

RXIX - Daily Technical Program Schedule

Sunday 10 July 2022

14:00 - 16:00 **Conference Check-In | Congress Foyer (-1)**

16:00 - 16:15 **Welcome by RXIX Conference Chairs | Salone dei Cavalieri (-1)**
Conference Chairs Suzanne Farid, University College London (UCL), United Kingdom
Nihal Tugcu, Sanofi, United States
Arne Staby, Novo Nordisk, Denmark

Oral Session 1: Respice, Adspice, Prospice – Past, Present & Future Case Studies | Salone dei Cavalieri (-1)

Session Chairs: Jennifer Pollard, Merck and Co., Inc., United States
Todd Przybycien, Rensselaer Polytechnic Institute, United States

16:15 - 16:20 **Introduction by Session Chairs**

16:20 - 16:45 **What's old is new – Continuous countercurrent staging for chromatographic separations and precipitation**
Andrew Zydney, Penn State University, United States

16:45 - 17:10 **Life-cycle Management and Process Enhancements for Over a Quarter-Century of Vaccine Supply**
Kristin Valente, Merck and Co., Inc., United States

17:10 - 17:35 **Veni, Vidi, Exemplavi - The past, present and future of industrial chromatography modeling**
Felix Wittkopp, Roche Diagnostics GmbH, Germany

17:35 - 18:00 **Purification Platform of the Future for Diverse Pipelines and Next Generation Manufacturing**
Benoit Mothes, Sanofi, France

18:00 - 19:30 **Welcome Reception | Tiepolo Terrace (0)**

19:30 - 21:00 **RXIX Opening Banquet | Salone dei Cavalieri (-1)**

After Dinner Keynote | Salone dei Cavalieri (-1)

Host Suzanne Farid, University College London (UCL), United Kingdom

21:00 - 21:45 **The Anatomy of Hope**
Kevin Fong, University College London Hospitals (UCLH), United Kingdom

21:45 - 23:00 **RXIX Rooftop Social Hour | Terrazza degli Aranci (9)**

Monday 11 July 2022

07:00 - 09:00 **Breakfast** | [Le Bella Arti \(-1\)](#)

Oral Session 2: A Call to Arms: Biotechnology's Approach to Address Pandemics | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Anne Kantardjieff, bluebird bio, United States
John Moscariello, Bristol Myers Squibb, United States

09:00 - 09:05 **Introduction by Session Chairs**

09:05 - 09:30 **mRNA as a Platform for On-Demand Therapeutics and Pandemic Vaccines**
Christopher Ladd Effio, Moderna, United States

09:30 - 09:55 **Accelerated Development of Bamlanivimab**
Richard Chen, Eli Lilly and Company, United States

09:55 - 10:20 **Accelerated Development of Neutralizing Antibodies Targeting SARS-CoV-2**
Christopher Cowan, Regeneron Pharmaceuticals, United States

10:20 - 10:45 **Meeting the challenges of COVID-19 from a CDMO perspective**
James Miskin, Oxford Biomedica, United Kingdom

10:45 - 11:15 **Morning Break** | [Garden Lobby \(-1\)](#)

Oral Session 3: Purification of Biologics with Chemical Synthesis Steps | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Michaela Wendeler, AstraZeneca, United States
Thanmaya Peram, Genentech, United States

11:15 - 11:20 **Introduction by Session Chairs**

11:20 - 23:45 **Assessment of Impurity & Product Variant Removal Methods for ADCs Conjugated with Novel Payloads**
Xin Xin Lin, Genentech, United States

11:45 - 12:10 **Oligonucleotide purification strategies and application of process modeling to define control strategy**
Pranay Ghosh, Roche, Switzerland, Michelle Butler, Roche, Switzerland

12:10 - 12:35 **mRNA-based therapeutics and vaccines - COVID-19 and beyond**
Andreas Kuhn, BioNTech SE, Germany

12:35 - 13:30 **Lunch (Boxed)** | [Garden Lobby \(-1\)](#)

13:30 - 18:30 **Afternoon Networking Activities (Optional)** | [Meeting Point: Congress Foyer \(-1\)](#)

18:45 - 19:15 **Cocktail Reception** | [Tiepolo Terrace \(0\)](#)

19:15 - 20:30 **Dinner** | [Tiepolo Terrace \(0\)](#)

Poster Snapshot Session & Poster Session | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Ana Azevedo, Instituto Superior Tecnico (IST), Portugal
Glen Bolton, Amgen, United States
Marco Rito-Palomares, Tecnologico de Monterrey, Mexico

