Agenda

PDA Combination Products Workshop 2024

Please note that there are no posters associated with this event.

Thursday, 24 October

07:45 – 08:45

Continental Breakfast

07:45 – 17:00

Registration Open

08:45 – 10:30

P1: Navigating the Complexities of Risk Management for Combination Products

Join us for an in-depth exploration of risk management complexities specific to combination products. This session will provide strategies for ensuring the safety and efficacy of these innovative therapies, drawing from key guidelines including AAMI TIR 105, ICH Q9, and ISO 14971. We will address system risks, with a particular focus on the interactions between drugs and devices. Experts will share their expertise, offering practical guidance and real-world examples to help you navigate the complexities of risk management for combination products. Enhance your understanding and skills to better manage risks and ensure the successful development and deployment of these advanced medical solutions.

Moderator: Maggie Bandel, **MBA**, Global Head Lifecycle Management ATSC MSAT, *Johnson & Johnson*

08:45 – 09:00

Welcome and Opening Remarks from Workshop Chair

Chair: Maggie Bandel, **MBA**, Global Head Lifecycle Management ATSC MSAT, *Johnson & Johnson*

09:00 – 09:15

Overview and Introduction

Presenter: Edwin Bills, Principal Consultant, *Edwin Bills Consultant*

09:15 – 09:45

Practical Application of Risk Management Part 1: Intraocular Injections

Presenter: Edwin Bills, Principal Consultant, *Edwin Bills Consultant*

09:45 – 10:15

Practical Application of Risk Management Part 2: On-Body Injectors

Presenter: Mahendran Ravichandran, Director (Assoc.) R&D Combination Product Development, *AbbVie (INVITED)*

10:15 – 10:30

Report Out and Discussion

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10:30 – 11:00

Networking Break in the Exhibit Area

11:00 – 12:30

P2: Building a Strong Foundation: Defining Comprehensive Product Requirements

Join us for an engaging session on how to build robust sets of requirements with only limited information to begin with. We'll explore the essentials, starting points, and tools you need before formally starting development, along with considerations and sources for establishing requirements. We will then explore how to develop design inputs and specifications, including Essential Performance Requirements (EPRs), through practical case studies. Learn how to create precise requirements for scenarios like intraocular and high-volume injections. These actionable strategies and valuable insights will enhance your approach to product development.

Moderator: Flora Felsovalyi, **PhD**, Associate Director, *Lonza*

11:15 – 11:45

Case Study on Developing Inputs and Specifications Part 1: Intraocular Injections

Presenter: Geoffrey Wise, Medical Device Platform Lead, *Genentech*

11:45 – 12:15

Case Study on Developing Inputs and Specifications Part 2: High Volume Injections

Presenter: Matthew J. Huddleston, **MS**, Chief Commercial Officer, *Enable Injections*

12:15 – 12:30

Report Out and Discussion

12:30 – 13:30

Networking Lunch in the Exhibit Area

13:30 – 15:00

P3: Technical Considerations for Health Authority Submissions

Combination products, with their unique blend of drugs, devices, and/or biologics, present distinct challenges in the regulatory arena. Understanding the intricacies of these products is crucial for ensuring compliance and expediting approval. In this interactive session, seasoned experts delve into the complexities of combination products and share invaluable insights into navigating the regulatory landscape and providing a comprehensive submission to health authorities.

Moderator: Lee Leichter, **RAC, MBA**, President, *P/L Biomedical*

13:30 – 13:45

Overview and Introduction

13:45 – 14:15

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Defining Expectations and Best Practices Part 1: Intraocular Injections

Presenter: Fran DeGrazio, President & Principal Consultant, *Strategic Parenteral Solutions LLC*

14:15 – 14:45

Defining Expectations and Best Practices Part 2: High Volume Injections

Presenter: Bettine Boltres, **PhD**, Director Scientific Affairs & Technical Solutions, Glass Systems, *West Pharmaceutical Services*

14:45 – 15:00

Report Out and Discussion

15:00 – 15:30

Networking Break in the Exhibit Area

15:30 – 17:00

P4: Mastering Tech Transfer and Product Launch Readiness

In this dynamic session, industry leaders share their expertise and practical guidance on navigating the complexities of tech transfer and preparing for a successful product launch. From establishing robust transfer protocols and optimizing manufacturing processes to ensuring regulatory compliance, participants will gain insights into every facet of the tech transfer and launch readiness journey.

Moderator: Flora Felsovalyi, **PhD**, Associate Director, *Lonza*

15:30 – 15:50

Navigating a Successful Product Launch

Presenter: Subhi Saadeh, Sr. Manager, Quality, *Gilead Sciences*

15:50 – 16:40

Hands-On Exercise: Preparing your Tech Transfer

Presenter: Subhi Saadeh, Sr. Manager, Quality, *Gilead Sciences*

16:40 – 17:00

Report Out and Discussion

17:00 – 18:00

Networking Reception in the Exhibit Area

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PDA Combination Products Workshop 2024

Friday, 25 October

08:00 – 09:00

Continental Breakfast

08:00 – 12:30

Registration Open

09:00 – 10:30

P5: Impact of Post-Market Changes to the Medical Device and Best Practices for Submitting Variations in the European Market

This session focuses on the intricacies of post-market changes for combination products marketed in Europe with real-world case studies. Attendees will work together in a small group interaction to define appropriate strategies and plans for successful submission in the European market. This hands-on approach provides valuable insights and practical experience, helping participants gain skills in managing post-market changes and navigate the complex regulatory landscape.

Presenter: Akshay R. Kamdar, **PhD**, Senior Director, *Eli Lilly and Company*

09:00 – 09:20

Overview and Introduction

Presenter: Anurag Patel, **PhD**, Director, Regulatory Affairs-CMC Device and Drug-Device Combinations, *Merck & Co., Inc.*

09:20 – 10:10

Developing Strategies for Successful EU Market Submissions: A Hands-On Exercise

Presenter: Anurag Patel, **PhD**, Director, Regulatory Affairs-CMC Device and Drug-Device Combinations, *Merck & Co., Inc.*

10:10 – 10:30

Report Out and Discussion

10:30 – 11:00

Networking Break in the Exhibit Area

11:00 – 12:30

P6: Navigating the Future: Unveiling Emerging Trends

Explore the future trajectory of our industry through new and emerging trends. Our panel of experts will engage in a thought-provoking discussion, sharing insights and perspectives shaping our industry's landscape. This diverse exploration will provide you with a comprehensive understanding of the emerging forces driving innovation and change. We invite active participation from the audience, encourage feedback on the trends and welcome contributions on additional insights. This interactive exchange ensures that we collectively create a holistic view of the evolving dynamics within our industry. Don't miss this opportunity to gain valuable

insights, engage in meaningful discussions, and contribute to shaping the future of our industry.

Moderator: Maggie Bandel, **MBA**, Global Head Lifecycle Management ATSC MSAT, *Johnson & Johnson*

11:00 – 11:15

Unlocking Opportunities Through PDA Activities

Presenter: Maggie Bandel, **MBA**, Global Head Lifecycle Management ATSC MSAT, *Johnson & Johnson*

11:15 – 11:40

Exploring Key Trends with Expert Insights

11:40 – 12:25

Interactive Discussion

12:25 – 12:30

Closing Remarks from Workshop Chair

Chair: Maggie Bandel, **MBA**, Global Head Lifecycle Management ATSC MSAT, *Johnson & Johnson*