

# 4th Certificate Course on PHARMACEUTICAL REGULATORY AFFAIRS

Organized by

**K. B. Institute of Pharmaceutical  
Education and Research**

Approved by

**Kadi Sarva Vishwavidyalaya**



**22nd Jan - 05th Feb, 2026**



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SECTOR 23,  
GANDHINAGAR,  
GUJARAT, INDIA

# About

## Kadi Sarva Vishwavidyalaya (KSV)

KSV is a university established vide Gujarat State Government Act 21, 2007 in May 2007. The university has been setup by Sarva Vidyalaya Kelavani Mandal (SVKM); a trust with more than 100 years of philanthropic existence. The trust provides need-based education by developing courses of contemporary relevance. KSV is a university of excellence promoting research based activities which would foster higher economic growth

## K. B. Institute of Pharmaceutical Education and Research (KBIPER)

**Vision:** The institute intends to be the prominent public research and teaching institute in the field of pharmacy, linking the people of Gujarat to the nation and the world.

**Mission:** Through the scholarly pursuits of teaching, research and service, KBIPER is dedicated to create pharmacy professionals committed to lifelong learning, fostering excellence and innovations in research, developing and participating in professional practice and community outreach.

Established in 1995, KBIPER is the first self-financed pharmacy institute in the state and a constituent college of Kadi Sarva Vishwavidyalaya (KSV). The institute offers B.Pharm., M.Pharm., Pharm.D., Pharm.D. (Post Baccalaureate), and Ph.D. programs in Pharmaceutical Sciences, and was the first in Gujarat to introduce the Pharm.D. program in 2009–2010.

The institute has established the first Drug Information Centre in Gujarat. Since its inception, the institute has shown remarkable progress in academics, research, and social outreach.

The institute's credible and glorious journey year after year is reflected through accreditations by multiple agencies, along with its NIRF and GSIRF rankings. Its well-equipped research laboratories, animal house, ethics committees, medicinal garden, museum, and strong alumni network further strengthen its academic and research excellence.

# Learning Objectives

- Concepts & processes involved in drug regulatory affairs
- Applicable regulatory requirements for Artificial Intelligence
- Global and Domestic regulatory frame work
- Global medical device regulations
- Knowledge & skills required to start career in DRA domain
- Herbals, biologics, nutraceuticals & clinical research

## Who can attend?

UG, PG and Research Students,  
Academicians,  
Pharmaceutical Industry Personnel

## Course Highlights

**MAX CREDITS: 2 Credits**

Timings: 20 hours Theory (Online)  
12 hours Practical (Offline)

(Including industrial visit & hands-on training of  
eCTD software)

## Course Duration

2 WEEKS :

TOTAL EFFORTS: 32 HRS

## Assessment

Online Objective Exam at the end of the course

Certificate of completion will be awarded to  
the participants securing minimum 50% marks



## Registration Details

**Registration Fees:** 500 INR

**Last Date for Registration:** 19th January 2026

**Intake:** 100 (First-come, first-served basis)

**Registration Link and QR code:**

<https://forms.gle/SHC64vM2VJnDT8gb6>

# Eminent Speakers

## **Ms. Zuki Patel**

Faculty, KBIPER

Introduction to Regulatory Affairs

## **Mr. Bhavik Joshi**

Neocubes Pharma

Business Development

## **Ms. Seema Dutt**

Regulatory Solutions India

MD regulations

## **Mr. Dhaval Sheth**

Neocubes Pharma

AI in Pharma regulations

## **Mr. Sanjay Modi**

Zydus Lifesciences Limited

ANDA Review Pathway

## **Dr. Ranju Nijhawan**

Zydus Lifesciences Limited

Pre-ANDA Communications

## **Dr. Devang Patel**

Zydus Lifesciences Limited

Pharmacovigilance Landscape and

Global Perspective

## **Mr. Stavan Dave**

Product Life Group

AI in CMC and regulatory affairs

FDA meetings

## **Mr. Dhamesh Kheni**

Validus Lifesciences Pvt. Ltd

Current regulations of Nutraceuticals

## **Mr. Meghal Mistry**

Zydus Lifesciences Limited

Biosimilar Portfolio

## **Mr. Varun Doshi**

Stivaph Healthcare Pvt. Ltd.

Regulatory pathway for EU market

## **Mr. Chetan Shingala**

Zydus Lifesciences Limited

Data Integrity

## **Mr. Darshan Doshi**

Zydus Lifesciences Limited

US Post Approval Lifecycle Management

## **Ms. Dipal Dave**

Zydus Lifesciences Limited

BCS based biowaiver

## **Mr. Devang Jani**

APDM Pharmaceuticals

Stability testing of pharmaceutical

products

## **Mr. Rohit Patel**

Zydus Lifesciences Limited

ANDA Submissions —

Content and Format

## **Ms. Jill Vaidhya**

Baxter Pharmaceuticals India

Private Limited

Audit Inspection process in regulatory

## **Dr. Bharat Patel**

Zydus Lifesciences Limited

Approaches for faster generic

approvals and marketing exclusivity

## **Dr. Nimisha Patel**

CBCC Global Research

ICH Clinical Guidelines

## **Mr. Ashish Rai**

Cliantha Research Limited

Clinical Trial Regulations

## Patrons

**Shri Vallabhbhai M. Patel**  
(Chairman - Sarva Vidyalaya Kelvani Mandal  
President - Kadi Sarva Vishwavidyalaya )

**Prof. Gargi Rajpara**  
Director In-Charge, Kadi Sarva Vishwavidyalaya

## Organizing Committee

**Dr. Divayang Dave**  
Course Director

**Dr. Maitreyi Zaveri**  
Course coordinator

**Dr. Niranjan Kanaki:** Co-cordinator  
Venue management & eCTD software training

**Ms. Zuki Patel**  
Event coordination with resource person

**Dr. Vinit Movaliya**  
Finance, Printing & Industrial Visit

**Dr. Bhavita Dhru**  
Registration

**eCTD Training Partner**  
Isazi Pharma and Techno Consultancy Pvt. Ltd

**Industry Visit Partner**  
Aum Research Labs Pvt. Ltd.