5-6-2018

Conference Program

Anne Skaja Robinson
Tulane University, USA

Raghavan Venkat
MedImmune, USA

Gene Schaefer
Janssen, USA

Program

Cell Culture Engineering XVI

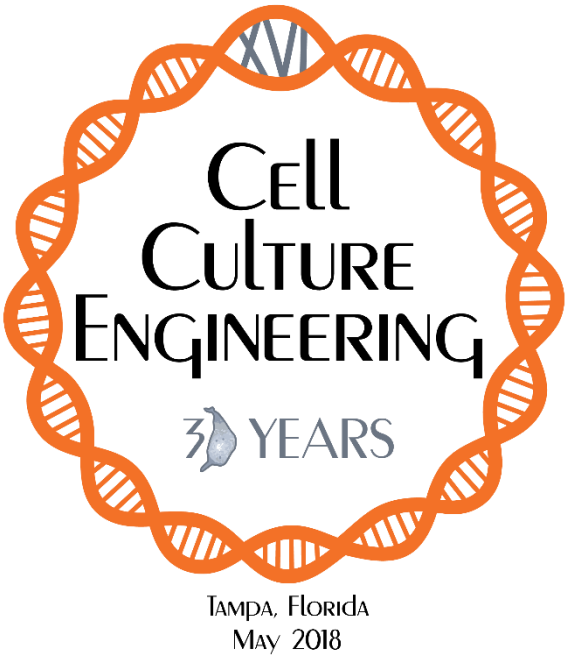
An ECI Conference Series

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



Engineering Conferences International
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Engineering Conferences International (ECI) is a not-for-profit global engineering conferences program, originally established in 1962, that provides opportunities for the exploration of problems and issues of concern to engineers and scientists from many disciplines.

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)
Kelvin Lee (University of Delaware, USA)
Mark Leonard (Pfizer, USA)
William Miller (Northwestern University, USA)
Jamie Piret (University of British Columbia, Canada)
Octavio Ramirez (Instituto de Biotecnología UNAM, Mexico)
Anne Skaja Robinson (Tulane University, USA)
Gene Schaefer (Janssen, USA)
Raghavan Venkat (MedImmune, USA)
Weichang Zhou (WuXi Biologics, China)

Organizing Committee

Karin Anderson (Pfizer, USA)
Bill Bentley (University of Maryland, USA)
Kris Chan (Michigan State University, USA)
Véronique Chotteau (KTH Royal Institute of Technology, Sweden)
Colin Clarke (NIBRT, Ireland)
Chris Frye (Eli Lilly, USA)
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Anthony Grippe (Merck, USA)
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Wei-Shou Hu (University of Minnesota, USA)
Weiwei Hu (Celgene, USA)
Cleo Kontoravdi (Imperial College, UK)
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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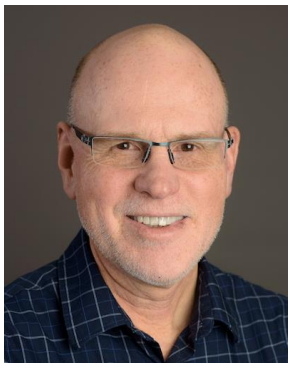
Weichang Zhou (WuXi Biologics, China)

2018 Cell Culture Engineering Award Winner

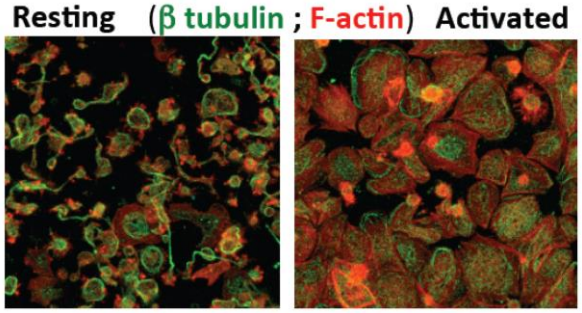
William M. Miller

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 pCO_2.
- **Blood stem cells and megakaryocytes:** Bill and collaborator Terry Papoutsakis were the first to show that low pO_2 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 O_2 distribution and confirmed that stem and primitive progenitor cells likely reside at low pO_2 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 pO_2 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.

This prestigious award recognizes outstanding contributions to the field of Cell Culture and is given bi-annually at the Cell Culture Engineering conference. Former recipients: Wei-Shou Hu (2002), Eleftherios T. Papoutsakis (2004), W. Robert Arathoon (2006), Martin Fussenegger (2008), Michael J. Betenbaugh (2010), James M. Piret (2012), Jeffrey J. Chalmers (2014), and Konstantin B. Konstantinov (2016).

