

*Program*

# Cell Culture Engineering XIV

May 4 - 9, 2014

Fairmont Le Château Frontenac  
Quebec City, Canada

## Conference Chairs

***Amine Kamen***

McGill University, Canada

***Weichang Zhou***

WuXi AppTec Co., Ltd, China



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## **Welcome from the CCE XIV Chairs**

Welcome to Quebec City and the 14th ECI Cell Culture Engineering (CCE) conference. Over almost 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. Over the years, 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 contribute to set trends and establish good practices.

With ~400 participants from 25 countries on 5 continents, this year's meeting is the largest ECI conference ever and one of the most diverse to date involving many students and young academics to invest in the future and sustain the growth of the cell culture engineering industry. This was only possible because of generous donations from more than fifty industrial partners. The program includes 34 oral presentations, and 5 keynote addresses, 10 thematic workshops and ~ 200 posters.

Building on a well received initiative started at the CCE XIII conference to recognize the very large number of high quality abstract submissions relative to the number of plenary session oral presentation slots, four parallel Chair Select sessions have been added to the program this year, enabling approximately 20 additional speaking slots. These are focused sessions covering relevant topics to include more new and up-and-coming members of the community, including students, in the oral program and complement the plenary sessions. 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 the 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 rapidly, and reached over US\$135 billion in 2013. These biologics products include recombinant proteins, monoclonal antibodies and antibody fusion proteins and are mainly expressed in mammalian cells. In particular, monoclonal antibodies and antibody fusion proteins are the best-selling class of biologics, six of which are among the top 10 of the pharmaceuticals. All of them are manufactured by large scale mammalian cell cultures. Thus, the mammalian cell culture field has been focusing the 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, as well as development of new clinical candidates.

In addition, many biosimilars are being developed and introduced into the market, which intensifies these efforts. Beyond accelerated timeline and process intensification for higher productivities and improved product quality, many efforts nowadays focus on development and design of flexible and cost effective manufacturing facilities using small-sized and disposable bioreactors. With this in mind, we've put a program together which will showcase successes and discuss new approaches, opportunities and technologies in addressing these challenges by leading academic and industrial experts. In addition to addressing challenges related to development of novel protein biologics, we have included a session on accelerating development of biosimilars, as well as talks and panel discussions on future cell culture engineering: beyond protein biologics. We hope this will facilitate information exchanges in terms of how cell culture engineering

principles applied to development of novel biologics products are similar to or different from when applied to development of biosimilars and cell therapy products in order to meet the needs for flexibility, high volumetric productivity and low costs, and consistent product quality. We strongly encourage you to engage in the dialogue, think broadly and to explore how expertise and technologies from different areas could be valuable in your work, as well as to share your expertise with others in addressing their challenges.

We invite you to enjoy the Old Quebec, one of the most beautiful and walkable cities in North America and a UNESCO world heritage site. We also invite you to enjoy your stay at the Chateau Frontenac, an urban resort with a historic charm and distinctive elegance. After quite a number of CCE conference series being organized in remote locations to facilitate participants' interactions, Quebec City as a conference venue has the advantage of having all participants together in one location and offering to everyone easy access to the city and its attractions. We are also looking forward to having you all at a memorable gala dinner in "Le Musée de la Civilisation" to connect with the culture of this city and region of the world, and to inspire great communications, exchange of new ideas, and establishment of future collaborations to sustain the growth of the field.

We would like to thank all of the session chairs, workshop chairs, poster session chairs, and organization and committee members who have worked with remarkable dedication to put together a balanced and high quality program. We also would like to thank once again the corporate sponsors for enabling a record level of academic attendance.

We would like you to convey to our cell culture community a message of deep regret to not having been able to accept many colleagues from Academia and Industry who were aiming to participate in this event. Clearly the conference is in high demand, but the implicit working principle of keeping the conference to a size of participants that would maximize interactions among scientists and allow cross fertilization between different sectors made it difficult this time to accommodate the numerous requests. This will be a key point to be discussed by the steering committee at their special on site meeting.

