Title: “Diploma Course in Pharmaceutical Computer System Validation (PCSV) – Exploring and Fulfilling the Current Needs of Pharma Industry”

About Pharmaceutical Computer System Validation (PCSV)

This course is designed to explain PCSV principles and related best practices to regulate the key functions and guidelines of GAMP (Good Automated Manufacturing Practices) governed by ISPE (International Society for Pharmaceutical Engineering). Computer system validation (CSV) is necessary to meet regulatory requirements in industries such as pharmaceuticals, healthcare, finance, and others. Regulatory bodies, such as the FDA, often require validation to ensure the safety, efficacy, and reliability of computerized systems. The purpose of PCSV is to ensure the accuracy, reliability, and consistent intended performance of computerized systems, which are critical in environments subject to regulatory compliance, such as Life Sciences, Pharmaceuticals and Medical devices industries. PCSV includes a series of activities and lifecycle deliverables that demonstrate that a system has been developed and implemented in a controlled and validated environment. The lifecycle activities phases involved are Planning, Requirement and Design, Implementation, Testing and Operations.

Course Outcomes: On completion of the course it is expected that students will be able to:

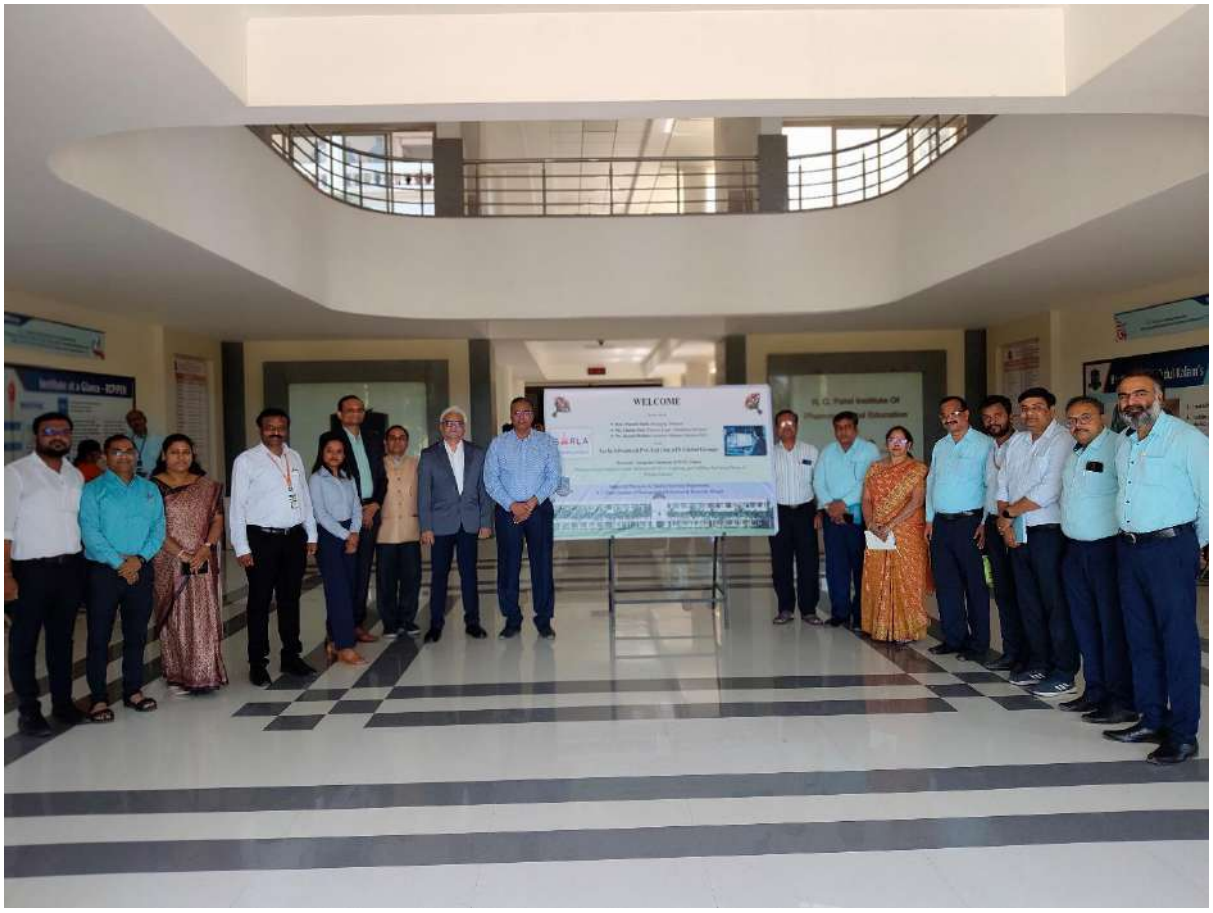
- Understands the provisions of 21 CFR Part 11.
- Categorize software and hardware according to GAMP.
- Understands different validation techniques.
- Understands the new Approach of CSV - Computer Software Assurance (CSA).