2018 Martin Sinacore Young Investigator Award Winner

Amanda M. Lewis
Bristol-Myers Squibb

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 Hickernell 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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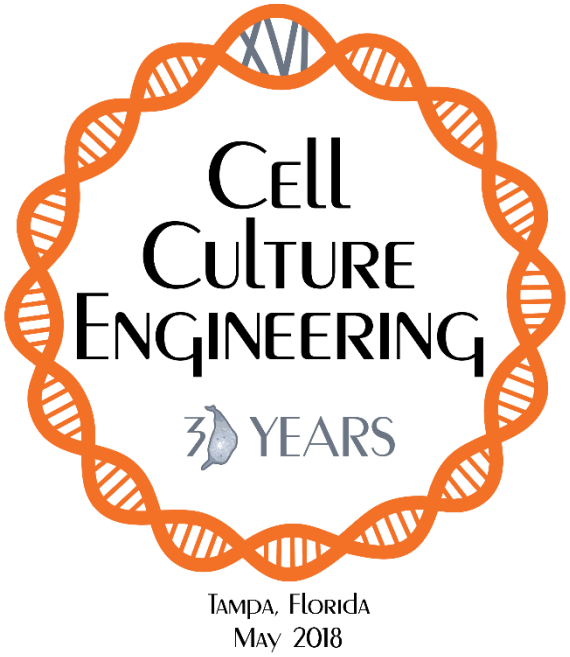
Program Schedule and Posters

Cell Culture Engineering XVI

An ECI Conference Series

May 6 – May 11, 2018

Saddlebrook Resort, Tampa, Florida, USA

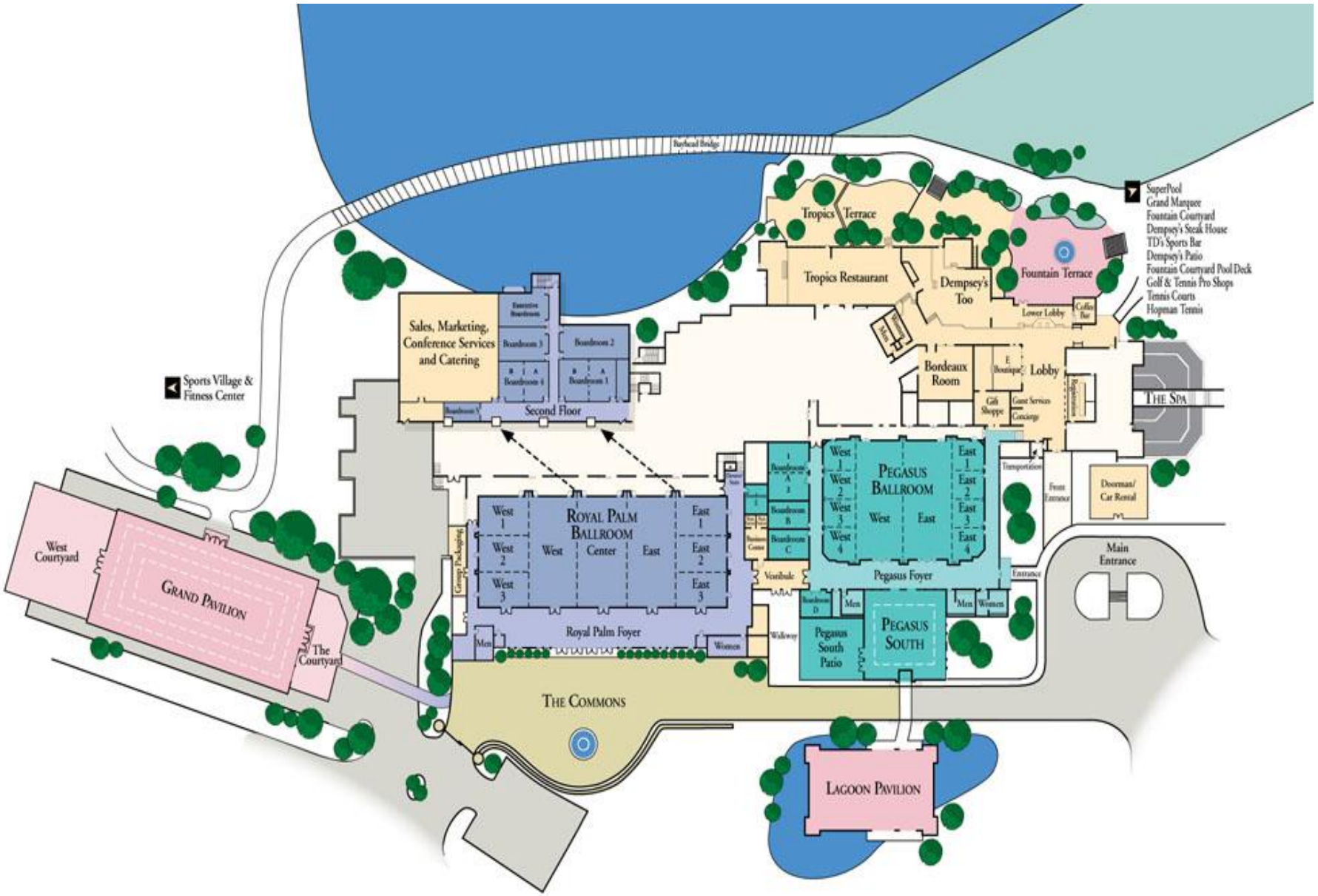


Engineering Conferences International

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.

