Engineering XVI
Conference Sponsors

The organizers wish to express their gratitude to the following companies who, through their generosity, have helped to make this conference possible.

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Visit Tampa Bay
Program Schedule and Posters

Cell Culture Engineering XVI

An ECI Conference Series

May 6 – May 11, 2018

Saddlebrook Resort, Tampa, Florida, USA
**Room locations and notes**

- General Sessions will be held in the Royal Palm East, Center, West 1-3.
- Poster Sessions will be in the Grand Pavilion. All posters will remain mounted for the entire conference. Authors of even-numbered posters are asked to stay with their presentations on Sunday and Tuesday evenings, and authors of odd-numbered posters are asked to stay with their presentations on Monday and Wednesday evenings. Posters must be taken down no later than 9:00 am on Thursday morning.
- The locations for workshops are listed in the program.
- All breakfasts and lunches will be in the Commons and Pegasus Ballroom.
- Dinner locations are listed in the program.
- Coffee breaks will be in the Royal Palm Foyer.
- The ECI office is in Boardroom C.
- Boardroom D is available for small *ad hoc* meetings during the week. Please see ECI staff if you would like to schedule a meeting.
- Audio, still photo and video recording by any device (e.g., cameras, cell phones, laptops, PDAs, watches) is strictly prohibited during the technical sessions, unless the author and ECI have granted prior permission.
- Speakers – Please have your presentation loaded onto the conference computer prior to the session start (preferably the day before).
- Speakers – Please leave discussion time as previously directed by your session chair.
- Please do not smoke at any conference functions.
- Turn your mobile telephones to vibrate or off during technical sessions.
- Please write your name on your program so that it can be returned to you if lost or misplaced.
- After the conference, ECI will send an updated participant list to all participants. Please check your listing now and if it needs updating, you may correct it at any time by logging into your ECI account.
- Emergency Contact Information: Because of privacy concerns, ECI does not collect or maintain emergency contact information for conference participants. If you would like to have this information available in case of emergency, please use the reverse side of your name badge.
Sunday, May 6, 2018

12:30 – 17:30 Conference Registration (Royal Palm Foyer)

15:00 – 15:15 **Opening Remarks**
Anne Skaja Robinson, Tulane University, USA
Raghavan Venkat, MedImmune, USA
Gene Schaefer, Janssen, USA

**Session 1: Views from the Younger Generation (and the Young at Heart)**
Session Chairs: Neil Templeton, Merck & Co., Inc., USA
Josh Leonard, Northwestern University, USA
Derrick Scott, Delaware State University, USA

15:15 – 15:20 **Introduction**
Neil Templeton, Merck & Co., Inc., USA
Josh Leonard, Northwestern University, USA
Derrick Scott, Delaware State University, USA

15:20 – 16:50 Short Poster Highlights

16:50 – 17:30 Break and Networking time

17:30 – 18:15 **Keynote**
The human protein atlas: Implications for human biology, drug development, and precision medicine
Mathias Uhlén, KTH Royal Institute of Technology and Karolinska Institute, Sweden

18:30 – 20:30 Dinner (Key West Buffet in Commons Area)

20:30 – 22:30 **Poster Session** and Reception (*sponsored by MilliporeSigma*)
(Authors of even-numbered posters are asked to stay with their posters)

Poster Chairs:
Anthony Grippe, Merck & Co., Inc., USA
Weiwei Hu, Celgene, USA
Devesh Radhakrishnan, BioMarin, USA
Nicholas Sandoval, Tulane University, USA
Monday, May 7, 2018

06:30 – 08:00  Breakfast
Organizing Committee Breakfast Meeting

08:00 – 08:10  Opening Remarks
Anne Skaja Robinson, Tulane University, USA
Raghavan Venkat, MedImmune, USA
Gene Schaefer, Janssen, USA

Session 2: Towards Other Cell Lines and Systems: Opportunities and Challenges Beyond CHO (sponsored by Lonza)
Session Chairs: Véronique Chotteau, KTH Royal Institute of Technology, Sweden
Rashmi Kshirsagar, Biogen, USA

08:20 – 08:45  Moving Beyond CHO: Alternative host systems may be the future of biotherapeutics
Christina Alves, Biogen, USA