RCPIPER-RUSA Certificate Courses Committee –

Sr. No.	Name of Faculty	Position
1.	Dr. S. J. Surana	Chairman
2.	Dr. N. G. Haswani	Co-Chairman
3.	Dr. A. A. Shirkhedkar	Secretory
4.	Dr. S. S. Chalikwar	PCSV Co-Ordinator
5.	Mrs. S. D. Raysing	PCSV Co-Coordinator

The inaugural ceremony of (2024-2025) batch Diploma Course on Pharmaceutical Computer System Validation (PCSV)

The ceremony commenced with an introductory speech by Principal, Dr. S. J. Surana Sir. Key note address explaining the role of software's in atomization & current industry was shared by Mr. Manish Shah, Managing Director, Sarla ATS Global group., Mr. Chetan Patil, Practice Lead-Validation, Sarla ATS Global group., further emphasized the importance of computer system validation in pharmaceuticals. The speaker highlighted the evolving challenges and regulatory needs within the pharmaceutical industry. The Coordinator, Dr. S. S. Chalikwar, provided a comprehensive overview of the PCSV diploma course. Emphasis was placed on how the course would explore and address the current needs of the pharmaceutical industry in maintaining compliance with evolving regulatory standards and best practices. Job opportunities along with selection criteria in Sarla Advantech was explored by Ms. Jayanti Haldar.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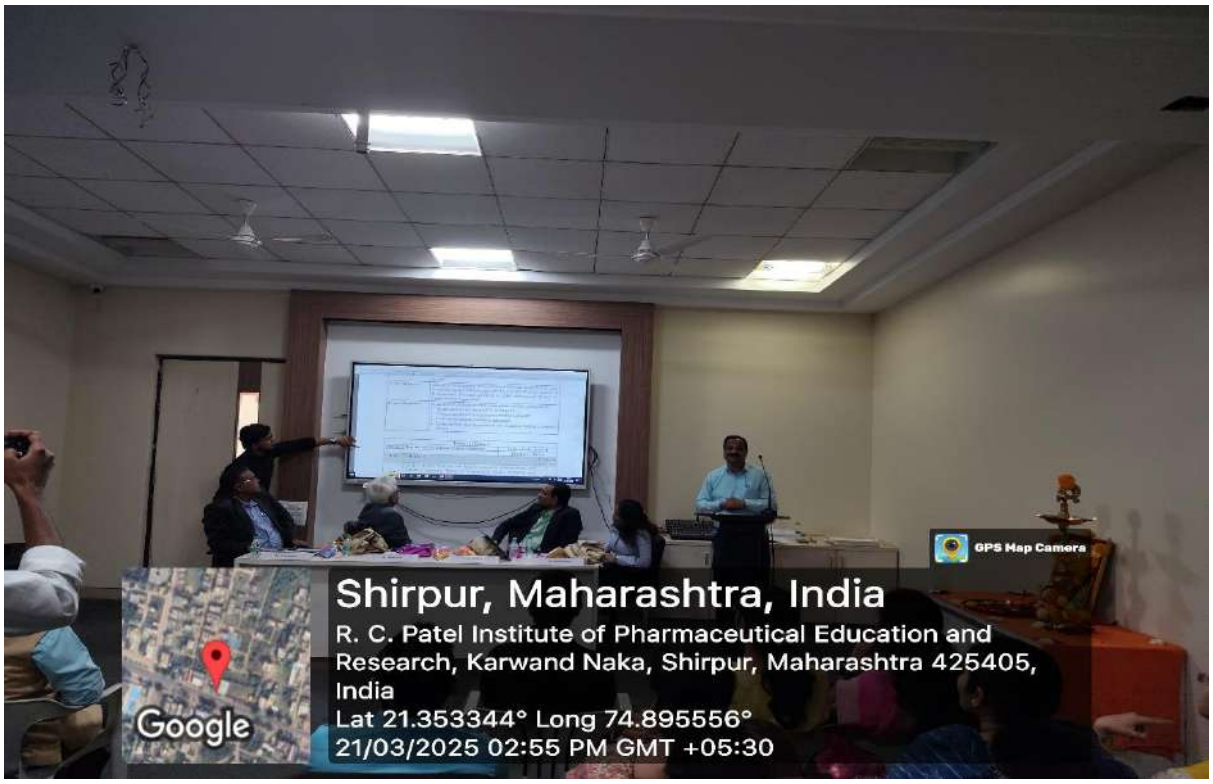
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Industry visit (Field experience)- along with practical completion of PCSV module course at Sarla Advantech Pvt. Ltd., Navi Mumbai.