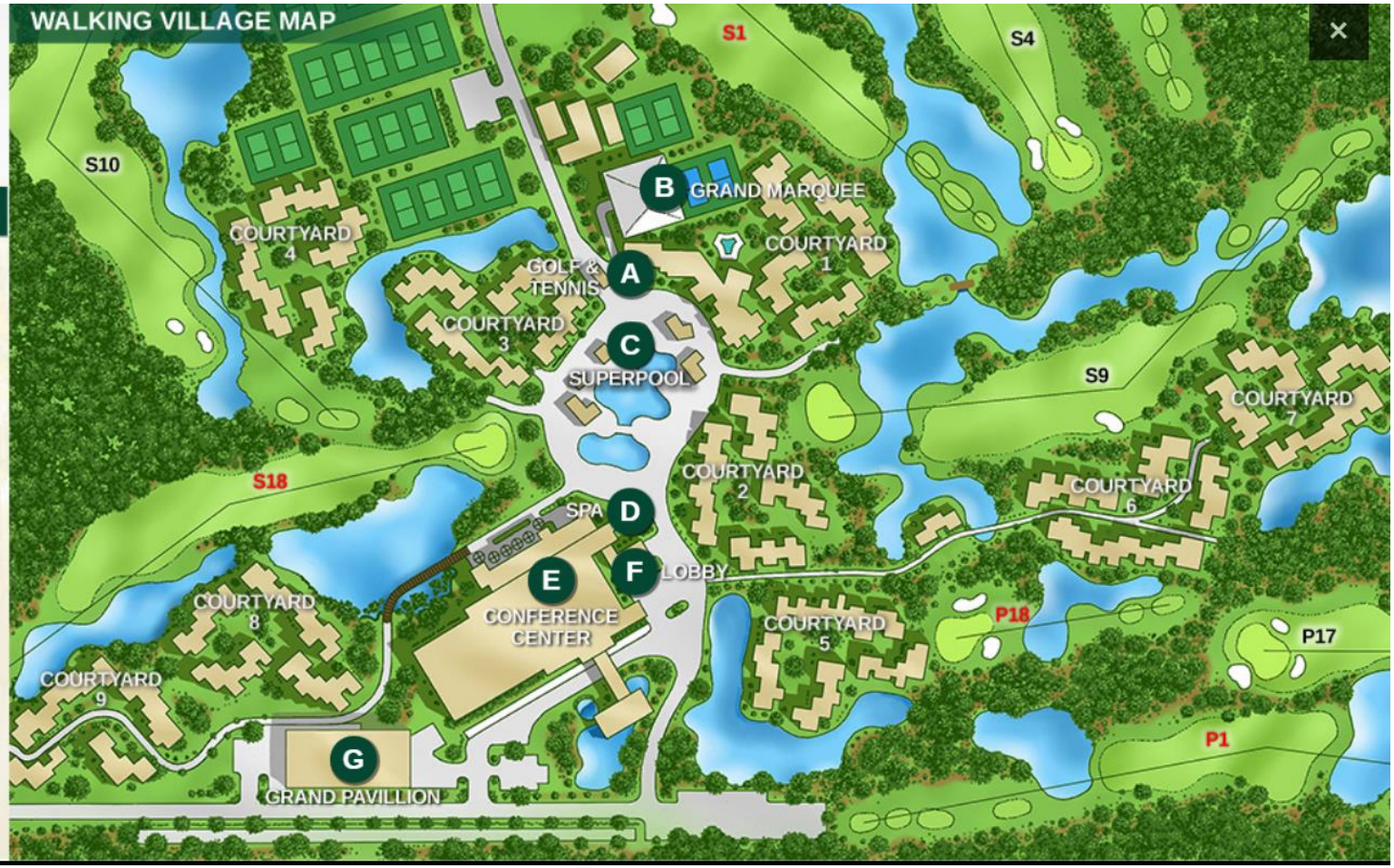
  Posters must be taken down no later than 9:00 am on Thursday morning.
- The locations for workshops are listed in the program.
- All breakfasts and lunches will be in the Commons and Pegasus Ballroom.
- Dinner locations are listed in the program.
- Coffee breaks will be in the Royal Palm Foyer.
- The 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.


Barbecad Bridge
Tropics Terrace
Tropics Restaurant
Dempsey's Too
Fountain Terrace
Lower Lobby
Coffee Bar
SuperPool
Grand Marquee
Fountain Courtyard
Dempsey's Steak House
TD's Sports Bar
Dempsey's Patio
Fountain Courtyard Pool Deck
Golf & Tennis Pro Shops
Tennis Courts
Hopman Tennis
Sales, Marketing, Conference Services and Catering
Executive Boardroom
Boardroom 3
Boardroom 2
Boardroom 4
Boardroom 1
Boardroom 5
Second Floor
Sports Village & Fitness Center
Bordeaux Room
Lobby
Gift Shoppe
Guest Services Concierge
Registration
THE SPA
West Courtyard
GRAND PAVILION
The Courtyard
ROYAL PALM BALLROOM
West
Center
East
West 1
West 2
West 3
East 1
East 2
East 3
Royal Palm Foyer
Men
Women
Group Packaging
Boardroom A
Boardroom B
Boardroom C
Business Center
PEGASUS BALLROOM
West 4
East 4
Pegasus Foyer
Vestibule
Boardroom D
Pegasus South Patio
PEGASUS SOUTH
Walkway
Transportation
Front Entrance
Doorman/ Car Rental
Main Entrance
Entrance
THE COMMONS
LAGOON PAVILION

