ON-DEMAND MICRO CLASS | LEVEL ONE | 55-MINUTES

SUGGESTED PREREQUISITE: NONE

biotechPrimer
Life Science Training From Industry Experts

Preclinical Development For Non-Scientists

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 are needed to support first-in-human clinical trials.

Five Takeaways:

1. In-depth knowledge of the preclinical development process.
2. State the key data generated during pharmacology studies and why those data are collected.
3. Ability to estimate clinical starting dose levels by interpreting preclinical pharmacology and toxicology results.
4. Integration of preclinical data into the Common Technical Document.
5. Fluency of criteria necessary to support first-in-human clinical trials.

AGENDA

The Big Picture

- Development timing and costs
- In silico, In vitro, in vivo studies
- Safety and efficacy endpoints
- Preclinical short term studies
- Animal models

Pharmacology

- Pharmacology defined
- Pharmacology: antagonists and agonist drugs
- Pharmacology measurements
- Binding assay
- Potency assay
- Dose-response curves
- Receptor occupancy assay
- Efficacy assay

Pharmacokinetics and Pharmacodynamics

- Pharmacokinetics explained
- Measuring pharmacokinetics
- Pharmacokinetics: absorption
- Pharmacokinetics: metabolism
- Measuring pharmacodynamics
- Regulatory requirements
- GXP compliance
- Bioanalytical assay: small/large molecule drugs
- Validation timeline