

Final Program

Cell Culture Engineering X

April 23 - 28, 2006

Whistler, BC, Canada

Conference Chairs

James M. Piret

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ECI

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Engineering Conferences International (ECI) is a 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. ECI is a not-for-profit partnership between the Engineering Conferences Foundation (ECF) and Polytechnic University.

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Sunday, April 23, 2006

14:00 – 16:30	Registration
16:30 – 18:00	Opening Reception
18:00 – 19:15	Dinner
19:15 – 19:45	Conference Welcome
19:45 – 20:30	Keynote Address: Building an Antibody Factory: A Job for the Unfolded Protein Response Linda M. Hendershot, St. Jude Children's Research Hospital, USA
20:30 – 23:00	Reception

Notes

All oral sessions will be held in the McDonald ABC.

Poster sessions will be held in the McDonald DEF and Empress BC rooms.

- **All Posters should be mounted Sunday, after 15:00.**
- **Odd numbered posters presented Monday 10:30-14:00 and Tuesday 20:15-23:00.**
- **Even numbered posters presented Monday 20:15-23:00 and Wednesday 21:00-23:00.**
- **All posters should be taken down on Thursday, between 13:30 and 14:30.**

Speakers: Presentations can be loaded onto the conference computer in the Beausejour Room.

Most meals will be held in the Frontenac Ballroom. **Lunches** will be in the Wildflower Restaurant on Tuesday, Wednesday, and Thursday. The Monday luncheon will be concurrent with the Poster Session. The Monday Poster Session luncheon will be stand up "Roving" style.

Friday lunch will be a box lunch and box lunches can be reserved for Tuesday, Wednesday or Thursday, as an alternative to the buffet at the Wildflower Restaurant. **However, you must sign up 48 hours in advance** at the ECI Registration Desk to receive a box lunch. Due to meal guarantee restrictions, we will not be able to get you a lunch if you do not sign up in advance.

Lift Tickets: If you are interested in purchasing ski lift tickets, a reduced rate will be offered at Mobile Ticket Unit set up exclusively for CCE X at the following times:
15:00 – 18:00 on Sunday, April 23 and 09:30 – 12:00 on Tuesday, April 25

Audio taping, videotaping and photography of presentations are strictly prohibited.

Please do not smoke at any conference functions.

Turn your cell phones to vibrate or off during technical sessions.

Monday, April 24, 2006

- 06:30 – 08:00 Breakfast
- 08:00 – 10:05 **Session I: Accelerating Cell Line Development and Clinical Candidate Optimization** (sponsored by Invitrogen)
Session Chairs: Georg Schmid (Hoffmann-La Roche, Switzerland) and Hansjörg Hauser (GBF, Germany)
- 08:00 – 08:25 **Cell Line Development by Fluorescence Activated Cell Sorting**
Nicole Borth, IAM, University of Applied Life Sciences, Austria
- 08:25 – 08:50 **Streamlining Cell Line Development: Improvements in Selection and Screening**
Rohini Deshpande, Amgen, USA
- 08:50 – 09:15 **A Novel One-Step Technology for Accelerating Discovery of Highly Productive Mammalian Cell Lines**
Christopher J. Mann, Genetix, United Kingdom
- 09:15 – 09:40 **Accelerated Cell Line Development Using FACS to Select Recombinant Antibody Producing Clones**
Noelle-Anne Sunstrom, ACYTE Biotech, Australia
- 09:40 – 10:05 **Multi-Host Transient Transfection – A Tool for Early Cell Line Development**
Dale L. Ludwig, ImClone Systems, USA
- 10:05 – 10:30 **The Role of the Product in Productivity**
Haley A. Laken, Wyeth BioPharma, USA
- 10:30 – 12:00 **Poster Session (Odd #s presenting)** and Coffee Break
Organizer: Robert Balcarcel (Vanderbilt University, USA)
Co-chairs: Nedim Altaras (Merck, USA)
Michael Kallos (University of Calgary, Canada)
Susan Sharfstein (Rensselaer Polytechnic Institute, USA)
- 12:00 – 14:00 Buffet Lunch and **Poster Session (Odd #s)**
Organizer: Robert Balcarcel (Vanderbilt University, USA)
Co-chairs: Nedim Altaras (Merck, USA)
Michael Kallos (University of Calgary, Canada)
Susan Sharfstein (Rensselaer Polytechnic Institute, USA)
- 14:00 – 15:40 **Session II: Physiology & Engineering of Production Cell Lines**
(sponsored by Wyeth Biopharma)
Session Chairs: William Miller (Northwestern University, USA) and Ilse Blumentals (GlaxoSmithKline, USA)
- 14:00 – 14:25 **XBP1-Based Engineering of Secretory Capacity Enhances the Productivity of Chinese Hamster Ovary Cells**
Martin Fussenegger, ETH Zurich, Switzerland

