Wednesday, October 10

7:00 a.m. – 5:15 p.m.
Registration Open

7:15 a.m. – 8:15 a.m.
Continental Breakfast

8:15 a.m. - 8:30 a.m.
Welcome and Opening Remarks from Committee Chair
Lee Leichter, President, P/L Biomedical

8:30 am. – 10:00 a.m.
P1: Connected Health and Drug Companies
Moderator: Richard (Rick) Chapman, Senior Director, Medical Device Software Factory, Sanofi

There has been a proliferation of digital tools and devices, and connected combination products, brought forward by Drug and Biologics companies in the last decade, and it seems to be accelerating. These digital things are used in clinical trials, adjuncts to labeling and in advertising and promotional materials, and in prescription and consumer products. In this session, we’ll discuss a few of the many issues (e.g. cybersecurity, impact of differences in drug versus device laws and regulations, company internal cultural adaptations, systems of digital things) that Drug companies face in bringing these new technologies forward.

8:30 a.m. - 9:00 a.m.
The Digitization of Drug Delivery
Paul Schultz, Head of Partnerships, Flex

9:00 a.m. –9:30 a.m.
How Digital Technologies Enhance Patient Engagement
Eric Chanie, Director, Healthcare Intelligence & Business Development, Merck Group

9:30 a.m. - 10:00 a.m.
Questions and Answers/Discussion

9:45 a.m. – 3:45 p.m.
Exhibit Area Open

10:00 a.m. –10:45 a.m.
Refreshment Break in Exhibit Area

10:45 a.m. –12:15 p.m.
Concurrent Sessions
## Concurrent Sessions

**A1: New Technologies**  
**Moderator:** Marc Rohrschneider, PhD, Head New Technologies, Novartis Pharma AG

The session will provide an overview of the latest trends for combination products and the future challenges and hurdles that the pharma pipelines provide for drug-device developments. In a world which has been strongly driven by new guidelines, regulations and therapies over the last few years, it is important to understand the future requirements and strategies for successful developments. We will discuss new technologies and regulatory options to transfer latest technology trends to clinic and market including insights into innovative delivery systems and their applications.

10:45 a.m. - 11:15 a.m.  
**Innovation Management for New Technology Delivery Systems: A Pharma Perspective**  
**Alexander Jung, PhD**, Senior Innovation Manager – Drug Delivery & Devices, Boehringer Ingelheim Pharma GmbH & Co. KG

11:15 a.m. - 11:45 a.m.  
**New Technology Delivery Systems: A Regulatory Perspective**  
**Sarah Mollo, PhD**, Biocompatibility Consultant and Lead Reviewer, General Hospital Devices, CDRH, FDA

11:45 a.m. - 12:15 p.m.  
**Questions and Answers/Discussion**

**B1: Products Intended to be Used Together: A Marriage of Convenience or Necessity?**  
**Moderator:** Anthony Watson, Associate Vice President, Regulatory Affairs, Devices, Sanofi

The combination product arena has many players. One area that is often overlooked but has several important challenges is the case where two or more different types of products are intended to be used together but not physically combined as a single entity. These products can be placed into the same packaging or they can reference each other through labeling only. We hear terms like convenience kit, co-packaged combination product, cross-labelled combination product. Are these really different products? Are there any differences in requirements or is this a distinction without a difference? History plays a significant role here that can have an impact on product development and regulatory pathways. Attend this engaging session to hear from regulators and experts in the field with practical experience.

10:45 a.m. - 11:15 a.m.  
**General Delivery vs. Cross-Labeled**  
**Carolyn Cochenour Dorgan, MS**, Acting Senior Lead Reviewer, General Hospital Devices Branch, CDRH, FDA

11:15 a.m. - 11:45 a.m.  
**Challenges of Establishing a Kit vs. Co-Packaged Combination Products**  
**Sugato De**, Principal Consultant, PAREXEL International

11:45 a.m. - 12:15 p.m.  
**Questions and Answers/Discussion**

12:15 p.m. - 1:30 p.m.  
**Lunch**

1:30 p.m. - 3:00 p.m.  
**Concurrent Sessions**

### A2: Generic and Biosimilar Combination Products

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

More products with delivery systems that were approved years ago are now subject to competition through generic (505(j) ANDA) and biosimilar (351(k) BLA) submissions. These present unique challenges in addition to those facing New Molecular Entity (NME) combination products. Development of these products, including establishing their comparability to the Reference Drugs or Biologics require different development strategies and assessment tools. In addition to validating that the drug entity is the same, Generic and Interchangeable Biosimilar products must establish that the delivery systems do not differ in any significant way, even though the products they are replacing may be old technology, not user friendly and may have never been subjected to the same requirements when they were approved. These presentations and discussions will identify, explain and help with the understanding of these the new approaches and expectations for these products.

### B2: Post-Commercialization

**Moderator:** Carolyn Cochenour Dorgan, MS, Acting Senior Lead Reviewer, General Hospital Devices Branch, CDRH, FDA

Change is an inherent part of the total product life cycle of a combination product. Consideration and management of that change is one of the most critical aspects of a quality management system, yet for combination product manufacturers, it can be nebulous and challenging due to the lack of established processes or best practices. How do manufacturers decide when to handle the change internally, versus notifying the appropriate regulatory body? How do you capture adverse events and where do you report them? How do you maintain a design history file that incorporates changes to the drug and device constituents of combination products? This session will explore best practices to the challenges facing combination product manufacturers including change management, adverse event reporting and knowledge management throughout the total product life cycle.
<table>
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<th>Time</th>
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| 1:30 p.m. - 2:00 p.m. | Combination Product Development for Biosimilars and Generics: The Devil is in the Detail  
Alastair Clarke, Managing Director, Weaver Technical Solutions LTD |
| 1:30 p.m. - 2:00 p.m. | ISO 20069: Assessment & Evaluation of Changes to Drug Delivery Systems  
Paul Jansen, PE, Board Member & Senior Advisor, Haselmeier |
| 2:00 p.m. - 2:30 p.m. | Human Factors for Generic and Biosimilars (Interchangeable)  
Christoph Jordi, Senior Usability Manager, Ypsomed AG |
| 2:00 p.m. - 2:30 p.m. | The Landscape of Post Market Surveillance (PMS)  
Dana Fashina, Software Quality Manager, Sanofi-MED |
| 2:30 p.m. - 3:00 p.m. | Questions and Answers/Discussion |
| 2:30 p.m. - 3:00 p.m. | Questions and Answers/Discussion |
| 3:00 p.m. - 3:45 p.m. | Refreshment Break in Exhibit Area |
| 3:45 p.m. - 5:15 p.m. | P2 - Challenges for Device Development in a Global Economy  
Moderator: Olivia Henderson, PhD, Principal Engineer, Amgen Inc. |
| 3:45 p.m. - 4:15 p.m. | Impact of MDR on Combination Products: Role of Notified Bodies  
Girish Kumar, PhD, Product Specialist, TÜV SÜD America |
| 4:15 p.m. - 4:45 p.m. | Medical Device Regulation (MDR, Article 117): Impact on Pharma and Biotech Companies and Related Survival Strategies  
Beat U. Steffen, Founder & CEO, Confinis AG |
| 4:45 p.m. - 5:15 p.m. | Questions and Answers/ Discussion |
| 5:15 p.m. | Closing Remarks from Committee Chair  
Lee Leichter, President, P/L Biomedical |