Spring 5-13-2016

Conference Program

Kathy Chan
ECI

Program

Cell Culture Engineering XV

MAY 8-13, 2016 PALM SPRINGS

Conference Chairs

Robert Kiss
Genentech, Inc., USA

Sarah Harcum
Clemson University, USA

Jeff Chalmers
The Ohio State University, USA

ECI

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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 (Janis Biologics, USA)
Mike Betenbaugh (Johns Hopkins University, USA)
Barry Buckland (BiologicB LLC., USA)
Jeff Chalmers (Ohio State University, USA)
Matt Croughan (Amgen Bioprocessing Center / Keck Graduate Institute, USA)
Peter Gray (University of Queensland, Australia)
Carole Heath (Amgen, USA)
Wei-Shou Hu (University of Minnesota, USA)
Amine Kamen (McGill University, Canada)
Konstantin Konstantinov (Codiak Biosciences, USA)
Lynne Krummen (Genentech, 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)
Weichang Zhou (Wuxi App Tec Co., Ltd, China)

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Michael Butler (University of Manitoba, Canada)
Anurag Khetan (Bristol-Myers Squibb, USA)
Thomas Ryll (Biogen Idec, USA)
Tongtong Wang (Eli Lilly & Company, USA)
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Alan Dickson (University of Manchester, UK)
Laura Palomares (Instituto de Biotecnología UNAM, Mexico)
Oscar Lara-Velascos (Glaxo Smithkline, USA)
Jamey Young (Vanderbilt University, USA)
Frank Chaplen (Oregon State University, USA)
Susan Sharfstein (SUNY Polytechnic Institute, USA)
Raghavan Venkat (MedImmune, USA)
Chetan Goudar (Amgen, USA)
Chris Ramsborg (Juno Therapeutics, USA)
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Rob Thomas (Loughborough University, UK)
Tiffany Rau (Evonik Industries, USA)
Marcella Yu (Sanofi, USA)
Teng Ma (Florida State University, USA)
Weiwei Hu (Celgene, USA)
Nitya Jacob (Amgen, USA)
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Yan Li (Florida State University, USA)
Sarah Harcum (Clemson University, USA)
Bob Kiss (Genentech, USA)
Jeff Chalmers (The Ohio State University, USA)

Welcome from the CCE XV Chairs

Welcome everyone to La Quinta for the 15th Cell Culture Engineering (CCE) conference! For three decades, this series has established a reputation as one of the premiere cell culture engineering conferences and has had a significant impact on the direction of cell culture technologies and on biotechnology industry growth. Throughout this time, the CCE series has also been the main forum where industry and academia met to assess the science and technology progress in the field and to guide trends and establish good practices.

With 400 participants from 25 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. This was only possible because of generous donations from about fifty industrial partners. The program includes 50 oral presentations, plus four keynote addresses. In addition, we have nine thematic workshops and ~ 200 posters. As it 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.

Global sales of biologics continue to increase, with sales for 2015 estimated at >$200 billion (US $). These biologics products include recombinant proteins, monoclonal antibodies, antibody fusion proteins, antibody drug complexes, and other antibody-like complex proteins, and are still mainly expressed in mammalian cells. In particular, monoclonal antibodies and antibody fusion proteins continue to be the best-selling class of biologics, with all the top sellers manufactured using large scale mammalian cell cultures. The past two years has seen new antibodies commercialized as part of the introduction of cancer immunotherapies. We've also seen the the FDA's first approval of a biosimilar in March 2015. And, importantly for patients, we've also seen multiple products approved extremely rapidly following breakthrough therapy pathways established by regulators. Now, more than ever, the mammalian cell culture field must focus efforts on rapid establishment of high producing cell lines, development, scale-up and implementation of robust manufacturing processes to support rapid launches and reliable supplies of these commercial products. At the same time, many biosimilar products are being developed and introduced into the market, which will intensify these efforts. Beyond accelerated timeline and process intensification for higher productivities and improved product quality, efforts must also address the need to deliver cost-effective manufacturing of biologics, particularly in terms of reaching additional markets previously unserved by these powerful medicines in addition to responding to the potential pricing pressures driven by biosimilars. With this in mind, we've put a program together which will showcase new directions, challenges, and successes in the cell culture engineering arena, as shared by leading academic and industrial experts. In addition to addressing challenges related to development of novel protein biologics, we will continue the efforts to address the future of cell culture engineering beyond protein biologics. We know this will facilitate information exchange on how cell culture engineering principles derived from the development of novel biologics products are applicable to development of biosimilars and cell therapy products, particularly in terms of flexibility, high productivity, low costs, and consistent product quality. Additionally, we have introduced an oral session on "Current Concerns", with which we aim to highlight the most current challenges facing our community, be they derived from business, technical, or regulatory origin. We strongly encourage each and every 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 invite you to enjoy the Palm Springs area. We also invite you to enjoy your stay at the La Quinta resort, a full-service resort that offers many opportunities to enjoy recreation or relaxation. This resort is large enough to comfortably accommodate all attendees within the same location, which we highly valued as an important element of creating the desired atmosphere for a CCE conference. In listening to the feedback from prior conferences, we have arranged the schedule so as to provide you with a large chunk of free time on Tuesday afternoon, and we hope you will take advantage of the many opportunities to explore the Palm Springs area, or just take the opportunity to refresh and relax on the grounds of this lovely resort with its extensive swimming pools, tennis courts, golf, and health spa. 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 2018, and enjoy our last opportunity together to network and enjoy the camaraderie of our incredible cell culture community.

We would like to thank all of the oral session chairs, workshop program and session chairs, and poster session chairs, all of whom have worked with a remarkable dedication to put together a balanced and high quality program. And, once again, thanks to the 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 to participate 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. On that note, we have embarked on a new technological milestone for CCE – that of moving to a primarily electronic-based program format. We have made this decision based on an interest to reduce the use of paper and the cost of printing massive program books, while still giving you full access to oral and poster abstracts. This is a bit of an experiment for the first time, so we hope you will bear with us as we move the technology forward based on the benefits it can deliver.

Once again, welcome to La Quinta and the Palm Springs area, and a warm (no pun intended) welcome to Cell Culture Engineering XV. We look forward to meeting each of you personally.

Bob Kiss, Sarah Harcum, and Jeff Chalmers
Chairs, Cell Culture Engineering XV

Cell Culture Engineering XV

An ECI Conference Series

May 8-13, 2016
Greater Palm Springs Area, California, USA

2016 Cell Culture Engineering Award Winner

Konstantin B. Konstantinov

Konstantin Konstantinov has served the cell culture community for over two decades with pioneering contributions to the field and through his leadership and vision for the future. He was instrumental in the development of perfusion cultivation processing which has been incorporated into current commercial processes, and his vision for integrated continuous bioprocessing has profoundly altered the landscape and future of cell culture bioprocessing and biopharmaceutical manufacturing. Konstantin has been involved in the process development and commercial support of many biotherapeutics including Kogenate®, Kogenate-FS®, Myozyme®, Cerezyme®, Fabrazyme®, Thyrogen®, Campath/Lemtrada, BAY 81-8973, and BAY 94-9027. While his impact to the industry has been transformational, Konstantin has also been an important contributor to the cell culture literature as well with over 50 peer-reviewed publications. He has given over 150 conference presentations, reflecting his openness in sharing advances with the larger community. He has also chaired the Cell Culture Engineering conference, together with James Piret, and was the visionary and one of the founders of the highly successful ECI series on Integrated Continuous Biomanufacturing. He has continued to make sustained contributions to the cell culture community by co-chairing sessions and serving as an active member of the CCE steering committee. Among his most significant contributions community are:

