

## **BP804ET. PHARMACEUTICAL REGULATORY SCIENCE (Theory)**

**45Hours**

### **Course content:**

#### **Unit-I**

**10 Hours**

##### **New Drug Discovery and development**

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

#### **Unit-II**

**10 Hours**

##### **Regulatory Approval Process**

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

##### **Regulatory authorities and agencies**

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications).

#### **Unit-III**

**10 Hours**

##### **Registration of Indian drug product in overseas market**

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.

#### **Unit-IV**

**08 Hours**

##### **Clinical trials**

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials.

#### **Unit-V**

**07 Hours**

##### **Regulatory Concepts**

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.