08:45 – 09:10  Insect cell platforms for production of pseudo-typed VLPs for drug and vaccine development
Antonio Roldao, iBET - Instituto de Biologia Experimental e Tecnológica, Portugal

09:10 – 09:35  Production of biopharmaceuticals in an intensified perfusion process of HEK 293 cells
Johan Rockberg, KTH Royal Institute of Technology, Sweden

09:35 – 10:00  Beyond CHO cells: Cell-free protein synthesis for biotherapeutics
Bob Kiss, Sutro Biopharma, USA

10:00 – 10:30 Coffee Break

Session 3: Impact of Novel Gene Editing Approaches to Engineering and Developing Cell Lines (sponsored by Genentech)
Session Chairs: Kris Chan, Michigan State University, USA
Karin Anderson, Pfizer, USA

10:40 – 11:05  Engineering CHO cells for the production of "Hard-To-Produce" proteins
Bjørn Voldborg, Technical University of Denmark, Denmark

11:05 – 11:30  CRISPR/Cas9 mediated knockout of microRNAs for precise cell engineering
Kerstin Otte, University of Applied Sciences Biberach, Germany

11:30 – 11:55  miR-CATCH identifies biologically active miRNA regulators of the pro-survival gene XIAP, in Chinese hamster ovary cells
Paul Kelly, National Institute for Bioprocessing Research and Training(NIBRT), Ireland

11:55 – 12:20 Glycoengineering of CHO cells for production of recombinant therapeutics with enhanced efficacy
Zhiwei Song, A*STAR Bioprocessing Technology Institute, Singapore
Monday, May 7, 2018 (continued)

12:20 – 12:45
Elimination of the “Essential” Warburg effect in CHO cells through a multiplex genome engineering strategy
Nate Lewis, University of California, San Diego, USA

12:45 – 14:00
Lunch

14:00 – 15:30
Workshops (Four concurrent)

Increasing Speed to the Clinic and Market B (Lagoon Pavilion)
(Sponsored by Amgen and Bristol-Myers Squibb)
Facilitators: Kevin Smith (Janssen R&D), Matt Croughan (Keck Graduate Institute), Inn Yuk (Genentech)

Advances and Challenges with Tech Transfer, Scale-up, and Comparability (Pegasus South)
(Sponsored by Celgene, GE Healthcare and Novo Nordisk)
Facilitators: Anurag Khetan (BMS), Kara Calhoun (Genentech)

Opportunities and challenges of adopting decades of cell culture knowledge for cell and gene therapy development (Royal Palm East 1-3)
(Sponsored by BioMarin, Gilead Sciences and Irvine Scientific)
Facilitators: Chapman Wright (Biogen), Amine Kamen (McGill University), John Piercvey (bluebird bio)

How can interactions within the ‘biomanufacturing ecosystem’ deliver value? (Pegasus Ballroom East)
(Sponsored by Janssen R&D and NIIMBL)
Facilitators: Tim Charlebois (Pfizer), Mike Betenbaugh (Johns Hopkins University)

15:30 – 16:00
Coffee Break

Session 4: Regulatory Strategies and Concerns in Current and Emerging Therapies
Session Chairs: Chris Frye, Eli Lilly, USA
Bill Bentley, University of Maryland, USA
Pranhitha Reddy, Gene-to-BLA, USA

16:05– 16:30
Limitations of subcloning as a tool to characterize homogeneity of a cell population
Jennitte Stevens, Amgen, USA

16:30 – 16:55
Registration enabling campaign for accelerated development: A PPQ strategy with minimal early investments to enable fast to market development for a promising monoclonal antibody
Jessica Wuu, Genentech, USA

16:55 – 17:20
Derivation of process control strategy for biosimilar: Is it different from the way a control strategy is derived for a novel biologic?
Dinesh Baskar, Biocon Research Limited, India