- **Advanced Process Control of Perfusion Processes:** Konstantin recognized that next-generation manufacturing processes could be substantially more sophisticated and he formulated a long-term vision which began with rigorous process monitoring and the evaluation of novel on-line sensors followed by early laboratory-scale proof of concept demonstrations. The latest iteration of the control system Konstantin pioneered is currently in use at Bayer both in process development labs and for GMP manufacturing of clinical material.
- **Perfusion Process Development:** No other individual in the cell culture community has influenced perfusion process development more than Konstantin. His group was the first to successfully demonstrate large-volume cryobag preservation of cells, considerably shortening seed-train expansion. Konstantin's group came up with an ingenious buffering system which reduced bioreactor pCO2 by ~70%. ddditionally, Konstantin was central to the advancement of Bayer's cell retention technology, recognized by the ACS Industrial Biotechnology Award in 2004.
- **Integrated Continuous Biomanufacturing:** Konstantin has pioneered the concept of extending continuous manufacturing to downstream processing and ultimately all the way to drug product manufacturing. For instance, his group demonstrated volumetric productivities about 10 times higher than current commercially licensed fed-batch processes. Higher productivities can considerably reduce the footprint of a manufacturing facility and capital costs.
- **Mentorship:** Attracting and nurturing talent has been another defining attribute of Konstantin's career. This is perhaps best exemplified by the success of former members of his cell culture group at Bayer whose success makes Konstantin's contribution unique in the cell culture field.

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

Cell Culture Engineering XV

An ECI Conference Series

May 8-13, 2016
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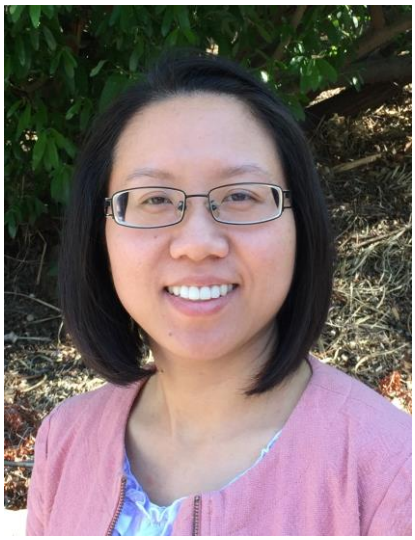
2016 Martin Sinacore Award Winner



Huong Le

Huong Le is the 2016 winner of the Martin Sinacore Outstanding Young Investigator Award. She joined the Process Development group at Amgen in 2012 after completion of a Chemical Engineering Ph.D. at the University of Minnesota. In her Ph.D. work she introduced advanced data mining to unveil hidden process characteristics from biomanufacturing data. Her work on systems analysis of transcriptome data helped advance transcriptomic applications in biopharmaceutical science. With her insight on transcriptomics she demonstrated a novel concept of dynamic cell engineering using endogenous promoters with various dynamics of expression profiles.

At Amgen, Huong continued engaging in first-principle based approaches to biopharmaceutical processes development despite the complexity and rigor associated with this approach, all while fully engaging in the core responsibility of advancing innovative programs in Amgen's early-stage pipeline. Recognizing gaps in reference sequence utilization for CHO transcriptomic studies, Huong led an effort to compare available public genomic references which resulted in an important recommendation for the approach of choice.

Furthermore, she has co-developed an integrated and automated transcriptomics analysis pipeline which substantially reduces the time and effort to analyze RNA-Seq data. Huong has extensively characterized intrinsic variability associated with metabolomic data in CHO cells and has shown that technical variability can surpass biological variability, highlighting the need to account for this variability during biological interpretation of -omics data. Collectively, her research efforts can accelerate wider adoption of omics-based approaches analysis to facilitate mechanism-driven biopharmaceutical cell line development and process optimization.

In addition to engaging in high quality first principles-based research over her ~4-year industrial career, Huong has played a key-role in the advancement of multiple innovative molecules in Amgen's early-stage pipeline, several of which have resulted in successful IND filings.

The **Martin Sinacore Outstanding Young Investigator Award** was established by ECI and Biogen to pay tribute to the many contributions Marty Sinacore made to the cell culture and bioprocessing community over the course of his productive thirty-year career. Although we have lost an influential thought leader, his influence will be felt for years to come given the role Marty played in shaping the way we approach the challenge of developing new therapeutics. Working with pre-adapted host cells, high throughput analytics to enable product quality assessments early in cell line development and the adoption of "omics" technology to improve bioprocessing are common place today thanks in part to the innovative vision Marty brought to the field over the years.

Beyond being a productive scientist, Marty will also be remembered for his genuine warmth and ability to connect with people of all types. He was deeply committed to working collaboratively and breaking down barriers so that common problems could be effectively solved. To this end, he formed the MassBio Up-stream Process Development Forum to provide a venue in which the Boston bioprocessing community could come together and share ideas.

His true passion however was sharing his knowledge, experiences and insights with junior scientists to help them grapple with challenging problems and grow as scientists. It is with this spirit in mind that the award has been created; to not only celebrate the immeasurable impact Marty's mentorship has had on the ca-reers of many young scientists but also acknowledge the accomplishments and exceptional promise of the recipients.

Previous winners of this award are **Colin Clarke** (Dublin City University, Ireland) and **Corinne Hoesli** (McGill University, Canada).

Conference Sponsors

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

Platinum Plus

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Kuhner Shaker Inc.

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Roche

Seattle Genetics

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Thomson Instrument Company

WuXi AppTech

Xell AG

Room locations and notes

- General sessions will be held in the Fiesta Ballroom.
- Poster Sessions will be in the Flores Ballroom. 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 and parallel sessions are listed in the program.
- All breakfasts and lunches will be in the All Grass Area.
- Dinner locations are listed in the program.
- Coffee breaks will be in Fiesta Veranda.
- Audiotaping, videotaping and photography of presentations are strictly prohibited.
- Speakers – Please leave at least 5 minutes for questions and discussion.
- Please do not smoke at any conference functions.
- The ECI office is in the Flores Office B and C.
- The Fountain Room is available for small *ad hoc* meetings during the week. Please see ECI staff if you would like to schedule a meeting.
- Turn your cellular telephones to vibrate or off during technical sessions.
- Please write your name in the front of this booklet in case it is misplaced.
- Be sure to check the participant list in this booklet to confirm that your listing is correct. If there are changes or updates, please login to the ECI website and update your listing so that the list that ECI will send to all participants after the conference will be correct.

Sunday, May 8, 2016

1:00 PM – 5:00 PM	**Conference Check-in (Flores Foyer)**
3:00 PM – 4:30 PM	**Workshops (3 in parallel)**
	Workshop 1: Advances in cell line engineering and protein expression strategies (Flores 6, 7, 8) ***Facilitators*:** Trent Munro (Amgen) and Richard Schwartz (NIH) *Sponsored by UCB Pharma SA*
	Workshop 2: Increasing speed to the clinic while ensuring future manufacturability (Fiesta 10, 13, 14) ***Facilitators*:** Suzanne Farid (UCL) and Steven Lang (Janssen Biotherapeutics) *Sponsored by Gilead Sciences*
	Workshop 3: Advances in analytical methods and their use for process characterization (Fiesta 9, 11, 12) ***Facilitators*:** Claudia Buser (Sanofi) and Rao Kandula (Celgene) *Sponsored by Biomarin*
4:45 PM – 5:30 PM	**Opening Remarks** (Fiesta) **Conference Chairs: Robert Kiss, Sarah Harcum, Jeff Chalmers** **ECI Technical Liaison: Mike Betenbaugh** **Native American Dance Performance – Eric Runningpath**
5:30 PM – 6:30 PM	**Keynote – Ira Mellman (Genentech)** **The renaissance of cancer immunotherapy is a revolution for patients**
6:45 pm - 8:15 pm	**Dinner** (La Casa)
8:30 PM – 10:30 PM	**Poster Session (Authors of even-numbered posters are asked to stay with their posters)** *Sponsored by Applikon Biotechnology, Inc. and Celgene*

