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Integrated Continuous Biomanufacturing V

Proceedings

10-9-2022

Conference Program

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Program

Integrated Continuous Biomanufacturing V

"Back to Barcelona: Progress & Potential of ICB"

October 9-13, 2022 Dolce Sitges Barcelona Resort Sitges, Spain

Conference Chairs

Ana Azevedo, Técnico Lisboa, Portugal Jason Walther, Sanofi, USA Rohini Deshpande, Amgen, USA





Engineering Conference International 32 Broadway, Suite 314 - New York, NY 10004, USA www.engconfintl.org - info@engconfintl.org

Dolce Sitges Barcelona

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Veena Warikoo, AstraZeneca

Previous conference in this series

Integrated Continuous Biomanufacturing October 20 - 24, 2013 Castelldefels, Spain

Conference Chairs:
Konstantin Konstantinov, Genzyme-Sanofi, USA
Chetan Goudar, Amgen, USA
Nigel Titchener-Hooker, University College London, UK

Integrated Continuous Biomanufacturing II November 1 - 5, 2015 Berkeley, California, USA

Conference Chairs:
Chetan Goudar, Amgen, USA
Suzanne Farid, University College London, UK
Christopher Hwang, Genzyme-Sanofi, USA
Karol Lacki, Novo Nordisk, Denmark

Integrated Continuous Biomanufacturing III September 17-21, 2017 Cascais, Portugal

Conference Chairs:
Suzanne Farid, University College London, UK
Chetan Goudar, Amgen, USA
Paula Alves, IBET, Portugal
Veena Warikoo, Axcella Health, Inc., USA

Integrated Continuous Biomanufacturing IV October 6 – 10, 2019 Brewster (Cape Cod), Massachusetts

Conference Chairs:
Veena Warikoo, Roche, USA
Alois Jungbauer, BOKU, Austria
Jon Coffman, AstraZeneca, USA
Jason Walther, Sanofi, USA

Integrated Continuous Biomanufacturing Award Winner



Veena Warikoo

Highlights of Contributions to Integrated Continuous Biomanufacturing (ICB)

Veena Warikoo is an innovator and organizational leader with more than 25 years of experience across a range of disciplines in biotechnology. Throughout her career, Veena has demonstrated her depth of capability in developing high-performing teams through strategic vision setting, consistently leading teams in the delivery of industry-pioneering, state-of-the-art process technologies and facility designs within multiple multinational biopharma companies. Veena's pragmatic and inspiring implementation-focused leadership was the primary driving force behind the earliest and most foundational successes in the field of ICB. Beyond the original achievements at Genzyme / Sanofi, Veena has broadened her impact through various leadership roles, most recently at Roche/Genentech, and across the ICB academic, supplier, and conference community. Last, but certainly not least, Veena recognized the critical interplay between people development and technology development and, in doing so, has inspired a generation of scientists across the field to carry forward her relentless focus on delivering ICB and other new technologies.

During her career, Veena has both broad and deep contributions to scientific literature via her excellent publication record. Her work has addressed a range of scientific subject matters including periodic counter-current chromatography, including critical partnership development with Cytiva (formerly GE); methods for resin sterilization and closed processing; fully continuous integrated continuous biomanufacturing; business cases justifying ICB; and general principles of manufacturability. In addition to the literature contributions, Veena is co-inventor on foundational, granted ICB patents as well as over ten ICB patent applications.

Industrially, Veena has held roles of increasing scope and responsibility. In these roles, Veena has led teams responsible for developing and delivering medicines to patients across all aspects of clinical development and commercialization, including work directly supporting the realization of several New Molecular Entities (NMEs) at multiple companies. Veena and her

teams have delivered ICB technology through to commercialization at Sanofi into a facility recognized as the Facility of the Future at the 2020 ISPE Awards. Veena's continuously increasing scope has culminated, thus far, with global leadership responsibilities for Engineering and Technology at Roche/Genentech, focusing on modernization of Roche Pharma's manufacturing network, leading generation of playbook for single use technology modular design and standards, and innovation leadership in the areas simplification of technology implementation governance.

Veena's best gift to the ICB field has been her recognition that success for ICB requires a different approach to people development, hiring, and team capability building. Veena recognized that successful development of ICB technology was not primarily a process development exercise. Instead, Veena's vision of ICB includes teams capable of integrating engineering, process control, and automation skills. In this way, Veena builds teams of "ICB Scientists" capable of understanding aspects of bioprocess, and unafraid of the challenges specific to integrating unit ops not typically within the purview of process development scientists. Above all, Veena has always put her team first, doing the hard work in the background to remove barriers, scrape together CAPEX, and almost always shying away from the spotlight of keynote presentations and associated accolades.

For the reasons described above, and for her future contributions to the ICB field undoubtedly still to come, Veena is a worthy recipient of the ICB Award, recognition granted by the ICB Award Committee on behalf of the broader ICB community.

