Program

Monday June 4, 2012

13.00–19.00 **Registration desk open**
Poster setup (Salle des Gardes)

15.00–18.00 **Workshop: Quality by Design – Design of Experiments, Theory, Tools, and Case Studies**
Organized by GE Healthcare Life Sciences, Sweden and Umetrics, Sweden

18.00–19.00 **Welcome reception**

19.00–19.15 **Welcome address**

19.15–20.00 **Plenary lecture: High-Throughput Process Development – Current and Future Developments**
Prof Jürgen Hubbuch, Karlsruhe Institute of Technology, Germany

20.00– **Free evening**

Tuesday June 5, 2012

Session 1: Upstream – Lessons Learned and Future Challenges

Chair: Jonathan Coffman, Pfizer, U.S.A.

08.00–08.30 **101 Launching an Automated Microtiter Cultivation Platform for Enhanced Bioprocess Optimization**
P. Rohe, D. Venkanna, O. Schweissgut, R. Freudl, W. Wiechert, and M. Oldiges*
Institute of Bio- and Geosciences, IBG-1: Biotechnology Forschungszentrum Jülich, Jülich, Germany

08.30–09.00 **102 Individualized Cancer Vaccines: An Automated System Approach to Sequence Identification and Vector Cloning**
Markus Zamponi*[1], Walter Weichel[1], Frank Thieme[2], and John-Edward Butler-Ransohoff[3]
1) Bayer Technology Services GmbH, Leverkusen, Germany
2) Icon Genetics GmbH, Halle, Germany
3) Bayer Innovation GmbH, Düsseldorf, Germany

09.00–09.30 **103 Medium and High-Throughput Screening for Feasibility Studies and Cell Line Development with ESETEC - Our Family of Secretory *E. coli* Strains**
Guido Seidel*, Stefanie Echt, and Martina Huber
Wacker Process Development, Hans Knöllstrasse 3, DE-07745 Jena, Germany

09.30–10.00 **Coffee break**

10.00–10.30 **104 The Need for More - Taking the Right Strain Decision in Early Process Development**
Olaf Christensen
Microbial R&D Lonza Biopharmaceuticals, Lonza AG, Switzerland

10.30–11.00 **105 Automated Evaluation of Microscale Linked Process Sequences for Generation of Scaleable Bioprocess Design Data**
J.Z. Baboo[1], J.M. Ward[2], G.J. Lye[1], and M. Micheletti*[1]
1) Department of Biochemical Engineering
2) Institute of Structural and Molecular Biology, University College London Torrington Place, London WC1E 7JE, U.K.

11.00–12.00 **Guided tour in Palais des Papes**

12.00–13.30 **Enjoy lunch on your own**

13.30–15.00 **Guided walking tour in Avignon**

Session 2: Downstream – Lessons Learned and Future Challenges

Chair: Jens H. Vogel, Bayer Healthcare, U.S.A.

15.00–15.30 **201 Evaluating formats for Automated High-Throughput Microscale Chromatography: Which One to Use?**

Marc Wenger*, Matthew Petroff, Matthew Troutman, Kristin Valente, and Matthew Woodling
Merck & Co., Inc, Vaccine Bioprocess R&D, WP42A-20, PO Box 4, West Point, PA 19486, U.S.A.

15.30–16.00 **202 Experimental Investigation of Scale Effects in High-Throughput Process Development Studies**

Charlotte Brink, Carina Engstrand, Eggert Brekkan, and Karol Łacki*
GE Healthcare Life Sciences, Björkgatan 30, 751 84 Uppsala, Sweden

16.00–16.30 **203 384-well Based HTS Batch Chromatography and Orientation Sensitive QSPR Modeling of Protein Adsorption on Ion Exchange**

Jörg Kittelmann*, Florian Dismer, and Jürgen Hubbuch
Karlsruhe Institute of Technology (KIT), Institute of Engineering in Life Sciences Section IV: Biomolecular Separation Engineering, Karlsruhe, Germany