Monday, May 9, 2016

6:30 AM – 8:00 AM	**Breakfast Buffet**
	Organizing Committee Breakfast Meeting (The Studios)
8:00 AM – 9:55 AM	**Session 1: Novel Protein Formats & Technologies** *Sponsored by Genentech*
8:00 AM – 8:05 AM	**Introduction** – Session Chairs John Joly (*Genentech*) Jennifer Maynard (University of Texas, Austin)
8:05 AM – 8:15 AM	**Poster Highlights** **8:05 AM Poster Highlight for Novel Protein Formats (Session 1):** Alyssa Powell (Ambrx) Antibody production with site-specific non-natural amino acid incorporation for generation of antibody drug conjugates **8:10 AM Poster Highlight for Non-Protein Products (Session 9):** Suzanne S. Farid (University College London) Cell therapy manufacturing strategies: Impact on cost of goods, cost of development and commercialization
8:15 AM – 8:40 AM	**Talk 1:** Steven Lang (Janssen R&D) Building quality novel formats and development processes
8:40 AM – 9:05 AM	**Talk 2:** Jennitte Stevens (Amgen) Engineering, expression screening, and production cell line development of hetero Ig molecules using charge pair mutations
9:05 AM – 9:30 AM	**Talk 3:** Christoph Spiess (Genentech) Bispecific antibodies: Strategies, considerations and challenges
9:30 AM – 9:55 AM	**Talk 4**: Pierre Moretti (Glenmark Pharma) A novel bispecific antibody for HER2^{+} breast cancer: The BEAT GBR 1302
10:00 AM – 10:30 AM	**Coffee Break / Networking**
10:30 AM – 11:15 AM	**Keynote – Stephen Hadley (Gates Foundation)** **Challenges developing biologics for the prevention and treatment of infectious diseases impacting global health**
11:15 AM – 12:20 PM	**Session 2a: Cell Line Development Advances**
11:15 AM – 11:20 AM	**Introduction** – Session Chairs Scott Estes (Codiak Biosciences) Alan Dickson (University of Manchester)

Monday, May 9, 2016 (continued)

11:20 AM – 11:30 AM	**Poster Highlights** **11:20 AM Poster Highlight for Cell Line Development Advances (Session 2)** Jae Seong Lee (Technical University of Denmark) Accelerated homology-directed targeted integration of transgenes in CHO cells via CRISPR/Cas9 and fluorescent enrichment **11:25 AM Poster Highlight for Application of 'Omics (Session 8):** Hooman Hefzi (UCSD) A community genome-scale model of Chinese hamster ovary cell metabolism identifies differences in the efficiency of resource utilization for various bioprocesses
11:30 AM – 11:55 AM	**Talk 5:** Wei-Shou Hu (University of Minnesota) Systems engineering of a CHO cell line for enhanced process robustness
11:55 AM – 12:20 PM	**Talk 6:** Wei-Kuang Chi (Development Center for Biotechnology of Taiwan) Omics approach for generating a high-yield CHO cell line producing monoclonal antibodies
12:20 PM – 1:45 PM	**Lunch**
1:45 PM – 3:30 PM	**Session 2b: Cell Line Development Advances (continued)**
1:45 PM – 1:50 PM	**Introduction** – Session Chairs Scott Estes (Biogen) Alan Dickson (University of Manchester)
1:50 PM – 2:15 PM	**Talk 7:** Nathan E. Lewis (University of California, San Diego) Predictive engineering of CHO cells using systems biology models
2:15 PM – 2:40 PM	**Talk 8:** Helene Faustrup Kildegaard (Technical University of Denmark) Generation of desirable CHO cell factories with predictive culture performance using CRISPR/Cas9-mediated genome engineering
2:40 PM – 3:05 PM	**Talk 9:** Kerstin Otte (Biberach University of Applied Sciences) Effective microRNAs for cell line engineering and cellular mechanisms of action
3:05 PM – 3:30 PM	**Talk 10:** Yongping Crawford (Genentech) Developing the host for targeted integration cell line development
3:30 PM – 4:00 PM	**Coffee Break / Networking**
4:00 PM – 6:20 PM	**Session 3: Integrated Continuous Processing for Biologics**
4:00 PM – 4:05 PM	**Introduction** – Session Chairs Oscar Lara-Velasco (GSK) Laura Palomares (UNAM)

Monday, May 9, 2016 (continued)

4:05 PM – 4:15 PM	**Poster Highlights** **4:05 PM Poster Highlight for Integrated Continuous Processing (Session 3)** Daniel Vázquez (Max Planck Institute) Process optimization for semi-continuous virus production at high cell densities **4:10 PM Poster Highlight for Applications of QbD & PAT (Session 10)** Gene Schaefer (Janssen) Moving from a bioreactor scale-up/scale-down approach to a more holistic operational design space view
4:15 PM – 4:40 PM	**Talk 11:** Udo Reichl (Max Planck Institute) Process optimization for semi-continuous virus production at high cell densities
4:40 PM – 5:05 PM	**Talk 12:** Zhimei Du (Merck) Evolution of an integrated continuous antibody manufacturing process
5:05 PM – 5:30 PM	**Talk 13:** Jason Walther (Sanofi) Overcoming process intensification challenges to deliver a manufacturable and competitive integrated continuous biomanufacturing platform
5:30 PM – 5:55 PM	**Talk 14:** Gregory W. Hiller (Pfizer) Cell-controlled high-intensity perfusion and hybrid fed-batch systems that drastically reduce perfusion rates and harmonize with continuous downstream processing
5:55 PM – 6:20 PM	**Talk 15:** Ricardo Silva (iBET) Purification of a hepatitis C vaccine candidate: Comparison between multi- column chromatographic processes operated in positive and negative mode
6:30 PM – 8:30 PM	**Dinner (Tennis Courtside)**
8:30 PM – 10:30 PM	**Poster Session (Authors of odd-numbered posters are asked to stay with their posters)** *Sponsored by GE Healthcare, Irvine Scientific and Kerry*

Tuesday, May 10, 2016

6:30 AM – 8:00 AM	**Breakfast Buffet**
8:00 AM – 10:15 AM	**Session 4a: Current Concerns**
8:00 AM – 8:05 AM	**Introduction** – Session Chairs Tongtong Wong (Lilly) Jamey Young (Vanderbilt University)
8:05 AM – 8:10 AM	**Poster Highlight for Current Concerns (Session 4):** Kelvin Lee (University of Delaware) A host cell protein that may impact polysorbate degradation
8:10 AM – 8:35 AM	**Talk 16:** Beth Junker (Merck) Life in the fast lane: Developing and commercializing KEYTRUDA®, a novel breakthrough therapy designation oncology therapy, in three years from first patient dosed to US approval
8:35 AM – 9:00 AM	**Talk 17:** Nicole Borth (BOKU University of Natural Resources and Applied Life Sciences) To clone or not to clone? – Wrong question! An investigation on genome heterogeneity and stability and on what controls cell behavior
9:00 AM – 9:25 AM	**Talk 18:** Brian E. Mickus (Gilead Sciences) Targeted sequencing for comprehensive genetic characterization of a recombinant CHO cell line
9:25 AM – 9:50 AM	**Talk 19:** Christopher C. Frye (Eli Lilly) Polysorbate 20 and 80 degradation by Group XV lysosomal phospholipase A2 Isomer X1 in monoclonal antibody formulations
9:50 AM – 10:15 AM	**Talk 20:** Kevin Kayser (SAFC) Genetic engineering of MMV virus resistance into CHO cells: Probing the role of various CHO sialyltransferases in virus binding and internalization
10:15 AM – 10:45 AM	**Coffee Break / Networking**
10:45 AM – 12:45 PM	**Session 5: Scale-up and Scale-down Challenges**
10:45 AM – 10:50 AM	**Introduction** – Session Chairs Anurag Khetan (Bristol-Myers Squibb) Frank Chaplen (Oregon State University)
10:50 AM – 10:55 AM	**Poster Highlight for Scale-up and Scale-down Challenges (Session 5):** Jin Yin (Sanofi) A holistic approach to the scale-up of a microcarrier-based perfusion cell culture process for the production of a therapeutic enzyme
10:55 AM – 11:20 AM	**Talk 21:** Alex Doane (Biogen) Implementation of a recirculating TFF N-1 perfusion system at manufacturing scale: Conquering process hurdles and scaling challenges