20:30 - 21:00 **Poster Snapshot Session 1**

#2. General approaches and considerations for purification of hydrodynamically large Fab conjugates

Eileen Duenas, Genentech, United States

#7. Machine learning and advanced data analytics to better exploit process analytical technology for chromatography operation

Stephen Goldrick, University College London (UCL), United Kingdom

#9. Implementation of novel affinity ligand for Lentiviral vector purification

Ana Sofia Moreira, Instituto de Biologia Experimental e Tecnológica (iBET), Portugal

#12. Production of complex recombinant proteins in plant-based systems – From case studies in process development to regulatory approval

Johannes Buyel, Fraunhofer IME/RWTH Aachen University, Germany

#21. Downstream Bioprocess Challenges of a Novel Class of Nanobodies; Understanding Protein A Capture Step Aggregation Removal, Aggregation Formation and Formulation Utilizing Biophysical Analysis and Computational Modeling

Sandra Rios, Merck and Co., Inc., United States

#27. Evaluation of Ecofriendly Alternatives for a Virus Inactivation Detergent used in Biologics Manufacturing Process

Dong Yang, Bristol Myers Squibb, United States

21:00 - 23:00

Poster Session 1 with Desserts and Drinks

Tuesday 12 July 2022

07:00 - 09:00 **Breakfast** | [Le Bella Arti \(-1\)](#)

Oral Session 4: Separation Sciences in Advancing Novel Gene and Cell Therapies | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Nooshafarin (Nooshie) Sanaie, Poseida Therapeutics, United States
Andrew Ramelmeier, Sangamo Therapeutics, United States

09:00 - 09:05 **Introduction by Session Chairs**

09:05 - 09:30 **From blood to drug product, the isolation and purification of Treg cells**
Pierre Heimendinger, Sangamo Therapeutics, France

09:30 - 09:55 **Towards continuous processes for advanced therapy medicinal products**
Manuel Carrondo, iBET, Portugal

09:55 - 10:20 **Implications of AAV affinity column reuse and processing conditions on product quality attributes**
Harshal Soni, Rensselaer Polytechnic Institute, United States

10:20 - 10:45 **Removal of Empty AAV Capsids to Undetectable Levels Using Orthogonal Purification Steps – Product Quality and Process Robustness Considerations**
Rahul Sheth, BioMarin Pharmaceutical Inc., United States

10:45 - 11:15 **Morning Break** | [Garden Lobby \(-1\)](#)

Oral Session 5: Modeling Next Generation Supply Chains & Facilities: Envisaging the Challenges – Engineering the Solutions | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Jan Griesbach, Roche, Germany
Nigel Titchener-Hooker, University College London (UCL), United Kingdom

11:15 - 11:20 **Introduction by Session Chairs**

11:20 - 11:45 **Next Generation Bioprocessing – Manufacturing and Facility Concepts**
Rob O'Keeffe, Eli Lilly / University College Dublin, Ireland

11:45 - 12:10 **What do all CGT supply chains have in common? Designing for platform capabilities that bring down CoG and increase the chance of successful commercialization**
Sebastian Schneider, Roche, Switzerland

12:10 - 12:35 **Decisional tools for successful commercialisation of cell and gene therapies: industrial case studies**
Christos Stamatis, University College London (UCL), United Kingdom

12:35 - 13:45 **Lunch Buffet** | [Le Bella Arti \(-1\)](#) & [Garden Lobby \(-1\)](#)

Keynote | [Salone dei Cavalieri \(-1\)](#)

Host Arne Staby, Novo Nordisk A/S, Denmark

13:45 - 14:30 **Precision Medicine for Cancer Treatment Leveraging Industrialized, Robust and Simple Bispecific Antibody Platform: Learnings from a 10-year Journey**
Hanne Bak, Regeneron Pharmaceuticals, United States

14:30 - 14:45 **Stretch Break**

Oral Session 6: All Roads Lead to Rome – But Which Roads Lead to Accelerated Bioprocess Development? | [Salone dei Cavalieri \(-1\)](#)

Session Chairs:

Sophie Karkov, Novo Nordisk, Denmark
Giorgio Carta, University of Virginia, United States

