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
### Schedule At-A-Glance

Sessions held in EST

#### 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

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<td>10:00-10:40AM</td>
<td><strong>Session 1:</strong> Welcome and Keynote: Integrated Risk Management Approach for Combination Products</td>
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<td>10:40-11:10AM</td>
<td>Break</td>
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<tr>
<td>11:10AM-12:10PM</td>
<td><strong>Session 2:</strong> Overview of Risk Management</td>
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<td>12:10-1:10PM</td>
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<td>1:10-2:10PM</td>
<td><strong>Session 3:</strong> Pre-Market Stage of the Product Lifecycle</td>
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<td><strong>Session 4:</strong> Risk Management and The Transfer to Operations: Including a Digital Health Perspective</td>
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<td>3:40-4:10PM</td>
<td>Break</td>
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<td>4:10-5:10PM</td>
<td><strong>Session 5:</strong> Post-Market Stage of the Product Lifecycle</td>
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#### DAY TWO | THURSDAY, OCTOBER 14

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<tr>
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<tr>
<td>11:15AM-12:15PM</td>
<td><strong>Session 7A:</strong> Utilizing Continuous Market Feedback to Inform Future Decision Making for Your Drug or Device</td>
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<td>12:15-1:35PM</td>
<td>Break</td>
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<tr>
<td>12:30-1:30PM</td>
<td><strong>Session 7B:</strong> Utilizing Continuous Market Feedback to Inform Future Decision Making for Your Drug or Device</td>
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<td>1:30-2:00PM</td>
<td>Break</td>
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<tr>
<td>2:00-3:30PM</td>
<td><strong>Session 8:</strong> Reacting to Market Feedback for Changes in Advanced Technology</td>
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<td>3:30-3:45PM</td>
<td>Break</td>
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<tr>
<td>3:45-5:15PM</td>
<td><strong>Session 9:</strong> Risk Management in Digital Combination Product Development and Lifecycle Management</td>
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<tr>
<td>5:15PM</td>
<td>Closing Remarks</td>
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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.

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 13.5 contact hours or 1.35 CEUs.

Type of Activity: Knowledge

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

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA’s My Transcript within 45-days post activity. If ACPE credit is not requested by Monday, November 22, 2021 the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit http://www.cpemonitor.net.

DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET). As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer .3* CEUs for this conference.

*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.

Continuing Education Credit and My Transcript

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, 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
2. Send back to CE@DIAglobal.org by October 21, 2021
3. Access your DIA account and select My Transcript to claim your ACPE credit, available on Thursday, October 28, 2021

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- Select My Transcripts then Manage My Transcripts

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- Select My Account from the menu
- Choose My Presentation

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DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to 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

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 L. Kumoluyi, Vice President and Chief Quality Officer, Pharmaceuticals, Janssen Pharmaceutica

John Barlow Weiner (Barr), 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, Executive Director & Head, Combination Products, Devices, Diagnostics & Digital, Amgen
12:10-1:10PM  
**Break**

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**

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 Lifecycle (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

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**DAY TWO | THURSDAY, OCTOBER 14**

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**Session Chair**
- **Susan Neadle, MS**, Executive Director & Head, Combination Products, Devices, Diagnostics & Digital, Amgen

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**
- **Representative Invited**, European Medicines Agency, Amsterdam, The Netherlands
- **Representative Invited**, TÜV SÜD bei TÜV SÜD, Germany
- **Representative Invited**, SFL Regulatory Affairs & Scientific Communication GmbH, Switzerland

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<td><strong>Session 7A: Utilizing Continuous Market Feedback to Inform Future Decision Making for Your Combination Product</strong></td>
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**Session Chairs**
- **Kimberly Trautman, MS**, Medical Device, IVD, and Combination Product Expert
- **Susan Neadle, MS**, Executive Director & Head, Combination Products, Devices, Diagnostics & Digital, Amgen, United States

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**, Executive Director & Head, Combination Products, Devices, Diagnostics & Digital, Amgen, United States

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**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**, Executive Director & Head, Combination Products, Devices, Diagnostics & Digital, Amgen, United States

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**Learning Objectives**
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- Discuss strategies to incorporate appropriate terminologies and codes

**Speakers**
**Kimberly Trautman, MS**, Medical Device, IVD, and Combination Product Expert  
**Susan Neadle, MS**, Executive Director & Head, Combination Products, Devices, Diagnostics & Digital, Amgen, United States

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**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
Representative Invited, 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