Tuesday, May 10, 2016 (continued)

11:20 AM – 11:45 AM	**Talk 22:** Weili Wang (MaxCyte) Seamless scalability, consistency and quality of transient protein production in CHO Cells by using MaxCyte flow electroporation technology
11:45 AM – 12:10 PM	**Talk 23:** Zizhuo Xing (Bristol- Myers Squibb) A carbon dioxide stripping model for mammalian cell culture in manufacturing scale bioreactors
12:10 AM – 12:35 PM	**Talk 24:** Weichang Zhou (WuXi AppTec) Scale-up and scale-down challenges for a high density long-term perfusion suspension cell culture in large-scale single use bioreactors
12:35 PM – 1:30 PM	**Pick-up Box Lunches**
1:30 PM – 5:30 PM	**Networking / Free Time**
5:30 PM – 7:00 PM	**Workshops (3 in parallel)** **Workshop 4:** Next generation manufacturing design: Batch to continuous (Fiesta 9, 11, 12) ***Facilitators*:** Chetan Goudar (Amgen) and Rashmi Kshirsagar (Biogen) *Sponsored by Genzyme* **Workshop 5:** Empowering the next generation of cell culture scientists and engineers: Training and funding (Fiesta 10, 13, 14) ***Facilitators*:** Matt Croughan (KGI), Anne Robinson (Tulane University) and Gene Schaefer (Janssen R&D) *Sponsored by Eppendorf, Inc.* **Workshop 6:** Lessons learned on quality by design approach through process development and characterization (Flores 6, 7, 8) ***Facilitators*:** Thomas Link (Roche) and Vijay Janakiraman (Merck) *Sponsored by Bristol-Myers Squibb*
7:00 PM – 9:00 PM	**Dinner (All Grass Area)**
9:00 PM – 10:30 PM	**Poster Session (Authors of even-numbered posters are asked to stay with their posters)** *Sponsored by Lonza Biologics plc, Novo Nordisk A/S and MilliporeSigma*

Wednesday, May 11, 2016

6:30 AM – 8:00 AM	**Breakfast Buffet**
8:00 AM – 9:50 AM	**Session 6a: Impact of Process Conditions on Product Quality** *Sponsored by Thermo Fisher Scientific*
8:00 AM – 8:05 AM	**Introduction** – Session Chairs Thomas Ryll (Immunogen) Susan Sharfstein (SUNY Polytechnic Institute)
8:05 AM – 8:10 AM	**Poster Highlight for Impact of process conditions on product Quality (Session 6)** Karin Anderson (Pfizer) Impact of culture conditions and cell age on sequence variant levels in monoclonal antibody biotherapeutics
8:10 AM – 8:35 AM	**Talk 25:** Jose C. Menezes (Lisbon University) Bioanalytical comparability of biotechnology products subject to changes in their manufacturing process
8:35 AM – 9:00 AM	**Talk 26:** David Bruehlmann (Merck Serono SA and University of Würzburg) The potential of small molecules to modulate glycosylation by media design
9:00 AM – 9:25 AM	**Talk 27:** Gyun Min Lee (KAIST) Factors affecting the sialylation of Fc- fusion protein in recombinant CHO cell culture
9:25 AM – 9:50 AM	**Talk 28:** Sigma S. Mostafa (KBI BioPhama) Optimization of glycosylation and charge distribution through culture parameters and supplements
9:50 AM – 10:20 AM	**Coffee Break / Networking**
10:20 AM – 11:15 AM	**Session 6b: Impact of Process Conditions on Product Quality**
10:20 AM – 10:25 AM	**Continuation** – Session Chairs Thomas Ryll (Immunogen) Susan Sharfstein (SUNY Polytechnic Institute)
10:25 AM – 10:50 AM	**Talk 29:** Masaru Shiratori (Genentech) Identification of cell culture levers to lower trisulfide modifications in monoclonal antibodies produced in CHO cell culture
10:50 AM – 11:15 AM	**Talk 30:** Sven Markert (Roche Diagnostics GmbH) From observation to control: Using cell culture automation for enhanced product quality optimization
11:15 AM – 12:15 PM	**Keynote – Jan Hillson (Momenta Pharmaceuticals)** **Cell culture engineering and biosimilars: The physician's perspective**

Wednesday, May 11, 2016 (continued)

12:15 PM – 1:45 PM	**Lunch**
1:45 PM – 2:15 PM	**Sinacore Award – Huoug Le (Amgen)** **Evaluation of public genome references for RNA-seq data analysis in Chinese hamster ovary cells**
2:15 PM – 3:15 PM	**Session 7a: Advanced Cell Culture Process Control**
2:15 PM – 2:20 PM	**Introduction** – Session Chairs Raghavan Venkat (MedImmune) Mike Butler (University of Manitoba)
2:20 PM – 2:25 PM	**Poster Highlight for Advanced Cell Culture Process Control (Session 7)** Sha Sha (University of Massachusetts Lowell) Real time prediction and control of glycoform profile of mammalian cell cultures using in silicoglycosylation model coupled with extracellular metabolites
2:25 PM – 2:50 PM	**Talk 31:** Bhanu Chandra Mulukutla (Pfizer) Systems Analysis of CHO cell metabolism for enhanced fed-batch process performance: Identification of novel growth inhibitors and their control
2:50 PM – 3:15 PM	**Talk 32:** Catarina Brito (iBET) 3D tumor models with defined cellular and physico- chemical components: Impact of recapitulative tumor microenvironment on disease progression
3:15 PM – 3:45 PM	**Coffee Break / Networking**
3:45 PM – 5:25 PM	**Session 7b: Advanced Cell Culture Process Control**
3:45 PM – 4:10 PM	**Talk 33:** Veronique Chotteau (KTH Royal Institute of Technology) Poly-pathway model approach: Simulation of multiple metabolic states
4:10 PM – 4:35 PM	**Talk 34:** Seongkyu Yoon (University of Massachusetts Lowell) Real time prediction and control of glycoform profile of mammalian cell cultures using in silico glycosylation model coupled with extracellular metabolites
4:35 PM – 5:00 PM	**Talk 35:** Stephen Goldrick (UCL/MedImmune) Application of multivariate data analysis in the monitoring and control of mammalian cell processes
5:00 PM – 5:25 PM	**Talk 36:** John Smelko (Biogen) Implementation of Raman spectroscopy at manufacturing scale: Overcoming modeling challenges while implementing advanced process control
5:25 PM – 6:30 PM	**Networking / Free Time**

Wednesday, May 11, 2016 (continued)

6:30 PM – 9:00 PM	**Dine-Around Town (transportation provided)**
9:00 PM – 10:30 PM	**Poster Session (Authors of odd-numbered posters are asked to stay with their posters)** *Sponsored by Solentim Ltd. and Takeda*