Previous Award Winners: Massimo Morbidelli, 2019

Konstantin Konstantinov, 2017

Welcome from the Chairs

It is our great pleasure to welcome you all Back to Barcelona (Dolce Sitges), Spain for Integrated Continuous Biomanufacturing V. This conference is organized under the auspices of the Engineering Conferences International (ECI). ECI is a not-for-profit 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 has held more than 2000 conferences covering a multitude of leading-edge topics that are uniquely cross-disciplinary and have served the engineering/scientific community for the past 57 years.

ECI's Integrated and Continuous Biomanufacturing Conference (ICB) series is the world's premiere conference in the area of continuous biomanufacturing. In the recent past, impressive technological advances have been made to enable implementation of continuous bioprocessing across the biopharmaceutical industry. Accordingly, the focus of this conference is to build on this momentum and showcase the case studies for breakthrough ICB technologies, ICB for emerging modalities, ICB industrialization, strategies to address industry challenges and opportunities, integrated control strategies for ICB, and application of smart manufacturing tools for ICB. The program was developed to engage thoughtful discussion and will feature oral, poster and workshop sessions, with presenters and session chairs from academia and industry with a wide range of experience and from many countries around the world.

We would like to thank the industrial sponsors for their generous support. We also would like to thank all the board members, session chairs, and dedicated ECI staff for putting together a great program. Finally, we would like to thank all the speakers, poster authors, and attendees for providing the superb scientific content and look forward to the interactions that make this meeting so invaluable and productive. We hope you will enjoy the conference and participate to the fullest extent.

Conference Chairs:

Jason Walther, Sanofi, Ana Azevedo, Técnico Lisboa and Rohini Deshpande, Amgen, Inc.

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Schedule

Integrated Continuous Biomanufacturing V

"Back to Barcelona: Progress & Potential of ICB"

October 9-13, 2022 Sitges, Spain





Engineering Conference International

Locations and Notes

- Technical sessions will be in Sitges I and II.
- Poster sessions will be in Mediterrani.
- Breakfasts will be in the Verema Restaurant. Lunches on Monday and Wednesday and dinners on Sunday and Monday will also be in the Verema Restaurant.
- The gala dinner on Wednesday will be in Mediterrani.
- Please wear your mask except when giving a presentation or actively eating or drinking. Please maintain physical distancing as much as possible.
- Audio, still photo and video recording by any device (e.g., cameras, cell phones, laptops, PDAs, watches) is strictly prohibited during the technical sessions, unless the author and ECI have granted prior permission.
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- Questions will be submitted via the Guidebook app that we will be using for the conference. The app will be used in place of the roving microphones we normally have.
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Sunday, October 9, 2022

14:00 – 16:30	Conference Ch	eck-in
16:30 – 16:45	Welcome	
16:45 – 17:30	Therapeutic P	gitalization in the Continuous Integrated Manufacturing of roteins idelli, Politecnico di Milano, Italy
17:30 – 18:15		on Digitalization Richard Braatz, Massachusetts Institute of Technology, USA
	Panelists:	Jennifer Pollard, Merck Sharpe & Dohme, USA Massimo Morbidelli, Politecnico di Milano, Italy Cenk Undey, Amgen Inc., USA Kevin Brower, Sanofi, USA Anurag Rathore, Indian Institute of Technology Delhi, India
18:15 – 19:00	Free Time	
19:00 – 20:00	Reception (Poo	ol Area)
20:00 – 21:30	Dinner	
21:30 – 23:00	Networking	

Monday, October 10, 2022

07:00 - 08:30	Breakfast
	Session 1: Breakthrough ICB technologies on the horizon (Sponsored by YMC Process Technologies, Inc.) Chairs: Astrid Dürauer, BOKU, Austria Michael Coolbaugh, Sanofi, USA
08:30 – 08:55	A truly continuous counter-current downstream Jon Coffman, AstraZeneca, USA
08:55 – 09:20	Democratizing global supply of recombinant proteins Kerry Love, Sunflower Therapeutics, USA
09:20 – 09:45	A fully continuous and modular monoclonal antibody purification process with capture via precipitation Todd Przybycien, Rensselaer Polytechnic Institute, USA
09:45 – 10:10	Exploring different medium exchange regimes in ultra scale-down models Marie Dorn, University College London, United Kingdom
10:10 – 10:35	2-stage continuous growth-decoupled biomolecules production using Escherichia coli – Towards microbial small-footprint manufacturing Juergen Mairhofer, enGenes Biotech GmbH, Austria
10:35 – 11:15	Coffee / Networking Break (Sponsored by Sanofi)
	Poster Snapshot Session Chairs: Todd Przybycien, Rensselaer Polytechnic Institute, USA Mattia Sponchioni, Politecnico Di Milano, Italy Marcella Yu, Sutro Bio, USA
11:15 – 11:21	Overcoming key challenges during the upstream development of a continuus manufacturing process at 500L scale Leon Pybus, FUJIFILM Diosynth Biotechnologies, United Kingdom
11:21 – 11:27	Understanding factors that cause product retention and fouling of hollow fiber filters in intensified perfusion processes Sri Madabhushi, Merck Sharpe & Dohme, USA
11:27 – 11:33	Automated control of osmolality in a perfusion bioreactor system via in situ conductivity sensors Amanda Ramsdell, Sanofi, USA
11:33 – 11:39	Transcriptomics and modelling to understand the benefits of low perfusion rate Meeri Mäkinen, Cell Technology Group, Industrial Biotechnology KTH, Sweden
11:39 – 11:45	Dynamic process control of continuous twin-column chromatography Giulio Lievore, ChromaCon AG, Switzerland
11:45 – 11:51	Residence time distribution of continuous protein a chromatography Narges Lali, acib- Austrian Centre of Industrial Biotechnology, Austria