17:20 – 17:45
Confronting the Analytical Challenges of Chimeric Antigen Receptor T Cell
Heidi Zhang, Juno Therapeutics, USA
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>17:45 – 18:30</td>
<td><strong>Cell Culture Engineering Award Lecture</strong>&lt;br&gt;<code>Large scale production and characterization of exosomes</code>&lt;br&gt;Konstantin Konstantinov, Codiaq BioSciences, USA</td>
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<tr>
<td>18:30 – 20:30</td>
<td>Dinner (18th Fairway of the Saddlebrook Golf Course)</td>
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<tr>
<td>20:30 – 22:30</td>
<td><strong>Poster Session</strong> and Reception <em>(sponsored by Roche and Solentim)</em>&lt;br&gt;(Authors of odd-numbered posters are asked to stay with their posters)*</td>
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Tuesday, May 8, 2018

06:30 – 08:00  Breakfast
Organizing Committee Breakfast Meeting

08:00 – 08:05  Opening Remarks
Anne Skaja Robinson, Tulane University, USA
Raghavan Venkat, MedImmune, USA
Gene Schaefer, Janssen, USA

08:05 – 08:50  Keynote
Cell Culture Bioprocess Learnings: Past successes and future challenges
Günter Jagschies, GE Healthcare Life Sciences, Germany

Session 5: Pushing the Limits on Process Intensification: 10 g/L and Beyond
Session Chairs: Greg Hiller, Pfizer, USA
Marcella Yu, Boehringer Ingelheim, USA

09:00 – 09:30  Intensification of a multi-product perfusion platform – managing growth characteristics at high cell density for maximized volumetric productivity
Shawn Barrett, Sanofi, USA

09:30 – 10:00  Evolution of TFF-based perfusion: A path towards non product sieving and direct chromatography integration
Nuno D. S. Pinto, Merck & Co., Inc., USA

10:00 – 10:30  Coffee Break

10:30 – 11:00  Development towards a high-titer fed-batch CHO platform process yielding product titers > 10 g/L
Laurel Zhang, Genentech, USA

11:00 – 11:30  Development of a novel automated perfusion mini-bioreactor ambr® 250 perfusion
Barney Zoro, Sartorius, UK

11:30 – 12:00  Intensified cell culture using a linked bioreactor system
Matthew Gagnon, Pfizer, USA

12:00 – 13:30  Lunch
Tuesday, May 8, 2018 (continued)

13:30 – 15:00 Workshops (Four concurrent)

**Increasing Global Access to Biotherapeutics: What Role Does Upstream Play?**
(Lagoon Pavilion)
*(Sponsored by Boehringer Ingelheim, MedImmune and Shire)*
Facilitators: Brian Kelley (Vir), Jeff McGrew (Just Biotherapeutics)

**Advances in Cell Line Engineering and Protein Expression Strategies**
(Pegasus South)
*(Sponsored by Eli Lilly and Company and Merck and Co., Inc.)*
Facilitators: Steven Lang (Genentech), Diane Hatton (MedImmune)

**Applications of ‘Omics Tools in Cell Culture**
(Royal Palm East 1-3)
*(Sponsored by AbbVie and Biogen)*
Facilitators: Mike Laird (Genentech), Nate Lewis (University of California, San Diego), Bhanu Mulukutla (Pfizer)

**PAT Implementation: Key Challenges and Opportunities**
(Pegasus Ballroom East)
*(Sponsored by Eppendorf AG, GlaxoSmithKline and Sartorius Stedim Biotech)*
Facilitators: Kelly Wiltberger (Biogen), Stephen Goldrick (University College London)

15:00 – 15:30 Coffee Break

15:30 – 16:15 **Keynote**
**CAR T Cell Therapy: Fifteen years of academic driving**
Isabelle Rivière, Memorial Sloan Kettering Cancer Center, USA

Session 6 - Innovation in Cell and Gene Therapies
Session Chairs: Greg Russotti, Celgene Corporation, USA
Eleftherios T Papoutsakis, University of Delaware, USA

16:25 – 16:50 **Engineered CAR T cell therapy for solid tumors**
Juan F Vera, Center for Cell and Gene Therapy, Baylor College of Medicine, Texas Children’s Hospital, USA

16:50 – 17:15 **iPSC-derived neurospheroids recapitulate development and pathological signatures of human brain microenvironment**
Catarina Brito, iBET - Instituto de Biologia Experimental e Tecnológica, Portugal

17:15 – 17:40 **Biomanufacturing of platelet-like cells and cell microparticles for cell therapy applications**
Eleftherios T Papoutsakis, University of Delaware, USA