16.30–16.45 **Break**

16.45–17.15 **204 Fast Track Process Development Using High-Throughput System; a Case Study**

Susanne Nath*, Iris Fritze, Stefan Hepbildikler, and Wolfgang Kuhne
Roche Diagnostics GmbH, Nonnenwald 2, DE-82377 Penzberg, Germany

17.15–17.45 **205 Evaluation of MultiChannel Arm with Micro-tip Columns for Process Development: A Static and Dynamic Comparison**

J. Pollard*, M. Petroff, M. Rauscher, and J. Welsh
Merck & Co., Inc, 126 E. Lincoln Ave, RY805S-100, Rahway, NJ 07065, U.S.A.

17.45–19.45 **Poster session and refreshments**

19.45– **Free evening**

Wednesday June 6, 2012

Session 3: Formulation - Lessons Learned and Future Challenges

Chair: Andrew Kosky, Genentech, U.S.A.

08.30–09.00 **301 Protein Formulation Studies: Using High-Throughput Technology to Assess Aggregation Behavior, Solubility and Viscosity**

Dierk Roessner and Roger Scherrers*
Wyatt Technology Europe GmbH, Dernbach, Germany

09.00–09.30 **302 Buffer-Catalyzed Chemical Degradation of Proteins: Application of QSAR to High-Throughput Formulation Development**

Brian D. Connolly*, Ben Tran, Jamie Moore, and Andrew Kosky
Genentech, 1 DNA Way, South San Francisco, CA, U.S.A.

09.30–10.00 **Coffee break**

10.00–10.30 **303 Assessing In-Process Pool Stability of Monoclonal Antibodies Using a High-Throughput Approach**

Ben Tran* and Paul McDonald
Genentech, 1 DNA Way, South San Francisco, CA, U.S.A.

10.30–11.00 **304 High-Throughput Formulation Development**

Angela Cifelli, Sang-Kyu Lee, Sandra Ramer, and Sergey Paramonov*
Genencor / DuPont, 925 Page Mill Rd, Palo Alto, CA 94304, U.S.A.

11.00–12.30 **Lunch** (Espace Jeanne Laurent)

Session 4: Data Analysis and Managing Large Datasets – Challenges and Opportunities

Chair: Prof Nigel Titchener-Hooker, University College London, U.K.

12.30–13.00 **401 Development of Pareto Optimization Algorithm for the Downstream Process Development of a Monoclonal Antibody**

Brian O'Mara
Bristol-Myers Squibb, 311 Pennington Rocky Hill Road, Bldg 9 - 151, U.S.A.

13.00–13.30 **402 Error Analysis and Characterization of Microliter-Scale Column Chromatography Technology Performed on Liquid Handling Stations**

Patrick Diederich*, Anna Osberghaus, and Jürgen Hubbuch
Institute of Process Engineering in Life Sciences, Section IV: Biomolecular Separation Engineering; Karlsruhe Institute of Technology, Germany

13.30–14.00 **403 Using Batch Binding Chromatography and Separation Factor Analysis to Develop Chromatography Processes**

Chris Williams* and Paul McDonald
Genentech, 1 DNA Way, South San Francisco, CA, U.S.A.

14.00–14.30 **404 The Hybrid Experimental Simplex Algorithm for Early Bioprocess Development**

Spyridon Konstantinidis*[1], Sunil Chhatre[1], Ajoy Velayudhan[1], Eva Heldin[2], and Nigel Titchener-Hooker[1]
1) The Advanced Centre for Biochemical Engineering, Department of Biochemical Engineering, University College London, Torrington Place, London, United Kingdom, WC1E 7JE
2) GE Healthcare Life Sciences, Björkgatan 30, 751 84 Uppsala, Sweden

14.30–15.00 **405 Realizing the Benefits of HT Bioprocessing with HT Analytics: Tools and Strategies**

Peter DePhillips*, Kristine Kearns, Matt Troutman, and Marc Wenger
Merck & Co., Inc., West Point, PA 19486, U.S.A.