Monday, October 10, 2022 (continued)

11:51 – 11:57	Process and cost modeling approaches for manufacturing operations utilizing multi-column chromatography applications Mattia Sponchioni, Bristol Myers Squibb, USA
11:57 – 12:03	Process Analytical Technology (PAT) for automated, real-time control of continuous manufacturing of mAbs Shantanu Banerjee, Indian Institute of Technology, Delhi, India
12:03 – 12:09	Advanced control strategies for the continuous production of monoclonal antibodies Markus Kampmann, Sartorius, Corporate Research, Germany
12:09 – 12:15	Pilot scale technical establishment and commercial scale business case on integrated continuous biomanufacturing Takuo Kawase, Chugai Pharmaceutical Co., Ltd., Japan
12:15 – 12:21	Successful transition from fed-batch to continuous manufacturing within a mAb process development cycle Karthik P. Jayapal, Merck Sharpe & Dohme, USA
12:21 – 12:27	Establishing a highly automated and digitalized end-to-end bioprocess Martin Purtscher, Baxalta Innovations GmbH, Austria
12:27 – 12:33	Design & construction of a truly continuous and fully automated process skid for the production and purification of a monoclonal antibody Magdalena Pappenreiter, Bilfinger Life Science GmbH, Austria
12:33 – 12:39	Enhanced process control of an integrated and scalable bioprocess for production and isolation of MSC-derived extracellular vesicles for cardiac repair Marta Costa, iBET, Portugal
12:39 – 12:45	Plug-and-play software for mechanistic modelling of end-to-end continuous manufacturing of monoclonal antibodies Moo Sun Hong, Massachusetts Institute of Technology, USA
12:45 – 14:00	Lunch
	Session 2: Continuous manufacturing of emerging therapeutic modalities (Sponsored by Roche) Chairs: Joseph Shultz, Evelo Biosciences, USA Cristina Peixoto, iBET, Portugal
14:00 – 14:25	The multidimensional evolution of ICB: New concepts, technology, and therapeutic modalities Konstantin Konstantinov, Codiak BioSciences, USA
14:25 – 14:50	Mechanistic modeling to predict titers and infected cells in the two-stage continuous production of a viral vaccine Krystian Ganko, Massachusetts Institute of Technology, USA
14:50 – 15:15	Towards an integrated continuous manufacturing process of adeno- associated virus (AAVs) João Mendes, iBET, Portugal

Monday, October 10, 2022 (continued)

15:15 – 15:40	Continuous manufacturing of lentiviral vectors Dale Stibbs, University College London, United Kingdom
15:40 — 16:05	Progress towards making a global supply of microbial extracellular vesicles,100-times cheaper than a typical biologic Collin McKenna, Evelo Biosciences, Inc., USA
16:05 – 16:30	Looking beyond the horizon: Exosomes at the vanguard of integrated continuous processing of bionanoparticles Aaron Noyes, Codiak BioSciences, USA
16:30 – 17:15	Coffee / Networking Break (Sponsored by Regeneron)
17:15 – 18:00	Keynote 2 A race to contain a global pandemic: The development of the Pfizer/BioNTech mRNA vaccine Ranga Godavarti, Pfizer, USA
18:00 – 20:00	Poster Session 1 (Authors of odd-numbered posters are asked to stay with their presentations) Chairs: Todd Przybycien, Rensselaer Polytechnic Institute, USA Mattia Sponchioni, Politecnico Di Milano, Italy Marcella Yu, Sutro Bio, USA
20:00 – 21:30	Dinner
21:30 – 23:00	Social Hour