Monday, April 24, 2006 (continued)

- 14:25 – 14:50 **Modulation of p21, bcl-2 and c-myc Genes for Enhanced Adaptation to Suspension and Serum Free Culture of Mammalian Cell Lines**
Mohamed Al-Rubeai, University College Dublin, Ireland
- 14:50 – 15:15 **Rapid Generation of Stable, High Expressing Cell Lines for Manufacture of Monoclonal Antibodies Using the ACE System**
Malcolm Kennard, Chromos, Canada
- 15:15 – 15:40 **A Non-Viral Transformed New Cell Substrate Used for Production of Vaccines**
Heidi Trusheim, Chiron Vaccines, Germany
- 15:40 – 16:45 Refreshments
- 16:45 – 18:15 **Session III: Proteomics & Genomics for Process Development**
(sponsored by Genentech)
Kelvin H. Lee (Cornell University, USA) and
Dana Andersen (Genentech, USA)
- 16:45 – 17:15 **Establishment of a Genomic Context for Chinese Hamster Ovary Cells Through Transcriptome and Proteome Profiling**
Wei-Shou Hu, University of Minnesota, USA
- 17:15 – 17:45 **Empirical Modeling of mRNA Translation Efficiency in Mammalian Cells using Combined Proteomic and Transcriptomic Analyses**
David C. James, University of Queensland, Australia
- 17:45 – 18:15 **Differential Expression Profiling Analysis of “Industrially Relevant” CHO Cell Phenotypes Through Integrated Use of DNA Microarray and Proteomics Analysis Platforms**
Martin S. Sinacore, Wyeth BioPharma, USA
- 18:15 – 19:00 **2004 Merck Award for Cell Culture Engineering
2006 Keynote: At Crossroads**
E. Terry Papoutsakis, Northwestern University, USA
- 19:00 – 20:15 Dinner
- 20:15 – 23:00 **Poster Session (Even #s presenting) and Reception**
Organizer: Robert Balcarcel (Vanderbilt University, USA)
Co-chairs: Nedim Altaras (Merck, USA)
Michael Kallos (University of Calgary, Canada)
Susan Sharfstein (Rensselaer Polytechnic Institute, USA)

