USP Workshop on Raw Materials for Manufacturing of Biologics: Best Practices and Quality Standards
April 12-16, 2021 Virtual Workshop

DRAFT AGENDA~ January 5, 2021

Session One, Monday, April 12, 2021: Regulatory Considerations and Control Strategies

10:00 a.m. EDT — **USP Welcome**
Fouad Atouf
Vice President, Global Biologics, USP

10:10 a.m. — **Workshop Overview and Introduction to Session 1**
Christopher Bravery
USP Raw Materials for Manufacturing of Biologics Workshop Steering Committee and USP Bio5 Advanced Therapies Expert Committee member

10:20 a.m. — **Title to be confirmed**
Ashutosh Rao
Chief, Laboratory of Applied Biochemistry, CDER, US FDA

10:45 a.m. — **Title to be confirmed**
TBD
US FDA

11:10 a.m. — **Key Quality Considerations for Sourcing Viral, Microbial or Plasmid DNA Vector Procurement Services for Delivery of Gene Therapies**
Gary du Moulin
Consultant

11:35 a.m. — **BioPhorum Cell and Gene Therapy Raw Materials Risk Assessments and Plasmid Specifications**
Lili Belcastro
Janssen; speaking on behalf of BioPhorum workstream

12:00 p.m. — **Break (10 min)**

12:10 p.m. — **New Understanding Relating to Existing Excipients and Formulation Approaches: How Current Work to Update Compendial Specifications for Polysorbates can Impact Formulation Approaches and Delivery Systems**
TBD
USP Excipients Expert Committee and Polysorbate Expert Panel

12:35 p.m. — **Panel Discussion and Q&A Moderated by Christopher Bravery and Mehrshid Alai**
USP Raw Materials for Manufacturing of Biologics Workshop Steering Committee and Bio5 Advanced Therapies Expert Committee members

1:00 p.m. — **Adjourn**

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Session Two, Wednesday, April 14, 2021: Assessment of Quality and Suitability

10:00 a.m. EST	**Welcome to Session 2 and Highlights of Session 1** Yao-Ming Huang *USP Raw Materials for Manufacturing of Biologics Workshop Steering Committee member*
10:20 a.m.	**Analytical Aspects of Control and Characterization: Polysorbate case study** Michael Jahn *Lonza*
10:45 a.m.	**Applying Online Analytical Tools to Characterize Cell Culture Medium Preparation** Gaurav Chauhan *Merck*
11:10 a.m.	**Advanced Raw Material Control: Rapid ID and Raw Material Informatics** Thomas Matthews *Biogen*
11:35 a.m.	**Viral Safety of Raw Materials Used in Production of ATMPs** Johannes Blümel *Head of Virus Safety Section, Paul-Ehrlich-Institut*
12:00 p.m.	**Break (10 min)**
12:10 p.m.	**An Attribute Focused Approach to Identify and Control Raw Material Variability** Jackie Milne *Amgen*
12:35 p.m.	**Panel Discussion and Q&A Moderated by Yao-Ming Huang and Rajesh Patel** *USP Raw Materials for Manufacturing of Biologics Workshop Steering Committee members*
1:00 p.m.	**Adjourn**

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Session Three, Friday, April 16, 2021: Minimizing Risk of Raw Materials and Supply Chain Disruptions

10:00 a.m. EST	**Welcome to Session 3 and Highlights of Session 2** Bala Ramanathan *USP Raw Materials for Manufacturing of Biologics Workshop Steering Committee and USP Trace Metals in Cell Culture Media Expert Panel member*
10:20 a.m.	**A Combination of Strategic Planning and Technical Assessment to Overcome Raw Material Management Challenges** Min Zhang *Thermo Fisher Scientific*
10:45 a.m.	**Impact of Elemental Impurities in Biologics development and Manufacturing & Risk Management for Control Measures** John Cunningham *Janssen*
11:10 a.m.	**Practical Considerations for Gamma Irradiation of Serum** Mark Plavsic *Lysogene*
11:35 a.m.	**Establishing a Strategy to Study the Impact of Variability in Complex Raw Materials on Process Performance** Sandeep Salunke *Takeda*
12:00 p.m.	**Break (10 min)**
12:10 p.m.	**Raw Materials Quality: Requirements, Limitations, and Recommendations (from an Ancillary Material Manufacturer's Perspective)** Patricia Chimot-Marolle *Cellgenix*
12:35 p.m.	**Opportunities and Challenges in Raw Material and Starting Material Qualification for Cell and Gene Therapy Products** Stefan Yohe *Genentech*
1:00 p.m.	**Panel Discussion and Q&A Moderated by Bala Ramanathan and Clarice Hutchens** *USP Raw Materials for Manufacturing of Biologics Workshop Steering Committee members*
1:30 p.m.	**Adjourn**