DIA

Special Topic: Risk Management in Combination Product Development Conference

Short Course: October 7 | Conference: October 13-14 | Virtual Event

PROGRAM CHAIR

James Wabby, MHS
Executive Director, Regulatory Affairs, Devices and Combination Products
AbbVie

John Barlow Weiner, JD
Associate Director, Policy and Product Classification Officer, OC/OCPP
FDA

PROGRAM COMMITTEE

Jonathan Amaya-Hodges
Senior Principal Consultant
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Karthik Balasubramanian, PhD, MS
Director, Combination Products and Semisolids, Generic CPD
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Susan Neadle, MS, FAAO
Medical Device, Combination Products, Design Thinking/Design & Process Excellence Expert

Chin-Wei Soo, DRSc
Global Regulatory Head, PTR Devices and Combination Products
Genentech, A Member of the Roche Group

Kimberly Trautman, MS
Medical Device, IVD, and Combination Product Expert

Overview

Combination products can advance patient therapy by combining and utilizing innovative technologies to deliver treatment. Although these products can be beneficial and lifesaving to the patient, industry may find it difficult to develop and maintain a sound, consistent approach to lifecycle management. Industry is keenly aware that the key to ensuring quality and safety in the lifecycle of a combination product is effective risk management. Properly conceived, risk management offers a holistic framework and process to identify and address the full sweep of considerations for development, efficacy, as well as safety investigation, manufacturing, and the safety and efficacy of post-marketing changes. However, risk management may be complicated by the challenges of managing the regulatory expectations within and across jurisdictions, and the complexity of applying multiple guidance's from pharmaceutical and device development to the combination product.

The DIA 2021 *Special Topic: Risk Management in Combination Product Development Conference* will focus its efforts on educating attendees about risk management from both an industry and global regulatory perspective, to continue to create the framework for a clear and consistent approach to product development, management, and regulation. This conference will showcase how a risk-based approach can help guide an understanding of ways in which drug and device-led combination product categories may be similar and different, and how these attributes should inform product stewardship and regulation.

This event will provide a space for global stakeholders to virtually gather to solve a complex problem and provide answers to key questions:

- How can we develop a consistent strategy for the application of risk management documents and for clarity of engagement with regulators?
- How can risk management be leveraged across the product lifecycle with an emphasis on premarket considerations from an industry and global health regulator perspective?
- How can case studies from combination product development be applied to assess best practices for industry and regulators considering the relative risk profiles of these categories of products?

Who Should Attend

Senior level professionals and decision-makers involved in:

- Biopharmaceutical, Generics, Biosimilars, Device, and Combination Product R&D and Development
- Business Development
- Clinical Research
- Consulting
- CMC
- eClinical
- Legal, Government Affairs
- Policy
- Quality Assurance and Control
- Regulatory Affairs, Regulatory Operations
- Research and Development
- Submissions

SHORT COURSE | THURSDAY, OCTOBER 7

Short Courses requires an additional registration fee. You do not need to be registered for the Forum to attend

10:00AM-1:00PM	FDA Regulation of Digital Health Products - CDRH and CDER Perspectives

DAY ONE | WEDNESDAY, OCTOBER 13

10:00-10:40AM	**Session 1:** Welcome and Keynote: Integrated Risk Management Approach for Combination Products
10:40-11:10AM	Break/Visit Virtual Exhibit Hall
11:10AM-12:10PM	**Session 2:** Overview of Risk Management
12:10-1:10PM	Break/Visit Virtual Exhibit Hall
1:10-2:10PM	**Session 3:** Pre-Market Stage of the Product Lifecycle
2:10-2:40PM	Break/Visit Virtual Exhibit Hall
2:10-2:40PM	**Exhibitor Event/Non-CE: Case Study Spotlight**
2:40-3:40PM	**Session 4**: Risk Management and The Transfer to Operations: Including a Digital Health Perspective
3:40-4:10PM	Break/Visit Virtual Exhibit Hall
4:10-5:10PM	**Session 5:** Post-Market Stage of the Product Lifecycle

