



**PROGRAM  
CO-DIRECTOR:**

**Mr. Mrinmoy Roy**  
Assistant Professor  
IIHMR Bangalore



**PROGRAM  
DIRECTOR:**

**Dr. Subodh S Satheesh**  
Assistant Professor  
IIHMR Bangalore

**Management Development Program on**

# Regulatory affairs in PHARMA AND MEDICAL DEVICES



**Date**  
August 2022



**Duration**  
10 Days



**Fees**  
₹ 5500

## Course overview:

Pharmaceutical and Medical device companies rely on the regulatory affairs department for ensuring that their products comply with the laws, guidelines, and other regulations in the industry. The regulatory affairs department of an organization makes it certain that the products are developed, manufactured and regulated at desired level of quality safety and efficacy. They set up strategies and uses their scientific and management skills to achieve a goal of quality assurance throughout the lifecycle of a medicinal product. The RA team ensure meeting the standards of filing and submissions along with contributions towards to quality assurance and clinical affairs. Over the years the standards of regulatory affairs of pharmaceutical and medicinal products had a rapid advancement with the transitions in technology and pharmacovigilance. This specialization will provide you an overview of Regulatory affairs in Pharmaceutical and medicinal devices.

## Course outline

- ✦ Basic Fundamentals of Regulatory Affairs
- ✦ Introduction to Regulatory Bodies
- ✦ Introduction to Quality Standards for Regulatory Compliance
- ✦ Marketing, import and export guidelines on Pharma and healthcare products
- ✦ Drug registration Procedures/ Channels in Europe
- ✦ Drug registration Procedures in India
- ✦ Compliance guidelines

## Objective:



To develop a understanding on concepts of regulatory affairs



To provide sound knowledge on regulatory strategies and approval around the world



To provide thorough understanding of various regulatory agencies



To understand the essential qualities of a RA professional



To encourage learning on marketing guidelines of different products

## Eligibility Criteria:

- ☑ Graduates and Post-Graduates in Pharmacy, Microbiology, Biotechnology or any other discipline in science
- ☑ Professionals in Pharmaceutical sector and life sciences
- ☑ Employees in Pharmaceutical Industries and Pharma entrepreneurs



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+91-9742722000

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