The FDA Drug Approval Process
**Course Description:** The training course will provide a general introduction to all aspects of the drug approval process. It will also cover the organisation and structure of the Food and Drug Administration, recent amendments to the FDA’s procedures designed to expedite the testing and approval of new medicines and other topics of current interest. **Course Objectives:**

- Structure and functions of the FDA
- Historical background
- General regulatory requirements
- Regulation of preclinical and clinical research
- New drug application process
- Biologics (including biosimilars)
- Generic drugs
- OTC drugs
- Special issues

**Who Should Attend?** This training course will be especially helpful for persons responsible for preparing the registration documents (INDs, NDAs, biologics licence applications, etc), regulatory affairs personnel, lawyers and others responsible for advising companies on strategies for developing new drugs. The seminar will emphasise issues of interest to innovative manufacturers, but will also deal with issues relating to generic drugs and over-the-counter drugs. **Course Content:**

- Drug definition (drugs versus cosmetics, foods, biologics and medical devices)
- Labelling rules
- Patient information requirements
- Good manufacturing practice regulations
- Establishment registration and product listing

*Regulation of pharmaceutical research* Preclinical research
• Good laboratory practice
• Guidelines for toxicity testing and special studies
• ICH guidelines

Clinical Research

• The investigational new drug (IND) application
  ○ Content
  ○ Procedure for FDA review
  ○ Clinical holds
• Good Clinical Practice
  ○ Responsibilities of sponsors and monitors
  ○ Responsibilities of investigators
  ○ Transfer of responsibilities to contract research organisations (CROs)
• Informed consent and institutional review boards (IRBs)
• FDA guidelines for clinical studies
• ICH guidelines
• Expanded access programs, including treatment INDs
• FDA enforcement programmes
  ○ Clinical site inspections
  ○ Disqualification of investigators
  ○ Other

The new drug application (NDA) process When an NDA is required Content of NDAs

• Common Technical Document

Electronic submissions Requirements for approval

• Safety
• Effectiveness
• Acceptance of foreign clinical data
• Manufacturing, chemistry and controls
• Labelling
• Other

Procedures for review of NDAs

• User fees
• PDUFA commitments
• Acceptance for filing
• 74-day letter
• Review priorities
- Divisional review
- Mid-cycle meetings
- Amendments to pending applications
- Advisory committees
- Action letters and approvals
- Dealing with a complete response letter
- Dispute resolution procedures
  - Ombudsman
  - Informal appeals
  - Administrative hearings and judicial review
- Accelerated approval, fast track and breakthrough status
- Preapproval inspections
- Review of initial promotional materials

**Phase 4 studies, REMs and other post-market requirements Supplemental NDAs**

- Labelling changes, new indications
- Changes-being-effected (CBE) supplements
- Manufacturing and formulation changes

**Annual reports Special issues Safety reporting**

- Preclinical studies
- Clinical studies
- Post-marketing safety reports
- Field alert reports and biological product deviation reports

**Biological products, including biosimilars**

- Abbreviated new drug applications (ANDAs)
- General requirements
- Bioequivalence issues
- Data exclusivity and patent linkage

**Over-the-counter drugs (including switches) Orphan drugs**

- Designation procedures
- Market exclusivity

**Incentives for Paediatric Studies Incentives for drugs to treat resistant microorganisms (GAIN Act) Drug imports and exports Freedom of Information Act Recent developments including 21st Century Cures proposals**