AGENDA

7:30 a.m. – 8:30 a.m. Registration and Continental Breakfast

8:30 a.m. – 9:00 a.m. **Welcome**

9:00 a.m. – 9:45 a.m. **FDA's Expectations for Combination Products Manufacturers — Review of 21 CFR Part 4 Requirements**

- Update on current regulations and guidance documents recently released and what to expect.
- Update on the FDA Inter-Center Survey, high level activities
- Understanding the roles and responsibilities of FDA Centers and Office of Regulatory Affairs
- Opportunities for industry to improve RFD process

John (Barr) Weiner, Associate Director for Policy and Product Classification Officer, Office of Combination Products, FDA (Invited)

9:45 a.m. – 10:30 a.m. **Challenges of Combination Product Manufacturers – Lessons Learned**

Key Learnings:

- Understanding the "Cultural impact" of integrating Combination Products
- Portfolio Management — how to look back at legacy as well as how to build product for the future
- Device Manufactures — top challenges
- Drug Manufactures — top challenges
- Recent combination product inspections and observations

Dr. Mary C. Getz, Vice President, NSF Health Sciences, Medical Device Consulting

10:30 a.m. – 10:45 a.m. Break

10:45 a.m. – 12:15 p.m. **FDA and Industry — Expert Panel Discussion —**

- Challenges of working with the various organizational units within the FDA. How does industry navigate the multicenter process?
- Enforcement of Part 4 — what trends do the centers see where industry is still struggling to comply.

- How does industry translate to the ORA inspectors what strategies have been discussed and agreed to by the FDA Center?
- Final rule on Postmarketing Safety Reporting for Combination Products
  - How to work with the FDA to streamline the process
  - Challenges that the agency has seen since the ruling was issued
- How to Prepare a Pre-Request for Designation (Pre-RFD) —what are some of the critical information that the agency is seeking?
  - Challenges that the Agency has seen since issuance of guidance
- How to develop a working relationship with the FDA when I don't know even know where to start the dialog?

Moderator:
Dr. Mary C. Getz, Vice President, NSF Health Sciences, Medical Device Consulting

Panelists:
Office of Combination Products, FDA, CDRH, FDA
CBER
CDRH
CDER
Field Inspector/District Dir (Request)

12:15 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 2:15 p.m. **Analytical Methods Needed for Combination Pharmaceutical/Medical Devices**

Key Learnings:

- Overview of the typical analytical methods that are needed to support a combination pharmaceutical/medical devices.
- Validation strategies that accommodate unique sample requirements and the intended use of the method.

Case study:

Develop an analytical testing plan for a hypothetical combination medical device.

Dr. Kurt Moyer, General Manager, NSF Health Sciences Bristol Laboratory

2:15 p.m. – 2:30 p.m. Break

2:30 p.m. – 3:45 p.m. **Combination Product Development Process**

Key Learnings:

- The drug development process
- The device development process
- Cultural differences between drug and device development
- Common problems and misunderstandings

Case study:

Review some of the challenges that industry encounters

Amit Khanolkar, Director, Combination Products & Emerging Technologies, Product Quality Management, Janssen Pharmaceuticals

3:45 p.m. – 5:00 p.m. **Combination Product Challenges: A Pharmaceutical Industry Perspective from a Medical Device Developer**

- Delivery of 21 CFR Part 4 compliance from a medical device versus a pharmaceutical company perspective
- Unique challenges associated with developing essential systems in a pharmaceutical quality system
- Hybridizing pharmaceutical and medical device product development efforts
- Future challenges associated with developing the ultimate combination product

Case Studies:

1. Implementation of Medical Device Purchasing Controls in a CMO Model
2. Creating the Next Generation of Combination Product: Connected Health

Dr. James Oberhauser, Associate Director, Device Development and Clinical Packaging Engineering, Gilead Sciences