Program

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

April 23-26, 2017

Lansdowne Resort
Leesburg, VA, USA

Conference Co-Chairs

Prof. Antonio Moreira
University of Maryland, Baltimore County, USA

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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 allotted time 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 crisis
Jayanthi Wolf, Director Global Regulatory Affairs, Merck & Co Inc/MSD

09:30 – 10:00 Facilitation of a rapid response by self-amplifying mRNA vaccines
Jeffrey B. Ulmer, GSK Vaccines

10:00 – 10:30 Coffee break (Sponsored by Pfizer)

10:30 – 11:00 Platforms prepare manufacturing for rapid responses,
Jeffrey Welch, Emergent Biosolutions

11:00 – 11:30 Rapid vaccine responses to emerging pathogens using a platform technology
Tim Hahn, Novavax

11:30 – 12:00 Rapid response to pandemic influenza using a licensed recombinant seasonal influenza vaccine platform
Penny Post, Protein Sciences

12:00 – 13:00 Lunch

13:00 – 15:20 Oral Session 2 – Managing Products in a Complex Environment
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 environment
Roger Nosal, Pfizer Inc

14:20 – 14:50 Managing CMC for global accelerated marketing approvals
Pradip Ghosh-Dastidar, BMS, presenting on behalf of IFPMA

14:50 – 15:20 PATH - A global health nonprofit organization in support of international vaccine manufacturing
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)**

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<td>19:00 – 21:00</td>
<td><strong>Oral Session 3 – Accelerating Development</strong>&lt;br&gt;Chair: Tony Mire-Sluis, Head of Global Quality, AstraZeneca</td>
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<td>19:10 – 20:00</td>
<td>Plenary Lecture – Leveraging knowledge to accelerate the development of biological products&lt;br&gt;Tony Mire Sluis, Head of Global Quality, Astra Zeneca</td>
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<td>20:00 – 20:30</td>
<td>Accelerating strategies for FIH process development&lt;br&gt;Margaret Ricci, Amgen</td>
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<td>20:30 – 21:00</td>
<td>Systems analysis and design for accelerating process and cell line development&lt;br&gt;Wei-Shou Hu, University of Minnesota</td>
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<td>21:00 – 21:15</td>
<td><strong>Rapid Fire Oral Presentations/Poster Session Preview</strong>&lt;br&gt;Chair: Sevda Deldari, UMBC</td>
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<td>21:15 – 22:15</td>
<td><strong>Poster Session 1 / Social Hour</strong></td>
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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 risk  
Tony Lubiniecki, Senior Fellow, Janssen Pharmaceuticals R&D

09:30 – 10:00  Managing and Mitigating Risk in Biologics Process Transfer  
Charles Goochee, Janssen Pharmaceuticals

10:00 – 10:30  Coffee break *(Sponsored by Amgen)*

10:30 – 11:00  Transforming operations with next generation Biomanufacturing  
Arleen Paulino, Amgen Singapore

11:00 – 11:30  Lifecycle approach to validation supports accelerated approvals  
Julia O’Neill, Tunnell Consulting

11:30 – 12:00  Continuous bioprocessing: Technology and regulatory challenges and mitigation strategies  
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 proteins  
Marjorie Shapiro, FDA

13:30 – 14:00  Modernizing analytics for improved manufacturing efficiency – regulatory considerations  
Steven Rubin, FDA

14:00 – 14:30  Physicochemical assays and characterization  
Yang Wang, MedImmune

14:30 – 15:00  Bioassays and Effector Function  
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
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 quality

Chris Kwiatkowski, Biogen

10:30 – 11:00  Comparability and similarity protocols for biotechnology products

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 manufacturing

Sarwat Khattak, Biogen

11:30 – 12:00  Comparability assessment of an antibody-drug conjugate (ADC)

Alex Lazar, ImmunoGen

12:00 – 12:30  Global implementation of a cell culture change: Strategies, lessons learned and challenges

Marie-Pierre Gentile, Genentech

12:30 – 12:45  Closing Comments: Tony Moreira and David Robinson

12:45 – 1:45  Lunch and departures
Poster Presentations

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 assessment 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