Finally, special thanks to Barbara Hickernell and her dedicated team at ECI, particularly Kathy Chan and Kevin Korpics, for their tireless help and enormous assistance with the logistics and details. Certainly, many of you received a personalized email from Kathy that took care of any special request.

We hope that this conference will live up to the high standard that has been set for the CCE series by preceding Chairs.

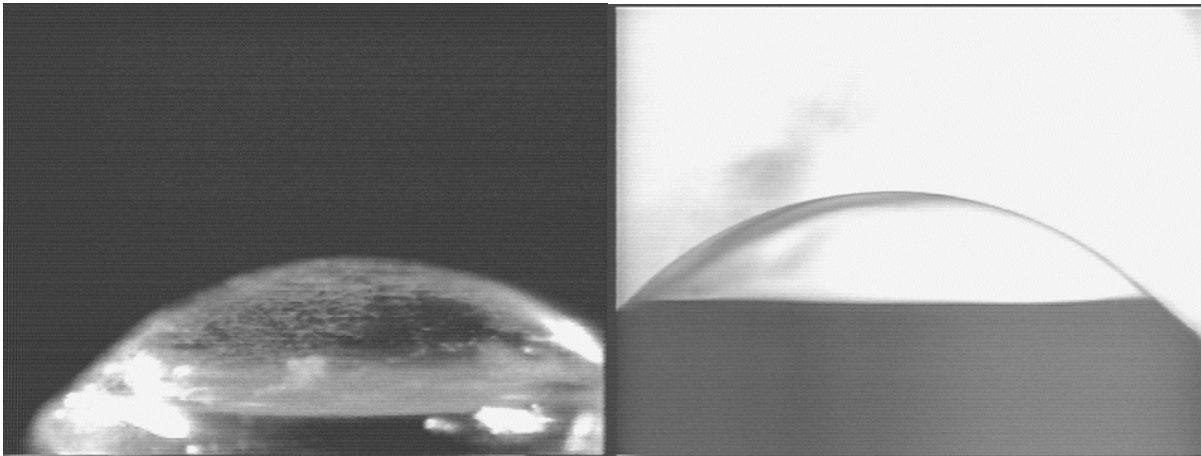
Once again, welcome to Quebec City and Canada and warm welcome to Cell Culture Engineering XIV. We look forward to meeting each of you personally.

Amine Kamen & Weichang Zhou  
Chairs, Cell Culture Engineering XIV

## 2014 Cell Culture Engineering Award Winner Jeffrey J Chalmers The Ohio State University



Jeff Chalmers, Professor of Chemical and Biomolecular Engineering at the Ohio State University and, since 2001, director of the OSU Comprehensive Cancer Center's Analytical Cytometry's Shared Resource and his team of researchers are recognized for their outstanding contributions to the cell culture field. These include contributing to the elucidation of the mechanisms of cell damage in large-scale cell culture processes and advocating the use of a hydrodynamic parameter, energy dissipation rate, EDR, to quantify the hydrodynamic conditions in several types of bioprocess equipment. To begin to quantify the effect of EDR on cells, he and his students developed a device (also known as the "torture chamber"), and subsequently advocated its use in the biotechnology industry to quantify the hydrodynamic sensitivity of a number of animal cell lines, and their specific clones. His most significant accomplishment in this area was his detailed study of how animal cells attach to bubbles, and how Pluronic F-68 prevents this attachment. Through use of high-speed imaging technology (below, presented at Cell Culture Engineering III and IV) Chalmers and his team showed cells in the bubble film (white spots) in media without Pluronic F-68, and the same system containing F-68 (no white spots on the bubble film). In addition, Chalmers and his team developed and patented an alternative to the well-known cell protective agent, Pluronic F-68, which prevents this adhesion.



