DEPARTMENT OF DRUG REGULATORY AFFAIRS

Scope and Area of Research

Bharati Vidyapeeth Deemed University Poona College of Pharmacy is first in the state of Maharashtra to introduce post-graduation in Drug Regulatory Affairs (DRA). Department of DRA aims to provide a comprehensive education and skills in the important aspects of Regulatory Compliance in the pharmaceutical industry as well as clinical testing of drugs. Regulation approvals are the major step that drives the R &D efforts of the industry to the market where the timely marketing approvals from a particular country to dominate the current global competitiveness. Some of such major international agencies include USFDA-US, EDQM-Europe, TGA-Australia, MHRA-UK and TPD-Canada, etc.

During the course of studies, students have to present specific regulatory issues for a drug or device along with justification and strategy. This help students to acquire up-to-date knowledge, scientific and legal writing, analytic and reasoning skills as well as effective communication.

After completing the M. Pharm. in Drug Regulatory Affairs, the students will be able:

- To understand regulatory concepts, write and review regulatory documents.
- To optimize and maintain regulatory procedures,
- To develop documentation / research writing expertise,
- To update knowledge with new legislation in a constantly changing environment,
- To know the regulatory process in drug development, formulations, novel drug delivery systems and devices.
- To understand the system for the submission of DMF, e-CTD, Dossier, etc.
- To understand the marketing authorization, regulatory compliance systems of different countries
- To do the preparation for audits and inspections,
- To promote to higher level in RA career ladder and
- To become an RA professional in Totality.

The DRA department is more focused towards current regulatory needs for development and growth of pharmaceutical sector with continuous input on advanced research in the following areas:

- Regulatory affairs for clinical trials
- Regulatory requirements of pharmaceutical products
- Emerging Concept in Regulatory Affairs
- GMP & Validation
- Intellectual Property Rights & Bioethics
- International Regulatory Systems
- National and International Drug Approvals & Bio-ethics
- National Regulatory Affairs
- Clinical Trials & Healthcare Policies
- Modern Analytical Techniques
- Pharmaceutical Biostatistics & Computer Applications
- Pharmaceutical companies and regulatory guidelines
- Pharmaceutical ethics
- Quality Assurance GLP
- Quality assurance in regulatory affairs
- Research Methodology & Pharmacological Screening