Tuesday, October 11, 2022

07:00 – 08:30	Breakfast
	Session 3: The case for ICB industrialization
	(Sponsored by Sanofi) Chairs: Jennifer Pollard, Merck Sharpe & Dohme, USA Andrea Rayat, University College London, United Kingdom
08:30 – 08:55	GMP implementation of continuous manufacturing: A case study Neil Soice, Amgen, Inc., USA
08:55 – 09:20	Business case for continuous mAb production with novel design strategies and enhanced control Catarina Neves, University College London, United Kingdom
09:20 – 09:45	Key enablers of continuous manufacturing success through a flexible J.POD® platform Eva Gefroh, Just Evotec Biologics, USA
09:45 – 10:10	Demonstration of a commercial scale end-to-end continuous purification process Chad Varner, Sanofi, USA
10:10 – 10:35	From lab coats to hard hats: Implementation of GMP continuous manufacturing on the road to commercial readiness Mark Brower, Merck Sharpe & Dohme, USA
10:35 – 11:15	Coffee / Networking Break (Biopharm Services Ltd)
11:15 – 12:45	Workshop 1: Standardization and modularization: A rising tide lifts all ICB processes (Sponsored by Pfizer) Chairs: Paul Randolph, Janssen, USA Michael Phillips, Merck Life Sciences, USA
	Workshop 2: Promoting academic, industrial, government, and non-profit collaborations for next-generation biomanufacturing Chairs: Kerry Love, Sunflower Therapeutics, USA John Erickson, NIIMBL, USA Veronique Chotteau, KTH, Sweden
	Workshop 3: Continuous biomanufacturing: Opportunities and challenges for a sustainable future Chairs: Sara Badr, The University of Tokyo, Japan Priyanka Gupta, Sartorius Stedim, USA
12:45 – 14:45	Poster Session 2 and Lunch (Authors of even-numbered posters are asked to stay with their presentations) Chairs: Todd Przybycien, Rensselaer Polytechnic Institute, USA Mattia Sponchioni, Politecnico Di Milano, Italy Marcella Yu, Sutro Bio, USA
14:45 – 15:30	Keynote 3 FDA's progress in advanced manufacturing Larry Lee, FDA, USA
15:30 –	Excursion (Winery tour and tasting) followed by dinner on your own in Sitges

Wednesday, October 12, 2022

07:00 - 08:30	Breakfast
	Session 4: ICB strategies to address industry challenges and opportunities (Sponsored by Cytiva) Chairs: Lisa Connell-Crowley, Just-Evotec Biologics, USA Anurag S. Rathore, Indian Institute of Technology Delhi, India
08:30 – 08:55	Process intensification: Modeling the impact of technology and process scenario selection on cost, throughput, facility volume, footprint and sustainability Priyanka Gupta, Sartorius Stedim Biotech, USA
08:55 – 09:20	Development of a flexible and modular approach for integrated continuous biomanufacturing Michael Coolbaugh, Sanofi, USA
09:20 – 09:45	Highly automated bioburden-free continuous manufacturing biologics GMP operations: How to get there? Lara Fernandez Cerezo, Merck Sharpe & Dohme, USA
09:45 – 10:10	Continuous downstream process of monoclonal antibody developed based on the process analysis/understanding and its validation Shuichi Yamamoto, Yamaguchi University, Japan
10:10 – 10:35	Intensified bioprocessing: Data, data, everywhere Marc Bisschops, Pall Biotech, Netherlands
10:35 – 11:15	Coffee / Networking Break
11:15 – 12:45	Workshop 4: GMP implications for fully E2E processes: Are we fulfilling our expectations? Chairs: Mark Brower, Merck Sharpe & Dohme, USA Neil Soice, Amgen, Inc., USA
	Workshop 5: Solving the problems of ICB process development to unlock the full potential of continuous manufacturing (Sponsored by Sartorius) Chairs: Steven Cramer, Rensselaer Polytechnic Institute, USA
	David Garcia, Novartis Pharma, Switzerland
	Workshop 6: Risk assessment for the adoption of ICB: What factors still stand in our way? Chairs: Chris Hwang, Transcenta Therapeutics, USA Julie Kozaili, Asahi Kasei Bioprocess, USA
12:45 – 14:00	Lunch
	Session 5: Integrated control strategies to advance ICB (Sponsored by Merck) Chairs: Bernt Nilsson, Lund University, Sweden Irina Ramos, AstraZeneca, USA
14:00 – 14:25	Pilot-scale integrated continuous biomanufacturing for monoclonal antibodies including mild pH Veronique Chotteau, KTH, Sweden

Wednesday, October 12, 2022 (continued)

14:25 – 14:50	Design considerations when scaling from 3-L to 3000-L or larger Kenneth Lee, AstraZeneca, USA
14:50 – 15:15	Real-time process analytical technology: Fluorescent dye-based miniaturized sensor for aggregate detection Mariana Neves Sao Pedro, Delft University of Technology, Netherlands
15:15 – 15:40	Enabling PAT in insect cell bioprocesses: A monitoring toolbox for rAAV production Inês A. Isidro, iBET, Portugal
15:40 – 16:20	Coffee / Networking Break
	Session 6: Application of smart manufacturing tools to ICB (Sponsored by Amgen) Chairs: Cenk Ündey, Amgen, USA Christoph Herwig, TU Wien, Austria
16:20 – 16:45	Development of the PAT toolkit for continuous bioprocessing Tiziano Brogna, Merck Healthcare, Switzerland
16:45 – 17:10	Advanced process control and process analytical technology for continuous bioprocessing Lukas Kuerten, Centre for Process Innovation Ltd., United Kingdom
17:10 – 17:35	Model based control of continuous bioprocesse Anurag Rathore, Indian Institute of Technology, Delhi, India
17:35 – 18:00	Advanced process control strategies for continuous influenza viral particle production Pavan Inguva, Massachusetts Institute of Technology, USA
18:00 – 18:45	Award Keynote Veena Warikoo, AstraZeneca, USA
18:45 – 19:30	Free Time
19:30 – 20:30	Reception
20:30 – 22:30	Banquet and Awards Ceremony
22:30 – 23:30	Social Hour