Professor Chalmers has mentored more than 40 graduate students, many of whom work directly in the cell culture field. Jeff is also actively involved in the cell culture community, serving as co-chair for Cell Culture Engineering V and Cell Culture Engineering VI in 1996 and 1998 respectively. He has authored more than 150 peer-reviewed articles and patents and has given more than 150 invited seminars. He is on the editorial board of *Biotechnology and Bioengineering* since 2003.

This prestigious award recognizes outstanding contributions to the field of Cell Culture Technology and Engineering, and significant service and dedication to the profession. The award was established in 2001, and is given bi-annually at the Cell Culture Engineering conference (CCI Conferences). Former recipients were: Wei-Shou Hu (2002), Eleftherios T. Papoutsakis (2004), W. Robert Arathoon (2006), Martin Fussenegger (2008), Michael Betenbaugh (2010), and James M. Piret (2012).

# **Cell Culture Engineering Award**

## **List of Recipients**

**2002**

**Wei-Shou Hu**

**2004**

**Terry Papoutsakis**

**2006**

**W. Robert Arathoon**

**2008**

**Martin Fussenegger**

**2010**

**Michael Betenbaugh**

**2012**

**James Piret**

**2014**

**Jeffrey Chalmers**



## Martin Sinacore Outstanding Young Investigator Award

The **Martin Sinacore Outstanding Young Investigator Award** was established by ECI and Biogen Idec 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. Tragically, Marty's life was cut short as the result of injuries he sustained from a bike accident in the autumn of 2012. 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 Upstream 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 careers of many young scientists but also acknowledge the accomplishments and exceptional promise of the recipients.

## 2014 Martin Sinacore Outstanding Young Investigator Award Winners

**Dr. Colin Clarke** from Dublin City University is a co-winner of the 2014 Martin Sinacore Outstanding Young Investigator Award sponsored by Biogen Idec and Engineering Conferences International. Colin is one of the leading international bioinformaticians in the cell culture arena. As CHO cell omics datasets become more prolific, there is an increasingly urgent need to analyze and interpret the overwhelming information obtained in these datasets. Colin has been leading the way in this regard with a number of impactful publications that have been instrumental to cell culture engineering analysis. He has developed several novel statistical methods for integrating multiple types of genetic information including protein, mRNA, and relating this information with complex phenotypic traits such as mammalian cell growth. Dr. Clarke has also been highly active in the development of online resource and software tools in order to make these CHO genome datasets accessible to the overall CHO resource community. His valuable contributions in this area has been recognized through a number of invited talks at international conferences, running genomics workshops, and invitations to write book chapters and participate on journal editorial boards. Dr. Clarke will continue to be a key contributor to cell culture engineering as the importance of bioinformatics expands in the future.



**Dr. Corinne Hoesli** currently at Université Laval and McGill University in August is a co-winner of the 2014 Martin Sinacore Award sponsored by Biogen Idec and Engineering Conferences International. Corinne is developing novel technologies for the optimization and scale up of stem cells for the treatment of diabetes and cardiovascular disease. She has focused primarily on the development of novel biomaterials that will control cell fate decisions in order to enhance the function and quality of the differentiated cell products. In addition, her work has centered on the development of novel devices such as immunoisolation systems that can enhance the survival of transplanted cells. Corinne has received numerous grants and awards including a Best Student Poster Award from Cell Culture Engineering X. Her efforts in the laboratory are addressing key questions in bioprocessing by moving stem cell technology from the laboratory to the larger scales that will be required for clinical applications. Application of her encapsulated insulin producing cells can be used as a future treatment for patients with diabetes. In addition, she has implemented high through-put studies to define optimal culture conditions for growth of these cell types. Dr. Hoesli's work will be increasing important to cell culture engineering as cell therapy treatments for chronic ailments such as diabetes and heart disease become increasingly important in the coming decades.