Thursday, May 12, 2016

6:30 AM – 8:00 AM	**Breakfast Buffet**
	Organizing Committee Breakfast Meeting (Diego Rivera Room)
8:00 AM – 9:45 AM	**Session 8a: Application of 'Omics and other Technologies for Accelerating and Enhancing Bioprocess Development**
8:00 AM – 8:05 AM	**Introduction** – Session Chairs Chetan Goudar (Amgen) Hal Alper (University of Texas, Austin)
8:05 AM – 8:30 AM	**Talk 37:** Jamey D. Young (Vanderbilt University) Application of ^{13}C flux analysis to identify high-productivity CHO metabolic phenotypes
8:30 AM – 8:55 AM	**Talk 38:** Amanda Lewis (Bristol-Myers Squibb) Understanding and controlling sialyation in a CHO fusion protein at lab and manufacturing scale using targeted omics techniques
8:55 AM – 9:20 AM	**Talk 39:** Markus Michael Mueller (Boehringer Ingelheim Pharma GmbH) Targeting product quality: Where systems biotechnology and process design meet
9:20 AM – 9:45 AM	**Talk 40:** Neil Templeton (Merck) Fluxomics: The integration of metabolic flux analysis (MFA) with multivariate data analysis (MVDA) to identify key process parameters for CHO cell culture
9:45 AM – 10:15 AM	**Coffee Break / Networking**
10:15 AM – 12:05 AM	**Session 8b: 'Omics Applications**
10:15 AM – 10:40 AM	**Talk 41:** Chapman Wright (Biogen) Biotherapeutic development in the 'Omics Age: The CHO genome and beyond
10:40 AM – 11:05 AM	**Talk 42:** Dong-Yup Lee (National University of Singapore) Mammalian systems biotechnology: An integrative framework for combining *in silico* modeling and multi-Omics datasets in different CHO parental cell lines
11:05 AM – 12:05 PM	**Keynote – Michael Jensen (Juno Therapeutics)** **Next Gen CAR T-cells**
12:05 PM – 1:45 PM	**Lunch**

Thursday, May 12, 2016 (continued)

Two Parallel Oral Sessions

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

Thursday, May 12, 2016 (continued)

4:00 PM – 5:30 PM — **Workshops (3 in parallel)**

Workshop 7: Applications of omics technologies
***Facilitators*:** Erdmann Rapp (Max Planck Institute) & Manuel Carrondo (iBET) (Fiesta 9-13)
Sponsored by Amgen

Workshop 8: Modulating product quality through cell culture process
***Facilitators*:** Kara Calhoun (Genentech) and Shyamsundar Subramanian (Teva) (Fiesta 1-8)
Sponsored by Lilly

Workshop 9: Opportunities for and challenges of process transfer and Scale-up (Flores 1, 2, 3)
Facilitators: Gayle Derfus (Gilead) and Arthi Narayanan (Genentech)
Sponsored by MilliporeSigma

5:30 PM – 6:00 PM — **Coffee Break / Networking**

6:00 PM – 7:00 PM — **CCE Award Lecture** — Jeff Chalmers (Ohio State University)

7:00 PM – 7:30 PM — **Reception** (Flores Foyer and Veranda)

7:30 PM – 10:30 PM — **Banquet** (Flores 4-8)
Sponsored by Genentech

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

Friday, May 13, 2016

6:30 AM – 8:30 AM — **Breakfast Buffet**

8:30 AM – 9:30 AM — **Departures**

Poster Presentations

Session I: Cell Line Development Advances

1. **Automated, high throughput imaging during cell line development to increase the assurance of clonality**
   David Shaw, Genentech, Inc., USA

2. **Establishing a robust two-step cloning strategy for the generation of cell lines with a high probability of monoclonality**
   Alison Young, Fujifilm Diosynth Biotechnologies, United Kingdom

3. **Proof that can travel - documented clonality report for regulatory submission**
   Paul Miller, Solentim Inc, United Kingdom

4. **Insight into single cell cloning in serum-free media**
   Tsuyoshi Yamaguchi, Kyowa Hakko Kirin Co., Ltd., Japan

5. **Karyotype-based analysis of cell line instability and clonality in CHO cells**
   Jong Youn Baik, University of Delaware, USA

6. **Assessment of genomic instability in Chinese Hamster ovary (CHO) cells**
   Sabine Vcelar, ACIB GmbH, Austria

7. **Identifying low-Level sequence variants via next generation sequencing to aid stable CHO cell line screening**
   Sheng Zhang, AbbVie, USA

8. **Time course of transcription and chromatin states during batch culture in Chinese Hamster ovary cells**
   Inmaculada Hernandez, Austrian Center of Industrial Biotechnology, Austria

9. **Prediction of stable and transient expression of recombinant proteins from CHO cells based upon translational reprogramming**
   Charlotte Godfrey, University of Kent, United Kingdom

10. **Generation of a stable pluripotent cell line from Chinese Hamster embryonic fibroblasts**
    Dong Seong Cho, University of Minnesota, USA

11. **Microfluidic accelerated evaluation of CHO cell clones by perfusion of fed-batch conditioned media**
    Darek Sikorski, University of British Columbia, Canada

12. **Genome-wide RNAi screen for improved functional expression of recombinant proteins from HEK 293 cells**
    Joseph Shiloach, NIDDK, USA

13. **Bridging the gap of screening and scale up in CHO, hybridoma, HEK293 and other cell lines: Single use optimum growth flasks 30mL-5L flasks with transfer caps, and ports**
    Sam Ellis, Thomson Instrument Company, USA

14. **Sub-physiological culture temperature boosts expression levels of membrane proteins in CHO cells**
Sampath Kumar, Adimab LLC, USA

15. **Varied productivity according to the differences between targeted locations of antibody expression vectors in Chinese Hamster ovary cells**
Noriko Yamano, Tokushima University, Japan

16. **Targeted integration of multiple active sites in CHO genome for rapid generation of stable and high monoclonal antibody producing cell lines**
Yuansheng Yang, Bioprocessing Technology Institute, Singapore

17. **Identifying opportunities in cell engineering for the production of 'difficult to express' recombinant proteins**
Hirra Hussain, The University of Manchester, United Kingdom

18. **CHO-K1 host cell engineering strategy enabling the establishment of strains producing higher yields of recycling antibodies**
Hisahiro Tabuchi, Chugai Pharmaceutical, Japan

19. **Flow cytometry screening strategy for the enrichment of high-producing Chinese Hamster ovary cells for monoclonal antibody manufacturing**
Takeshi Okumura, Daiichi Sankyo Co., Ltd., Japan

20. **Reduction of metabolic waste products, ammonia and lactate, through the coupling of GS selection and LDH-A down-regulation in CHO cells**
Soo Min Noh, KAIST, South Korea

21. **Cre-loxP-controlled cell-cycle checkpoint engineering in Chinese Hamster ovary cells**
Takeshi Omasa, Osaka University, Japan

22. **Expression of glycoproteins with excellent pharmacokinetic properties on the novel CAP-Go expression platform**
Silke Wissing, CEVEC Pharmaceuticals, Germany

23. **An integrated cell line development platform for generation of high yielding CHO stable cell lines expressing a stabilized trimeric pre-fusion RSV F recombinant viral glycoprotein**
Richard Schwartz, Vaccine Research Center, NIAID, NIH, USA

24. **Development of hyper osmotic resistant CHO host cells**
Yasuharu Kamachi, Takeda Pharmaceutical Company Limited, Japan

25. **Genetic engineering of CHO cells for viral resistance to MMV: Targeting virus binding, internalization, intracellular trafficking and transport to nucleus**
Joaquina Mascarenahs, SAFC, USA

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

27. **CRISPR-CAS9 knockout library for CHO**
Lasse E. Pedersen, Technical University of Denmark, Denmark

28. **Glycoengineering of Chinese Hamster ovary cell for modulating glycoprotein N-linked sialylation**
Chengyu Chung, Johns Hopkins University, USA

29. **Re-programming CHO cell metabolism using miR-23 tips the balance towards a highly productive phenotype**
Niall Barron, Dublin City University, Ireland