DAY TWO | THURSDAY, OCTOBER 14

9:50-10:00AM	**Welcome to Day Two**
10:00-11:00AM	**Session 6:** Informational Session with EU
11:00-11:15AM	Break/Visit Virtual Exhibit Hall
11:15AM-12:15PM	**Session 7A:** Utilizing Continuous Market Feedback to Inform Future Decision Making for Your Drug or Device
12:15-1:35PM	Break/Visit Virtual Exhibit Hall
12:30-1:30PM	**Session 7B:** Utilizing Continuous Market Feedback to Inform Future Decision Making for Your Drug or Device
1:30-2:00PM	Break/Visit Virtual Exhibit Hall
2:00-3:30PM	**Session 8:** Reacting to Market Feedback for Changes in Advanced Technology
3:30-3:45PM	Break/Visit Virtual Exhibit Hall
3:45-5:15PM	**Session 9:** Risk Management in Digital Combination Product Development and Lifecycle Management
5:15PM	Closing Remarks

Learning Objectives

At the conclusion of this activity, participants should be able to:

- Discuss the holistic risk-based approach for combination product life cycle management and become familiar with best practice considerations for successful implementation
- Create a risk management process that encompasses all stages of the lifecycle for a device-led, drug-led, or digital combination product
- Discuss the necessary risk management knowledge and skills needed to meet global regulatory requirements for combination products
- Apply lessons learned from real-world examples using market feedback to continuously update earlier risk management assumptions and living risk files
- Discuss the current digital health regulatory frameworks, and apply FDA guidance and documents to determine whether your digital health product meets the definition of device

Continuing Education Credit

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The Drug Information Association designates this educational activity for up to 13 contact hours or 1.3 CEUs. Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY MONDAY, NOVEMBER 22, 2021

CE Allocation

October 7 Short Course: FDA Regulation of Digital Health Products - CDRH and CDER Perspectives: 2.5 contact hours or .25 CEUs Type of Activity: Knowledge, 0286-0000-21-071-L04-P

October 13 Day 1: Combination Products Conference: 4.5 contact hours or .45 CEUs Type of Activity: Knowledge, 0286-0000-21-069-L04-P

October 14 Day 2: Combination Products Conference: 6 contact hours or .6 CEUs Type of Activity: Knowledge, 0286-0000-21-070-L04-P

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*IACET CEUs are only available for the Short Course. Participants must complete the entire short course in order to receive an IACET statement of credit.

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If you would like to receive a statement of credit for the day(s) you attend the live virtual conference, you must virtually attend the entire Primer and/or one or both days of the conference, of the conference, complete and return a CE Verification of Attendance Form (see instructions below), complete the program evaluation, and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Thursday, October 28, 2021**.

If you are claiming ACPE credit for this event you must:

1. Complete a Verification of Attendance Form
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3. Access your DIA account and select My Transcript to claim your ACPE credit, available on Thursday, October 28, 2021

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This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed regarding unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose. To view DIA's Disclosure and Grievance Policies, visit **DIAglobal.org/CE**.

SHORT COURSE | THURSDAY, OCTOBER 7

Sessions held in EST

10:00AM-1:00PM

FDA Regulation of Digital Health Products - CDRH and CDER Perspective

Short Courses requires an additional registration fee. You do not need to be registered for the Forum to attend

Speakers

An Overview of the CDRH Approach to Digital Health Regulation
Sarah Mollo, BS, PhD, Combination Product Policy Analyst, FDA/CDRH

Policy and Regulatory Developments in Digital Health
Sarah Mollo, BS, PhD, Combination Product Policy Analyst, FDA/CDRH

Combining Digital Health Products with Drugs and Biological Products
Kristina Lauritsen, BS, PhD, Combination Product Policy Advisor, FDA/CDER

This short course will provide an overview of device, drug, and combination product regulations with a focus on the application of the existing scheme to digital health products. The course will also cover recent policy developments that have been implemented to assess whether a digital health product is considered a medical device as well as when a premarket application is needed. The course will discuss considerations for combining mobile apps/software with a drug or biologic product to understand the holistic regulatory environment that should be considered for digital health products.

Learning Objectives

- Recognize how the current digital health regulatory framework interfaces with existing medical device and drug laws and regulations
- Apply the CDRH Guidance Documents/policies to assess whether a digital health product meets the definition of a device
- Identify when a digital health product would be considered promotional labeling or required labeling for a drug or biologic application

DAY ONE | WEDNESDAY, OCTOBER 13

10:00-10:40AM

Session 1: Welcome and Keynote: Integrated Risk Management Approach for Combination Products

Session Chair
James Wabby, MHS, Executive Director, Regulatory Affairs, Devices and Combination Products AbbVie

Risk is everywhere and it encompasses your combination products within the lifecycle management cycle. Combination products are emerging as innovative medical products due to their contribution to advancing medical care and are thus expected to have major impact in the coming years. Future

technologies are most appealing to patients with ongoing medical conditions that require consistent treatment with daily injections or weekly procedures and unmet medical needs. Overall, the successful development of combination products will require an integrated risk management approach within the lifecycle management of combination products to ensure a safe and effective product for patient utilization.