# 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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## **Sunday, May 4, 2014**

- 13:00 – 17:00 Conference check-in (Lobby 3 Escalier)  
Poster set-up (Frontenac, Petit Frontenac and Bellevue Rooms)
- 15:00 – 16:30 **Workshops (2 in parallel)**  
**Overall Co-chairs:** Ellen Johnson, Amgen, Inc., USA; Alain Garnier, Université Laval, Quebec, Canada; Marcella Yu, Genzyme, USA and Georg Schmid, Roche, Switzerland
- Future Manufacturing Design** (Salle Montmagny)  
Co-Chairs: Suzanne Farid, University College London, United Kingdom  
Jason Walther, Genzyme, USA
- Product Comparability Assessment During Development and Post-Launch**  
***Sponsored by Medimmune*** (Jacques Cartier Room)  
Co-Chairs: Gino Grampp, Amgen, USA  
Mark Moody, Merrimack, USA
- 17:00 – 17:15 **Welcoming Remarks and Opening of Conference** (Salle de Bal)  
Conference Chairs: Amine Kamen and Weichang Zhou  
  
ECI Liaison: Mike Betenbaugh - A few words about ECI on its 52nd anniversary
- 17:15 – 18:15 **Opening Keynote: Mammalian synthetic biology: From parts to modules to therapeutic systems**  
Ron Weiss, Massachusetts Institute of Technology, USA
- 18:15 – 20:15 Dinner
- 20:15 – 22:30 **Poster Session / Reception** (Frontenac, Petit Frontenac and Bellevue Rooms)  
***Sponsored by Irvine Scientific***  
(Authors of even-numbered posters are asked to stay by their posters)
- Poster session chairs:** Anne Kantardjieff, Alexion Pharmaceuticals, USA; Marie Zhu, Agensys, an Affiliate of Astellas Pharma Inc., USA; Olivier Henry, Ecole Polytechnique, Canada and Peter Russo, Merck, USA

### ***Notes***

- Technical Sessions will be held in Salle de Bal.
- Poster Sessions will be held in the Frontenac, Petit Frontenac and Bellevue Rooms.
- Meals will be in the Jacques Cartier, Place D'armes and Cellar rooms.
- Workshop locations and Chair Select Session locations will be announced on site.
- Audiotaping, videotaping and photography of presentations are prohibited.
- Speakers – Please leave at least 5 minutes for questions and discussion.
- Please do not smoke at any conference functions.
- Turn your cellular telephones to vibrate or off during technical sessions.
- Be sure to check your contact information on the Participant List in this program and make any corrections to your name/contact information online. A corrected copy will be sent to all participants after the conference.

## **Monday, May 5, 2014**

07:00 – 08:30

Breakfast

(Steering Committee Breakfast meeting – Beauharnois)

### **Session I: Novel protein biologics development**

Chairs: Kenneth Karey (Genzyme, USA) and Mike Butler (University of Manitoba, Canada)

08:30 – 09:00

**Bioengineering coagulation factor VIII: Insertions of unstructured polypeptides (XTEN) result in enhanced expression and extended in vivo half-life**

Sampath Kumar, Biogen Idec, USA

09:00 – 09:30

**Development of complex antibody-cytokine fusion proteins at high quality by an integrative early development approach**

Markus Neubauer, Roche, Pharma Research and Early Development, Germany

09:30 – 10:00

**Attribute-based cell line selection and process optimization to improve product quality and reduce timelines for development of novel molecule drugs**

Christopher Sellick, Medimmune, United Kingdom

10:00 – 10:30

**Rational design of immunotherapeutics to treat disease caused by Bordetella**

Jennifer Maynard, University of Texas at Austin, USA

10:30 – 11:00

Coffee break

11:00 – 11:50

**Keynote 2: Cell culture engineering-Thriving after all these years**

Wei-Shou Hu, University of Minnesota, USA

12:00 – 13:30

Lunch

*(All graduate students are invited to a private lunch in Salon Rose)*

**Session II: Cell line engineering and accelerating development: Vector design, novel approaches for cell engineering, solutions to difficult to express proteins**

***Sponsored by Genentech***

Chairs: Chetan Goudar, Amgen, Inc., USA and Yves Durocher, NRC, Canada

13:30 – 14:00

**Case studies on improving cell line productivity, product quality, and the efficiency of cell line generation through cell line engineering**