15.00–15.30 **Coffee break**

Session 5: Quality by Design – An HTPD Perspective

Chair: Stefan Hepbildikler, Roche, Germany

15.30–16.00 **501 Quality by Design - An HTPD Perspective**

Conny Vikström
Umetrics, Umeå, Sweden

16.00–16.30 **502 High-Throughput Process Development Platform for a priori Prediction of Chromatographic Behavior in Ion-Exchange Chromatography**

Rahul Bhambure* and Anurag S. Rathore
Department of Chemical Engineering, Indian Institute of Technology, Hauz Khas, New Delhi, India

16.30–17.00 **503 Characterization of Complex Mixtures for Bioseparation Process Development Using Modern, High-Throughput Compatible Analytics**

F.C. Kröner*[1], A.T.Hanke[2], D. Elsäßer[1], B.K. Nfor[2], M.W.H Pinkse[2], P.D.E.M. Verhaert[2], M. Ottens[2], and J. Hubbuch[1]
1) Biomolecular Separation Engineering, KIT, Karlsruhe, Germany
2) Department of Biotechnology, TU Delft, Delft, The Netherlands

17.00–17.30 **504 An Integrated Process Design Methodology by Modelling, Model Based Experimental Design and High-Throughput Experimentation**

Yu Ji and Yuhong Zhou*
Department of Biochemical Engineering, University College London, Torrington Place, London, WC1E 7JE, U.K.

17.30–18.00 **505 Accelerating Process Development into the QbD Arena Using the Micro24 System**

Andrew I. Kaja
Domantis Ltd, 315 Cambridge Science Park, Cambridge, CB4 0WG U.K.

19.00–22.00 **Closing dinner** (at St Bénezet Bridge)

Thursday June 7, 2012

Session 6: Case Studies - HTPD in Action

Chair: Thomas Linden, Merck & Co., Inc, U.S.A.

08.30–09.00 **601 Combining High-Throughput Tools to Support Efficient Development of Monoclonal Antibody Drugs**

Ashley Hesslein*, Brian To, Anil Salgotra, Annett Lorenz, Tim Herrmann, Henry Stosch, and Jens H. Vogel
Bayer Healthcare LLC, Global Biologics Development, Berkeley, CA, U.S.A.

09.00–09.30 **602 Streamlining Processes and Process Development with High-Throughput Screening and Analytical Tools**

Hans Rogl*, Stephanie Combe, Denise Dieterle, Michael Dieterle, Philine Dobberthien, Olga Haas, Alexander Jacobi, Franz Nothelfer, Michael Schorpp, Jessica Stolzenburger, Joey M. Studts, and Hitto Kaufmann
Boehringer Ingelheim Pharma GmbH & Co. KG, Dep. Process Science Germany, D-88397 Biberach/Riss, Germany

09.30–10.00 **603 Surviving and Thriving as Challenges Confront Modern Purification Process Development**

Aaron Goerke*, Sheng-ching Wang, Thomas Svab, Kristen Valente, Christopher Daniels, Jon T. Shanter, and Michael E. Laska
Merck & Co., Inc, West Point, PA 19486, U.S.A.

10.00–10.30 **Coffee break**

10.30–11.00 **604 High-Throughput Screening, Lab-Scale Optimization and Pilot-Scale Transfer of a 4-step Purification Process of a Recombinant Human Serum Globulin**

Christian Rodriguez*[1], Anne-Françoise Hennen[1], Virginie Brochier[2], Vincent Ravault[2], and Marcel Mersel[3]
1) EUROGENTEC, Belgium
2) PALL BioSepra, France
3) BETA-INNOV, France

11.00–11.30 **605 Selectivity Screening in Batch Format for Development of an Intermediate Insulin Purification Step**

