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Conference Program

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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

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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.
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- 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)

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 products  
Tony Mire Sluis, Head of Global Quality, AstraZeneca

20:00 – 20:30  Accelerating strategies for FIH process development  
Margaret Ricci, Amgen

20:30 – 21:00  Systems analysis and design for accelerating process and cell line development  
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 risk
Tony Lubieniecki, 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
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 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