

Regulatory Sciences for Biologics and Vaccines: Accelerating Development and Enabling Manufacturing Innovation

An ECI Conference Series Volume 17AR

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Sunday, April 23, 2017

16:00 – 17:15	Conference Check-in
17:30 – 18:30	Dinner
18:30 – 19:00	Opening comments
19:00 – 20:00	Keynote Speaker 1 – Harnessing Science and Technology to Accelerate High Impact Drug Discovery Dr. Ron dePinho, CEO, MD Anderson Cancer Center
20:00 – 21:00	Keynote Speaker 2 – Opportunities to Improve Global Human Health Katey Owen, Director, The Bill & Melinda Gates Foundation
21:00 – 22:00	Social hour

NOTES

- Locations for the technical and poster sessions will be announced on site.
- All meals will be in the Riverside Hearth Restaurant.
- Audiotaping, videotaping and photography of presentations are prohibited.
- Speakers – Please leave at least 5 minutes for questions and discussion.
- Speakers – Please ensure your talk adheres to your given time allotment. Talks that go over their allotment reduce time for valuable discussion and can disrupt the conference program.
- Turn your cellular telephones to vibrate or off during technical sessions.
- After the conference, ECI will send an updated participant list to all participants. Please check your listing now and if it needs updating, you may correct it at any time by logging into your ECI account.
- Please do not smoke at any conference functions.
- Please write your name in the front of this program booklet so it can be returned if misplaced.

Monday, April 24, 2017

- 07:30 – 08:30 Breakfast
- 08:30 – 12:00 **Oral Session 1 – Vaccines – Rapid Responses to Global Health Challenges**
Chair: Vijay Yabannavar, Vice President, Technical Operations Merck & Co Inc/MSD
- 08:40 – 09:30 Plenary Lecture – Rapid response to the Ebola crisisN/A
Jayanthi Wolf, Director Global Regulatory Affairs, Merck & Co Inc/MSD
- 09:30 – 10:00 Facilitation of a rapid response by self-amplifying mRNA vaccines1
Jeffrey B. Ulmer, GSK Vaccines
- 10:00 – 10:30 Coffee break (*Sponsored by Pfizer*)
- 10:30 – 11:00 Platforms prepare manufacturing for rapid responses,2
Jeffrey Welch, Emergent Biosolutions
- 11:00 – 11:30 Rapid vaccine responses to emerging pathogens using a platform technology3
Tim Hahn, Novavax
- 11:30 – 12:00 Rapid response to pandemic influenza using a licensed recombinant seasonal influenza vaccine platform4
Penny Post, Protein Sciences
- 12:00 – 13:00 Lunch
- 13:00 – 15:20 **Oral Session 2 – Managing Products in a Complex Environment5**
Chair: Stefanie Pluschkell, Executive Director, Pfizer
- 13:00 – 13:50 Plenary Lecture: Title TBA
Jeff Baker, FDA
- 13:50 – 14:20 Innovation and continuous improvement in a seemingly accelerated regulatory environmentN/A
Roger Nosal, Pfizer Inc
- 14:20 – 14:50 Managing CMC for global accelerated marketing approvals6
Pradip Ghosh-Dastidar, BMS, presenting on behalf of IFPMA
- 14:50 – 15:20 PATH - A global health nonprofit organization in support of international vaccine manufacturing7
George Robertson, PATH
- 15:20 – 16:00 Coffee break
- 16:00 – 18:00 **Workshops**
Workshop 1 – National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)
(Chairs: Barry Buckland, Stacy Springs and Louise Johnson, NIIMBL)
Workshop 2 – Managing Complexity
(Chairs: Steffi Pluschkell, Pfizer, and Kumar Namdev, Sanofi)
- 18:00 – 19:00 Dinner

Monday, April 24, 2017 (continued)

- 19:00 – 21:00 **Oral Session 3 – Accelerating Development**
Chair: Tony Mire-Sluis, Head of Global Quality, AstraZeneca
- 19:10 – 20:00 Plenary Lecture – Leveraging knowledge to accelerate the development of biological productsN/A
Tony Mire Sluis, Head of Global Quality, Astra Zeneca
- 20:00 – 20:30 Accelerating strategies for FIH process development8
Margaret Ricci, Amgen
- 20:30 – 21:00 Systems analysis and design for accelerating process and cell line development9
Wei-Shou Hu, University of Minnesota
- 21:00 – 21:15 **Rapid Fire Oral Presentations/Poster Session Preview**
Chair: Sevda Deldari, UMBC
- 21:15 – 22:15 **Poster Session 1 / Social Hour**