Saddlebrook RESORT • TAMPA
Golf • Tennis • Spa • Meetings

PROPERTY OVERVIEW | WALKING VILLAGE | MEETING FACILITIES

- A Golf Start
  - Golf Shop
  - Tennis Shop
  - T.D.'s Sports Bar
  - Dempsey's Steakhouse
- B Grand Marquee
  - Fountain Courtyard
- C Superpool
  - Poolside Cafe
  - Pool Bar
- D Spa
- E Conference Center
- F Lobby
  - Coffee Bar
  - Tropics Restaurant
  - Dempsey's Too
- G Grand Pavilion



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 Pierciey (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

Monday, May 7, 2018 (continued)

17:45 – 18:30	**Cell Culture Engineering Award Lecture** **Large scale production and characterization of exosomes** Konstantin Konstantinov, Codiak BioSciences, USA
18:30 – 20:30	Dinner (18th Fairway of the Saddlebrook Golf Course)
20:30 – 22:30	**Poster Session** and Reception (*sponsored by Roche and Solentim)* (Authors of odd-numbered posters are asked to stay with their posters)

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 *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 chromsome 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

I: Towards Other Cell Lines and Systems

15 **The C1 gene expression system, disrupting the way biologic vaccines, and drugs are developed & manufactured**
Ronen Tchelet, Dyadic International Inc, USA

16 **Opportunities to leverage cell culture technology to create sustainable food systems: The development of "Clean Meat"**
Liz Specht, Good Food Institute, USA

17 **Expanding the vector toolkit for complex recombinant protein expression**
Peter M. O'Callaghan, Lonza Biologics, USA

18 **Identifying Hipk1 as a target of Mir-22-3p enhancing recombinant protein production from Hek 293 by using microarray and Htp sirna screen**
Sarah Inwood, National Institutes of Health (NIH), USA

19 **spERt Technology: A novel strategy to improve productivity through enhanced polyribosome assembly on the endoplasmic reticulum in CHO cells**
Kiyoko Ogawa-Goto, Nippi Research Institute of Biomatrix, Japan

20 **Newly established cell lines derived from Chinese hamster for production of biologics**
Takeshi Omasa, Osaka University, Japan

21 **Improving vaccine production with a serum-free medium for MRC-5 cells**
Anna-Barbara Hachmann, Thermo Fisher Scientific, USA

22 **Use of a 'molecular tug' to overcome limitations in the production of 'difficult to express' recombinant proteins**
Hirra Hussain, University of Manchester, United Kingdom

II: Computational Strategies to Enhance Bioprocess Performance

23 **Improving bioreactor design through pH mapping of bioreactors employing Computational Fluid Dynamics coupled with equilibrium calculations**
Natraj Ram, AbbVie, USA

24 **Empowering manufacturing decisions through process simulation models**
Tiffany Rau, BioProcess Technology Consultants, USA

25 **Applying genome scale metabolic models integrated with OMICs technologies for improvemwent of commercial CHO cell culture process**
Jianlin Xu, Bristol-Myers Squibb Company, USA

26 **WITHDRAWN**

27 **A bioinformatics approach to genome to phenome predictions in CHO cell lines**
Derrick Scott, Delaware State University, USA

28 **Multiscale modeling of monoclonal antibody (mAb) production and glycosylation in a CHO cell culture process**
Yu Luo, University of Delaware, USA

29 **Bioprocess intelligent for the improvements and prediction on fed-batch cell culture in bioreactor**
Ching-Jen Yang, Development Center for Biotechnology, Taiwan

30 **Development of an in silico molecule assessment method for product expression**
Misha Lazebnik, Genentech, Inc., USA

31 **Monitoring the production of AAV vectors in insect cells by fluorescence spectroscopy**
Daniel Alexandre Marques Pais, Instituto de Biologia Experimental e Tecnológica (iBET), Portugal

32 **Towards model-based bioprocess characterization: A mathematical model of cell cycle, metabolism and apoptosis of mAb-producing mammalian cells**
António Lima Grilo, Imperial College London, United Kingdom

33 **Application of a genome-based predictive CHO model for increased mAb production and Glycosylation control**
J. Vincent Price, Janssen Pharmaceutical, USA

34 **WITHDRAWN**

35 **Dynamics of intracellular metabolite pools in MDCK suspension cells during growth and influenza virus infection**
Thomas Bissinger, Max Planck Institute for Dynamics of Complex Technical Systems, Germany

36 **Application of metabolomics and fluxomics to increase productivity and predict product quality**
Neil Templeton, Merck & Co., Inc., USA

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

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

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

40 **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

41 **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

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

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

44 **RNA-seq data reveals metabolic regulation in Chinese Hamster Ovary cell culture**
Sha Sha, University of Massachusetts Lowell, USA

45 **Metabolic pathway engineering in mammalian cells through kinetic model optimization**
Conor M. O'Brien, University of Minnesota, USA

46 **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 Indistrial Biotechnology, Austria

47 **13C flux analysis in industrial CHO cell culture applications**
Jamey Young, Vanderbilt University, USA