Lianchun Fan, Eli Lilly & Company, USA

14:00 – 14:30

**Modulation of Monoclonal Antibodies Quality Attributes using Micro-L Scale Fed-Batch Cultures**

Matthieu Stettler, Merck Serono, Switzerland

14:30 – 15:00

**Development of a phase i/ii transient gene expression upstream platform process for an enveloped virus-like particle vaccine**

Richard Schwartz, Vaccine Research Center, NIAID, NIH, USA

**Monday, May 5, 2014 (continued)**

15:00 – 15:30      **Multi-gene engineering of mammalian cell metabolism: New approaches and tools in the pursuit of hyperproductivity**  
Ana Sofia Coroadinha, IBET, Portugal/University of Minnesota

15:30 – 16:00      Coffee break

16:00 – 18:00      **Workshops (4 in parallel)**

**Opportunities for International Collaboration**

Co-Chairs:      Manuel Carrondo, IBET, Portugal  
                    Wen-Song Tan, East China University of Science and  
                    Technology, China

**Scale-Up and Scale-Down Challenges**

Co-Chairs:      Ashraf Amanullah, Gilead Sciences, USA  
                    Gregg Nyberg, Amgen, USA

**Reducing Time from Product Candidate to the Clinic**

***Sponsored by Amgen***

Co-Chairs:      Tiffany Rau, Eli Lilly, USA  
                    Martin Allen, Pfizer, USA

**Novel Development of Cell Culture Media**

***Sponsored by Life Technologies***

Co-Chairs:      Marc Aucoin, University of Waterloo, Canada  
                    Yao-Ming Huang, Biogen Idec, USA

18:30 – 20:30      Dinner

20:30 – 22:30      **Evening Poster Session / Reception**

***Sponsored by Novo Nordisk A/S***

(Authors of odd-numbered posters are asked to stay by their posters)



**Tuesday, May 6, 2014**

- 07:00 – 08:30 Breakfast
- Session III: Process development, scale-up and implementation for commercial manufacturing**  
***Sponsored by Regeneron Pharmaceuticals***  
Chairs: Kevin Bailey, Regeneron; Gyun Min Lee, KAIST; Bob Kiss, Genentech
- 08:30 – 09:00 **Pluronic F-68 cell culture raw material evaluation: Scale down model development and mechanism investigation**  
Wei Wei Hu, Biogen Idec, USA
- 09:00 – 09:30 **Development and manufacturability assessment of chemically defined protein free medium to support therapeutic protein production in mammalian cells**  
Wai Lam Ling, Merck &Co, USA
- 09:30 – 10:00 **Resolution of process development and scale-up challenges with a sensitive CHO cell line**  
Rajesh Krishnan, Gilead, USA
- 10:00 – 10:30 Coffee break
- 10:30 – 11:00 **Development of a scaleable and productive insect cell culture based process for making Flublok, the first FDA licensed recombinant influenza vaccine**  
Barry Buckland, Protein Sciences, USA
- 11:00 – 11:30 **The colorful side of scaling-up to 20,000 liters**  
Stefanos Grammatikos, UCB, Belgium
- 11:30 – 12:00 **Multivariate statistical data analysis for continuous cell culture manufacturing process improvement: A case study of temperature control impact on cell culture performance**  
Ting-Kuo Huang, Genentech, USA
- 12:00 Pick up box lunch
- 12:00 – 15:30 Free Time / *ad hoc* sessions
- 15:30 – 16:15 **Keynote 3: Cell culture technology in the 21<sup>st</sup> century: From empiricism to predictive modeling**  
Jim Thomas, Vice President, Amgen, USA
- Session IV: Cell culture process intensification: Higher titers and higher productivity**  
Chairs: Thomas Ryll, Biogen Idec, USA and Takeshi Omasa (Osaka University, Japan)
- 16:30 – 17:00 **Intensification of a batch/re-feed process for a licensed product**  
Kesav Reddy, Pfizer, USA

