

The Regulatory Process

Level One

The Regulatory Process provides a summary of the regulatory bodies involved in approving both small molecule drugs and biologics. Understand the application process involved in moving a drug candidate from preclinical studies in animals to human clinical studies, to final approval allowing for marketing and sale of a drug product. Learn the ways a drug candidate approval can be expedited so life saving medicines can get to patients faster. Familiarize yourself with the US Prescription Drug User Fee Act (PDUFA) which governs it all. The Regulatory Process class gives an overview of all regulatory considerations a drug manufacturer should take into account as it seeks to prove their drug is safe and effective.

Five Takeaways

1. Discuss the components and timing of an Investigational New Drug (IND) application for the United States and a Clinical Trials Application (CTA) for the European Union.
2. Explain the purpose of the Prescription Drug User Fee Act of 1992 (PDUFA) and how it is a win/win for both the drug manufacturers, the FDA and patients.
3. Understand the criteria of various expedited drug approval pathways (including orphan designation) and discuss how these designations effect the timing of the regulatory process.
4. Describe the process of filing for either New Drug Application (NDA) or Biologics License Application (BLA) in the US.
5. Compare and contrast generics and biosimilar approval pathways.

Agenda

Introduction to the Regulatory Process: Describes the organization and mission of the FDA and EMA and discusses the global harmonization of drug testing requirements.

IND/CTA Filing: Explains the importance of both an Investigational New Drug (IND) application and a Clinical Trial Application (CTA) and discusses the components of each. Learn about the different types of INDs, which you should file for your situation and the timing of an IND application.

User Fee Programs: Understand why the Prescription Drug Fee User Act (PDUFA) is advantageous to both the drug manufacturers, the FDA and patients. Learn the purpose and timing of FDA formal meetings and other tools the FDA and EMA uses to interact with industry.

Orphan Drugs and Expedited Pathways: Defines the regulatory meaning and criteria for the speeding up drug reviews to meet serious conditions and unmet medical needs including the FDA's breakthrough therapies, fast track, accelerated approval, priority review and orphan drug designations and similar pathways employed by the EMA.

Market Approval: Describes the process of a New Drug Application (NDA) and Biologics License Application (BLA) in the US and lists the different paths to approval in the EU. The class finishes with a comparison of the generics and biosimilars approval pathways.