III: Advances in Cell Culture Control

48 **Controlling continuous high cell density perfusion culture with the Alternating Tangential Flow system in real time using radio-frequency impendance**
Aditya Bhat, Aber Instruments Ltd, USA

49 **Demonstrating a powerful scale-up strategy for Biosimilar mAb in single use systems via physicochemical and functional characterization**
Serdar Alpan, Turgut Ilaclari A.S., Turkey

50 **Impact of raw materials on sialyation for a therapeutic protein**
Wei-Chien Hung, Alexion, USA

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

52 **WITHDRAWN**

53 **Modulation of half antibody and aggregate formation in a CHO cell line expressing a bispecific antibody**
Natalia Gomez, Amgen, USA

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

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

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

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

58 **Study of an unusually high level of N-glycolylneuraminic acid (NGNA) sialylation on a monoclonal antibody expressed in Chinese hamster ovary cells**
Shumin Yang, Boehringer Ingelheim Fremont Inc, USA

59 **A Master Cell Bank (MCB) banking troubleshooting case study: Challenges and process improvements with comprehensive root cause analysis**
Lianchun Fan, Bristol-Myers Squibb Company, USA

60 **Effect of lactate media concentration on induced pluripotent stem cell proliferation and metabolism**
Daniel Odenwelder, Clemson University, USA

61 **Strategies to modulate charge variants of a Biosmilar monoclonal antibody through cell culture conditions**
Prafulla M. Mahajan, Dr.Reddys Laboratories Limited, India

62 **WITHDRAWN**

63 **Generating glycan variants for biological activity testing by means of parallel experimental design and multivariate analysis**
David Bruehlmann, EMD Serono, Switzerland

64 **A systematic approach for process development and quality control in continuous perfusion cultures**
Moritz Wolf, ETH Zurich, Switzerland

65 **Genotype of CHO host cell line has higher impact on mAb production and quality than process strategy or cell culture medium**
Andreas Castan, GE Healthcare, Sweden

66 **Maintaining product quality from early to late stage process development**
Jason C. Goodrick, Genentech, Inc., USA

67 **Effects of cryopreservation on recombinant CHO cell lines**
Inn Yuk, Genentech, Inc., USA

68 **Improving glycosylation profiles and cell culture performance with a sensitive cell line in commercial manufacturing**
Lisa L. Vulliet, Genentech, Inc., USA

69 **Evaluation of Raman spectroscopy for online monitoring of cell culture product quality**
Barbara Chiang, Genentech, Inc., USA

70 **Using PLS to understand potential sources of process variation & assessing medium components to alter afucosylation**
Angela Meier, Genentech, Inc., USA

71 **Comprehensive manipulation of glycosylation profiles across development scales**
Sven Loebrich, ImmunoGen, USA

72 **Controlling fab terminal sialylation of antibodies through culture conditions**
Calum McIntosh, Imperial College London, United Kingdom

73 **Elucidating amino acid metabolism in CHO cells**
Michael J. Betenbaugh, Johns Hopkins University, USA

74 **Towards a universal CHO reference platform with epigenome characterization for the biotechnology community**
Michael Betenbaugh, Johns Hopkins University, USA

75 **Intact glycopeptide analysis of recombinant protein from CHO cells**
Qiong Wang, Johns Hopkins University, USA

76 **Modulation of Mannose levels in N-linked glycosylation through cell culture process conditions in order to increase ADCC activity for an antibody Biosimilar**
Shahid Rameez, KBI Biopharma Inc., USA

77 **A highly automated, continuous method for developing active controllers of product quality attributes in early phase clinical development**
Brandon Downey, Lonza, USA

78 **Developing integrated platforms for the generation of cell lines expressing bispecific proteins with desired qualities**
Jie Zhu, MedImmune/AstraZeneca, USA

79 **Impact of S-sulfocysteine on fragments and trisulfide bond linkages in monoclonal antibodies**
Aline Zimmer, Merck KGaA, Germany

80 **Process and raw material control strategies to manage variability in charge variant species of a monoclonal antibody**
Vijay Janakiraman, Merck & Co., Inc., USA

81 **Development of a platform expression system using targeted integration in Chinese Hamster Ovary cells**
Scott Bahr, MilliporeSigma, USA

82 **Defining scalable cell culture processes for Biosimilar candidates**
Carmen Ho, Momenta Pharmaceuticals, USA

83 **Dielectric monitoring of mammalian cells in a bioreactor**
Michael Butler, National Institute for Bioprocessing Research and Training (NIBRT), Ireland

84 **HIV-1 envelope vaccine production with improved yields and glycosylation profile through mannose supplementation**
J. Isaac Godfroy, National Institute of Allergy and Infectious Disease, USA

85 **Control strategies for the regulation of protease clipping during mAb production in CHO cells**
Daniel Blackstock, National Institutes of Health (NIH), USA

86 **Regulation of recombinant protein expression during CHO pool selection enhances high producer frequency**
Yves Durocher, National Research Council Canada, Canada

87 **Novel engineered CHO DG44 host cell line demonstrates lowered UPR, increased titers and superior quality of recombinant vaccines**
Hussain Dahodwala, National Institutes of Health (NIH), USA

