

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. Niranjana Kanaki: Co-coordinator

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.