SPICA 2014

Programme

Sunday October 5, 2014

13:00 **Registration**

Session Workshop 1

14:00 **Preparative HPLC: Phase Screening, Method Optimisation, Process Development. Troubleshooting a Preparative Chromatographic Device**

Michael SCHULTE
(MERCK KGAA, Darmstadt, Germany)

Session Workshop 2

14:00 **From Development to Commercial Scale: Rules to Scale up, QbD, Regulatory, Process Validation**

Alessandro BUTTE
(ETH ZURICH, Zurich, Switzerland)

Session Workshop 3

14:00 **Multicolumn Processes: From Historical SMB to the Latest Advances in the Purification of Biomolecules**

Arvind RAJENDRAN
(UNIVERSITY OF ALBERTA, Edmonton, AB, Canada)

15:30 **Coffee Break**

Session Workshop 4

16:00 **Solving a Purification Process: Choice of the Appropriate Process (Centrifugal Partition Chromatography vs Countercurrent Chromatography, Batch vs Continuous, Low Pressure vs High Pressure, Liquid vs SFC)**

Eric VALERY
(NOVASEP CDMO, AN AXPLORA COMPANY, Pompey, France)

Session Workshop 5

16:00 **Process Design for Purification of Small Molecules and Peptides**

Jochen STRUBE
(CLAUSTHAL UNIVERSITY OF TECHNOLOGY, Clausthal-Zellerfeld, Germany)

Session Workshop 6

16:00 **Process Design for Purification of Biomolecules**

Alois JUNGBAUER
(UNIVERSITY OF NATURAL RESOURCES AND LIFE SCIENCES, Vienna, Austria)

18:00 **Welcome Reception**

19:30 **End of Day 1**

Programme

Monday October 6, 2014

08:45 **Welcome**

Session 1: Process Modeling and Optimization 1

Session Chair
Andreas SEIDEL-MORGENSTERN
(MAX PLANCK INSTITUTE FOR DYNAMICS OF COMPLEX TECHNICAL SYSTEMS, Magdeburg, Germany)

Session Co-Chair
Tuomo SAINIO
(LAPPEENRANTA UNIVERSITY OF TECHNOLOGY, Lappeenranta, Finland)

09:00 **Keynote Lecture**
Chromatographer: What Could Modeling Do for You?
Roger-Marc NICOUD
(FOUNDER AND FORMER CEO NOVASEP, CONSULTANT, Nancy, France)

09:40 **Advances in Model-Based Inline Peak Deconvolution: Process-Data-Based Model Calibration and Real-Time Pooling Decisions**
Nina BRESTRICH
(KARLSRUHE INSTITUTE OF TECHNOLOGY, Karlsruhe, Germany)

10:00 **Modeling and Optimization of the Twin Column Capture SMB Process**
Daniel BAUR
(ETH ZÜRICH, Zurich, Switzerland)

10:20 **Coffee Break sponsored by LABOMATIC AG**

Session 2: Process Modeling and Optimization 2

Session Chair
Jochen STRUBE
(CLAUSTHAL UNIVERSITY OF TECHNOLOGY, Clausthal-Zellerfeld, Germany)

Session Co-Chair
Mirjana MINCEVA
(TECHNISCHE UNIVERSITÄT MÜNCHEN, Freising, Germany)

10:50 **Implementation of Model-Based Approach for Chromatography Development**
Bertrand GUELAT
(NOVARTIS PHARMA AG, Basel, Switzerland)

11:10 **Modelling and Simulation of the Purification of Cell Culture-Derived Influenza Virus Via Continuous Size Exclusion Chromatoghraphy**
Laura M. FISCHER
(MAX PLANCK INSTITUTE FOR DYNAMICS OF COMPLEX TECHNICAL SYSTEMS, Magdeburg, Germany)

11:30 **Unified Design of Chromatographic Separation Processes**
Tuomo SAINIO
(LAPPEENRANTA UNIVERSITY OF TECHNOLOGY, Lappeenranta, Finland)

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11:50 **Modelling and Optimization of Preparative Chromatography Separation of Rare Earth Elements**
Bernt NILSSON
(LUND UNIVERSITY, Lund, Sweden)

12:10 **Lunch Break**
Vendor Seminars by AkzoNobel, LEWA and Waters Corporation (12:20-13:20)

Session 3: Purification and Resolution of Small Molecules

Session Chair
José Paulo MOTA
(REQUIMTE/CQFB, FFCT, Caparica, Portugal)

Session Co-Chair
António E. RIBEIRO
(POLYTECHNIC INSTITUTE OF BRAGANÇA, Braganca, Portugal)

13:20 **Keynote Lecture**
Pharmaceutical Small Molecule Purification: Where Are We and Where Do We Need to Be?
Larry MILLER
(AMGEN, Thousand Oaks, United States)

14:00 **Preparative Chiral Chromatography. Summa Chiralogica**
Pilar FRANCO
(CHIRAL TECHNOLOGIES EUROPE, Illkirch, France)