88 **Monitor and control of multiple bioreactor parameters using in situ raman spectroscopy**
Michelle LaFond, Regeneron Pharmaceuticals Inc., USA

89 **Proteolysis of non-IgG molecules in transient HEK293 and stable CHO-K1 bioprocesses**
Alfred M. Engel, Roche Diagnostics GmbH, Germany

90 **Implementing automated pCO2 control in small scale cell culture models**
Lia Tescione, Sanofi, USA

91 **Bioreactor scale down model case study: Ensuring nutrient feed strategy is representative of clinical and commercial scale**
Matthew Leith, Seattle Genetics, USA

92 **Controlling the product quality attributes of a complex recombinant protein in a high cell density perfusion bioreactor process**
Rahul Chelikani, Shire Pharmaceuticals, USA

93 **Controlling monoclonal antibody product quality using High Throughput Systems (HTS)**
Amlan Das, Teva Pharmaceuticals, USA

94 **Comparison of transfection methods on yield of recombinant human IgG1 Fc**
Evan Wells, Tulane University, USA

95 **Raman spectroscopic analysis of cell differentiation and death modes**
James M. Piret, University of British Columbia, Canada

96 **Proteasome-based selection systems for generation of recombinant CHOK1SV GS-KO™ cell lines with enhanced productivity**
Daniel Wan, University of Kent and Lonza Biologics PLC, United Kingdom

97 **Understanding the zinc induced lactate shift in CHO cell culture at transcriptomics level to improve the protein production**
Hemlata Bhatia, University of Massachusetts Lowell, USA

98 **Systems engineering N-glycans of recombinant therapeutic proteins**
Meghan G. McCann, University of Minnesota, Twin Cities, USA

99 **Antibody charge heterogeneity formation in a mammalian cell culture fed-batch process**
Bernhard Sissolak, University of Natural Resources and Life Sciences, Vienna, Austrian Center of Indistrial Biotechnology, Austria

IV: Advanced Cell Culture Processes

100 **Evaluation of redox potential of the Golgi of CHO cells**
Laura Palomares, Universidad Nacional Autónoma de México, Mexico

101 **Use of biocapacitance probes for optimized process control at large-scale manufacturing**
Christoffer Bro, Biogen, Denmark

102 **Online capacitance probes precisely control cell biomass growth through temperature regulation**
Jeffrey Swanberg, Bristol-Myers Squibb Company, USA

103 **Evaluation of bioanalyzers for upstream commercial manufacturing**
Pani Apostolidis, Bristol-Myers Squibb Company, USA

104 **Boundary of oxidative and overflow metabolism (boom) controller for CHO cell feed control**
Kathryn Elliott, Clemson University, USA

105 **High-density Vero cell perfusion culture in BioBLU 5p Single-Use Vessels**
Sebastian Selzer, Eppendor AG Bioprocess Center, Germany

106 **High-throughput screening for best clone manufacturing using scale-down models**
Maria Wendt, Genedata AG, Switzerland

107 **Substrate kinetics screening method for mitigating low titer yields at large scale production**
Beril Ereren, Genentech, Inc., USA

108 **Increasing efficiency in cell line development through automated workflows**
David Shaw, Genentech, Inc., USA

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

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

111 **Use of the Cyto-Mine for rapid generation of high-producing clonal cell lines**
Kevin D. Smith, Janssen Pharmaceutical, USA

112 **Investigating the use of integrated analytics and automation to enhance process development capabilities**
Melisa Carpio, Sartorius Stedim Biotech (2), USA

113 **Transcriptomic signatures classifying CHO quasispecies**
Ankita Singh, Technical University of Denmark, Denmark

114 **Development of a CHO production medium utilizing proteomic and metabolomics analysis**
Paul Gulde, Thermo Fisher Scientific, USA

115 **Rapid process monitoring & control in mammalian cell culture using off-gas mass spectrometry analysis**
Hai-Yuan Goh, University College London, United Kingdom

V: Regulatory Strategies and Concerns

116 **WITHDRAWN**

117 **Strategies to improve productivity of CHO-S cells expressing an anti-TNFα monoclonal antibody with biosimilar potential**
Ana M. Moro, Instituto Butantan, Brazil

VI: Pushing the Limits on Process Intensification

118 **Getting more for less: Leveraging epigenetics to increase process yield**
Chris Kwiatkowski, Biogen, USA

119 **Product sieving challenges in TFF perfusion cell culture**
Marcella Yu, Boehringer Ingelheim, USA

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

121 **Mammalian cell perfusion cultures: “Intensification by growth inhibition”**
Moritz Wolf, ETH Zurich, Switzerland

122 **Evaluation of IRES-mediated expression and different signal peptides for the development of CHO clones producing an anti-PCSK9 monoclonal antibody**
Thayana Araujo da Cruz, PEQ/COPPE/UFRJ, IQ/UFRJ, Brazil

123 **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

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

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

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

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

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

129 **Moved to Oral Session 5**

130 **Cellular behavior in high density perfusion processess**
Delia Lyons, MilliporeSigma, USA

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

132 **Evaluation of an n-1 perfusion/high-seed fed-batch technology for the intensification of recombinant protein production processes: From AMBR250 to 200 L STR**
Daniel Vazquez Ramirez, Sanofi, Germany