E. Heldin*[1], E. Hallgren[1], J. Shanagar[1], S. Grönlund[1], K. Eriksson[1], H. Tunes[2], M. Xavier[2], and L. Vilela[2]
1) GE Healthcare Life Sciences, Björkgatan 30, 751 84 Uppsala, Sweden
2) BIOMM S.A., Belo Horizonte, Brazil

11.30–12.00 **Closing remarks**

701 **Process Development Balancing Solubility and Partitioning Aqueous Two-Phase Extraction of Proteins**
Stefan Oelmeier
Karlruhe Institute of Technology, Engler-Bunte-Ring 1, Karlsruhe, Germany

702 **Characterization of Lysozyme PEGylation Reactions with a High-Throughput Approach**
Benjamin Maiser*, Florian Dismer, and Jürgen Hubbuch
Karlsruhe Institute of Technology, Biomolecular Separation Engineering, 76131 Karlsruhe, Germany

703 **Fluorescent Protein as Model Systems for High-Throughput Bioprocess Optimization: Chances and Pitfalls**
P. Rohe*[1], U. Krauss[2], K. Klein[2], W. Wiechert[1], and M. Oldiges[1]
1) Institute for Bio- and Geosciences, IBG-1: Biotechnology Forschungszentrum Jülich, Germany
2) Institute for Molecular Enzyme Technology, Heinrich-Heine Universität, Düsseldorf, Germany

704 **High-Throughput Screening of HIC Media in PreDictor Plates for Capturing Recombinant Green Fluorescent Protein from *E. coli***
Charlotte Brink, Carina Engstrand, Eva Heldin, and Susanne Nyholm Westin
Presented by Sara Ullsten
GE Healthcare Life Sciences, Björkgatan 30, 751 84 Uppsala, Sweden

705 **Mechanism of Interaction Between Proteins and Multimodal Chromatographic Media**
Nils Wallménius[1], Kristina Nilsson-Välimaa*[1], Enrique Carredano[1], Karol Łacki[1], Hans Rogl[2,3], Susanne Konrad[2], and Eggert Brekkan[1]
1) GE Healthcare Life Sciences, Björkgatan 30, 751 84 Uppsala, Sweden
2) Roche Diagnostics GmbH, Penzberg, Germany
3) Presently at Boehringer Ingelheim Pharma GmbH & Co, Biberach an der Riss, Germany

706 **Application of High-Throughput Technology in Purification Process Development**
Cindy Xin Li* and Yan-Ping Yang
Bioprocess Research and Development, Sanofi Pasteur, Toronto, Canada

707 **High-Throughput Cell Separation in Aqueous Two Phase Systems (ATPS)**
Sarah Nagel*, Stefan Oelmeier, and Jürgen Hubbuch
Karlsruhe Institute of Technology, Biomolecular Separation Engineering, 76131 Karlsruhe, Germany

708 **Issues Encountered and Key Understanding for Implementation of Automated High-Throughput Process Development**
Nicola Roberts
Downstream Process Development, Biopharma Process Sciences, UCB Pharma, U.K.

709 **How to Establish a Full Scale Design Space**
Conny Vikström
Umetrics, Umeå, Sweden

710 **Quality by Design and Design Space in Formulation**
Conny Vikström
Umetrics, Umeå, Sweden

711 **Use of Multivariate Technology to Utilize the Information Content in Several and Connected Data Sourses**
Conny Vikström
Umetrics, Umeå, Sweden

712 **HTPD for Weak Partitioning Chromatography**
Susanne Nilsson* and Bernd Kalbfuss-Zimmermann
Protein Processing, Novartis Pharma AG, Basel, Switzerland

713 **Biosensor and Chromatography Based Strategies for High-Throughput Measurement of Protein Self-Association During Formulation Development**
Krisztina Kovacs-Schreiner*[1], Olatomirin Kolade[1], Brendan Fish[2], and Daniel G. Bracewell[1]
1) Advanced Centre for Biochemical Engineering, Department of Biochemical Engineering, University College London, U.K.
2) GlaxoSmithKline, Barnard Castle, U.K.

