Maharashtra State Branch

Bombay College of Pharmacy
Estd 1957 Autonomous

Pharma Literati

Jointly organizes 2-months online certificate course on
'Fundamentals of Global Drug Regulatory Affairs'

About the course

This course is designed considering the need of Global Pharmaceutical industry and the changing regulatory requirements in various domains like specialty products, herbal products, drug device combinations, biological.

The course is suited for students and industry professionals aiming career in drug regulatory affairs. The course is useful for professionals in formulation development, analytical development, drug discovery, intellectual property rights, clinical research, quality assurance, production, project management, portfolio management and business development.

Who should enroll for the course

- Undergraduate / PG students in Pharmacy, Life Sciences
- Industry professionals willing to make careers in Regulatory affairs
- Researchers Faculty members

Course highlights

- Live sessions on weekend via Zoom.
- Designed by industry experts.
- Faculty from life sciences industry.
- Session on interlinking of Pharma RnD, Regulatory Affairs and Intellectual Property Rights.
- Live interaction with industry experts on careers in Regulatory affairs.
- Whatsapp support with industry faculties throughout the course.
- Joint certificate from Bombay College of Pharmacy and Pharma Literati.

Course Methodology

- Live lectures on every Saturday and Sunday between 4 to 5.30 pm via Zoom platform.
- Recorded sessions to be provided till examination.
- Reading materials
- Examination based on the syllabus in MCQ format.
- Certificate after clearing the examination.

Registration link - https://lnkd.in/eh4EDXS3 [Register before 15th May 2022] or Scan QR code

Fees [Inclusive of GST] - 5000 Rs for students, researchers and academicians. 7000 Rs for industry professionals and Pharma Entrepreneurs.

For group discounts, write an email to pharmaliterati@gmail.com or call Mr. Rushabh on 09820900762

COURSE CO-ORDINATORS **Dr. Clara Fernandes** clara.fernandes@bcp.edu.in; **Mr. Rushabh Sheregar** pharmaliterati@gmail.com

Course commencement - 21st May 2022; Course sessions - Every Saturday and Sunday 4 to 5.30 pm; Course examination - 17th July 2022

Maharashtra State Branch

Bombay College of Pharmacy
Estd 1957 Autonomous

Pharma Literati

Jointly organizes 2-months online certificate course on

‘Fundamentals of Global Drug Regulatory Affairs’ - Course contents

Module 1 - Pharma Industry overview	**Module 2 -** Overview of Drug Regulatory Affairs	**Module 3 -** Good Manufacturing Practices	**Moule 4 -** CTD, eCTD, ACTD	**Module 5 -** Marketing Authorization procedures	**Module 6 -** Para I, II, III, IV Certifications in US	**Module 7 -** Regulatory for herbal, medical devices and biologics
1. Brands v/s Generics 2. Drug discovery process 3. Market dynamics 4. Regulated v/s Non-regulated markets 5. Complex generics	1. Terms in Regulatory affairs 2. Regulatory agencies 3. DRA v/s IPR 4. Interlinking of RND, regulatory affairs and IPR 5. ICH	1. Data integrity 2. Quality management systems 3. Validation 4. Risk management	1. Common technical document 2. Electronic common technical document 3. ASEAN Common Technical Dossier	1. US pathways including NDA, ANDA, sNDA 2. European pathways including National authorization; Centralized; Decentralized; MRP	1.Orange book 2. US live case sdudies with respect to P-IV certifications 3. Assignment 4. Data exclusivity 5. Orphan drugs 6. 180 days exclusivity	1. Purple book 2. Drug master file 3. Biological licensing application 4. Biosimilars 5. Drug - device combinations