Thursday, October 13, 2022

07:00 – 09:00 Breakfast and Departure

Poster Presentations

1. Automated control of osmolality in a perfusion bioreactor system via in situ conductivity sensors

Amanda Ramsdell, Sanofi, USA

2. Dissolved oxygen control in intensified perfusion bioreactors at benchtop and pilot scale

Ethan Penner, Sanofi, USA

- 3. Fully automated on demand cell culture media preparation for perfusion bioreactors Lisa Wolowczyk, Merck KGaA, Germany
- 4. Automated sampling in upstream process development for accelerated access to Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs)
 Srijana Chapagain, MilliporeSigma, USA
- 5. **Transcriptomics and modelling to understand the benefits of low perfusion rate**Meeri Mäkinen, Cell Technology group, Industrial Biotechnology KTH; AdBIOPRO, Centre for Advanced BioProduction by Continuous Processing. Sweden
- 6. Amino acids and antibody N-glycosylation based on Raman spectroscopy in high cell density perfusion culture

Veronique Chotteau, KTH; AdBIOPRO, Competence Centre for Advanced BioProduction by Continuous Processing, Sweden

- 7. **Preliminary metabolic screening method for clone selection in the ambr15** Christine Ferng, AstraZeneca, USA
- 8. Understanding factors that cause product retention and fouling of hollow fiber filters in intensified perfusion processes

Sri Madabhushi, Merck & Co., Inc., USA

9. Challenges of mass transfer for perfusion cultures in single use bioreactors part 1:Oxygen

Anthony Beaney, Lonza Biologics, United Kingdom

10. Biomanufacturing and testbed development for the continuous production of monoclonal antibodies

Dragana Bozinovski, Massachusetts Institute of Technology, Center for Biomedical Innovation, USA

11. Process Analytical Technology (PAT) for automated, real-time control of continuous manufacturing of mAbs

Shantanu Banerjee, Indian Institute of Technology Delhi, India

- 12. Advanced control strategies for the continuous production of monoclonal antibodies Markus Kampmann, Sartorius, Corporate Research, Germany
- 13. **N-mAb: A case study supporting adoption of integrated continuous bioprocesses** Kevin Brower, Sanofi, USA
- 14. **Accelerating adenovirus manufacturing by perfusion-based process optimization** Piergiuseppe Nestola, Sartorius Stedim Biotech, Switzerland

15. Enabling AAV production by transient transfection with high cell density perfusion process

Ye Zhang, KTH, AdBIOPRO, Sweden

16. Process intensification combined with Adaptive Laboratory Evolution enhance VLP-based vaccine candidates production in insect cells

Ricardo Correia, iBET, ITQB-NOVA, Portugal

17. Enhanced process control of an integrated and scalable bioprocess for production and isolation of MSC-derived extracellular vesicles for cardiac repair

Marta Costa, iBET, Portugal

18. Integrated & continuous processing: A proven solution to tackle gene therapy manufacturing challenges

Rimenys Carvalho, Univercells Technologies S.A., Belgium

- 19. **Pichia pastoris, a promising microbial cell factory for continuous manufacturing** Xavier Garcia-Ortega, Universitat Autònoma de Barcelona, Spain
- 20. Do more with less: Fit-for-purpose tools to speed up upstream process development for continuous biomanufacturing

Channing McLaurin, MilliporeSigma, USA

- 21. **Next generation perfusion process development for production of biologics**Jianlin Xu, Bristol Myers Squibb, USA
- 22. Optimization of a dynamic perfusion process using a combination of high throughput experimentation and hybrid modeling approaches

Maarten Pennings, BiosanaPharma, Netherlands

23. Two small-scale perfusion models for the ambr250 to enable the study of production stability

Sarah Harcum, Clemson University, USA

24. Process and cost modeling approaches for manufacturing operations utilizing multicolumn chromatography applications

Mattia Sponchioni, Bristol Myers Squibb, USA

25. A scale-down model to investigate cell retention for continuous monoclonal antibody manufacture

Delphine Tavernier, University College London, United Kingdom

26. Implementation of intensified and continuous processing to increase yield of lentivirus manufacturing

Keen Chung, Repligen Corporation, USA

27. Real-time model-based control of single pass tangential flow filtration for production of monoclonal antibodies

Venkataramana Runkana, Tata Consultancy Services, India

28. **Dynamic process control of continuous twin-column chromatography** Giulio Lievore, ChromaCon AG, Switzerland

29. Miniaturization of chromatographic process development: Achieving fast results with minimal costs

Tiago Castanheira Silva, Technische Universiteit Delft, Netherlands

30. Residence time distribution of continuous protein a chromatography

Narges Lali, acib- Austrian Centre of Industrial Biotechnology; University of Natural Resources and Life Sciences, Vienna, Austria, Austria

31. Continuous purification of antifungal peptide with a continuous chromatographic system based on fluidized bed technology

Lisa-Marie Herlevi, Jacobs University Bremen, Germany

32. Design and optimization of membrane chromatography process for monoclonal antibody charge variant separation

Sathish Nadar, The University of Queensland, The Australian Institute of Bioengineering and Nanotechnology, Australia

