Value Added Course On

Analytical Process Validation: Principles, Practices and Regulatory Compliances (PHV-E-10)

30 May 2026 - 17 June 2026

About the Course

Process Validation: Principles, Practices, and Regulatory Compliances is a course typically offered in pharmaceutical, biotechnology, or life sciences training programs. It focuses on ensuring that manufacturing processes produce consistent, high-quality products that meet predefined specifications. This course provides comprehensive training on the concepts, methodologies, and regulatory expectations surrounding process validation in industries such as pharmaceuticals, medical devices, and biotechnology.

Throughout the value-added course, participants will gain a comprehensive understanding of process validation, including its definitions, scope, and significance in pharmaceutical and biopharmaceutical manufacturing. Learn the principles and stages of process validation Process Design, Process Qualification, and Continued Process Verification as outlined by regulatory authorities. Develop the skills to apply industry best practices for planning, executing, and documenting process validation activities. Learn how to prepare for audits and inspections by ensuring that validation documentation and practices meet regulatory standards. Equip learners with tools and techniques for process monitoring, deviation handling, CAPA (Corrective and Preventive Actions), and lifecycle management of validated processes.

This is an online course divided into five modules. Lectures will be conducted through Integral Learning Initiative - Learning Management System (ILI-LMS) / Google meet. *Upon successful completion of the course, each candidate shall receive a certificate.*

Key USPs

- Provides deep insight into **GMP and cGMP expectations** for process validation.
- Prepares participants to face **regulatory inspections confidently** with validation-ready documentation and evidence.
- Covers **global regulatory guidelines.**
- Emphasizes **practical approaches** to process design, qualification, and continued process verification.
- Suitable for professionals in **Quality Assurance, Manufacturing, R & D, Regulatory Affairs**, and **Engineering**.
- Bridges gaps between departments for better compliance and product consistency.
- Identifies and mitigates risk in the manufacturing process.

Course Objective

- Understand Fundamental Concepts
- Recognize Regulatory Requirements
- Differentiate Validation Stages
- Apply Validation Methodologies
- Analyze Critical Process Parameters (CPPs) and Quality Attributes (CQAs)
- Interpret Validation Data
- Document Validation Activities
- Ensure Lifecycle Approach

Learning Outcomes (PO-1, PO-2, PO-3, PO-4, PO-5, PO-10, PO-11)

After the successful course completion, participants will attain:

- Understand and apply validation concepts in regulated environments.
- Plan and execute validation protocols.
- Interpret and implement regulatory guidelines.
- Ensure compliance through effective documentation and audit preparedness.

Course Coordinators

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Dr. Shom Prakash Kushwaha, Associate Professor, Department of Pharmacy, Integral University, Lucknow. Email: shompk@iul.ac.in Mobile: +91-6306088175.

Name of Instructors

1. **Prof. Kuldeep Singh,** Professor, Faculty of Pharmacy, Integral University, Lucknow
2. **Dr. Arun Kumar,** Associate Professor, Faculty of Pharmacy, Integral University, Lucknow
3. **Dr. Shom Prakash Kushwaha,** Associate Professor, Faculty of Pharmacy, Integral University, Lucknow
4. **Dr. Irfan Khan,** Associate Professor, Faculty of Pharmacy, Integral University, Lucknow
5. **Dr. Muhammad Arif,** Associate Professor, Faculty of Pharmacy, Integral University, Lucknow
6. **Dr. Ahsan Ahmad Khan,** Associate Professor, Faculty of Pharmacy, Integral University, Lucknow
7. **Dr. Reshu Tiwari,** Assistant Professor, Faculty of Pharmacy, Integral University, Lucknow
8. **Dr. Mohammad Shariq,** Assistant Professor, Faculty of Pharmacy, Integral University, Lucknow
9. **Mr. Ranjan Kumar,** Assistant Professor, Faculty of Pharmacy, Integral University, Lucknow
10. **Dr. Suvaiv,** Lecturer, Faculty of Pharmacy, Integral University, Lucknow

Eligible candidates

- Faculty Members
- Technical Persons involved In Pharmaceutical Analysis and Pharmaceutical Research
- Research Scholars
- Students

Eligible Departments

- ✓ Pharmacy
- ✓ IIMSR
- ✓ Bioscience
- ✓ Bioengineering

How to Apply

Registration Link: https://forms.gle/F3iSgoGiAW3Jv3Xb7

Last Date of Registration: May 28, 2026

Course Fee: Nil

Maximum number of Participants: 50

Course Details

Course Platform:
Online: Integral Learning Initiative - Learning Management System (ILI-LMS) and Google meet.
Course duration: 30 Hours

Course commencement: May 30, 2026

End of course: June 17, 2026

Note: The timings of the lectures may be altered by the course coordinator as per requirement. The rescheduled timing will be informed well in advance to all the participants.