Tuesday, April 25, 2017

- 07:30 – 08:30 Breakfast
- 08:30 – 12:00 **Oral Session 4 – Approaches to innovative and streamlined manufacturing,**
Chair: Aine Hanly, VP Drug Substance Technologies & Site Head Amgen Cambridge
- 08:40 – 09:30 Plenary Lecture – Accelerating development and managing risk10
Tony Lubiniecki, Senior Fellow, Janssen Pharmaceuticals R&D
- 09:30 – 10:00 Managing and Mitigating Risk in Biologics Process Transfer11
Charles Goochee, Janssen Pharmaceuticals
- 10:00 – 10:30 Coffee break (*Sponsored by Amgen*)
- 10:30 – 11:00 Transforming operations with next generation BiomanufacturingN/A
Arleen Paulino, Amgen Singapore
- 11:00 – 11:30 Lifecycle approach to validation supports accelerated approvals12
Julia O'Neill, Tunnell Consulting
- 11:30 – 12:00 Continuous bioprocessing: Technology and regulatory challenges and mitigation strategiesN/A
Mani Krishnan, Pall Lifesciences
- 12:00 – 13:00 Lunch
- 13:00 – 15:00 **Oral Session 5 – It's All About the Analytics**
Chair: Mark Schenerman, Vice President, MedImmune
- 13:00 – 13:30 An FDA perspective on the implementation of state-of-the-art analytical methods for
therapeutic proteins13
Marjorie Shapiro, FDA
- 13:30 – 14:00 Modernizing analytics for improved manufacturing efficiency – regulatory considerations28
Steven Rubin, FDA
- 14:00 – 14:30 Advanced Analytics to Enable Development of Biologic-Biologic Combination Therapy29
Yang Wang, MedImmune
- 14:30 – 15:00 Bioassays and Effector Function30
Raju Shantha, MedImmune
- 15:00 – 15:30 Coffee break
- 15:30 – 17:30 **Workshops**
Workshop 3 – It's all about the analytics
(Chair: Mark Schenerman, MedImmune)
Workshop 4 – Hot topics
(Chair: Beth Junker, Bioprocess Advantage)
- 17:30 – 18:00 Coffee break

Tuesday, April 25, 2017 (continued)

- 18:00 – 19:00 **Keynote Lecture 3, Regulatory Sciences from a Regulator's, an Industrialist's and an Academic's Perspective**
Robert Meyer, Virginia Center for Translational and Regulatory Sciences, University of Virginia
- 19:00 – 19:15 **Rapid Fire Oral Presentations/Poster Session Preview**
Chair: Sevda Deldari, UMBC
- 19:15 – 20:30 Dinner
- 20:30 – 21:30 **Poster Session 2 / Social Hour**

Wednesday, April 26, 2017

- 07:30 – 08:30 Breakfast
- 08:30 – 09:30 **Keynote 4, Steven Kozlowski, FDA**
- 09:30 – 10:00 Coffee break
- 10:00 – 12:30 **Oral Session 6 – Risk-based characterization**
Chairs: Thomas Ryll, Vice President, Immunogen and Jose Menezes, Professor, Instituto Superior Técnico, Portugal
- 10:00 – 10:30 Leveraging Mab cell culture platform to predict product quality31
Chris Kwiatkowski, Biogen
- 10:30 – 11:00 Comparability and similarity protocols for biotechnology products32
Francisca F. Gouveia, Pedro M. Felizardo, and José C. Menezes, 4Tune Engineering Ltd.
- 11:00 – 11:30 Pre-clinical to Phase III upstream process changes to support next generation manufacturing33
Sarwat Khattak, Biogen
- 11:30 – 12:00 Comparability assessment of an antibody-drug conjugate (ADC)34
Alex Lazar, ImmunoGen
- 12:00 – 12:30 Global implementation of a cell culture change: Strategies, lessons learned and challenges35
Marie-Pierre Gentile, Genentech
- 12:30 – 12:45 Closing Comments: Tony Moreira and David Robinson
- 12:45 – 1:45 Lunch and departures

Poster Presentations - N/A

1. **Influenza hemagglutinin glycoproteins with different N-glycan patterns activate dendritic cells in vitro**
Suh-Chin Wu, Institute of Biotechnology, National Tsing Hua University, Taiwan
2. **Rapid transient and stable protein production with consistent quality to accelerate biotherapeutic development**
Weili Wang, MaxCyte, Inc., USA
3. **Streamlining viral clearance strategy with generic claims and worst case studies**
Brad Stanley, Biogen, USA
4. **Utility of GMP Next Generation Sequencing (NGS) for biosafety assesment of biological products**
Audrey Chang, BioReliance/MilliporeSigma, USA
5. **Defining established conditions under ICH Q12 for Pre-QbD commercial products**
Jose Menezes, 4Tune Engineering Ltd, Portugal
6. **Critical considerations in bioreactor design to optimize cell-free protein expression in CHO**
Chariz Johnstone, University of Maryland Baltimore County, USA
7. **Reactivity and specificity of mice antisera generated from Coxsackievirus A6 and A10 vaccinations**
Chia-Chyi Liu, National Health Research Institutes, Taiwan
8. **Platform analytical methods approach “compendial-like” status**
Carrie R. Lewis, MedImmune, USA
9. **Development and validation of an IMAC purification platform for His-tagged proteins expressed in a CHO cell-free system**
Sevda Deldari, University of Maryland Baltimore County, USA
10. **Transferring methods for vaccine release between the industry, academy and a regulatory agency: Lessons learned**
Elizabeth Carrasco, LAMMB, Instituto de Biotecnología, Mexico
11. **Impact of a mutation in the podB gene on protein productivity in filamentous fungi**
Karthik R. Boppidi, University of Maryland Baltimore County, USA
12. **Fundamental studies of the mechanism of Ion exchange chromatography**
Payam Rezaei, University of Maryland Baltimore County, USA
13. **NIIMBL: The National Institute for Innovation in Manufacturing Biopharmaceuticals**
Barry Buckland, BiologicB, USA
14. **Expression and purification of highly complex therapeutics, tPA in a mammalian cell-free expression system**
David Burgenson, University of Maryland Baltimore County, USA
15. **Process development tools and initial results for the purification of therapeutic antibody products with neutral to acidic pI values using a non-affinity capture method**
Yang Liu, University of Maryland Baltimore County, USA