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

Proceedings

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Conference Program

Antonio Moreira
University of Maryland,USA

David Robinson
Robinson Vaccines and Biologics LLC, USA

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

Dr. David Robinson
Robinson Vaccines and Biologics LLC, USA

Engineering Conferences International
32 Broadway, Suite 314
New York, NY 10004, USA
Phone: 1-212-514-6760
www.engconfintl.org – info@engconfintl.org

Lansdowne Resort
44050 Woodridge Parkway
Leesburg, Virginia 20176
Tel: 1-703-729-8400

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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.
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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, Astra Zeneca
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 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

<u>Tuesday, April 25, 2017</u> (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 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