30. **A novel platform for high throughput cell line screening & development**
Maria Wendt, Genedata AG, Switzerland

31. **Cell Express 100TM - A robust, simple and cost effective alternative to high-throughput automated platforms for cell line development**
Raj Kumar Kunaparaju, USHA Bio-tech, India

Session II: Impact of Process Conditions on Product Quality

32. **Changes in product quality – what is comparable "enough" and what is "similar enough?"**
David K. Robinson, Robinson Vaccines and Biologics LLC, USA

33. **Improving the productivity and product quality of antibodies expressed from a CHO transient system**
Athena Wong, Genentech, Inc., USA

34. **A systematic development approach to optimize and control biopharmaceutical product quality**
Min Zhang, Fujifilm Diosynth Biotechnologies, USA

35. **Strategies for optimizing a cell culture platform to achieve high recombinant protein titer without impacting product quality**
Natarajan Vijayasankaran, Genentech, Inc., USA

36. **Impact of harvest conditions on the glycosylation profile of a therapeutic antibody**
Raghavan Venkat, MedImmune LLC, USA

37. **Investigating the impact of process optimization on productivity, product quality, cell metabolism, and intracellular environment**
Shailendra Singh, MedImmune, USA

38. **Enhancing enveloped viral particles production by targeted supplementation design: Releasing bottlenecks in IC-BEVS**
António Roldão, iBET, Portugal

39. **Efforts to reduce impact of media variability on product quality for a commercial perfusion process**
Nirel Rillera, BioMarin Pharmaceutical Inc., USA

40. **Bioreactor perfusion via single-use centrifugation has fewer product quality implications than tangential flow filtration**
Rustin Shenkman, Shire, USA

41. **Impact of culture conditions and cell age on sequence variant levels in monoclonal antibody biotherapeutics**
Karin Anderson, Pfizer, Inc., USA

42. **Evaluation of product antibody (mAb) heterogeneity in non-clonal cell pools for early pre-clinical development**
Gabi Tremml, Bristol-Myers Squibb, USA

43. **A biphasic cultivation strategy to optimize protein expression and minimize aggregation of the final product**
Andreas Castan, GE Healthcare, Ireland

44. **Adjusting product quality attributes of a biosimilar using process levers**
Brett Belongia, Momenta Pharmaceuticals, USA

45. **Improving the metabolic efficiency of mammalian cells and its impact on glycoproteins quality**
Eric Karengera, École Polytechnique de Montréal, Canada

46. **CHO cell culture process impacts monoclonal antibody trisulfide modification and sulfhydryl-drug conjugation**
Michael Hippach, Agensys, Inc, USA

47. **Critical process parameter identification using the ambr15(tm) for process characterization**
Matthew Zustiak, Patheon Biologics, USA

48. **Influence of cultivation parameters or supplement on product qualities and culture performances during perfusion**
Kyu-Yong Kim, LG Life Sciences, Ltd., South Korea

Session III: Advanced Cell Culture Process Controls and Modeling

49. **Reduction of N-glycan profile variation by using capacitance probes for optimized process control**
Christoffer Bro, Biogen, Denmark

50. **Advanced process monitoring and feedback control to enhance cell culture process production and robustness**
An Zhang, Biogen, USA

51. **Monitoring live stem cells in suspension and attached to carriers in conventional and single use bioreactors**
John Carvell, Aber Instruments Ltd., United Kingdom

52. **Monitoring live biomass in disposable bioreactors in range of vessel formats**
Dan Kopec, Sartorius Stedim Biotech, Germany

53. **Use of an automated, integrated laboratory environment to enable predictive modeling approaches for identifying critical process parameters and controlling key quality attributes**
Brandon J. Downey, Bend Research, Inc., USA

54. **Softsensors: New approach for process monitoring cell growth in small scale fermentation systems**
Wolfgang Paul, Roche Innovation Center, Germany

55. **Advancement of cell culture process understanding and control through real-time multivariate process monitoring, use of statistical process modes and deployment of process analytical technologies**
Patrick O. Gammell, Amgen, USA

56. **Agent-based model predictive framework to control cell culture bioreactors**
Elif S. Bayrak, Amgen Inc., USA

57. **Kinetic physico-chemical model for cell culture processes – applications and opportunities**
Natraj Ram, AbbVie, USA

58. **Accelerate cell culture development using the modular automated sampling technology (MASTTM) platform in an integrated bioprocess lab environment**
Clinton B. Pepper, Bend Research, USA

59. **Development of bioreactor auto-sampling system for real time product quality monitoring in mammalian cell culture**
Meena George, Boehringer Ingelheim Fremont Inc, USA

60. **Lensless imaging for continuous CHO viable cell density monitoring in bioreactors**
Geoffrey Esteban, IPRASENSE, France

61. **Continuous suspension cell culture monitoring in bioreactors using quantitative imaging**
Ann D'Ambruoso, Applikon, USA

62. **Investigating the reverse Warburg effect: How high extracellular lactate alters breast cancer metabolism**
Daniel C. Odenwelder, Clemson University, USA

63. **Real time prediction and control of glycoform profile of mammalian cell cultures using in silicoglycosylation model coupled with extracellular metabolites**
Sha Sha, University of Massachusetts Lowell, USA

64. **A stochastic model to study genetic and metabolic effects on N-linked protein glycosylation**
Philipp N. Spahn, University of California, San Diego, USA

65. **CHO-specific recombinant protein glycosylation reaction network**
Benjamin G. Kremkow, University of Delaware, USA

66. **Controller design for effective glycosylation control in mAbs**
Devesh Radhakrishnan, University of Delaware, USA

67. **Elucidating glycosylation pattern of protein produced in mammalian cells**
Tung S. Le, University of Minnesota, USA

68. **Poly-pathway model approach: Simulation of multiple metabolic states**
Erika Hagrot, KTH Royal Institute of Technology, Sweden

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

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

70. **Characterization of TAP Ambr250 disposable bioreactors as a reliable scale-down model for biologics process development**
Ping Xu, Bristol-Myers Squibb, USA

71. **Metabolomic analysis for scale-down model improvement**
Eric Garr, Bristol-Myers Squibb, USA

72. **Demonstrating process performance comparability of the Keytruda® upstream process after transfer and scale-up to different manufacturing sites**
Jürgen van de Lagemaat, MSD, Netherlands

73. **Challenges in the use of scale-down models for understanding and mitigating process variations of a monoclonal antibody production process**
A. Peter Russo, Merck & Co., Inc., USA

74. **Scale-up in the single use age: Does geometry matter?**
Colin Jaques, Lonza Biologics, United Kingdom

75. **A rapid approach for basal and feed media optimization in ambr® 15 bioreactors**
Michael Gillmeister, Lonza, USA

76. **Tubespins as a suitable scale-down model of 2L high cell density bioreactors for CHO cell culture**
Natalia Gomez, Amgen , USA

77. **Process scale-up issues: Relics of the past or continues to cause major headaches**
Sadettin Ozturk, MassBiologics, USA

78. **Novel, efficient scale-up of inclined settlers for perfusion bioreactor cultures**
Dhinakar S. Kompala, Sudhin Biopharma Company, USA

79. **Bioreactor scale-up harmonization - From process development to manufacturing**
Claudia Berdugo-Davis, Cook Pharmica LLC, USA

80. **Scale-up and scale-down topics facing the industry**
Markus M. Mueller, Boehringer Ingelheim Pharma GmbH & Co.KG, Germany

81. **Case study for improved process robustness at manufacturing scale for a mammalian cell culture process: Troubleshooting medium preparation and gas entrance velocity effects**
Robin Luo, Boehringer Ingelheim, USA

82. **Performance consistency of fed-batch cultures across multiple systems used in upstream process development**
Matthieu Stettler, Merck Serono, Switzerland