133 **Optimization and evaluation of perfusion media in high cell density mammalian cell culture systems**
Christopher Brau, Thermo Fisher Scientific, USA

VII: Innovation in Cell and Gene Therapies

134 **Producer cell line engineering for large volume manufacturing of therapeutic Aav**
Chapman Wright, Biogen, USA

135 **Enhanced cell growth with physiologically relevant media supplements**
Stephen Orzell, Nucleus Biologics, USA

136 **Generation of helper virus-free adeno-associated viral vector packaging/producer cell lines based on a human suspension cell line**
Kerstin Hein, CEVEC Pharmaceuticals, Germany

137 **Bioprocess optimization for the expansion of early memory T cells in serum-free conditions**
Ernesto Scibona, ETH Zurich, Switzerland

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

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

140 **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

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

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

143 **Evaluating a gas-permeable culture surface for the generation of megakaryocytes for in-vitro platelet production**
Andres Martinez, Northwestern University, USA

144 **Optimization of human T cell expansion ex vivo using serum-free medium and the gas-permeable rapid expansion cell culture devices (G-Rex)**
Evan R. Zynda, Thermo Fisher Scientific, USA

145 **Engineering of exosomes for targeted delivery of therapeutic microRNAs**
Nadja Raab, Biberach University of Applied Sciences, Germany

146 **Megakaryocytic microparticles-mediated nucleic acid delivery for gene therapy**
Chen-Yuan Kao, University of Delaware, USA

VIII: Impact of Novel Gene Editing Approaches

147 **CRISPR-Cas9 mediated cell line engineering of apoptosis pathways increases antibody expression with site-specific modifications for antibody drug conjugation**
Yingchun Lu, Ambrx, USA

148 **Challenges in cell culture platform development of mAb production with site-specific incorporation of non-natural amino acid for ADC generation**
Weimin Lin, Ambrx, USA

149 **Novel transposase tools for cell-line engineering**
Ferenc Boldog, ATUM (formerly DNA2.0), USA

150 **Dxb11/taut host cell engineering strategy enabling the establishment of strains producing the highest yield of advanced recycling antibodies**
Hisahiro Tabuchi, Chugai Pharmaceutical Co., Ltd., Japan

151 **Development of high-producing CHO cell lines through target-designed strategy**
Dalton Chen, Development Center for Biotechnology, Taiwan

152 **High-yield antibody production using targeted integration and engineering CHO host**
Wei-Kuang Chi, Development Center for Biotechnology, Taiwan

153 **WITHDRAWN**

154 **Evolution of rCHO cells under mild ER stress to make them super producers**
Sarika Mehra, IIT Bombay, India

155 **Overexpression of the mitochondrial pyruvate carrier increases CHO cell and recombinant protein productivity and reduces lactate production**
Dubhe Bulté, Universidad Nacional Autónoma de México, Mexico

156 **Rolling cycle translation of circularized infinite open reading frames; fooling the ribosome**
Alan Costello, Dublin City University, Ireland

157 **CRISPR/Cas9 mediated targeting of microRNA-24 improves the bioprocess phenotype of Chinese Hamster Ovary cells**
Niamh Keogh, The National Institute for Bioprocessing Research and Training (NIBRT), Ireland

158 **Elimination of the Warburg effect in Chinese hamster ovary (CHO) cells improves cell phenotype as a protein production platform**
Hooman Hefzi, Novo Nordisk Foundation Center for Biosustainability and University of California, San Diego, USA

159 **Metabolic engineering of CHO cells towards reduced novel growth inhibitor production and amino acid prototropy**
Bhanu Chandra Mulukutla, Pfizer Inc., USA

160 **WITHDRAWN**

161 **Targeted epigenetic glyco-engineering in CHO cells**
Nicolas Marx, University of Natural Resources and Life Sciences, Vienna, Austrian Center of Indistrial Biotechnology, Austria

162 **Enhancement by reduction - Pushing the N-glycosylation capacity of CHO cells by cleaning up the Golgi**
Nina Bydlinski, University of Natural Resources and Life Sciences, Vienna, Austrian Center of Indistrial Biotechnology, Austria

IX: Process Scale Up/Down, Characterization and Control Strategy Definition

163 **Improving developmental timelines through the generation of predictive scale down models**
Nicholas Abu-Absi, AbbVie, USA

164 **Upstream process development and scale-up of complex glycoprotein production using a long duration perfusion process**
Adriane Schilling and Kumar Dhanasekharan, Amicus Therapeutics, USA

165 **A systematic approach to implement HTST for legacy mammalian cell culture processes**
LiYing Yang, AstraZeneca, USA

166 **On-line monitoring and controlling of cell apoptosis in mammalian cell culture processes using dielectric spectroscopy**
An Zhang, Biogen, USA

167 **Leveraging a deeper understanding of Poloxamer188 to improve cell culture processes**
Kevin Chang, Biogen, USA

168 **WITHDRAWN**

169 **Enhancing and enabling advanced process controls - reducing variability at the source**
Mats Akesson, Biogen, Denmark