Tuesday, April 25, 2006

- 06:30 – 08:00 Breakfast
- 08:00 – 10:15 **Session IV: Product Quality / Immunogenicity**
(sponsored by Eli Lilly)
Session Chairs: Michael Butler (University of Manitoba, Canada)
and Nigel Jenkins (Serono, Switzerland)
- 08:00 – 08:45 **Keynote Address: Sugar or Splice? Solving the Immunogenicity Problem, Pre and Post Development**
Annie De Groot, Brown Medical School and EpiVax, USA
- 08:45 – 09:05 **The Impact of the Bioprocess on the Glycosylation of Recombinant Human Erythropoietin**
Laura A. Palomares, UNAM, Cuernavaca, Mexico
- 09:05 – 09:25 **Improved Glycosylation in Perfusion Cultures Over Batch and Fed-Batch Cultures**
Dhinakar S. Kompala, University of Colorado, USA
- 09:25 - 09:45 **Product Quality Challenges During Process Development Using GS-CHO and GS-NS0 Cell Lines**
Sigma S. Mostafa, Eli Lilly, USA
- 09:45 – 10:15 Coffee Break
- 10:15 – 14:00 Open time for activities and all posters available for viewing
- 12:00 – 14:00 Wildflower Restaurant Buffet or Boxed Lunch
- 14:00 – 14:30 Coffee Break
- 14:30 – 16:30 **Session V: Accelerating Process Development and Scale-Up**
Session Chairs: Weichang Zhou (PDL BioPharma, USA) and
Lynne Krummen (Genentech, USA)
- 14:30 – 14:55 **Streamlining Process Development: Evolution of a Cell Culture Platform for Monoclonal Antibodies**
Carole Heath, Amgen, USA
- 14:55 – 15:20 **The Use of Energy Dissipation Rate as a Parameter to Assist in the Evaluation, Scale-Up, and Scale-Down of Bioprocesses**
Jeffrey Chalmers, Ohio State University, USA
- 15:20 – 15:45 **Implementation of a High Yield Cell Culture Process for Production of Phase II Clinical Material**
Martin Gawlitzek, Genentech, USA

Tuesday, April 25, 2006 (continued)

- 15:45 – 16:10 **Reactor Engineering in Large Scale Animal Culture**
Alvin W. Nienow, University of Birmingham, UK
- 16:10 – 16:35 **A Case Study in Accelerated Post-Commercial Cell-Culture Development for Monoclonal Antibody Production**
Helena Yusuf Makagiansar, Biogen IDEC, USA
- 16:35 – 17:00 Refreshments
- 17:00 – 19:00 **Workshops I**
Organizers: Carole Heath (Amgen, USA) and Bob Kiss (Genentech, USA)
- Empress A: Cell Banking, Inoculum Expansion, and Cryopreservation in Biopharmaceutical Manufacturing**
Marshall Dinowitz (Pacific BioDevelopment, USA) and Chun Zhang (Bayer, USA)
- MacDonald AB: Genomic and Proteomic Exploration for Cell Culture Bioprocessing**
Timothy Griffin (University of Minnesota) and Wei-Shou Hu (University of Minnesota)
- MacDonald C: Scale-Down Modeling of MAb and r-Protein Cell Culture Manufacturing Processes for Approval and Post-Marketing Process Changes**
Steven Meier (Genentech, USA) and Craig Zupke (Amgen, USA)
- 19:00 – 20:15 Dinner
- 20:15 – 23:00 **Poster Session (Odd #s presenting) and Reception**
Organizer: Robert Balcarcel (Vanderbilt University, USA)
Co-chairs: Nedim Altaras (Merck, USA)
Michael Kallos (University of Calgary, Canada)
Susan Sharfstein (Rensselaer Polytechnic Institute, USA)

