SVKM'S NMIMS Deemed to be UNIVERSITY

SHOBHABEN PRATAPBHAI PATEL SCHOOL OF PHARMACY & TECHNOLOGY MANAGEMENT

SVKM's NMIMS SPPSPTM

nirf RANKED 10TH 2024

ONE WEEK SUMMER SCHOOL 2025

Regulatory Approaches in Enhancing Pharmaceutical Development, eCTD and Quality Assurance

1st to 5th July 2025

Organised by

Department of Regulatory Affairs and Department of Quality Assurance

Techniques covered

- QA Systems & Compliance
- Validation & Audit Prep
- Global RA & Submissions
- RegTech & Innovation
- Career Skills & Assessment

Eligibility

Any passionate learner is eligible to participate, preferably

- B.Pharm, M.Pharm Students
- Phd Research Scholars
- Faculty, Industry Professionals

Committee

Convener Dr. Jagannath Sahoo, Dean, SPPSPTM

Workshop Coordinators

Dr. Khushwant Yadav
Dept of Regulatory Affairs

Dr. Sanjay Sharma
Dept QualityAssurance

Objectives

- Strengthen Foundations in Regulatory Affairs by exploring global regulatory frameworks (ICH, US FDA, EMA), regional submission requirements, regulatory strategy development, and lifecycle management of medicinal products.
- Develop Practical Skills in Quality Assurance through hands-on workshops covering validation strategies, quality risk management, CAPA, data integrity (ALCOA+), and audit preparedness.
- Foster Regulatory Affairs Career Readiness by submission tools.

Registration

Online RegistrationProcess

- Registration Fee:

Faculty / Students -Rs. 2000/-
Students (NMIMS) -Rs. 1500/-

- Working lunch included on all the days
- Fill the below registration form

https://forms.gle/8faSoaevq1bhJZgG9

Limited 45seats(On a first come, first serve basis)

- Last Date to Register: 20th June2025

Venue: SPPSPTM, SVKM's NMIMS Deemed to be University, V.L. Mehta Road, Vile Parle (W), Mumbai-400056

For any queries, please contact: Workshop Facilitators
shankar.kurbet@nmims.edu, vibhasingh773@gmail.com or
dhrruvshah08@gmail.com

DAY-1

- Inauguration & Welcome Address
- Advanced Quality Systems & Global Expectations
- Quality Risk Management in Manufacturing
- Discussion
- Lunch Break
- Data Integrity & ALCOA+ in Digital Environments
- Supplier Qualification & Audit Strategy
- Q & A Session

DAY-2

- Process Validation: Beyond the Basics and IPR
- Discussion
- CAPA Management: From Investigation to Execution Change Control & Quality Metrics
- Q & A Session

DAY-3

- Introduction to regulatory affairs, AI in regulatory affairs and Significance of QbD
- Analytical Method Validation and related ICH Guidelines
- Regulatory Framework: USFDA, EMA, CDSCO Common Deficiencies in Regulatory Submissions, Audit Readiness
- Q & A Session

DAY-4

- eCTD Software Introduction
- Discussion
- eCTD Demo
- Q & A Session

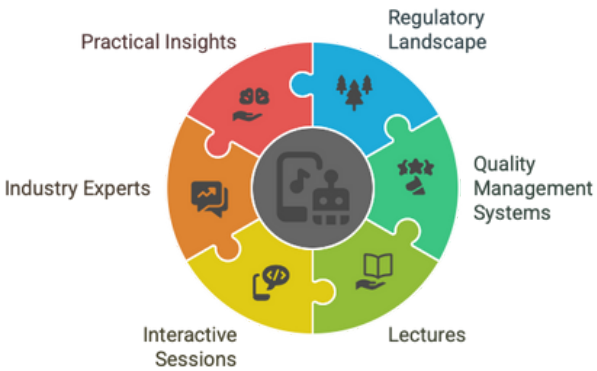
DAY-5

- Group Activity: Mock Dossier Submission or Audit Readiness
- Q & A Session
- Quiz/Knowledge Challenge
- Group Presentations & Feedback
- Valedictory Ceremony, Vote of Thanks

Registration

Name of the A/C Holder:	SVKM'S NMIMS
Bank Name:	Kotak Mahindra Bank
	JUHU -Vile Parle West
NEFT IFSC Code:	KKBK0000661
Account No:	2311578254
Type of Account:	Current
MICR Code:	400485022
Swift Code:	KKBKINBB

Enhancing Professional Development in Regulatory Affairs



For any queries, please contact: Workshop Coordinators
Khushwant.yadav@nmims.edu or Sanjay.Sharma@nmims.edu