17:40 – 18:05 **CAR T manufacturing: process modifications for a transformational autologous product on a rapid path to licensure**
Thomas Brieva, Celgene, USA

18:05 – 18:30 **Development of a large scale GMP compliant suspension cell culture system for the manufacturing of allogenic Exosome-based biotherapeutics**
Scott Estes, Codiak BioSciences, USA

18:30 – 20:30 Dinner on your own
Tuesday, May 8, 2018 (continued)

20:30 – 22:30 **Poster Session** and Reception (*sponsored by Wuxi Biologics*)
(Authors of even-numbered posters are asked to stay with their posters)
Wednesday, May 9, 2018

06:30 – 08:00  Breakfast

11:00 – 12:00  Grab 'n Go lunches (in Foyer)

08:00 – 12:30  Networking Time

Session 7 - Process Scale Up/Down, Characterization and Control Strategy

**Definition** *(sponsored by Kerry)*

Session Chairs: Shailen Singh, Merck and Co., Inc., USA
Gary Lye, University College London, UK

12:35 – 13:00
Probing lactate metabolism variations in large-scale bioreactors
Sen Xu, Merck and Co., Inc., USA

13:00 – 13:25
Medium development strategies and scale down models for a high density high productivity cell line
Amy Johnson, Regeneron, USA

13:25 – 13:50
Process scale up and characterization of an intensified perfusion process
Jiuyi Lu, Sanofi, USA

13:50 – 14:15
Leveraging a technical partnership to deliver high titer biologics manufacturing
Haofan (Eric) Peng, Biogen, USA

14:15 – 14:40
Efficient technology transfers to increase agility, flexibility, and productivity
Kara Calhoun, Genentech, USA

14:40 – 15:05
Towards advanced understanding of scale-up: From computational fluid dynamics to systems biotechnology approaches
Jochen Schaub, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

15:05 – 15:45
**Martin Sinacore Award Lecture**
Understanding and improving cell culture processes through omics technologies
Amanda Lewis, Bristol-Myers Squibb, USA

15:45 – 16:15  Coffee Break

Session 8: Computational Strategies to Enhance Bioprocess Performance

Session Chairs: Amanda Lewis, Bristol-Myers Squibb, USA
Colin Clarke, National Institute for Bioprocessing Research and Training (NIBRT), Ireland

16:25 – 16:50
Application of -omics knowledge yields enhanced bioprocess performance
Rashmi Kshirsagar, Biogen, USA

16:50 – 17:15
Multivariate data analysis enabling improved clone selection
Stephen Goldrick, University College London/MedImmune, UK

17:15 – 17:40
Quantifying the partition of metabolic resources between cellular and recombinant protein glycosylation in GS-CHO cells
Ioscani Jimenez del Val, University College Dublin, Ireland
Wednesday, May 9, 2018 (continued)

17:40 – 18:05  More accurate process understanding from process characterization studies using Monte Carlo simulation, regularized regression, and classification models  
Cary Opel, Gilead Sciences, USA

18:05 – 18:30  Enhancing CHO process understanding from CHO manufacturing process data  
Tom Mistretta, Amgen, USA

18:30 – 18:55  Gaussian mixture models and machine learning predict megakaryocytic growth and differentiation potential \textit{ex vivo}  
William M. Miller, Northwestern University, USA

19:00 – 20:30  Dinner (Poolside A)

20:30 – 22:30  Poster Session and Reception  
(Authors of odd-numbered posters are asked to stay with their posters)
Thursday, May 10, 2018

06:30 – 08:00  Breakfast
Steering Committee Breakfast Meeting

08:00 – 08:05  Opening Remarks
Anne Skaja Robinson, Tulane University, USA
Raghavan Venkat, MedImmune, USA
Gene Schaefer, Janssen, USA

Session 9: Advanced Cell Culture Processes with an Emphasis on New Analytical and Computational Technology
Session Chairs: Arthi Narayanan, Genentech, USA
Cleo Kontoravdi, Imperial College London, UK

08:20 – 08:45  Automated and enhanced clone screening using a fully automated microtiter plate-based system for suspension cell culture
Sven Markert, Roche Diagnostics GmbH, Germany