**Tuesday, May 6, 2014 (continued)**

- 17:00 – 17:30      **Advances in integrated continuous bioprocessing: Achieving high cell density and high volumetric productivity for therapeutic proteins**  
Jin Yin, Genzyme, a Sanofi Company, USA
- 17:30 – 18:00      Break
- 18:00 – 18:30      **Integrated continuous production: A bench-top factory framework for rapid pre-clinical supply of fragile proteins**  
Mats Åkesson, Novonordisk a/s, Denmark
- 18:30 – 19:00      **Integrated bioprocess development: Purification of extracellular proteins using membrane chromatography**  
Valerie Orr, The University of Western Ontario, Canada
- 19:00 – 21:00      Dinner
- 21:00 – 22:30      **Poster Session / Reception**  
***Sponsored by Gilead Sciences, Inc.***  
(Authors of even-numbered posters are asked to stay by their posters)

**Wednesday, May 7, 2014**

- 07:00 – 08:30 Breakfast
- Session V: Process impacts on product quality**  
***Sponsored by Kerry***  
Chairs: Laura A. Palomares (UNAM, Mexico) and Stacey M. Kaneshiro (Eli Lilly and Company, USA)
- 08:30 – 09:00 **The profile of intracellular lipid-linked oligosaccharides and nucleotide-sugars determine the distribution, site occupancy and the N-glycosylation profile of a chimeric human-camelid antibody**  
Michael Butler, University of Manitoba, Canada
- 09:00 – 09:30 **The effects of alternative carbon sources on CHO cell metabolism and product quality** (15 min)  
Peter Slade, Amgen, USA  
**Model predictive control of product quality in CHO cell process** (15 min)  
Craig Zupke, Amgen, USA
- 09:30 – 10:00 **Optimization of a bioprocess for production of a non-protein biopharmaceutical: Production of a bioengineered heparin**  
Susan Sharfstein, SUNY College of Nanoscale Science and Engineering, USA
- 10:00 – 10:30 Coffee break
- 10:30 – 11:00 **Establishing a link between cell culture media and feed formulations and drug substance aggregate growth for monoclonal antibodies**  
Jennifer Purdie, Eli Lilly, USA
- 11:00 – 12:00 **Martin Sinacore Young Investigator Award Lectures**  
Presentation of awards by Scott Estes (Biogen Idec) and Mike Betenbaugh (ECI Liaison) to Coriine A. Hoesli and Colin Clarke
- 11:10 – 11:30 **Bioprocess development for diabetes cellular therapy**  
Corinne A. Hoesli, University Laval, Canada
- 11:30 – 11:50 **Mining CHO cell ‘omics’ data: Beyond differential expression analysis**  
Colin Clarke, Dublin City University, Ireland
- 12:00 – 13:30 Lunch  
*(All speakers, session chairs, workshop chairs, and poster chairs are invited to a private lunch in Salon Rose)*
- Session VI: Big-data ‘omics and new technology applications for driving better process development**  
***Sponsored by Pfizer***  
Chair: Timothy Charlebois (Pfizer, USA)
- 13:30 – 14:00 **The genome as a one step towards enabling product attribute control**  
Kelvin Lee, University of Delaware, USA
- 14:00 – 14:30 **Investigating growth cessation in late stages of fed-batch cultures: Going beyond the conventional inhibitors, lactate and ammonia**  
Bhanu Mulukutla, Pfizer, USA

