Virtual TEMP Regulatory Bootcamp

Program Schedule

Day 1:

- Overview of FDA authority, structure, and responsibility
  - Interactive overview of FDA-regulated products
- Introduction to drugs, medical devices, and biologics
  - Definitions and examples of drugs, medical devices, and biologics
- Combination products overview
  - Definition and examples of combination products
- FDA product jurisdiction overview
  - Discussion on combination products jurisdiction
  - Insight into how the FDA determines product jurisdiction

Day 2:

- Overview of FDA regulatory pathways
- Medical device marketing pathways
  - In-depth case study on the 510(k)-decision-making process
- Biologic marketing pathways
  - 361 HCT/Ps versus 351 products
  - Good Tissue Practices
- Discussion on the intersection of regulatory and standards during product development
- Tips and best practices for navigating the FDA regulatory process

During the **two-day course**, participants will learn a basic understanding of how the FDA reviews and regulates human medical products.

Participants will test their newly acquired FDA regulatory knowledge with realistic **case studies**.

Learning Goals:

- Learn the products that the FDA is responsible for regulating
- Understand the FDA’s regulatory authority
- Learn the statutory definitions for biologic, drug, and medical device
- Learn the regulatory definition of HCT/Ps
- Learn the differences between “351” and “361” biologic products
- Learn the regulatory definition of a combination product
- Understand how the product definitions help determine jurisdiction
- Understand how the FDA determines jurisdiction for human medical products
- Describe and understand the main marketing pathways for medical devices
- Describe and understand the marketing pathway for biologics
- Learn best practices for navigating the FDA regulatory process