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

INSPIRED BY LIFE

Certificate Course on Generic Drug Regulations

Course Duration: 15 hours
Timings 9.30 am – 4.00 pm
Dates:
Following Saturdays
July 27, August 3rd and 10th
2019

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: July 15, 2019

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

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

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

- 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.

Syllabus

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