Learning Objectives

- Analyze latest Office of Combination Products (OCP) expectations and challenges utilizing an integrated risk management approach for combination products
- Discuss the importance of an integrated risk management approach to increase product understanding earlier within the product development phase
- Achieve a reduced amount of design/manufacturing changes later in development vs. potential costly changes with a non-integrated risk management approach leading to an increased amount of quality complaints, adverse events and poor product performance

Speakers

Robin Kumoluyi, MS, Vice President and Chief Quality Officer, Pharmaceuticals, Janssen Pharmaceutica

John Barlow Weiner, JD, Associate Director, Policy and Product Classification Officer, OC/OCPP, FDA

10:40-11:10AM **Break**

11:10AM-12:10PM **Session 2:** Overview of Risk Management

Session Chair

Kim Trautman, MS, Medical Device, IVD, and Combination Product Expert

Combination Products is evolving with global regulations and varied interpretations across regions. Yet manufacturers and health authorities have common objectives to bring safe, efficacious, and usable medical products to patients. This session will discuss the Risk-Based approach for Quality Requirements and Control Strategies. In addition, this session explores the life cycle of quality and risk management aspects and the need for continuous improvement to include:

- Quality by Design and Design Controls
- Essential Performance Requirements (EPR)
- Combination Products Risk Management
- Purchasing Controls
- Corrective and Preventive Action (CAPA)
- Post Marketing Safety Reporting (PMSR)

Learning Objectives

- Compare and contrast pharmaceutical and medical device development requirements and principles for quality and risk management
- Discuss the incorporation of the principles of combination product risk management into practice
- Discuss the holistic risk-based approach for combination product life cycle management and become familiar with best practice considerations for successful implementation

Speaker

Susan Neadle, MS, FAAO, Medical Device, Combination Products, Design Thinking/Design & Process Excellence Expert

12:10-1:10PM **Break**

2:10-2:40PM **Exhibitor Event/Non-CE:** Case Study Spotlight

1:10-2:10PM **Session 3:** Pre-Market Stage of the Product Lifecycle

Session Chair
Chin-Wei Soo, DRSc, Global Regulatory Head, PTR Devices and Combination Products Genentech, A Member of the Roche Group

An integrated and continuous application of risk management are crucial during development to ensure that combination products meet the intended use. This session will provide the audience with best practices to utilize risk analysis tools, quantify risk levels, implement mitigation approaches, and assess residual risks for drug-device combination products in an integrated manner.

Learning Objectives

- Apply risk management best practices for drug-device combination products in an integrated manner
- Discuss the necessary risk management knowledge and skills needed to meet global regulatory requirements

Speakers
Molly Story, PhD, MS, Senior Advisor, Medical Device Development Unit, Sanofi

Arlesa Hubbard, MS, Team Leader, Risk Management, Sanofi

Philip Robledo, Senior Manager - Quality Assurance, Abbvie

2:10-2:40PM **Break**

2:40-3:40PM **Session 4:** Risk Management and The Transfer to Operations: Including a Digital Health Perspective

Session Chair
Karthik Balasubramanian, PhD, MS, Director, Combination Products and Semisolids, Generic CPD, Teva Pharmaceuticals

This session will cover how to effectively handle risk management when transferring a combination product into manufacturing operations. The session will not only cover general principles of risk management and transfer, but also delve into a case study for a digitally connected drug-device combination product. In addition, the session will cover effective operational transfer of risk management for both software and a combination product.