- 14:45 - 14:50 **Introduction by Session Chairs**
- 14:50 - 15:15 **Scaling Down in HTPD**
Marcel Ottens, Delft University of Technology, Netherlands
- 15:15 - 15:40 **Predictive Models for Process Development and Multidimensional Real Time Monitoring in Downstream Processing**
Astrid Duerauer, BOKU & Austrian Centre of Industrial Biotechnology, Austria
- 15:40 - 16:05 **Evolving trends in monoclonal antibody production processes: From 'platforms' to 'pandemic pace' development**
Sanchayita Ghose, Bristol Myers Squibb, United States
- 16:05 - 16:30 **Rapid downstream process development for a SARS-CoV-2 vaccine candidate through High Throughput Process Development**
Spyridon Konstantinidis, Merck and Co., Inc., United States

17:00 - 20:00 **Vatican Tour | Meeting Point: Congress Foyer (-1)**

20:00 - 23:00 **Dinner (Offsite)**

Wednesday 13 July 2022

07:00 - 09:00 **Breakfast** | [Le Bella Arti \(-1\)](#)

08:30 - 13:30 **Morning Networking Activities (Optional)** | [Meeting Point: Congress Foyer \(-1\)](#)

13:00 - 14:00 **Lunch (Boxed) & Refresh** | [Garden Lobby \(-1\)](#)

Keynote | [Salone dei Cavalieri \(-1\)](#)

Host Arne Staby, Novo Nordisk A/S, Denmark

14:00 - 14:45 **A Look Back in Order to Look Forward; Analysis of Historical Recovery Progress to Guide Future Innovations in the Biopharmaceutical Industry**

Jill Myers, TG Therapeutics, United States

Oral Session 7: Manufacturability Assessment for Complex Biologics & Gene Therapies | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Hong Li, Merck and Co., Inc., United States
Juergen Hubbuch, Karlsruhe Institute of Technology, Germany

14:45 - 14:50 **Introduction by Session Chairs**

14:50 - 15:15 **Harnessing AAV Technology and Manufacturing Capabilities to Meet the Needs of the Gene Therapy Market**

John Pieracci, Biogen, United States

15:15 - 15:40 **Challenges During Recovery and Purification of AAV Gene Therapy**

Michael Winkler, Regenxbio, United States

15:40 - 16:05 **Predicting antibody developability**

Peter Tessier, University of Michigan, United States

16:05 - 16:35 **Afternoon Break** | [Garden Lobby \(-1\)](#)

Oral Session 8: Big Data Analytics and Modeling in Biomanufacturing | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Steven Cramer, Rensselaer Polytechnic Institute, United States
Joey Studts, Boehringer Ingelheim, Germany

16:35 - 16:40 **Introduction by Session Chairs**

16:40 - 17:05 **Digital twins for MCSGP: accelerated model development and systematic design**

Lisa Vetter-Joss, Novo Nordisk, Denmark

17:05 - 17:30 **Smart platform for fast development of small-scale integrated continuous downstream processes**

Bernt Nilsson, Lund University, Sweden

17:30 - 17:55 **Integrated mechanistic modeling to predict a commercial downstream process**

Federico Rischawy, Boehringer Ingelheim / Karlsruhe Institute of Technology (KIT), Germany

17:55 - 18:20 **Big Data Analytics for Control of Continuous Processes**

Anurag Rathore, Indian Institute of Technology Delhi, India

18:45 - 19:15 **Cocktail Reception** | [Tiepolo Terrace \(0\)](#)

19:15 - 20:30 **Dinner** | [Michelangelo \(0\)](#)

Poster Snapshot Session & Poster Session | Salone dei Cavalieri (-1)

Session Chairs: Ana Azevedo, Instituto Superior Tecnico (IST), Portugal
Glen Bolton, Amgen, United States
Marco Rito-Palomares, Tecnológico de Monterrey, Mexico

20:30 - 21:00 Poster Snapshot Session 2

#51. Continuous and integrated processing of viral capsomeres and virus-like particle purification using new generation multi-modal chromatography strategies

Lukas Gerstweiler, University of Adelaide, Australia

#64. To explore novel approaches to remove host cell proteins (HCPs) for antibodies and other Fc fusion proteins' production

Tingting Cui, AstraZeneca, United Kingdom

#65. Evolution of a clarification platform strategy using a novel chromatographic clarification technology

Agathe Drapé, Sanofi, France

#66. Designing high density isopore membranes with "à la carte" surface chemistries for downstream mAb purification and applications in cell and gene therapies & diagnostics