33. Continuous counter-current affinity colloidal purification

Jon Coffman, AstraZeneca, USA

34. Towards implementation of novel single-use devices in integrated processes for biopharmaceuticals

Marina Y. Linova, Technical University of Denmark, Denmark

35. Monoclonal antibody purification from gram to kilogram scale utilizing multi-column continuous rProtein A capture

J. Kevin O'Donnell, Tosoh Bioscience LLC, USA

36. Design of a twin-column countercurrent purification (MCSGP) unit for the polishing of an oligonucleotide sequence

Ismaele Fioretti, Politecnico di Milano, Italy

37. Moving adsorption belt system for continuous bioproduct recovery

Yijia Guo, Jacobs University Bremen, Germany

38. **Continuous vaccine purification utilizing multi-stage aqueous two-phase extraction**Caryn Heldt, Michigan Technological University, USA

39. Feedback control of particle morphology enables continuous monoclonal antibody capture via precipitation

Matthew Mergy, Rensselaer Polytechnic Institute, USA

40. Oscillatory flow reactor: A solution for continuous bioprocessing

Diogo Ferreira-Faria, IBB – Institute for Bioengineering and Biosciences, Instituto Superior Técnico, University of Lisbon, Portugal

41. Solid polyethylene glycol precipitation: Potential cost reduction in antibody downstream processing

Maria del Carme Pons Royo, Acib, BOKU, Austria

42. **Truly continuous downstream processing of antibodies, overcoming bottlenecks**Gabriele Recanati, University of Natural Resources and Life Sciences, Vienna, Austria

43. Continuous Counter-current Dialysis (C3D) - the Future of Diafiltration Irina Ramos, AstraZeneca, USA

44. A perspective on polishing operations for the continuous removal of process and product related impurities

Steven Cramer, Rensselaer Polytechnic Institute, USA

45. Constant flow rate viral clearance study of Planova™ BioEX virus removal filter and implementation into an integrated process for mAb purification

Hironobu Shirataki, Asahi Kasei Medical, Japan

46. Integration of low-pH viral inactivation and primary clarification processes in a single use disposable biosettler

Dhinakar Kompala, Sudhin Biopharma Co, USA

- 47. Continuous virus filtration: An existing technology with a promising future Julie Kozaili, Asahi Kasei Bioprocess, USA
- 48. **Implementation of PAT-based control strategy for continuous formulation** Sushmitha Krishnan, Sanofi, USA
- 49. Plug-and-play software for mechanistic modelling of end-to-end continuous manufacturing of monoclonal antibodies

Moo Sun Hong, Massachusetts Institute of Technology, USA

50. Model assisted design of an intensified bioprocess

Ruth de la Fuente, Pall Corporation, Germany

51. **Establishing a highly automated and digitalized end-to-end bioprocess**Martin Purtscher, Baxalta Innovations GmbH, Austria

52. Development and industrialization of advanced biomanufacturing platform to address business needs and affordability of biologics

Christopher Hwang, Transcenta Therapeutics Inc., China

53. Successful transition from fed-batch to continuous manufacturing within a mAb process development cycle

Karthik P. Jayapal, Merck & Co, USA

- 54. Conversion of an intensified fed-batch to an integrated continuous bioprocess
 Brian Follstad, Just Evotec Biologics, Inc., USA
- 55. A case study: Scale up from bench to 500L of a biologics continuous manufacturing process

Sarwat Khattak, Biogen, USA

56. Overcoming key challenges during the upstream development of a continous manufacturing process at 500L scale

Leon Pybus, FUJIFILM Diosynth Biotechnologies, United Kingdom

57. Design of an integrated continuous downstream process for emerging acid-sensitive antibodies based on a calcium-dependent protein A ligand

Joaquin Gomis Fons, Lund University, Lund, Sweden, Sweden

58. Design & Construction of a truly continuous and fully automated process skid for the production and purification of a monoclonal antibody

Magdalena Pappenreiter, Bilfinger Life Science GmbH, University of Natural Resources and Life Sciences Vienna, Austria

59. Accelerate process development and transfer for the implementation of integrated continuous biomanufacturing

David Garcia, Novartis Pharma, Switzerland

60. Simulated control strategy for product diversion management during continuous processing

Thomas Ransohoff, National Resilience, Inc, USA

61. **Bringing flexibility to integrated continuous biomanufacturing**Paul Randolph, Janssen R&D LLC, USA

62. Pilot scale technical establishment and commercial scale business case on integrated continuous biomanufacturing

Takuo Kawase, Chugai Pharmaceutical Co., Ltd., Japan

63. Intensified & connected processing for fast, cost effective, and robust monoclonal antibody manufacturing

Sanket Jadhav, Sartorius Stedim Biotech, Netherlands

- 64. **Cost and life cycle assessment of upstream monoclonal antibody production** Sara Badr, The University of Tokyo, Japan
- 65. **Process intensification So much more than continuous bioprocessing** Niklas Jungnelius, Cytiva, Sweden
- 66. Assessing the sustainability of fed batch and continuous process formats for mAb manufacturing via bioprocess modeling