Learning Objectives

- Identify key principles of risk management during transfer
- Recognize important watch-outs for operational transfer of a risk file
- Describe integration of internal and external manufacture into risk management

Speaker
Eric Chan, MS, Teva Pharmaceuticals, Director of Product Management, Digital Health

Enric Calderon, Associate Director, R&D, Teva Pharmaceuticals

Robert Labaczewski, Director, Device Quality, Bracco Diagnostics

3:40-4:10PM **Break**

4:10-5:10PM **Session 5:** Post-Market Stage of the Product Lifecycle

Session Chair
Jonathan Amaya-Hodges, Senior Principal Consultant, Suttons Creek, Inc

Risk Management is an ongoing and iterative process, inclusive of the post-market stage of the product lifecycle, which is of growing importance to medical products as highlighted by additions to

ISO 14971:2019 as well as initiative such as FDA's Total Product Lifecyle (TPLC) approach. Combination products pose unique challenges in post-market risk management, given divergent needs and requirements of the constituent parts and their respective data sources. This session will discuss how a manufacturer may bring together a cohesive and holistic post-market risk management process for combination products.

Learning Objectives

- Describe basic post-market risk management principles as they apply to individual medical devices and drugs/biologics
- Describe how post-market risk management expectations converge for combination products
- Create a strategy for a holistic post-market risk management process for combination products

Speakers

Jonathan Amaya-Hodges, Senior Principal Consultant, Suttons Creek, Inc

Kimberly Trautman, MS, Medical Device, IVD, and Combination Product Expert

DAY TWO | THURSDAY, OCTOBER 14

9:50-10:00AM — **Welcome to Day Two**

10:05-11:00AM — **Session 6:** Informational Session with EU

Session Chair

Susan Neadle, MS, **FAAO,** Medical Device, Combination Products, Design Thinking/Design & Process Excellence Expert

Regulatory frameworks are being introduced around the globe in efforts to ensure safe, efficacious and usable combination products for patients. Most recently, EMA has implemented updated combination products legislation under EU MDR (2017/745), and additional updates to pharmaceutical legislation are under consideration. This informational session will review Combination Products interpretation and expectations under EU MDR, and roles of EMA, National Competent Authorities and Notified bodies in the process.

Learning Objectives

- Evaluate the interpretation and expectations of combination products under EU MDR
- Distinguish roles and responsibilities of EMA, Competent Authorities and Notified Bodies as part of the process
- Recognize evolving efforts under pharmaceutical legislation in EU

Speakers

Christelle Bouygues, Scientific and Regulatory Management Department, Human Medicines Evaluation Division, European Medicines Agency, Amsterdam, The Netherlands

Christiana Hoffman, Regional Manager Focus Topics Article 117 & Annex XVI MDR at TÜV SÜD bei TÜV SÜD, Germany

Theresa Jeary, Head of Combination Products, SFL Regulatory Affairs & Scientific Communication GmbH, Switzerland

11:00-11:15AM — **Break**

11:15AM-12:15PM — **Session 7A:** Utilizing Continuous Market Feedback to Inform Future Decision Making for Your Combination Product

Session Chairs

Kimberly Trautman, MS, Medical Device, IVD, and Combination Product Expert

Susan Neadle, MS, FAAO, Medical Device, Combination Products, Design Thinking/Design & Process Excellence Expert

Risk Management and new regulatory expectations impact all Combination Product technical documentation and post-market surveillance files. Combination Product manufacturers should pay special attention to language around benefit-risk analysis, evaluation of overall, residual risk, and production and post-production activities. Discuss how premarket data and post-market data need to be aligned for continuous monitoring and how you can use the MedRA & IMDRF terminology and codes to bridge.

Learning Objectives

- Evaluate the correlation between risk management and other post-market surveillance activities
- Discuss the relationship of human factors or usability engineering as part of design validation and risk management
- Assess post-market data to continuously update earlier risk management assumptions and living risk files
- Discuss strategies to incorporate appropriate terminologies and codes

Speakers

Kimberly Trautman, MS, Medical Device, IVD, and Combination Product Expert

Susan Neadle, MS, FAAO, Medical Device, Combination Products, Design Thinking/Design & Process Excellence Expert

12:15-12:30PM **Break**

12:30-1:30PM **Session 7B:** Utilizing Continuous Market Feedback to Inform Future Decision Making for Your Drug or Device

Session Chairs

Kimberly Trautman, MS, Medical Device, IVD, and Combination Product Expert

Susan Neadle, MS, FAAO, Medical Device, Combination Products, Design Thinking/Design & Process Excellence Expert

Risk Management and new regulatory expectations impact all Combination Product technical documentation and post-market surveillance files. Combination Product manufacturers should pay special attention to language around benefit-risk analysis, evaluation of overall, residual risk, and production and post-production activities. Discuss how premarket data and post-market data need to be aligned for continuous monitoring and how you can use the MedRA & IMDRF terminology and codes to bridge.