83. **Overcoming scale-up challenges with a non-robust cell line**
Sigma Mostafa, KBI Biopharma, USA

84. **Application of online CO_2 monitoring to enable a better understanding of cell culture performance variation between GMP-scale and scaled-down bioreactors**
Ting-Kuo Huang, Genentech Inc., USA

85. **Establishing a pH measurement reference method for site/process transfer purposes**
Meg Tung, Genentech Inc., USA

86. **Case study: Lessons learned during tech transfer at a multi-product legacy launch facility**
Arthi Narayanan, Genentech Inc., USA

87. **Scale down model in industrial cell culture processes – A powerful tool to ensure reliable production**
Marco Jenzsch, Roche Pharma Biotech, Germany

88. **Advances in bioreactor scale-down modeling using Process Analytical Technology (PAT)**
Liying Yang, Astrazeneca, USA

89. **Challenges of scale down model for disposable bioreactors: Case studies on growth & product quality impacts**
Jincai Li, WuXi AppTec, China

90. **A holistic approach to the scale-up of a microcarrier-based perfusion cell culture process for the production of a therapeutic enzyme**
Jin Yin, Genzyme, A Sanofi Company, USA

91. **Bioreactor process improvements in a legacy perfusion-based process**
Mustafa Hanif, Genzyme, A Sanofi Company, USA

92. **Preferentially selecting cellular metabolism and improving productivity by controlling do and Pco2**
Sofie Goetschalckx, Genzyme, A Sanofi Company, USA

93. **Challenges and their resolutions during process development and tech transfer of a late stage bispecific antibody product**
Marcella Yu, Sanofi, USA

94. **Scalability of the Mobius® single-use bioreactor from bench to clinical scale: Examination of key engineering parameters and robustness**
Lee Madrid, EMD Millipore, USA

95. **Single-step flask to 250 L cell culture with a hybrid mixing single-use bioreactor**
Nephi Jones, Thermo Fisher Scientific, USA

Session V: Integrated Continuous Process Development for Cell Culture

96. **Rapid development of a perfusion process with high productivity**
Sen Xu, Merck Research Laboratories, USA

97. **Integrated continuous bioprocessing - a gold mine for cell culture process understanding?**
Mats Akesson, Novo Nordisk A/S, Denmark

98. **Perfusion media development and evaluation with spin tube and ambr15 high-throughput small-scale models**
Yang Wang, Thermo Fisher Scientific, Inc., USA

99. **Process intensification through integration of upstream perfusion cell culture with downstream continuous chromatography in monoclonal antibody production**
Andreas Castan, GE Healthcare, Sweden

100. **Modeling perfusion for medium component optimization using ambr15TM**
Delia Lyons, SAFC, USA

101. **Small-scale comparison of pseudoperfusion feeding strategies using basal and concentrated feed media**
Leda R. Castilho, Federal University of Rio de Janeiro, Brazil

102. **Towards integrated continuous viral vaccines production using two-stage bioreactor systems**
Felipe Tapia, Max Planck Institute Magdeburg, Germany

103. **Development of a qualtiy driven integrated continuous biomanufacturing process**
Daniel Karst, ETH Zurich, Switzerland

104. **mAb product consistency in long duration microfiltration-based CHO perfusion process**
Douglas Rank, EMD Millipore, USA

105. **Toward development of continuous bioprocesses: Comparison of fed-batch and perfusion upstream production processes in early development**
B. Jean McLarty, Sanofi, USA

106. **Process intensification of perfusion: To steady-state, or unsteady-state, that is the question**
Henry Lin, Boehringer Ingelheim, USA

107. **Size matters: Assessment of a larger pore hollow fiber to reduce product retention in perfusion**
Samantha B. Wang, Boehringer Ingelheim, USA

108. **Process robustness and cell line variation in N-1 high density perfusion system**
Haofan Peng, Biogen, USA

109. **Process optimization for semi-continuous virus production at high cell densities**
Daniel Vázquez, Max Planck Institute for Dynamics of Complex Technical Systems, Germany

110. **Non-invasive real-time monitoring of glucose and lactate by NIR-spectroscopy during perfusion CHO culture**
Jean-Francois P Hamel, Massachusetts Institute of Technology, USA

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

111. **Understanding and overcoming process insults through application of 'omics technologies**
Alan Gilbert, Biogen, USA

112. **Technical evaluation of RNA-Seq and microarray approaches in comparative transcriptomics analysis of CHO cells**
Chun Chen, Amgen Inc., USA

113. **Evaluation of public genome references for RNA-Seq data analysis in Chinese Hamster ovary cells**
Huong Le, Amgen Inc, USA

114. **Increasing diversity of production cell lines through miniaturization, automation, and high-throughput analytics**
Kim Le, Amgen Inc., USA

115. **Utilizing RNA-Seq technique to improve molecular understanding of Chinese Hamster ovary (CHO) cell bioprocessing**
Yogender Kumar Gowtham, Clemson University, USA

116. **Manipulation and exploitation of MicroRNAs for enhanced recombinant protein production in CHO cells**
Tulshi Patel, University of Kent, United Kingdom

117. **Implementation and evaluation of a high-throughput siRNA screening system for suspension CHO cells**
Gerald Klanert, University of Natural Resources and Life Sciences, Vienna, Austria

118. **Lipidomic analysis to enhance the understanding of Chinese Hamster ovary cells**
Yue Zhang, Johns Hopkins University, USA

119. **Lipidomics for robust high performance process development**
Laetitia Malphettes, UCB Pharma SA, Belgium

120. **High titer transient gene expression platform based on GS CHO cell line – rapid protein expression tool for preclinical drug development**
Yashas Rajendra, Eli Lilly & Company, USA

121. **Improving biologics development by high performance glycoanalysis**
Erdmann Rapp, Max Planck Institute for Dynamics of Complex Technical Systems, Germany

122. **Genomics based methodology of cell-culturemedia formulation for improved bio-therapeutic productivity and quality consistency**
Hemlata Bhatia, University of Massachusetts Lowell, USA

123. **Multi-omic profiling of EPO producing CHO cell panel reveals metabolic adaptation to heterologous protein production**
Daniel Ley, Technical University of Denmark, Denmark

124. **A multi-omic approach to understanding recombinant protein degradation in Chinese Hamster ovary cells**
Ronan M. Kelly, Eli Lilly & Company, USA

125. **Multi-omic modeling of translational efficiency for synthetic gene design**
Joseph Longworth, University of Sheffield, United Kingdom

126. **Enhancing site-specific CHO produced antibody through media optimization using metabolomics approach**
Ching-Jen Yang, Development Center for Biotechnology, Taiwan

127. **A correction method for systematic error in metabolomic time-course data**
Stanislav Sokolenko, University of Waterloo, Canada

128. **Integration of transcriptomic data with a genome-scale model reveals key metabolic features of high producer CHO cell lines**
Ziomara P. Gerdtzen, CeBiB, Universidad de Chile, Chile

129. **Development of plate-based sialic acid assays to support clone screening and early Stage upstream process development**
Julie Gardin, BioMarin Pharmaceutical, Inc., USA

130. **Site-specific glycan analysis of proteins in cell culture conditioned media and sub-cellular fractions by LC-MS/MS for understanding the impact of process conditions on N-glycosylation**
Karina Bora de Oliveira, MedImmune, USA

131. **A community genome-scale model of Chinese Hamster ovary cell metabolism identifies differences in the efficiency of resource utilization for various bioprocesses**
Hooman Hefzi, University of California, San Diego, USA

132. **A bioinformatic pipeline for studying ribosome occupancy in CHO cells**
Shangzhong Li, University of California San Diego, USA

133. **13C flux analysis in industrial CHO cell culture applications**
Allison G. McAtee, Vanderbilt University, USA