**Wednesday, May 7, 2014 (continued)**

- 14:30 – 15:00      **Systems biotechnology driven development of CHO expression host cell lines and biopharmaceutical production processes**  
Anne Tolstrup, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
- 15:00 – 15:30      **Omics guided cell line engineering: Reducing high mannose by over expressing n-glycosylation pathway regulators**  
Trent Munro, Amgen, USA
- 15:30 – 16:00      Coffee break
- 16:00 – 18:00      **Four Concurrent Chair Select Sessions**
- Session 1: Understanding and control of cell metabolism**  
                         **Chair: Weichang Zhou**
- 16:00 – 16:20      **The metabolic programming of industrial IgG expressing CHO**  
Neil Templeton, Vanderbilt University, USA
- 16:20 – 16:40      **CHO cell engineering to alter lactate metabolism and improve cell culture processes**  
Cecile Toussaint, Université de Montréal, Canada
- 16:40 – 17:00      **Multiple steady states in continuous culture of mammalian cells: Mechanism and control**  
Andrew Yongky, University of Minnesota, USA
- 17:00 – 17:20      **Using global, untargeted metabolomic profiling at a systems level to understand the impact of process conditions on a commercial CHO cell line**  
Amanda M. Lanza, Bristol-Myers Squibb, USA
- 17:20 – 17:40      **Metabolomic quantification of commercial process variability, facility transfer, and variable impact**  
Erik Hughes, Biogen Idec, USA
- Session 2: Transient transfection for rapid material preparation**  
                         **Chair: Amine Kamen**
- 16:00 – 16:20      **Intracellular trafficking of polyethylenimine/syndecan-1 complexes in HEK293 cells**  
Laurence Delafosse, Université de Montreal, Canada
- 16:20 – 16:40      **Extended gene expression for the optimization of protein production by transient transfection**  
Laura Cervera, Universitat Autònoma de Barcelona, Spain
- 16:40 – 17:00      **Rapid development of a high-producing CHO transient protein production method**  
Alex A. Jurisch, Irvine Scientific, USA
- 17:00 – 17:20      **Use of an anti-apoptotic CHO cell line for transient gene expression for multi-scale applications: automated tubespins to stirred tank bioreactors**  
Athena Wong, Genentech, USA

**Wednesday, May 7, 2014 (continued)**

**Session 3: Process transfer successes & challenges**

**Chair: Jim Michaels**

- 16:00 – 16:20      **A highly successful collaboration towards the commercialization of a humanized mAb**  
Hugh Graham, BMS, USA
- 16:20 – 16:40      **The devil is in the details: Strategies, case studies, and recommendations for successful tech transfer and product commercialization**  
Sadettin Ozturk, MassBiologics, USA
- 16:40 – 17:10      **Six month tech transfers: Process fit and scale-up for manufacturing biologicals**  
Craig Seamans, Merck & Co, USA (15 minutes)  
Brian Stamper, Medimmune, USA (15 minutes)
- 17:10 – 17:30      **Case studies for utilization of conventional and CFD approaches for successful scale up and scale down of bioreactor processes for monoclonal antibodies**  
Michel Lafond, Regeneron, USA

**Session 4: Control of glycosylation**

**Chair: Mike Betenbaugh**

- 16:00 – 16:20      **High performance glycoanalysis to improve biologics development**  
Erdmann Rapp, Max Planck Institute, Germany
- 16:20 – 16:40      **Tuning the glycan composition in CHO cells by genetic and metabolic approaches**  
Volker Sandig, ProBioGen, Germany
- 16:40 – 17:00      **Synthesis and enrichment efficiency of carboxymethyl chitosan for 'Pull Down' glycoproteomics**  
Edward D. Bodnar, University of Manitoba, Canada
- 17:00 – 17:20      **A framework for real-time glycosylation monitoring (RT-GM) in mammalian cell culture**  
Tharmala Tharmalingam, Amgen, USA
- 17:20 – 17:40      **Modulating the effector function of rMAbs by host cell glycoengineering**  
Ronan M. Kelly, Eli Lilly and Company, USA
- 18:30 – 21:00      Dinner on your own – Dine-a-round
- 21:00 – 22:30      **Poster Session / Reception**  
***Sponsored by Lilly***  
(Authors of odd-numbered posters are asked to stay by their posters)