170 **Overcoming scale-up challenges for a First-In-Human (FIH) antibody production process at the 2000L scale: Successful optimization of bioreactor equipment and harvest conditions to improve process performance and product yield**
Meena George, Boehringer Ingelheim Fremont Inc, USA

171 **Making large scale processes transparent – The application of CFD and classical engineering approaches to mitigate risk during cell culture process transfer**
Jochen Schaub, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

172 **Use of the ambr 250 to enable rapid clone selection and process development for large scale manufacturing processes**
Colleen Clark, Bristol-Myers Squibb Company, USA

173 **Development and qualification of a scale-down model of a commercial mammalian cell culture bioreactor using Computational Fluid Dynamics**
Brianna Biscardi, Bristol-Myers Squibb Company, USA

174 **Step-wise strategy to address process characterization - Toward the definion of a standardized approach**
Claudia Berdugo, Catalent, USA

175 **Suspension culture of Pk15 cells for veterinary antigen production**
Ziomara P. Gerdtzen, University of Chile, Chile

176 **Development of a highly efficient and flexible media system for CHO fed-batch culture**
Yang Li, Celgene, USA

177 **Integration of CHO cell culture process improvements with continued process verification**
Jun Luo, Genentech, Inc., USA

178 **Technical assessment approach for vendor initiated changes of direct materials**
Eric Huang, Genentech, Inc., USA

179 **Cell culture manufacturing of accelerated projects - Lessons from life in the fast lane**
Kyle Hirst, Genentech, Inc., USA

180 **Process characterization for an updated legacy product**
Sharat Varma, Genentech, Inc., USA

181 **Characterization and control of culture media and buffer preparation processes: Closing the gap**
Wayne Mauro, Irvine Scientific, USA

182 **Reduced scale model qualification of a 5-L bioreactor using multivariate visualization & Bayesian inferential methods**
Kevin Clark, Janssen Pharmaceutical, USA

183 **Bioreactor process optimization of the ambr15 for an IgG producing CHO cell line**
Michael Gillmeister, Lonza, USA

184 **The EB66® cell line for yellow fever vaccine production at high cell concentrations**
Alexander Nikolay, Max Planck Institute for Dynamics of Complex Technical Systems, Germany

185 **Understanding elevated lactate level in a large-scale perfusion process to improve performance**
Peter Amaya, MedImmune, USA

186 **Impact of mixing and aeration on cell culture performance and quality**
Pooja Jambunathan, Merck & Co., Inc., USA

187 **Experiences and challenges during the commercialization of a licensed-in monoclonal antibody**
Robert W. Leighty, Merck & Co., Inc., USA

188 **Characterization of a non-originator NISTmAb expression system**
Lila Kashi, NIST, IBBR, USA

189 **A combinatorial use of titer and titer normalized to confluence as early reporters allows for selecting Chinese Hamster Ovary cell clones with high volumetric productivity of Etanercept**
Nusa Pristovsek, Novo Nordisk Foundation Center for Biosustainability, Denmark

190 **Establishing a small scale model with MULTIVARIATE and bayesian statistics**
Peter Slade, Pfizer Inc., USA

191 **CFD applications in bioreactor development and strategies for scaling up and down**
Einer DosSantos, Regeneron Pharmaceuticals Inc., USA

192 **Off-target at-scale Scale Down Model verification of a marketed biopharmaceutical**
Markus Emmler, Roche Diagnostics GmbH, Germany

193 **Elimination of Fetal Calf Serum (FCS) in industrial cell culture media for manufacturing of diagnostic Anti-bodies**
Marco Jenzsch, Roche Diagnostics GmbH, Germany

194 **Carbon dioxide driven pH reference method for transfer and scaling of fermentation processes**
Christian Klinger, Roche Diagnostics GmbH, Germany

195 **Scale-down high-throughput perfusion development with ambr 250**
Jarno Robin, Sanofi, France

196 **Overcoming manufacturing challenges for an early phase development program**
Yang Yang, Shire Pharmaceuticals, USA

197 **Clone selection and process lever optimization using an AMBR® 15 system for conversion of a roller bottle process to a suspension, perfusion bioreactor platform**
Seshu Tummala, Shire Pharmaceuticals, USA

198 **The relevance of cell size in a CHO fed batch process: Metabolic and transcriptomic characterization**
Dirk Martens, Wageningen University, Netherlands

199 **The journey from tech transfer to BLA submission: Case study of a NS0 cell culture process from 2000L stainless steel bioreactor to 2000L disposable bioreactor**
Jincai Li, WuXi Biologics, China

200 **Rapid protein production using CHO cells: From transfection to 100g in 6 weeks**
Jill Cai, WuXi Biologics, China

X: 30 Years of Cell Culture Engineering

201 **Fast predictive expression platform – CHO-K1 with transposase**
Bram D. Estes, Amgen Inc., USA

202 **Sanofi in-house medium: Exceeding expectations in cell line development as an alternative to commercially available basal medium**
Christine DeMaria, Sanofi, USA

203 **Development of a novel high-throughput platform for efficient perfusion-based cell culture process development**
Thomas Gagliardi, Shire Pharmaceuticals, USA

204 **A reference genome for the Chinese hamster based on a hybrid assembly strategy**
Kelvin H. Lee, University of Delaware, USA