14:20 **Implementation of Continuous Chromatography Under cGMP for the Pharmaceutical Industry**
Olivier DAPREMONT
(AMPAC FINE CHEMICALS, Rancho Cordova, United States)

14:40 **Highly Active Small Molecules and Peptides: Intrinsic Reduction of Risks by the Use of Preparative Chromatography and Flow Technologies**
Ulf ALTENHOENER
(LONZA AG, Aarau , Switzerland)

15:00 **Coffee Break**

Session 4: Counter Current Chromatography

Session Chair
Joachim KINKEL
(GEORG-SIMON-OHM UNIVERSITY OF APPLIED SCIENCES, Nuernberg, Germany)

Session Co-Chair
Alain BERTHOD
(UNIVERSITÉ DE LYON 1 - CNRS, Villeurbanne, France)

15:30 **Keynote Lecture**
Continuous Processing by CCC/CPC: Where to Plug and How to Play When Everything is Fluid
Svetlana IGNATOVA
(BRUNEL UNIVERSITY, Uxbridge, United Kingdom)

16:10 **From Molecule to Process: Model-Based Design of Continuous Centrifugal Partition Chromatography**

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Mirjana MINCEVA
(TECHNISCHE UNIVERSITÄT MÜNCHEN, Freising, Germany)

16:30 **Methodology for Scale-Up in Countercurrent Chromatography**
Karine FAURE
(INSTITUT DES SCIENCES ANALYTIQUES, Villeurbanne, France)

16:50 **pH Zone Refining in Centrifugal Partition Extraction. A Step Change in Productivity for Liquid-Liquid Chromatography Processes?**
Paul HELLIER
(INSTITUT DE RECHERCHE PIERRE FABRE, GAILLAC, France)

17:10 **A New Dynamic Fractionation Method and Column Design for Size Separation of Bio-Polymer Particles**
Peter HEWITSON
(BRUNEL INSTITUTE FOR BIOENGINEERING, Uxbridge, United Kingdom)

17:30 **Poster Session #1 and Beer Party**
(presentation of posters with even numbers)

19:00 **End of Day 2**

Programme

Tuesday October 7, 2014

Session 5: Protein and Peptide Purification

Session Chair

Olivier LUDEMANN-HOMBOURGER
(POLYPEPTIDE LABORATORIES FRANCE, Strasbourg, France)

Session Co-Chair

Jeannie HORAK
(UNIVERSITY OF TUEBINGEN, Tuebingen, Germany)

08:30 **Keynote Lecture**
Peptide Purification: State-of-the-Art and Challenges

Thomas MEIER
(BACHEM AG, Bubendorf, Switzerland)

09:10 **High Yeld Protein Refolding by Integrating Single-Column Chromatoghraphy and Membrane Filtration**

Sebastian NIMMIG
(FRIEDRICH-ALEXANDER-UNIVERSITY, Hanau, Germany)

09:30 **Saturation Capacity for Proteins in Ion Exchange Chromatoghraphy**

Fabian STEINEBACH
(ETH ZÜRICH, Zurich, Switzerland)

09:50 **HTS Chromatographic Platforms: Small is Beautiful**

David DELVAILLE
(MERCKSERONO, Martillac, France)

10:10 **Peptide Purification Via Ion-Exchange Doped Reversed Phase Chromatography: a Combined Experimental and Modeling Approach**

Gianluca BUFFOLINO
(ZEOCHEM AG, Uetikon am See, Switzerland)

10:30 **Coffee Break**

Session 6: Purification of Biopharmaceuticals

Session Chair

Michael SCHULTE
(MERCK KGAA, Darmstadt, Germany)

Session Co-Chair

Kathleen MIHLBACHLER
(LEWA GMBH, Leonberg, Germany)

11:00 **Integration of Continuous Precipitation and Flow Through Chromatography with Monoliths for Purification of Recombinant Antibodies**

Alois JUNGBAUER
(UNIVERSITY OF NATURAL RESOURCES AND LIFE SCIENCES, Vienna, Austria)

11:20 **Purification of Antibody Conjugates by MCSGP Chromatography**

Thomas MÜLLER-SPÄTH
(CHROMACON AG, Zurich, Switzerland)

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11:40 **Implementation of a Negative Mode Platform for Virus Purification**
Ricardo SILVA
(IBET - INSTITUTO DE BIOLOGIA EXPERIMENTAL E TECHNOLOGICA, Oeiras, Portugal)

12:00 **Optimizing the Separation of MAB Charge Variants Using Model-Based Approaches**
Rushd KHALAF
(ETH ZÜRICH, Zurich, Switzerland)

12:20 **Lunch Break sponsored by AMPAC FINE CHEMICALS**
Vendor Seminars by Novasep, Merck Millipore, Chiral Technologies Europe and Agilent Technologies (12:30-13:30)

13:30 **Poster Session #2**
(presentation of posters with odd numbers)

Session 7: Industrial Purification Processes

Session Chair
Eric VALERY
(NOVASEP CDMO, AN AXPLORA COMPANY, Pompey, France)

