Preclinical Development

55 MINUTES ONLINE COURSE | LEVEL 1

OVERVIEW

Preclinical Development focuses on both small and large molecule drug safety assessments and regulatory requirements. This course also explains how clinical starting dose levels are estimated. Learn what preclinical criteria is needed to support first-in-human clinical trials.

Five Takeaways:

1. In-depth knowledge of the preclinical development process.
2. Understanding of the Animal Rule and how animal models enable clinical trials.
3. Ability to estimate clinical starting dose levels by interpreting preclinical results.
4. Knowledge of how to integrate preclinical data into the Common Technical Document.
5. Fluency of criteria necessary to support first-in-human clinical trials.

AGENDA

- **Preclinical Development Overview** describes timing and costs for the major drug development steps by reviewing industry statistics.
- **Pharmacology** discusses the key data generated during pharmacology studies and how that information is used to move from animal studies to human studies. In addition, specific challenges in assessing pharmacology in biologics and small molecule drug candidates is explored.
- **Pharmacokinetics** demonstrates how pharmacokinetics is used to characterize the exposure-response relationship for a drug candidate, discusses the typical endpoints calculated, and describes bioanalytical assay and validation criteria.
- **Toxicology** describes the importance of toxicity studies and how the information obtained helps select compounds, establishes safety parameters of those compounds and influences animal model choice, dose selection, and routes of administration for the candidate drug. Concepts such as therapeutic margins and subjectivity in making conclusions based on sample study data are explored.
- **Nonclinical IND/CTA** explains what to include and how to complete the Common Technical Document.