Learning Objectives

- Evaluate the correlation between risk management and other post-market surveillance activities
- Discuss the relationship of human factors or usability engineering as part of design validation and risk management
- Assess post-market data to continuously update earlier risk management assumptions and living risk files
- Discuss strategies to incorporate appropriate terminologies and codes

Speakers

Kimberly Trautman, MS, Medical Device, IVD, and Combination Product Expert

Susan Neadle, MS, FAAO, Medical Device, Combination Products, Design Thinking/Design & Process Excellence Expert

1:30-2:00PM **Break**

2:00-3:30PM

Session 8: Reacting to Market Feedback for Changes in Advanced Technology

Session Chair
Karthik Balasubramanian, PhD, MS, Director, Combination Products and Semisolids, Generic CPD, Teva Pharmaceuticals

Session Co-Chair
James Wabby, MHS, Global Head, Regulatory Affairs, Emerging Technologies and Combination Products, Abbvie

This panel will discuss the impact of changing advanced technology (microneedles, on-body injectors, e-connected technology) on your combination product and its risk management file. Participants will be able to understand the key risks and mitigations for ensuring that advanced combination products can remain safe and effective through ongoing market feedback. Topics to be covered will include appropriate threshold setting, safety signals, and integrating with safety physicians.

Learning Objectives

- Identify how market feedback changes advanced technology
- Create appropriate change thresholds for market feedback
- Identify key organizational stakeholders for integration

Speakers
Mark DeStefano, Director, Combination Product and Device R&D, Teva Pharmaceuticals
Tycho Speaker, PhD, Director, Drug Delivery and Biomaterials, Abbvie
Carolyn White, MS, Executive Director, R&D Quality, Allergan/AbbVie

3:30-3:45PM

Break

3:45-5:15PM

Session 9: Risk Management in Digital Combination Product Development and Lifecycle Management

Session Chair
Chin-Wei Soo, DrSc, Global Regulatory Head, PTR Devices and Combination Products Genentech, A Member of the Roche Group

Session Co-Chair
James Wabby, MHS, Global Head, Regulatory Affairs, Emerging Technologies and Combination Products, Abbvie

Risk management is an integral part of the development and lifecycle management of digital combination products. An effective deployment of an end-to-end risk management not only meets the regulatory requirements, it ensures the safety of the products. This session will provide the audience with the regulatory basis for implementing risk management and examples of risk management approaches in the pre-market and post-market settings. Risk management associated with cybersecurity will also be discussed.

Learning Objectives

- Describe the regulatory basis for implementing risk management
- Apply risk management best practices throughout the lifecycle of digital combination products

Speakers
Emily Luvison, Principal Lead Cybersecurity Compliance, Roche/Genentech
Matthew Gloss, JD, MBA, Co-Founder, V.P. of Global Operations, AI Data Compliance and Privacy, Belle Artificial Intelligence Corporation

5:15PM

Closing Remarks

Session Chair/Speaker
James Wabby, MHS, Global Head, Regulatory Affairs, Emerging Technologies and Combination Products, Abbvie

Special Topic: Risk Management in Combination Product Development Exhibitor Sponsored Events

Separate RSVP is required for each event. Visit the exhibitor directory for more information

WEDNESDAY | OCTOBER 13

2:10-2:40PM

Exhibitor Event/Non-CE: Case Study Spotlight hosted by Lachman Consultants

Importance of Risk Management in Development of Combination Products

In her Case Study "Importance of Risk Management in Development of Combination Products", Ricki Chase, former FDA Director of Investigations in the Chicago district and current Lachman Consultants Executive Director will discuss best practices and pitfalls in combination product development, focusing on a risk-based approach. Her presentation will cover risk management during combination product design and the importance of that focus at the interface between a pharmaceutical agent and the device component. She will discuss practical examples of situations in development of specific combination products where a robust risk-based approach was lacking and resulted in issues during approval at FDA that she has encountered while at FDA as well as observed in industry as a consultant. She will discuss how a proactive, risk-based focus among all members of the development cadre can speed combination products to market for use by patients in need. Please join us on October 13 to hear all about this.

Ricki Chase, Executive Director, Lachman Consultants, Inc.

Separate RSVP is required. **Click here to RSVP!**