Session Co-Chair
Galatea PAREDES
(NOVARTIS PHARMA, Basel, Switzerland)

14:30 **Keynote Lecture**
Industrial Preparative HPLC for Production of API Including Most Common Unit Operations; Membrane Operations, Evaporation, Crystallization
Roman BURJA
(LEK PHARMACEUTICALS D.D., Menges, Slovenia)

15:10 **Overcoming Challenges in the Industrial Production of OMEGA-3S**
Jean BLEHAUT
(NOVASEP GROUP, Pompey, France)

15:30 **Design of an Agarose Based Platform for Large Scale Chromatography**
Hans JOHANSSON
(PUROLITE, Uppsala, Sweden)

15:50 **Continuous Manufacturing in Biopharmaceutical Industries**
Holger FROEHLICH
(CLAUSTHAL UNIVERSITY OF TECHNOLOGY, Clausthal-Zellerfeld, Germany)

16:10 **Coffee Break**

Session 8: Multicolumn Chromatography

Session Chair
Massimo MORBIDELLI
(ETH ZÜRICH, Milano, Italy)

Session Co-Chair

Programme

Ernst FREUND
(NOVARTIS PHARMA AG, Basel, Switzerland)

16:30 **Keynote Lecture**
Multi-Column Chromatography: Challenges and Opportunities
Yoshiaki KAWAJIRI
(GEORGIA INSTITUTE OF TECHNOLOGY, Atlanta, United States)

17:10 **Three Column Intermittent Simulated Moving BED (3C-ISMB) Cromatoghraphy: Cascade Operation for Center-Cut Separations**
Simon JERMANN
(ETH ZÜRICH, Zurich, Switzerland)

17:30 **Purification of an Intermediately Eluting Component from a Complex Mixture**
Kiara KOCHENDOERFER
(BASF SE, Ludwigshafen, Germany)

17:50 **Continuous Processing of Self-Cleaving Fusion Proteins by Matrix-Assisted Refolding Separation Using SMB Size Exclusion Chromatography with Buffer Recycling**
Martin WELLHÖFER
(CELONIC AG, Basel, Switzerland)

18:10 **Panel discussion: Bridging Purification and Flow Chemistry?**
Discussion animated by Berthold SCHENKEL (Novartis, Switzerland), Andreas SEIDEL-MORGENSTERN (MPI for Dynamics of Complex Technical Systems, Germany) and Olivier DAPREMONT (AMPAC Fine Chemicals, United States)

19:00 **End of Day 3**

20:00 **Symposium Banquet**

Programme

Wednesday October 8, 2014

Session 9: Supercritical Fluid Chromatography

Session Chair
Arvind RAJENDRAN
(UNIVERSITY OF ALBERTA, Edmonton, AB, Canada)

Session Co-Chair
Antoine PRADINES
(SANOFI-AVENTIS, Toulouse Cedex 1, France)

08:30 **Separation of Lignans by Supercritical Fluid Simulated Moving BED**
Ming-Tsai LIANG
(I-SHOU UNIVERSITY, Kaohsiung, Taiwan)

08:50 **Scale-Up in Supercritical Fluid Chromatography**
Abhijit TARAFDER
(WATERS CORPORATION, Boston, United States)

09:10 **Reliable Scale-Up from Analytical to Large Scale Instrumentation in Chiral Supercritical Fluid Chromatography**
Torgny FORNSTEDT
(KARLSTAD UNIVERSITY, Karlstad, Sweden)

09:30 **Extraction-Injection: an Alternative Sample Introduction Method for SFC**
Geoffroy COX
(PIC SOLUTION, Media, United States)

09:50 **Poster Prize**

10:10 **Coffee Break**

Session 10: Integrated Continuous Processes

Session Chair
Olivier DAPREMONT
(AMPAC FINE CHEMICALS, Rancho Cordova, United States)

Session Co-Chair
Martin WELLHÖFER
(CELONIC AG, Basel, Switzerland)

10:40 **Keynote Lecture**
Chromatography and Crystallization: Good Partners in Separating Enantiomers
Andreas SEIDEL-MORGENSTERN
(MAX PLANCK INSTITUTE FOR DYNAMICS OF COMPLEX TECHNICAL SYSTEMS, Magdeburg, Germany)

11:20 **Implementing Integrated Continuous Downstream Processing**
Kathleen MIHLBACHLER
(LEWA GMBH, Leonberg, Germany)

Programme

11:40 **Integrated Reaction/Separation Process for High-Yield Pegylation**
David PFISTER
(ETH ZÜRICH, Zürich, Switzerland)

12:00 **Hardware Solutions Enabling Continuous Biomanufacturing**
Roger NORDBERG
(GE HEALTHCARE, Uppsala, Sweden)

12:20 **Integrated Counetr Current Chromatography (ICCC) - From SMB to a Fully Integrated Process**
Steffen ZOBEL-ROOS
(CLAUSTHAL UNIVERSITY OF TECHNOLOGY, Clausthal-Zellerfeld, Germany)

12:40 **Closing Remarks**

13:00 **End of Day 4**