





# REGULATORY AFFAIRS

UNDER
LOAC
SIPS 2022
2023

ADD ON / VALUE ADDED CERTIFICATE COURSES

Duration of course 21st Jan 2023- 18th Feb 2023

Our Program structures offers students the flexibility to enhance their academic experience by enrolling in Two Courses per academic year, with option to take one course per semester. This approach allows students to delve deeper into their areas of interest, diversify their skill set and tailor their learning journey to align with their career aspirations

# **COURSE OBJECTIVES**

#### Understanding Regulatory Landscape

Develop a comprehensive understanding of national and international regulatory frameworks governing the pharmaceutical and healthcare industries.

# Regulatory Compliance

Learn to interpret and ensure compliance with regulatory requirements related to drug development, manufacturing, and marketing.

#### Submission and Documentation Skills

Acquire skills in preparing and submitting regulatory documents, including applications for product approval, labeling, and safety reporting.

## » Interaction with Regulatory Agencies

Familiarize yourself with the processes and protocols for interacting with regulatory agencies, including responding to inquiries and participating in regulatory inspections.

# **COURSE OUTCOMES**

## » Comprehensive Regulatory Knowledge

Demonstrate a comprehensive understanding of the regulatory landscape, ensuring adherence to relevant laws and standards.

#### Ensured Regulatory Compliance

Ensure compliance with regulatory requirements throughout the drug development lifecycle, minimizing risks and ensuring product quality and safety.

#### Effective Document Preparation

Prepare and submit regulatory documents accurately and efficiently, facilitating the approval and marketing of pharmaceutical products.

#### Positive Regulatory Interactions

Engage effectively with regulatory agencies, fostering positive interactions and demonstrating a commitment to regulatory compliance.

# **CHIEF PATRON**

Hon'ble Dr. Sandip N. Jha

Chairman

Sandip Foundation

## **PATRON**

Prof. Pramod Karole Academic Facilitator Sandip Foundation

#### CONVENER

**Dr. Laxmikant B. Borse**Principal

SIPS, Nashik

**COORDINATOR & REGISTRATION DETAILS** 

**Dr. Swati G. Talele:** 9850165808