Preliminary Program (Feb 19, 2014)

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

ECI

Engineering Conferences International
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### Sunday, May 4, 2014

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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| 13:00 – 17:00 | Conference check-in  
              Poster set-up                                                      |
| 15:00 – 16:30 | **Workshops (2 in parallel)**  
      *Overall Co-chairs:* Ellen Johnson, Amgen, Inc., USA; Alain Garnier, Universite Laval, Quebec, Canada; Marcella Yu, Genzyme Corporation, USA and Georg Schmid, Roche, Switzerland |
| 17:00 – 17:15 | **Welcoming Remarks and Opening of Conference**  
      Conference Chairs  
      ECI Liaison: 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, MIT, USA |
| 18:15 – 20:15 | Dinner                                                                |
| 20:15 – 22:30 | **Poster Session / Social Hour**  
      (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 |
Monday, May 5, 2014

07:00 – 08:30 Breakfast

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 Cambridge, 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, Penzberg 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, Cambridge, USA

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

Session II: Cell line engineering and accelerating development: Vector design, novel approaches for cell engineering, solutions to difficult to express proteins
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 Breaking Fc-fusion production bottlenecks: Utilization and Integration of cell culture engineering strategies
David James, University of Sheffield, UK

14:30 – 15:00 Development of a phase i/ii transient gene expression upstream platform process for an enveloped virus-like particle vaccine
Richards Schwartz, Vaccine Research Center, NIAID, NIH, USA

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)**
18:30 – 20:30  Dinner
20:30 – 22:30  **Evening Poster Session / Social Hour**
   (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**
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

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

12:15  Pick up box lunch

12:00 – 15:30  Free Time / ad hoc sessions

15:30 – 16:30  Afternoon Poster Session
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

17:10 – 17:30  Advances in integrated continuous bioprocessing: Achieving high cell density and high volumetric productivity for therapeutic proteins
Jin Yin, Genzyme, USA

17:30 – 18:00  Integrated continuous production: A bench-top factory framework for rapid pre-clinical supply of fragile proteins
Mats Åkesson, Novonordisk a/s, Denmark

18:00 – 18:30  Integrated bioprocess development: Purification of extracellular proteins using membrane chromatography
Valerie Orr, The University of Western Ontario, Canada

18:30 – 20:30  Dinner

20:30 – 22:30  Poster Session / Social Hour
(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
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

09:00 – 09:30  The effects of alternative carbon sources on CHO cell metabolism and product quality
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 – 11:40  Young Investigator Keynote (Martin Sinacore award)

12:00 – 13:30  Lunch

Session VI: Big-data ‘omics and new technology applications for driving better process development
Chairs: Hal S Alper (University of Texas Austin, USA) and 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

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
18:30 – 21:00  Dinner on your own – Dine-a-round

21:00 – 22:30  Poster Session / Social Hour
(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, AINB, 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 – 10:10  Bioprocess development for diabetes cellular therapy
Corinne A. Hoesli, Universite Laval, Canada

10:10 – 10:40  Coffee break

10:40 – 11:50  Panel Discussion on TOPIC: 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 & optimization - Bioreactor design and operation - Process controls / product characterization & 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, WuXi AppTec Co., Ltd. (China) and Yuan Xu, Novartis (Switzerland)

13:30 – 14:15
Keynote 3: The Canadian approach to the regulation of subsequent entry biologics (biosimilars)
Anthony Ridgway, Biologics and Genetic Therapies Directorate, Health Canada

14:15 – 14:45
Biosimilarity by design (tentative title)
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

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)

18:00 – 19:00
CCE Award Lecture
James Piret, UBC University, Canada

19:30 – 22:30
Banquet

Poster Award Winners

2014 CCE Award roast of winner
Announcement of chairs for CCE XIV
Announcement of upcoming ECI conferences
Closing remarks by Conference co-chairs

Friday, May 9, 2012

07:00 – 08:30
Breakfast and departures