Drug Development Primer

Drug Development Primer is a one-day course concentrating on the FDA regulatory considerations required to successfully bring a drug to market in the US. Discussion points focus on biologic products. Numerous personal accounts illustrate the decision-making process biopharma's use, giving you an overview of strategic development.

Four takeaways:
1. Overview of the FDA regulatory process
2. Introduction to drug development terminology and most used acronyms
3. Familiarity with preclinical testing requirements
4. Understanding of the clinical studies process

Course Agenda

Drug Development Overview *9:00–9:45*
Success metrics and chances of success
Timelines and costs
Commercial considerations

Drug Discovery *9:45-10:45*
Target identification
Potential targets: pharmacology
Target validation
Assay development and screening
Lead optimization
Case study: multiple sclerosis

Break *10:45–11:00*

The FDA Regulatory Process *11:00-12:00*
FDA mission and organization
PDUFA
REMS and black box warning
FDA formal meetings with sponsors
Regulatory interactions and tools
Generics, biosimilars, orphan drugs
Regulatory compliance
Activity: key risk factors

Lunch *12:00-1:00*

Preclinical Development *1:00–2:00*
Preclinical trials
Preclinical testing
Initial new drug (IND) application
New drug application (NDA)
Biologics license agreement (BLA)

Break *2:00–2:15*

Clinical Development *2:00–4:15*
Ethical considerations
Investigator sites
Clinical protocols
Endpoint: clinical vs surrogate
Study design considerations and choices:
    parallel, crossover, basket, umbrella, adaptive designs
Phase I
Pharmacokinetics (PK) and pharmacodynamics (PD)
Phase IIA and IIB
Phase IIIA and IIIB
FDA approval process
Phase IV
Drug safety and pharmacovigilance

Wrap-Up *4:15-4:30*

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