

Drug Development Briefing

Drug Development Briefing delivers an overview of the discovery, development, and regulatory processes for bringing a new drug (large and small molecule) to market. Participants learn about the business and scientific decisions involved in moving a product forward from basic research into preclinical and clinical trials, as well as a detailed consideration of the regulatory requirements of clinical development. Post-approval commercial considerations and risk management are also discussed.

Drug Development Overview 9:00–10:00

- Success Metrics & Chances of Success
- Timelines & Costs
- Milestones
- Go/No Go Decisions
- Integrated & Global Development

Origin of New Drugs 10:00–10:50

- Plants, Animals & Laboratories
- Rational Drug Design & Targets
- Combinatorial Chemistry
- Alliances
- Start-Ups

Break 10:50–11:00

Selecting Drug Candidates 11:00–11:45

- Macro Commercial Input
- Market Dynamics
- Chemistry
- Drugability
- Early Toxicology
- Pharmacology
- ADME

Target Product Profile 11:45–12:15

- Draft Label
- Commercial Evaluation
- Exclusivity & Patents
- Waxman Hatch

Lunch 12:15–1:00

The Regulatory Process 1:00–1:45

- History of Regulation
- Initial New Drug Application (IND) & Clinical Trial Application (CTA)
- FDA, European Medicines Evaluation Agency (EMA) & International Conference on Harmonization (ICH)
- New Drug Application (NDA), Marketing Authorization Application (MAA) & Common Technical Document (CTD)
- Clinical Holds
- Quality Assurance
- Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) & Good Clinical Practices (GCP)

Drug Development Pre-IND 1:45–2:30

- Chemistry, Manufacturing & Controls (CMC)
- Characterization, Purity & Stability
- Formulation
- Preclinical

Break 2:30–2:45

Clinical Development 2:45–4:15

- Clinical Trial Considerations
- Design, End Points & Statistics
- Phase 1
- Phase 2a & 2b
- Phase 3a & 3b
- Phase 4
- Safety
- Pharmacogenomics
- Life Cycle Management
- Risk Management Plan

Q&A/Review 4:15–4:30