Course Description

CONTACT HOUR	METHODOLOGY	CONTENTS
MODULE I: INTRODUCTION TO ANALYTICAL PROCESS VALIDATION		
1 30/05/2026 5:00 PM – 6:00 PM	Theoretical	Overview of analytical method development vs. validation
2 30/05/2026 6:30 PM – 7:30 PM	Theoretical	Purpose, scope and benefits of validation
3 01/06/2026 5:00 PM – 6:00 PM	Theoretical	Types: Prospectives, Concurrent, Retrospective
4 01/06/2026 6:30 PM – 7:30 PM	Theoretical	Validation vs. Qualification
5 02/06/2026 5:00 PM – 6:00 PM	Group discussion 1	
6 02/06/2026 6:30 PM – 7:30 PM	Module Assessment	Quiz 1

MODULE II: REGULATORY GUIDELINES AND COMPLIANCE

7 03/06/2026 5:00 PM – 6:00 PM	Theoretical	ICH Q2(R2), Q8, Q9, Q10, Q14 (analytical procedure development)
8 03/06/2026 6:30 PM – 7:30 PM	Theoretical	USFDA, EMA, WHO guidelines
9 04/06/2026 5:00 PM – 6:00 PM	Theoretical	Regulatory expectations in method validation
10 04/06/2026 6:30 PM – 7:30 PM	Theoretical	GLP & GMP considerations
11 05/06/2026 5:00 PM – 6:00 PM	Group discussion 2	
12 05/06/2026 6:30 PM – 7:30 PM	Module Assessment	Quiz 2

MODULE III: UV-VISIBLE SPECTROSCOPY

13 06/06/2026 5:00 PM – 6:00 PM	Theoretical	Principle and instrumentation overview
14 06/06/2026 6:30 PM – 7:30 PM	Theoretical	Validation of UV-Visible methods ○ Linearity, Absorbance range, λmax identification ○ Interference study and robustness
15 08/06/2026 5:00 PM – 6:00 PM	Theoretical	Applications in assay and impurity testing
16 08/06/2026 6:30 PM – 7:30 PM	Theoretical	Case Study: Validation of assay by UV-Vis
17 09/06/2026 5:00 PM – 6:00 PM	Group discussion 3	
18 09/06/2026 6:30 PM – 7:30 PM	Module Assessment	Quiz 3

MODULE IV: HPLC		
19 10/06/2026 5:00 PM – 6:00 PM	Theoretical	HPLC instrumentation: Detectors, columns, mobile phase
20 10/06/2026 6:30 PM – 7:30 PM	Theoretical	Validation of assay/dissolution/stability-indicating methods
21 11/06/2026 5:00 PM – 6:00 PM	Theoretical	SST: Resolution, tailing factor, theoretical plates
22 11/06/2026 6:30 PM – 7:30 PM	Theoretical	Example: HPLC validation for paracetamol assay
23 12/06/2026 5:00 PM – 6:00 PM	Group discussion 4	
24 12/06/2026 6:30 PM – 7:30 PM	Module Assessment	Quiz 4
MODULE V: IR SPECTROSCOPY		
25 13/06/2026 6:30 PM –7:30 PM	Theoretical	Introduction to IR Spectroscopy and its applications
26 15/06/2026 5:00 PM – 6:00 PM	Theoretical	Sample Handling
27 15/06/2026 6:30 PM – 7:30 PM	Theoretical	FTIR Spectrophotometer
28 16/06/2026 5:00 PM – 6:00 PM	Theoretical	IR Validation
29 16/06/2026 6:30 PM – 7:30 PM	Group discussion 5	
30 17/06/2026 5:00 PM – 6:00 PM	Module Assessment	Quiz 5