Caroline Mueller, Just-Evotec Biologics, Inc., USA



Engineering Conferences International

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Calendar of ECI Conferences

Celebrating 60 years of international, interdisciplinary engineering conferences

<u>2022</u>		
Oct 2-7	21AN	NANOMECHANICAL TESTING IN MATERIALS RESEARCH AND DEVELOPMENT VIII (Split, Croatia) S. Korte-Kerzel, RWTH Aachen University
Oct 9-13	22AA	INTEGRATED CONTINUOUS BIOMANUFACTURING V (Sitges, Spain) J. Walther, Sanofi; A. Azevedo, Instituto Superior Técnico; R. Deshpande, Amgen
Oct 30-Nov 3	20AE	ELECTROPHORETIC DEPOSITION VII: FUNDAMENTALS AND APPLICATIONS (Santa Fe, New Mexico) A.R. Boccaccini, Univ. of Erlangen-Nuremberg; B. Ferrari, Spanish Research Council; A.J. Pascall, Brookhaven National Laboratory; T. Uchikoshi, National Institute for Materials Science
Nov 13-18	21AS	CERAMIC MATRIX COMPOSITES II (Santa Fe, New Mexico) Y. Kagawa, Tokyo University of Technology; R. Darolia, GE Aviation (retired); R. Raj, University of Colorado; G. Singh, Kansas State University; D. Koch, University of Augsburg; G. Vignoles, University of Bordeaux; J. Binner, University of Birmingham
Dec 10-14	21AB	POLYMER REACTION ENGINEERING XI (Scottsdale, AZ) T. Mckenna, Universite Claude Bernard, France; C. Sayer, Federal University of Santa Catania, Brazil; J. Reimers, ExxonMobil, USA
Dec 18-21	20AY	ADVANCES IN COSMETIC FORMULATION DESIGN II (Durham, NC) S. Amin, Manhattan College; P. Somasundaran, Columbia University
2023 March 19-24	22AD	ELECTRIC FIELD ENHANCED PROCESSING OF ADVANCED MATERIALS III: COMPLEXITIES AND OPPORTUNITIES (Tomar, Portugal) R. Raj, University of Colorado at Boulder; Luis Perez-Maqueda, CICA, Spain
April 23-29	23AC	CELL CULTURE ENGINEERING XVIII (Cancun, Mexico) L. Palomares, IBT-UNAM; C. Goudar, Amgen; T. Wang, Roche
May 7-12	23AP	PYROLIQ II – 2023: Pyrolysis and Liquefaction of Biomass and Wastes (Hernstein, Austria) F. Berruti, ICFAR & Western University; A. Dufour, CNRS, ENSIC; M. Garcia-Perez, Washington State University; W. Prins, University of Ghent
May 28-June 2	21AG	ALKALI ACTIVATED MATERIALS AND GEOPOLYMERS: SUSTAINABLE CONSTRUCTION MATERIALS AND CERAMICS MADE UNDER AMBIENT CONDITIONS (Cetraro (Calabria), Italy) W.M. Kriven, University of Illinois at Urbana-Champaign; C. Leonelli, Universita' degli Studi di Modena e Reggio Emilia; J.L. Provis, University of Sheffield; A.R. Boccaccini, University of Erlangen-Nuremberg
June 11-15	21AO	ADVANCES IN OPTICS FOR BIOTECHNOLOGY, MEDICINE AND SURGERY (Tomar, Portugal) M. Niedre, Northeastern University; F. Leblond, Polytecnique Montreal