Daniele Gerion, Terapore Technologies, United States

#70. 3D printed stationary phases for bioseparations: control of morphology across scales, from mm to μm to nm

Simone Dimartino, University of Edinburgh, United Kingdom

#74. Using real-time data to enable smart decision making on the manufacturing floor

Christine O'Sullivan, Amgen, Ireland

21:00 - 23:00 Poster Session 2 with Desserts & Drinks

Thursday 14 July 2022

07:00 - 09:00 **Breakfast | [Le Bella Arti \(-1\)](#)**

Oral Session 9: New and Transformative Purification Technologies | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Raquel Orozco, Bayer, United States
Abraham Lenhoff, University of Delaware, United States

09:00 - 09:05 **Introduction by Session Chairs**

09:05 - 09:30 **Novel Ligands and Modalities for the Purification of Gene Editing Products: CRISPR-Cas and Viral Vectors**
Stefano Menegatti, NC State University, United States

09:30 - 09:55 **Challenging the Paradigm: An Innovative and Scalable Purification Platform for AAV and Other Biologics**
Kelli Luginbuhl, Isolere Bio, United States

09:55 - 10:20 **Novel DNA Removal Technology for Exosomes**
Aaron Noyes, Codiak BioSciences, United States

10:20 - 10:45 **Enabling a design cycle for bioseparation materials with X-ray imaging and 3D printing**
Thomas Johnson, University College London (UCL), United Kingdom

10:45 - 11:15 **Morning Break | [Garden Lobby \(-1\)](#)**

11:15 - 12:45 **Roundtables: Yield! | [Michelangelo 1/ 2/ 3/ San Pietro \(0\)](#)**
1. Assessing Protein Manufacturability (Chairs: M Butler (Roche), R Willson (U. Houston))
2. Continuous Processing: Opportunities and Challenges (Chairs: K Brower (Sanofi), A Jungbauer (BOKU))
3. Overcoming Constraints in Gene Therapy Manufacture (Chairs: S D'Costa (Alcyone), A Tustian (Regeneron), J Pieracci (Biogen))
4. Manufacturability for Pandemic Preparedness (Chairs: A Rayat (UCL), G Ferreira (AstraZeneca), B Kelley (Vir))

12:45 - 14:15 **Lunch Buffet | [Le Bella Arti \(-1\)](#) & [Garden Lobby \(-1\)](#)**

Oral Session 10: Impact of Diverse Expression Systems | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Jean Bender, Visterra, Inc., United States
Ranga Godavarti, Pfizer, United States

14:15 - 14:20 **Introduction by Session Chairs**

14:20 - 14:45 **The development and manufacture of products from a cell-free expression system**
Judy Hsui, Sutro Biopharma, United States

14:45 - 15:10 **Insulin Purification – Innovation Continuum via Synthesis of Fundamentals, Technology and Modeling**
David Roush, Merck and Co., Inc., United States

15:10 - 15:35 **Why Downstream Teams Should Root for Alternative Expression Hosts**
J. Christopher Love, MIT, United States

15:35 - 16:05 **Afternoon Break | [Garden Lobby \(-1\)](#)**

Oral Session 11: Future Facility Design Concepts | [Salone dei Cavalieri \(-1\)](#)

Session Chairs: Lisa Connell-Crowley, Just - Evotec Biologics, United States
Victor Goetz, Eli Lilly and Company, United States

16:05 - 16:10 **Introduction by Session Chairs**

- 16:10 - 16:35 **Biopharmaceutical Manufacturing Facilities of the Future: Rigidity, Risk, Resilience, and Veritas' Mirror**
Jeffrey Baker, NIIMBL, United States
- 16:35 - 17:00 **Advancing Manufacturing Technology Through a Flexible J.POD® Facility**
Robert Casey, Just - Evotec Biologics, Inc., United States
- 17:00 - 17:25 **A truly continuous counter-current downstream**
Jon Coffman, AstraZeneca, United States

Keynote | Salone dei Cavalieri (-1)

Host Nihal Tugcu, Sanofi, United States

- 17:25 - 18:10 **New therapeutic modalities and Moore's Law in biomanufacturing**
Hari Pujar, Tessera Therapeutics and Flagship Pioneering, United States

19:00 - 00:00 **Closing Banquet & Awards (Offsite) | Meeting Point: Hotel Lobby (0)**

Friday 15 July 2022

07:00 - 10:00 **Breakfast & Departures | Le Bella Arti (-1)**

10:00 **RXIX Conference Close**