08:45 – 09:10  Systems biology approach in the development of chemically-defined media for production of protein therapeutics in Chinese hamster ovary cells
Wai Lam Ling, Merck and Co., Inc., USA

09:10 – 09:35  Feedback control of lactate using Raman spectroscopy
Peter Slade, Pfizer, USA

09:35 – 10:05  Coffee Break

10:05 – 10:30  An energy-based modelling tool for culture medium design and biomanufacturing optimization
Athanasios Mantalaris, Imperial College London, UK

10:30 – 10:55  Novel modeling methodology to predict product quality and cell culture performance in fed-batch and perfusion cultures
Bassem Ben Yahia, UCB Pharma S.A., Belgium

10:55 – 11:45  Keynote
From bioreactors for protein therapeutic production to bioreactors for testing efficacy and safety of protein therapeutics
Linda Griffith, Massachusetts Institute of Technology, USA

11:45 – 13:15  Lunch

Session 10: Advances In Cell Culture Control of Product Quality Attributes
(sponsored by Regeneron Pharmaceuticals, Inc.)
Session Chairs: Martin Gawlitzek, Genentech, USA
Seongkyu Yoon, University of Massachusetts, Lowell, USA

13:20 – 13:45  Tailoring antibody glycosylation via integrating genome and protein engineering to generate preferred glycoforms on the Fc region
Mike Betenbaugh, Johns Hopkins University, USA
Thursday, May 10, 2018 (continued)

13:45 – 14:05  **Product quality control strategy development for non-mAb complex modalities by using combinatorial cell engineering and OMICS screening tools**  
Zhimei Du, Merck and Co., Inc., USA

14:05 – 14:25  **Controlling tryptophan oxidation through medium/feed modifications and potential MOA unveiled by transcriptomics analysis**  
Luhong He, Eli Lilly, USA

14:25 – 14:45  **Online control of cell culture redox potential prevents antibody reduction**  
Michael Handlogten, MedImmune, USA

14:45 – 15:05  **Identification of copper as a cell culture media component causing metabolite depletion and product sequence variants**  
Brian Mickus, Gilead Sciences, USA

15:05 – 15:30  **A synthetic biology based cell line engineering pipeline**  
Wei-Shou Hu, University of Minnesota, USA

15:30 – 16:00  Break

**Session 11: 30 Years of Cell Culture Engineering**  
Session Chairs: Weichang Zhou, WuXi Biologics, China  
Wei-Shou Hu, University of Minnesota, USA

16:15 – 16:40  **Engineering stem cell fate**  
Peter Zandstra, University of British Columbia, Canada

16:40 – 17:05  **Future challenges in biologics cell culture engineering**  
Mike Laird, Genentech, Inc., USA

17:05 – 17:30  **Ignorant empiricism in cell culture engineering: 30 years of expensive lessons**  
Matt Croughan, Keck Graduate Institute, USA

17:30 – 18:30  Panel Discussion

18:30 – 19:30  Reception

19:30 – 21:00  **Banquet (Pegasus Ballroom)**  
(sponsored by Genentech)
Friday, May 11, 2018

06:30 – 10:00 Networking Breakfast and Departure
Poster Presentations

**Clonality and Stability**

1. **Limitations of subcloning as a tool to characterize homogeneity of a cell population**  
Hedieh Barkhordarian, Amgen Inc., USA

2. **Interrogating cell culture populations for the selection of production cell lines using microfluidic culturing, single cell analysis, and predictive modelling**  
Kim Le, Amgen Inc., USA

3. **Rethinking clonality using modeling approaches**  
Chun Chen, Amgen Inc., USA

4. **Tools and methods for providing assurance of clonality for legacy cell lines**  
Paul Wu, Bayer HealthCare, USA

5. **Variation in karyotype and chromosome numbers in CHO cell lines and subclones**  
Nicole Borth, BOKU University, Austrian Center of Industrial Biotechnology, Austria

6. **Genomic understanding of clonal variation in recombinant CHO cells**  
Gyun Min Lee, KAIST, South Korea

7. **Characterisation of Chinese Hamster Ovary (CHO) cells at the single cell level**  
Eva Pekle, MedImmune, United Kingdom