Wednesday, April 26, 2006

- 06:30 – 08:00 Breakfast (Steering Committee Meeting)
- 08:00 – 10:00 **Session VI: Viral Vectors for Gene Therapy and Vaccination**
(sponsored by Chiron Vaccines)
Session Chairs: Amine Kamen (Biotechnology Research Institute, Canada) and John Aunins (Merck, USA)
- 08:00 – 08:30 **Influenza Vaccines Production Using MDCK Cells**
Ulrich Valley, Chiron, Germany
- 08:30 – 09:00 **Dynamics of Influenza Virus Replication in Mammalian Cell Culture**
Udo Reichl, Max Planck Institute for Dynamics of Complex Technical Systems, Germany
- 09:00 – 09:30 **Development and Characterization of a Per.C6® Cell Line Expressing the Desired Attributes for Adenovirus Production**
Nedim E. Altaras, Merck, USA
- 09:30 – 10:00 **Modeling Rotavirus VLPs Production: Infection, Gene Expression and VLPs Assembly**
Manuel J.T. Carrondo, IBET/ITQB, Portugal
- 10:00 – 10:30 Coffee Break
- 10:30 – 14:00 Open time for activities and all posters available for viewing
- 12:00 – 14:00 Wildflower Restaurant Buffet or Boxed Lunch
- 14:00 – 14:30 Coffee Break
- 14:30 – 16:30 **Session VII: Case Studies in Cell Culture Process Development and Technology Transfer** (sponsored by Amgen)
Session Chairs: Charles Goochee (Merck, USA) and Geoff Slaff (Amgen, USA)
- 14:30 – 15:00 **Development and Commercial Implementation of the Alternating Tangential Flow Filtration System for the Production of Monoclonal Antibodies by Perfusion Cell Culture**
Janice A. Phillips, Centocor/GBSC, USA
- 15:00 – 15:30 **Successful Biologicals Trigger Cell Culture Engineering Challenges: Rituximab Post-Approval Changes and Process Transfers**
Robert Kiss, Genentech, USA

Wednesday, April 26, 2006 (continued)

- 15:30 – 16:00 **From Construct to Half a Gram Endotoxin Free Recombinant IgG in Less Than 3 Weeks Using a Generic Transient Transfection Process in 100L Scale**
Ola Tuveesson, AstraZeneca, Sweden
- 16:00 – 16:30 **Cell Line Heterogeneity During Development: Challenges and Opportunities**
Tim Charlebois, Wyeth BioPharma, USA
- 16:30 – 17:00 Refreshments
- 17:00 – 19:00 **Workshops II**
Organizers: Carole Heath (Amgen, USA) and Bob Kiss (Genentech, USA)
- Empress A: Viral Dynamics**
Manuel Carrondo (IBET, Portugal) and Udo Reichl (MPI Magdeburg, Germany)
- MacDonald AB: Challenges in the Transfer of Therapeutic Protein Processes**
Steve Lee (Bristol Myers Squibb, USA) and Tom Monica (Berlex, USA)
- MacDonald C: Raw Material Quality Issues in Cell Culture Manufacturing**
Jason Carstens (ICOS, USA) and Raquel Iverson (Genentech, USA)
- 19:00 - 21:00 Dinner outside hotel, recommended restaurant list provided
- 21:00 – 23:00 **Poster Session (Even #s presenting) and Reception**
Organizer: Robert Balcarcel (Vanderbilt University, USA)
Co-chairs: Nedim Altaras (Merck, USA)
Michael Kallos (University of Calgary, Canada)
Susan Sharfstein (Rensselaer Polytechnic Institute, USA)

Thursday, April 27, 2006

- 06:30 – 08:00 Breakfast
- 08:00 – 09:20 **Session VIII: High-Throughput Screening Systems for Mammalian Cell Bioprocessing**
(sponsored by SAFC Biosciences)
Session Chairs: Florian Wurm (EPFL, Switzerland) and Matthew Caple (SAFC Biosciences, USA)
- 08:00 – 08:20 **Experiences with a New High Throughput System for Upstream Development**
Alice S. Chuck, Amgen, USA
- 08:20 – 08:40 **Monitoring of Cell Concentration and Cellular Activity in Adherent and Suspension Cells Culture in a Minibioreactor Platform**
Francesc Gòdia, Universitat Autònoma de Barcelona, Spain
- 08:40 – 09:00 **Engineering Characterisation of a Microwell Platform for High Throughput Culture of Suspension & Adherent Cell Lines**
Gary Lye, University College London, UK
- 09:00 – 09:20 **Faster and Better: High-Throughput Assays for Cell Line and Cell Culture Development**
Judy H. Chou, Wyeth Biopharma, USA
- 09:20 – 10:00 **Keynote Address:
Trends in Healthcare and Biotechnology Financing**
David Naveh, Bayer HealthCare, USA
- 10:00 – 10:30 Coffee Break
- 10:30 – 13:30 Open time for activities and all posters available for viewing
- 12:00 – 14:00 Wildflower Restaurant Buffet or Boxed Lunch
- 13:30 – 14:30 Removal of all posters
- 14:00 – 14:30 Coffee Break
- 14:30 – 16:00 **Session IX: Downstream Processing, Challenges & Prospects**
(sponsored by Pall Life Sciences)
Session Chairs: Charles Haynes (University of British Columbia, Canada) and Jens Vogel (Bayer HealthCare, USA)
- 14:30 – 15:10 **Keynote Address:
Binding Capacity Differences for Antibodies and Fc-fusion Proteins on Protein A Chromatographic Materials**
Steven Cramer, Rensselaer Polytechnic Institute, USA