July 16-21	21AV	SIXTH INTERNATIONAL WORKSHOP ON STRESS-ASSISTED CORROSION DAMAGE (Washington, DC area) A.K. Vasudevan, Office of Naval Research (retired); R. Latanision, Exponent, Inc.; H. Holroyd, Luxfer (retired); F. Friedersdorf, Luna Innovations Inc.
July 24-28	21AH	ASSOCIATION IN SOLUTION V (Azores, Portugal) I. Voets, Eindhoven University of Technology; J. Strakel, Wageningen University; J. Conrad, University of Houston
Summer	20AF	SYNTACTIC AND COMPOSITE FOAMS VI (TBA-Europe) G.M. Gladysz and K.K. Chawla, University of Alabama at Birmingham; A. R. Boccaccini, University of Erlangen-Nuremberg; M. Fukushima, National Institute of Advanced Industrial Science and Technology
September 10-13	23AT	SINGLE USE TECHNOLOGIES VI (Boston, USA) M. Barbaroux, Sartorius; S. Kane, Takeda; S. Yoon, University of Massachusetts, Lowell
September 17-21	23-AH	INTERNATIONAL HYDROGEN CONFERENCE: UNDERSTANDING HYDROGEN-MATRIALS INTERACTIONS (Park City, Utah) M. Martin, NIST; J. Burns, University of Virginia
September 17-21	23AB	BIO-CHAR III (Tomar, Portugal) F. Berruti, Western University, Canada; D. Chiaramonti, Politecnico di Torino and RE-CORD, Italy; S. Fiore, Politecnico di Torino, Italy; M. Garcia-Perez, Washington State University, USA; O. Masek, University of Edinburgh, UK
October TBA	23AE	ENZYME ENGINEERING XXVII (Singapore) Ang Ee Lui, A*Research, Singapore; Li Zhi, National University of Singapore; Yan Feng, Shanghai Jiao Tong University
Nov TBA	20AO	NONSTOICHIOMETRIC COMPOUNDS VIII (Tainan, Taiwan) W. Chueh, Stanford University; F-Z Fung, National Cheng Kung University; R. Waser, RWTH Aachen; H. Takamura, Tohoku University
2024 January 7-12	20AT	TRANSITION OF ENERGY SYSTEMS TOWARDS SUSTAINABILITY (India TBA) S. De, S. Bandyopadhyay, IIT, Bombay
February 4-8	24AT	ADVANCING MANUFACTURE OF CELL AND GENE THERAPIES VIII (Coronado, CA) F. Masri, Cell & Gene Catapult; C. Yeager, Georgia Institute of Technology; G. Maheshwari, BMS; J. Moscariello, BMS
February TBA	21AD	ADVANCED MEMBRANE TECHNOLOGY VIII: ENVIRONMENT, FOOD, HEALTH AND NEW FRONTIERS (Casablanca, Morocco) J. Hestekin, University of Arkansas; U. Beusche, W.L. Gore, Inc.; D. Bhattacharyya, University of Kentucky
April 4-7	20AP	DELIVERY OF NUCLEIC ACID THERAPEUTICS II: BIOLOGY, ENGINEERING AND DEVELOPMENT (Siracusa, Sicily) L. Sepp-Lorenzino, Intellia Therapeutics; S. F. Dowdy, University of California San Diego School of Medicine; M. Stanton, Generational Bio
Spring	24AI	ULTRA-HIGH TEMPERATURE CERAMICS: MATERIALS FOR EXTREME ENVIRONMENT APPLICATIONS V (Italy) D. Sciti, Institute for Science and Technology of Ceramics, CNR;
April TBA	24AK	MICROBIAL ENGINEERING III (TBA) E. Keshavarz-Moore, University College London; T. Sauer, Sanofi
May 19-24	24AA	VACCINE TECHNOLOGY IX (Los Cabos, Mexico) C. Lutsch, Sanofi Pasteur; L. Lua, University of Queensland; F. Godia, Universitat Autònoma de Barcelona; T. Tagmyer, Merck

Engineering Conferences International

Engineering Conferences International (ECI) is a not-for-profit global engineering conferences program that has served the engineering/scientific community since 1962 as successor program to Engineering Foundation Conferences. ECI has received recognition as a 501(c)3 organization by the U.S. Internal Revenue Service and is incorporated in the State of New York as a not-for-profit corporation.

The program has been developed and is overseen by volunteers both on the international Board of Directors and international Conferences Committee. More than 1,900 conferences have taken place to date. The conferences program is administered by a professional staff and the conferences are designed to be self-supporting.

ECI Mission

To serve the engineering/scientific community with international, interdisciplinary, leading edge engineering research conferences

ECI Purposes

The advancement of engineering arts and sciences by providing a forum for the discussion of advances in the field of science and engineering for the good of mankind by identification and administration of international interdisciplinary conferences

To work with engineering, scientific and social science societies and the interested general public to jointly sponsor conferences and to take other actions that will foster complementary programming.

To initiate conferences that will have a significant impact on engineering education, research practice and/or development.

ECI Encouragement of New Conference Topics

The ECI Conferences Committee invites you to suggest topics and leaders for additional conferences and encourages you to submit a proposal for an ECI conference.

Ideally, proposals should be submitted from 18 to 24 months in advance of the conference although the staff can work on a shorter timeline.

The traditional format for an ECI conference is registration Sunday afternoon with technical sessions held each morning and evening through Thursday or Friday noon. Afternoons are used for informal gatherings, poster sessions, field trips, subgroup meetings and relaxation. This format has served well to build important professional networks in many areas.

ECI welcomes proposals for shorter conferences and for conferences which span weekends in order to reduce the number of working days participants are away from their offices.

ECI Works With You

ECI works with conference chairs in two complementary ways. First, an experienced member of the Conferences Committee acts as your technical liaison from the proposal stage through the conference itself. He or she is always available to consult with you on any conference issue.

Second, after your proposal has been approved by the Conferences Committee, the ECI staff will assume responsibility for the administration of the conference.

Your primary responsibilities will be recruiting the organizing committee, developing the technical program and securing third-party funding necessary to support the travel of key speakers.

The responsibilities of ECI's "full service" staff include -- but are not limited to -- the following:

- Recommend, negotiate, contract and make substantial deposits for housing, meals, meeting space, A/V equipment and tours.
- Maintain web sites for the conference and for submission of abstracts.
- Publicize via electronic and print media.
- Administer all finances including grants, contributions and purchase orders. (ECI makes
 grant funds available as soon as a grant is approved.) There is no need for chairs to set up a
 conference bank account or file tax returns for their conference.
- Process all applications and registrations.
- Produce bound program/abstracts book.
- Contract for the publication of print or electronic proceedings, if any.
- Provide on-site staff during the conference.

For more information, please contact the ECI Director at Barbara@engconfintl.org