8. **Population dynamics in cloned CHO cell lines**  
Tzihsuan Jennifer Lin, Pfizer Inc., USA

9. **The relationship between clonality, cellular heterogeneity, and process consistency**  
Jack J. Scarcelli, Pfizer Inc., USA

10. **Process improvement delivered by a high efficiency, automated single cell cloning system**  
Andrea Gough, Solentim Ltd., United Kingdom

11. **Using nanoscale bioreactors to characterize sub-populations of CHO clones and screen transfected pools**  
Tanner Nevill, Berkeley Lights, Inc., USA

12. **Quantification of genomic DNA repair capabilities in CHO and identification of genes impacting genomic stability**  
Philipp N. Spahn, University of California, San Diego, USA

13. **Analysis of DNA DSB repair and production stability in CHO cells**  
Xiaolin Zhang, University of Delaware, USA

14. **Integrated analysis of genomic and epigenomic instability for CHO cell line engineering**  
Sofie O'Brien, University of Minnesota, USA
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### II: Computational Strategies to Enhance Bioprocess Performance

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Towards model-based bioprocess characterization: A mathematical model of cell cycle, metabolism and apoptosis of mAb-producing mammalian cells
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Application of a genome-based predictive CHO model for increased mAb production and Glycosylation control
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Thomas Bissinger, Max Planck Institute for Dynamics of Complex Technical Systems, Germany

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Neil Templeton, Merck & Co., Inc., USA

Characterizing the effect of glutamine supplementation on asparagine and glutamine metabolism using 13C metabolic flux analysis
Sandra V. Bennun, Regeneron Pharmaceuticals Inc., USA

Innovative metabolic data integration applicable for Therapeutic Protein Development 2.0
Wolfgang Paul, Roche Diagnostics GmbH, Germany

Biologically consistent annotation of CHO cell culture metabolomics data
Nicholas Alden, Tufts University, USA

Curation of a CHO DG44 genome scale model and application to support cell culture development process
Cyrielle Calmels, UCB Pharma and Technical University of Denmark, Belgium

Filling the gap between experimentalists and modelers by determining a mammalian cell's metabolic capabilities based on transcriptomic data
Anne Richelle, University of California, San Diego, USA

A priori optimization of cell culture feeds using metabolic engineering
Nicholas Trunfio, University of Massachusetts Lowell and US Food and Drug Administration, USA

Media formulation optimization based on multi-scale modeling of heterogeniety in mammalian cell culture process
Shaun Galbraith, University of Massachusetts Lowell, USA

RNA-seq data reveals metabolic regulation in Chinese Hamster Ovary cell culture
Sha Sha, University of Massachusetts Lowell, USA
Metabolic pathway engineering in mammalian cells through kinetic model optimization
Conor M. O'Brien, University of Minnesota, USA

Epigenetic regulation of gene expression in response to a changing environment in CHO cell batch culture
Heena Dhiman, University of Natural Resources and Life Sciences, Vienna, Austrian Center of Industrial Biotechnology, Austria

13C flux analysis in industrial CHO cell culture applications
Jamey Young, Vanderbilt University, USA

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Wei-Chien Hung, Alexion, USA

Delivery of consistent and high-quality antibody therapeutics by actively monitoring and controlling critical quality attributes
Megan Blewis, Amgen Inc., USA

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Natalia Gomez, Amgen, USA

Controllability analysis to identify manipulated variables for a glycosylation control strategy
Melissa M. St. Amand, Belcan Corporation, DARPA, USA

A novel additive for controlling glycosylation of monoclonal antibodies
Fernie Mitchelson, Biogen, USA

Perfusion cell culture: Challenges and potentials between lab and manufacturing scale
Daniel J. Karst, Biogen, Switzerland

Process optimization for high volumetric productivity with product quality control
Rashmi Kshirsagar, Biogen, USA

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Michael Betenbaugh, Johns Hopkins University, USA

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Rahul Chelikani, Shire Pharmaceuticals, USA

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Amlan Das, Teva Pharmaceuticals, USA

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Evan Wells, Tulane University, USA

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James M. Piret, University of British Columbia, Canada

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Daniel Wan, University of Kent and Lonza Biologics PLC, United Kingdom