714 **Faster Development of Flocculation Recipes in a High-Throughput Set-up**
M.R. Sahoo*, A.M.C. Janse, P. van Hee, J.A. Vente, H. Robers, T. Verkaik, and E.J.A.X. van de Sandt
DSM Biotechnology Center, Dep. Downstream Processing, A. Fleminglaan 1, 2613 AX, Delft, The Netherlands

715 **Automated Platform for Cell Culture Process Development High-Throughput Analysis**
Caroline Sellin*, Carole Borosvek, Eric Calvosa, and Jean-Marc Guillaume
Sanofi Pasteur Bioprocessing Research & Development-Upstream, 1541 Avenue Marcel Merieux, FR- 69280 Marcy l'Etoile, France

716 **Keeping up with the Screeners: High-Throughput Evaluation of Newly Discovered Enzymes for Product Development**
Angela Cifelli, Sang-Kyu Lee, Sandra Ramer, Doug Dale, and Sergey Paramonov*
Genencor / DuPont, 925 Page Mill Rd, Palo Alto, CA 94304, U.S.A.

717 **Prediction of the Dynamic Binding Capacity for a Column Chromatography from a Filter Plate Based Experiment**
Xiaonan Li*, Guy de Roo, Kim Burgers, and Michel Eppink
Synthon Biopharmaceuticals BV, Microweg 22, 6503 GN, Nijmegen, The Netherlands

718 **Effect of Column Size on Determination of Chromatographic Selectivity Using High-Throughput Experimentations**
Charlotte Brink* and Eggert Brekkan
GE Healthcare Life Sciences, Björkgatan 30, 751 84 Uppsala, Sweden

719 **Overcoming the Analytical Bottleneck in High-Throughput Process Development MARS1 and ELECSYS®**
Markus Haindl*, Michael Wiedmann, and Harald Wegele
Roche Diagnostics GmbH, Pharma Technical Development Europe Analytics (PTDEA), Penzberg, Germany

720 **Strategy for Implementing Automated High-Throughput Process Development for Purification of a Lysosomal Enzyme**
Kieu Tran*, John Maga, Frank Haemmerling, Ben Youn, Simon Gu, Denise Krawitz, and Kris Antonsen
BioMarin Pharmaceutical Inc., Process Development, Novato, CA, U.S.A.

721 **High-Throughput ScreenExpertSM Platform using Robotics and Analytics for the Development of Sorbent and Membrane Chromatography Purification Strategies**
Virginie Brochier*, Vincent Ravault, Anthony Schapman, and Clément Despres
PALL BioSepra, France

722 **High-Throughput Viscosity Measurement for Assessing Biologic Formulations**
Y. Shu, T. Lambert, T. McWaid, J. Kirkwood, J. Varni, B. Wong, B. Ehnebuske, and S. Crouse
Presented by David Yamane
Freeslate, Inc., Sunnyvale, CA, U.S.A.

723 **A Parallel, Microscale, Automated Approach to Biologic Formulation Development and Stress-Test Studies**
E. Carlson, S. Lambert, and S. Cypes
Presented by Grant Gavaranovic
Freeslate, Inc. Sunnyvale, CA, U.S.A.

724 **The Hybrid Experimental Simplex Algorithm (HESA) for 'Sweet Spot' Identification in Early Bioprocess Development: Applications, Challenges and Recommendations**
Spyridon Konstantinidis*[1], Sunil Chhatre[1], Ajoy Velayudhan[1], Eva Heldin[2], and Nigel Titchener-Hooker[1]
1) The Advanced Centre for Biochemical Engineering, Department of Biochemical Engineering, University College London, Torrington Place, London, United Kingdom, WC1E 7JE
2) GE Healthcare Life Sciences, Björkgatan 30, 751 84 Uppsala, Sweden

725 **Membrane Adsorber Based HTPD for Antibody Purification**
Martin Leuthold, Louis Villain, and Claire Roulin*
Sartorius Stedim Biotech GmbH, Göttingen, Germany