134. **Elucidating cell line and tissue differences derived from cricetulus griseus by transcriptomics and proteomics**
Kelley Heffner, Johns Hopkins University, USA

Session VII: Non-Protein Products of Cell Culture

135. **Scale-down and initial characterization studies of an allogeneic cell therapy manufacturing process**
John Gaut, Celgene Cellular Therapeutics, USA

136. ***Poster Withdrawn***

137. **Expansion and differentiation of T cells under defined xeno-free culture conditions**
Jessie H.T. Ni, Irvine Scientific, USA

138. **Cell therapy manufacturing strategies: Impact on cost of goods, cost of development and commercialisation**
Suzanne S. Farid, University College London, United Kingdom

139. **An innovative protein delivery system for therapeutic cells**
Jean-Pascal Lepetit-Stoffaes, Université Laval, Canada

140. **Effect of cell-surface interactions on monocyte-derived immunotherapy products**
Corinne A. Hoesli, McGill University, Canada

141. **Optimization of a defined serum-free medium for the production of therapeutic human myoblasts**
Jean-Pascal Lepetit-Stoffaes, Université Laval, Canada

142. **Biological relevance of YAP regulation by Wnt signaling during neural tissue patterning of human induced pluripotent stem cells**
Yan Li, Florida State University, USA

143. **PCL-PDMS-PCL copolymer-based microspheres mediate cardiovascular differentiation from embryonic stem cells**
Yan Li, Florida State University, USA

144. **Neural patterning of human induced pluripotent stem cells for studying neurotoxicity**
Yuanwei Yan, Florida State University, USA

145. **Human cardiac stem cells for allogeneic cell therapies: integrating bioprocess development and 'omics characterization tools**
Paula Alves, iBET/NOVA-ITQB, Portugal

146. **Integrated strategies for the production, maturation and storage of functional cardiomyocytes derived from human pluripotent stem cells**
Margarida Serra, iBET, Portugal

147. **Integration of bioprocess design with transcriptomic and metabolomic characterization for the expansion of human pluripotent stem cells**
Margarida Serra, iBET, Portugal

148. **Scalable production of mesenchymal stem/stromal cells from different human sources in microcarrier-based stirred culture systems**
Ana Fernandes-Platzgummer, Universidade de Lisboa, Portugal

149. **Development of an adherent cell based virus production process in Mobius® sIngle-use bioreactor**
Michael Cunningham, EMD Millipore, USA

150. **Scaling microcarrier-based cell expansion processes**
Mark Szczypka, Pall Life Sciences, USA

151. **Transient production of VLPs in HEK 293 cells and the evaluation of parameters influencing transfection and expression**
Daniel Blackstock, NIH, USA

152. **Production of stable, immunogenic foot-and-mouth disease vaccine in a chemically-defined, serum-free medium optimized for BHK-21 Cells**
Paul Gulde, Thermo Fisher Scentific, USA

153. **Development of chemically-defined, animal component-free medium for suspension MDCK cell-based influenza vaccine production**
Jenny Bang, Irvine Scientific, USA

154. **Fluorescent influenza-like particles and control over their composition**
Marc G. Aucoin, University of Waterloo, Canada

155. **HEK293 suspension cell culture platform for production of viruses and viral vectors**
Sven Ansorge, National Research Council of Canada, Canada

156. **Efficient production of influenza virus-like particles in HEK-293SF cells**
Alina Venereo-Sanchez, Ecole Polytechnique de Montreal/National Research Council Canada, Canada

157. **A flow cytometric granularity assay for the quantification of infectious virus**
Megan Logan, University of Waterloo, Canada

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

158. **Impact of Poloxamer 188 variability on biologics manufacturing: Mitigations and causal investigation**
Salim Charaniya, Roche Pharma Technical Development, USA

159. **Evaluating sugar-based detergents as a potential alternative to poloxamer bubble protectant**
Jessica Wuu, Genentech, Inc., USA

160. **A host cell protein that may impact polysorbate degradataion**
Kelvin Lee, University of Delaware, USA

161. **Troubleshooting the recover of mater cell bank for a commerical product**
Mei Shao, Alexion Pharmaceuticals, USA

162. **Adapting an in-licensed/acquired cell culture process to platform conditions**
Raghu Shivappa, Johnson & Johnson, USA

163. **Challenges in the development and adaptation of platform process to existing pipeline**
Edmund Scarfo, Takeda Pharmaceutical Co Ltd, USA

164. **A holistic approach to facility protection from adventitious agents – A case study**
Matthew D. Osborne, Eli Lilly and Co., Ireland

165. **Nanofiltration as an effective means to prevent virus contamination of cell culture processes**
Kimberly Mann, EMD Millipore, USA

166. **The oxygen binding protein, HEMOXCell(R), increases CHO cell growth and extends viability by enhancing oxygen delivery**
Katrin Braasch, University of Manitoba, Canada

167. **The differential polarizability of CHO cells can be used to monitor changes in metabolism**
Katrin Braasch, University of Manitoba, Canada

168. **Development of antibody detection methods for active product at the cell culture stage**
Gregory Walsh, Genzyme, A Sanofi Company, USA

169. **Development and application of glycosyltransferases for in vitro glycoengineering**
Alfred Michael Engel, Roche Diagnostics GmbH, Germany

170. **Improvement of CHO specific productivity using amino acid derivatives**
Aline Zimmer, Merck KGaA, Germany

171. **Deepening Knowledge on CHO cells metabolism using multiple tracer substrates**
Manuel Carrondo, iBET, Portugal

172. **NMR-based design of chemically-defined protein-free feed medium for the CHO expression system**
Marina Goldfeld, Merck & Co., Inc., USA

173. **How to select the most suitable media for your cells**
Marcella CF Dalm, Synthon Biopharmaceuticals BV, Netherlands

174. **Comparison of commercial CHO cell media formulations using material-oriented recurrent spectral libraries**
Kelly H. Telu, NIST, USA

175. **Using definitive screening design to effectively assess the combinatorial impacts of media supplements on monoclonal antibody production in mammalian cells**
Aaron Chen, Seattle Genetics, USA

176. **Integrating emerging trends in upstream process development: Autosampling, nutrient feedback control, and single use tanks**
T. Craig Seamans, Merck Research Labs, USA

177. **Implementation activities for a chemically-defined media platform to minimize media variability impact to cell culture performance and product quality**
Martin Gawlitzek, Genentech, Inc., USA

178. **Development of a chemically defined media and a chemically defined feeding strategy for extended growth and enhanced productivity in CHO-K1 and CHO DG44 cultures**
Sagar Kokal, Kerry, USA

179. **Evaluation of performance enhancing effects of supplementation with complex feed system and supplements with Sheff-CHO CD complete media in CHO-K1 and CHO DG44 cultures**
John F. Menton, Kerry, USA

180. **Incidence and potential implications of methylglyoxal in industrial cell culture revisited**
Frank Chaplen, Oregon State University, USA

181. **An addition of lithium chloride improves the transient gene expression yield in CHO cells**
Che Lin Kim, KAIST, South Korea

182. **Anti-oxidant addition to CD-CHO media to prevent damage induced by UV disinfection**
Emma V. Dare, University of Waterloo, Canada

183. **Development of an enriched CHO feed media for quality therapeutic antibody production from high performing clones**
David T. Ho, Irvine Scientific, USA

184. **Fed-batch process development using metabolically efficient CHO cells**
Cecile Toussaint, Universite de Montréal, Canada

185. **Adaptation of CHO metabolism to long term phosphate limitation**
Mugdha Gadgil, National Chemical Laboratory, India

186. **Separation of IgG glycoforms for biosimilars development using Fc gamma receptors as affinity-based chromatography ligands**
Austin Boesch, Dartmouth College, USA

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

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

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

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

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

Session X: Novel Protein Formats

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