West

Practical Strategies to Reduce Risk for Drug-Device Combination Products

Workshop | April 13–15, 2021

Agenda at a Glance

REGISTER HERE

This free 3-day virtual workshop (4 hours per day) brings together industry experts and thought leaders in a unique forum to address a series of challenges and practical strategies to de-risk their Injectable Combination Product development and commercialization.

Key Challenges & Risks to be addressed are:

- Translation of regulation to development execution
- Drug & Device Integration
- Device reliability & robustness
- Change & Lifecycle management

Featuring Industry Experts from Sanofi, Eli Lilly and Co., Amgen and More!

Learning Objectives:

- Understand latest regulatory expectations including understanding risk
- Understand clinical, human factors and usability considerations
- Learn strategies to de-risk the combination product development process and use testing to inform it
- Lifecycle management considerations

A Certificate of Completion will be provided to all attendees that join all 3 days of the event.

Tuesday
April 13, 2021

The New Landscape:
Changing Regulatory and Patient Needs

10:00 AM	**Welcome** **Erin O'Brien** *Vice President, Integrated Marketing, West*
10:10 AM	**Dynamic Regulatory Environment of Drug-Device Combination Products** **Diane Paskiet** *Director of Scientific Affairs, West*
10:45 AM	**Combination Products Dictionary and Thesaurus** **Susan Neadle** *MS, BS, FAAO, DEx & PE BB, Executive Director, Combination Products & Medical Devices Regulatory Affairs, Amgen*
11:00 AM	**Combination Products Risk Management** **Susan Neadle** *MS, BS, FAAO, DEx & PE BB, Executive Director, Combination Products & Medical Devices Regulatory Affairs, Amgen*
11:30 AM	**Q&A**
11:45 AM	**Break**
12:15 PM	**Biologics Combination Products Necessitate Integrated Development Combining Molecule, Formulation, Process and Device Design** **Atul Saluja** *Senior Director and Head, Biologics Drug Product Development US, Sanofi*
12:45 PM	**From Discovery to Lifecycle Management – Developability Assessment and Device Feasibility** **Atul Patel** *Vice President, Devices and Delivery Systems, West*
1:15 PM	**Considerations for Clinical Outcomes of Combination Products** **Allison Radwick** *R.Ph., Ph.D., Manager, Scientific Affairs, West*
1:45 PM	**Q&A**

Wednesday
April 14, 2021

Technical Strategy:
Development Considerations for Combination Products

10:00 AM	**Welcome** **Erin O'Brien** *Vice President, Integrated Marketing, West*
10:05 AM	**The Importance of Human Centered Approach to Product Development** **Binita Bhattacharya** *Manager, User Response and Patient Experience, West*
10:30 AM	**A Risk-based Approach to the Development of an Injectable Combination Product** **Fran DeGrazio** *Chief Scientific Officer, West*
11:00 AM	**Analytical Considerations for Combination Products** **Jennifer Riter** *Senior Director, Business and Technical Operations, Services and Solutions, West*
11:30 AM	**Q&A**
11:45 AM	**Break**
12:15 PM	**Biological Evaluation of Drug-device Combination Products** **Cheryl Stults** *Principal at C & M Technical Consulting, LLC*
12:45 PM	**Extractables and Leachables Approach to Combination Products** **Doug Kiehl** *Research Advisor, Eli Lilly and Co.*
1:15 PM	**Combination Product Functional Suitability Assessments** **Daniel Bantz** *Manager, Scientific Communications, Self-Injection Systems, West*
1:45 PM	**Q&A**

Thursday
April 15, 2021

Sustaining Success:
Effective Planning and Lifecycle Management for Combination Products

10:00 AM	**Welcome** **Erin O'Brien** *Vice President, Integrated Marketing, West*
10:05 AM	**Technical and Regulatory Aspects of Pharmaceutical Product Lifecycle Management: ICH Q12** **Moheb Nasr** *Principal, ICH Q12 Rapporteur* *Nasr Pharma Regulatory Consulting*
10:30 AM	**PMSR Readiness** **Khaudeja Bano, MD** *VExecutive Medical Director, Combination Product Safety Head, Amgen*
11:00 AM	**Purchasing Controls: An Important Part of cGMPs** **Fran DeGrazio** *Chief Scientific Officer, West*
11:30 AM	**Q&A**
11:45 AM	**Break**
12:30 PM	**A Platform Approach to Combination Products** **Megan Doyle** *Director, Global Regulatory and R&D Policy, Amgen*
1:00 PM	**QMS and RMS Expectations on Combination Product Life Cycle** **Kim Trautman,** *Executive Vice President Medical Device International Services, NSF Medical Devices*
1:30 PM	**Q&A**
1:45 PM	**Event summary and wrap up**