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Hemlata Bhatia, University of Massachusetts Lowell, USA

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Meghan G. McCann, University of Minnesota, Twin Cities, USA

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Bernhard Sissolak, University of Natural Resources and Life Sciences, Vienna, Austrian Center of Industrial Biotechnology, Austria

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Laura Palomares, Universidad Nacional Autónoma de México, Mexico

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Christofer Bro, Biogen, Denmark

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Pani Apostolidis, Bristol-Myers Squibb Company, USA

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Kathryn Elliott, Clemson University, USA

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Sebastian Selzer, Eppendorf AG Bioprocess Center, Germany
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Maria Wendt, Genedata AG, Switzerland

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David Shaw, Genentech, Inc., USA

Improving transient gene expression in CHO-EBNA1 cells
Eric Grazzini, National Research Council Canada, Canada

Novel downstream process and analytical tools developed for Influenza VLP vaccine
Patricia Alves, Instituto de Biologia Experimental e Tecnológica (IBET), Portugal

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Kevin D. Smith, Janssen Pharmaceutical, USA

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Paul Gulde, Thermo Fisher Scientific, USA

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Chris Kwiatkowski, Biogen, USA

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Marcella Yu, Boehringer Ingelheim, USA

Dipeptides in cell culture - Tools for performance increase and risk reduction
Christian Kessler, Evonik Nutrition & Care GmbH, Germany

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Moritz Wolf, ETH Zurich, Switzerland
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Thayana Araujo da Cruz, PEQ/COPPE/UFRJ, IQ/UFRJ, Brazil

Development of perfusion processes for mAb production aiming at high cell densities sustained by low cell-specific perfusion rates
Renata Alvim, Leda Castilho, Federal University of Rio de Janeiro (UFRJ), Brazil

Platform based screening strategies that deliver reliable and high quality continous biomanufacturing processes
Leon Pybus, FUJIFILM Diosynth Biotechnologies, United Kingdom

Process intensification: Case study with a CHO-based monoclonal antibody production process
Isam A. Hararah, Genentech, Inc., USA

Rapid and flexible scale-down media development and optimization for perfusion culture
James Kevin Y. Tan, Irvine Scientific, USA

Development of a chemically defined medium for optimal growth and recombinant protein production in HEK293 cells
Chaya Kataru, Kerry, USA

Implications of feeds and supplements on the productivity and quality of recombinant proteins produced in CHO cells
John F. Menton, Kerry, USA

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Delia Lyons, MilliporeSigma, USA

Hybrid fed-batch cultures using XCell ATF for better yield and robust clarification process
Shashi Kudugunti, Repligen, USA

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Daniel Vazquez Ramirez, Sanofi, Germany

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Christopher Brau, Thermo Fisher Scientific, USA

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Chapman Wright, Biogen, USA

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Stephen Orzell, Nucleus Biologics, USA

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Kerstin Hein, CEVEC Pharmaceuticals, Germany
Bioprocess optimization for the expansion of early memory T cells in serum-free conditions
Ernesto Scibona, ETH Zurich, Switzerland

Heterotypic cell-cell interaction of human stem cells for neural differentiation of hybrid spheroids
Liqing Song, Florida State University, USA

Metabolic regulation of functional decline during in vitro expansion of human mesenchymal stem cells
Xuegang Yuan, Florida State University, USA

Engineering culture environment of human pluripotent stem cells to direct their commitment and maturation towards functional cardiomyocytes: An “-Omics” driven approach
Margarida Serra, Instituto de Biologia Experimental e Tecnológica (iBET), Portugal

Scalable lentiviral vector production using stable producer cell lines in perfusion mode
Sven Ansorge, National Research Council, Canada

Quantitative characterization of all single amino acid variants of a viral capsid-based delivery vehicle
Danielle Tullman-Ercek, Northwestern University, USA

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Andres Martinez, Northwestern University, USA

Optimization of human T cell expansion ex vivo using serum-free medium and the gas-permeable rapid expansion cell culture devices (G-Rex)
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Nadja Raab, Biberach University of Applied Sciences, Germany

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Chen-Yuan Kao, University of Delaware, USA

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Hooman Hefzi, Novo Nordisk Foundation Center for Biosustainability and University of California, San Diego, USA

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