## **Thursday, May 8, 2014**

- 07:00 – 08:30 Breakfast
- Session VII: Future cell culture engineering: Beyond protein biologics**  
Chairs: Peter Zandstra, University of Toronto, Canada and Madhusudan V. Peshwa, MaxCyte, Inc., USA
- 08:30 – 08:50 **Breaking through the paradigm shift of cell therapies: The development of a fully defined enzyme and inhibitor free method of sub-culturing human stem cells**  
Peter Gray, AIBN, University of Queensland, Australia
- 08:50 – 09:10 **Integrating bioprocess optimization and omics tools towards the design of novel cardiac stem cell therapies**  
Paula Alves, IBET, Portugal
- 09:30 – 09:50 **Producing and harvesting culture-derived platelets with functional activity from blood stem cells**  
William Miller, Northwestern University, USA
- 09:50 - 10:20 Coffee break
- 10:20 – 11:50 **Panel Discussion:** How are cell culture engineering principles applied to biological products similar / different to when applied to cell therapy products:  
Cell culture engineering principles - Medium design and optimization - Bioreactor design and operation - Process controls/product characterization and potency/scaling-up for clinical /commercial use
- Panelists:**  
Eleftherios (Terry) Papoutsakis, University of Delaware, USA  
Angel Varela-Rohena, Life Technologies, USA  
Brian Lee, PBS Biotech. Inc. USA  
Peter Zandstra, University of Toronto, Canada  
Madhusudan Peshwa, MaxCyte Inc., USA  
Suzanne Farid, University College London, UK
- 12:00 – 13:30 Lunch
- Session VIII: Accelerating development of biosimilars**  
Co-Chairs: Ana Maria Moro, Instituto Butantan, Brazil, Chris Chen, WuXiAppTec Ltd., China, and Yuan Xu, Gilead, USA
- 13:30 – 14:15 **Keynote 4: The Canadian approach to the regulation of subsequent entry biologics (biosimilars)**  
Anthony Ridgway, Biologics and Genetic Therapies Directorate, Health Canada
- 14:15 – 14:45 **Development of a safe and effective biosimilar monoclonal antibody following international guidelines**  
Esteban Corley, PharmADN, Buenos Aires, Argentina
- 14:45 – 15:05 **Overcoming biosimilarity challenges through optimization of parameters for a CHO cell culture process**  
Gargi Seth, Intas Pharmaceuticals Limited, Ahmedabad, India

**Thursday, May 8, 2014 (continued)**

15:05 – 15:25            **Quality consideration in Biosimilar Development**  
Hyungseok Choi, Biologics Unit R&D Center, Hanwha Chemical, Republic of Korea

15:25 – 16:00            Coffee break

16:00 – 17:45            **Workshops (4 in parallel)**

**Single-Use Technologies**

Co-Chairs:            Sadettin Ozturk, MassBiologics, USA  
Jean-Marc Guillaume, Sanofi Pasteur, France

**Applications of -omics Technology**

***Sponsored by Bristol-Myers Squibb***

Co-Chairs:            Lars Nielsen, University of Queensland, Australia  
Terry Papoutsakis, University of Delaware, USA

**Cell Culture Manufacturing Safety: Prevention of Contamination of Adventitious Agents**

***Sponsored by Biomarin***

Co-Chairs:            Armin Opitz, Genzyme, USA  
Harmit Vora, BioMarin, USA

**QbD and Design Space**

***Sponsored by Genzyme***

Co-Chairs:            Brian Kelley, Genentech, USA  
Tongtong Wang, Eli Lilly, USA

18:00 – 19:00            **CCE Award Lecture: Our fantastic voyage: From immobilized cell bioreactors to stem cell Raman microspectroscopy**  
James Piret, University of British Columbia, Canada

19:30 – 22:30            Banquet (Le Musée de la Civilisation)

- **Presentation of Poster Awards**
- **Presentation of Cell Culture Engineering Award**
- **Roast of CCE Award Winner – Jeff Chalmers, Ohio State University**
- **Announcement of Chairs for CCE XV**
- **Announcement of Upcoming ECI Conferences**
- **Closing Remarks by Conference Chairs**

**Friday, May 9, 2014**

07:00 – 08:30

Breakfast and departures