Thursday, April 27, 2006 (continued)

- 15:10 – 15:35 **Development and Implementation of Robust Harvest and Downstream Processes for Monoclonal Antibodies**
Philip Lester, Genentech, USA
- 15:35 – 16:00 **Platform Approaches to Process Scale Purification of Monoclonal Antibodies: Interfacing with Cell Culture Process Development**
Abhinav A. Shukla, Amgen, USA
- 16:00 – 16:30 Refreshments
- 16:30 – 18:30 **Session X: Stem Cell Culture and Tissue Engineering**
Session Chairs: Peter Zandstra (University of Toronto, Canada) and Robert Deans (Athersys, USA)
- 16:30 – 17:10 **Keynote Address: The Cell Biological Basis of Human Embryonic Stem Cell Technology**
Martin Pera, Monash University & the Australian Stem Cell Centre
- 17:10 – 17:30 **Advanced Systems for Controlled Growth and Differentiation of hESC**
Chris Cannizzaro, Massachusetts Institute of Technology, USA
- 17:30 – 17:50 **Bioprocessing of Embryonic Stem Cells for Drug Discovery**
Hazel Thomson, Stem Cell Sciences, United Kingdom
- 17:50 – 18:10 **Regulation of Human Hematopoietic Progenitor Cell Differentiation in Culture**
William Miller, Northwestern University, USA
- 18:10 – 18:30 **Behavior-Activated Cell Selection (BACS): Application to Hematopoietic Stem Cell Expansion Cultures**
Eric Jervis, University of Waterloo, Canada
- 19:00 – 21:30 **Conference Banquet**
- 21:30 – 23:00 Reception

Friday, April 28, 2006

- 06:30 – 08:00 Breakfast
- 08:00 – 10:00 **Session XI: New Regulatory Issues/Process Analytical Technology**
Session Chairs: Thomas Scheper (U. Hannover, Germany) and Michael Howaldt (Boehringer Ingelheim, Germany)
- 08:00 – 08:40 **Keynote Address: PAT for Biologicals**
Duncan Low, Amgen, USA
- 08:40 – 09:00 **Monitoring and Control of CHO Cultures Using Automated Flow Cytometry**
Friedrich Srienc, University of Minnesota, USA
- 09:00 – 09:20 **Rapid Detection of Bacterial Contamination in Mammalian Cell Culture Manufacturing**
Steven Max, Wyeth BioPharma, USA
- 09:20 – 09:40 **Implementing Process Improvements for a Commercial Product Based on Increased Process Understanding: Quality and Regulatory Aspects**
Roderick W Geldart, Amgen, USA
- 09:40 – 10:00 **Standardisation and Regulation of New Cell-Based Therapeutic Products: The UK Stem Cell Bank Perspective**
Glyn N. Stacey, UK Stem Cell Bank, UK
- 10:00 – 10:15 **Conclusion**
- 10:15 – 11:30 Coffee Break, Boxed Lunch distribution