Virtual Conference

Managing Initial and Interim Reference Materials (IRM) for Relative Potency

June 24-28, 2024

All times are in Pacific Standard Time

Day 1 | Monday, June 24

Workshops: Day 1

7:00 Workshop 1: Overview of Reference Material Programs
Nadine Ritter, President, Global Biotech Experts

9:30 Break

12:00 Workshops Conclude

Day 2 | Tuesday, June 25

Session Topic: Challenges With The First Relative Potency IRM

7:00 BEBPA Opening Remarks
Laureen Little, President, BEBPA

7:15 Conference Opening Remarks
Nadine Ritter, President, Global Biotech Experts

7:30 Regulatory Perspectives: First Vaccine Relative Potency IRM
FDA Invited Speaker, CBER, Office of Vaccines Research & Review

8:15 Regulatory Perspectives: First Therapeutic Relative Potency IRM
FDA Invited Speaker, CDER, Office of Therapeutic Biologics and Biosimilars

9:00 Break and Audience Survey

9:15 Industry Case Study: First Vaccine Relative Potency IRM
Industry Invited Speaker

10:00 Building a Foundation for Success: Establishment and Management of Relative Potency Reference Material during Early Development
Ken Miller, Director, BioMarin Pharmaceutical Inc.

10:45 Break

11:00 Panel Discussion with Q&A

12:45 Closing Remarks
Nadine Ritter, President, Global Biotech Experts

12:00 Virtual Conference Adjourns

Day 3 | Wednesday, June 26

Session Topic: Potency IRM Bridging and Stability Challenges

7:00 Session Introduction
Nadine Ritter, President, Global Biotech Experts

7:15 Regulatory Perspectives: Bridging Biological Relative Potency IRMs
Regulatory Invited Speaker

7:45 Design And Preparation of Reference Materials to Standardise Biological Activity Measurements
Dr. Paul Matejtschuk, Section Head Formulation Science, MHRA

8:45 Break and Audience Survey

9:00 An Overview of Analytical Development Activities for Establishing and Maintaining Biologics Reference Standards
Isabelle Meira Silva, Associate Director, Alkermes

9:45 mAb Case Study on Challenges for Bridging Reference Standard Potency during Clinical Phases and Monitoring of its Stability
Vanessa Auquier, Head of Clinical Stability and Specifications, UCB

10:30 Break

10:45 Panel Discussion with Q&A

12:00 Virtual Conference Adjourns

Join The Conversation

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Submit Online

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Day 4 | Thursday, June 27

Session Topic: Relative Potency IRM Challenges New Modalities

7:00 Session Introduction
Nadine Ritter, President, Global Biotech Experts

7:15 Regulatory Perspectives: Relative Potency IRM for Novel Vaccines
FDA Invited Speaker, CBER, Office of Tissues and Advanced Therapies

7:45 Regulatory Perspectives: Relative Potency IRM for Novel Therapeutics
FDA Invited Speaker, CDER, Office of Therapeutic Biologics and Biosimilars

8:45 Break and Audience Survey

9:00 Industry Case Study: Implementing a Reference Standard Control Strategy In A Complex Cell-Based Potency Assay
Industry Speaker To Be Announced

9:45 Connecting the Dots: Primary and Working Reference Standards for Allogeneic CAR T Cells
Mike Sadick, Senior Director, Imugene

10:30 Break

10:45 Panel Discussion with Q&A

11:45 Conference Closing Remarks

12:00 Virtual Conference Adjourns

Day 5 | Friday, June 28

Workshops: Day 2

7:00 Workshop 2: Cell & Gene Therapy Reference Standards
Mike Sadick, Senior Director, Imugene
Laureen Little, President, BEBPA

7:00 Workshop 3: Biosimilar Reference Standards
Nadine Ritter, President, Global Biotech Experts

9:30 Break

12:00 Workshops Conclude

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