MANIPAL
ACADEMY of HIGHER EDUCATION
*(Deemed to be University under Section 3 of the UGC Act, 1956)*

# Certificate Course on Generic Drug Regulations

**Course Duration: 15 hours**

Timings 9.30 am – 4.00 pm

**Dates:**

Following Saturdays

August 7th, August 14th and 28th 2021

**Credits: One**

**Course Fee**

₹ 4,000.00

**Number of Seats: 15**

**Eligibility**

- Faculty – Beginners
- Research Scholars
- Final Year Undergraduate & Postgraduate students

**Registration:**

https://sis.manipal.edu/CertificateCourses.aspx.

**Code – C61**

**Last Date: August 1, 2021**

## Organised by

Centre for Excellence in Drug Regulatory Affairs
Manipal College of Pharmaceutical Sciences, MAHE Manipal

## About the Course

Drugs are the most regulated commodity. Every stage of life cycle of the drugs is governed by regulations and often they are country specific. India supplies generic drugs to more than 80 countries in the world. It is known as “Pharmacy of the world” for the same reasons. Indian Pharmaceutical industry employs large number of non pharmacy professionals who should know basic regulations governing the drug development, registration and marketing. This course aims to create that basic understanding in the new professionals who are planning to have a professional career in pharmaceutical, biotechnology and other related fields.

## Scope

The course aims at creating an understanding of regulatory submission requirements for a generic drug especially to USFDA.

## Course Objective

1. Understanding the stages of regulatory control.
2. Regulatory forms and procedures of USFDA.
3. Hands-on training in Pharma Ready® an eCTD software.
4. Detailed content and requirements of USFDA form.

## Course Outline

Syllabus

- Birth of generic market in United Sates of America.
- Contribution of Indian drug manufacturers.
- Registration of a drug product in USA.
- Research to be done, data required for registration.
- Forms to be filled and the process.
- Contents of various forms.
- Electronic submission.
- Hands on experience of the e-submission.
- Hatch Waxman act and its impact on India’s drug manufacturing landscape.
- Content and format of Abbreviated New Drug Application
- eCTD hands-on training with simulated data
- Bioequivalence Regulations
- Post approval changes