The *Independent* Solution Provider for Smart Digital Transformation

Pharmaceutical Validation Services

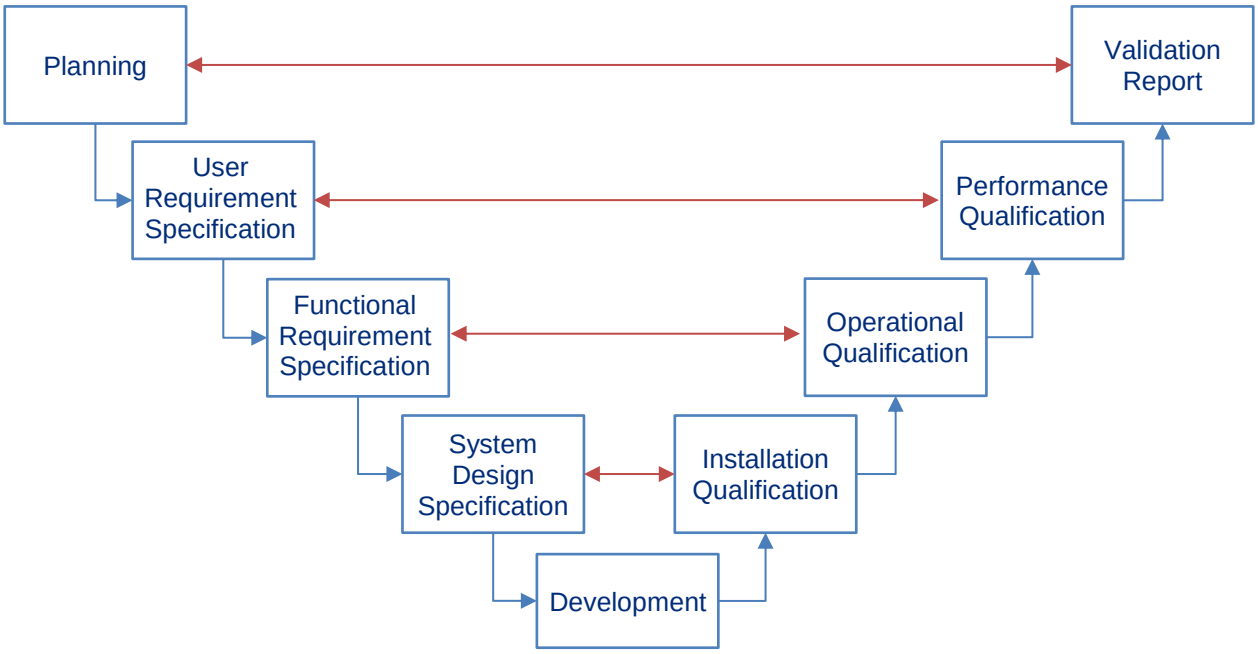
Sarla Advantech Pvt. Ltd. (part of ATS Global B.V., The Netherlands) provides comprehensive Pharmaceutical Validation services to empower organization for complying with GAMP 5 guidelines.

Our Computerized System Validation (CSV) offerings enable organizations to reduce the compliance risks associated with global manufacturing.

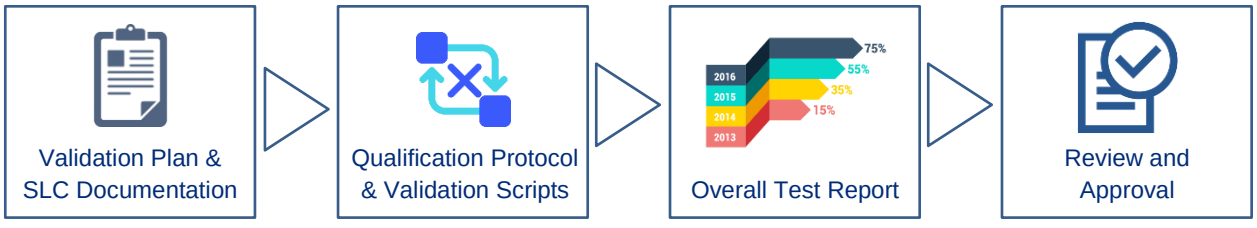
We leverage our 17+ years of experience in Industrial Automation and combine it with rich domain expertise in validation services for Pharmaceutical and Life Sciences industries. Our consultants command subject matter expertise in recommending solutions complying with 21 CFR Part 11, GAMP 5 and EU Annexure 11.

GAMP 5 V - Model Approach

We follow the proven and reliable “V” Model approach for regulatory compliance service offering.



Process for Creating Testing Documents



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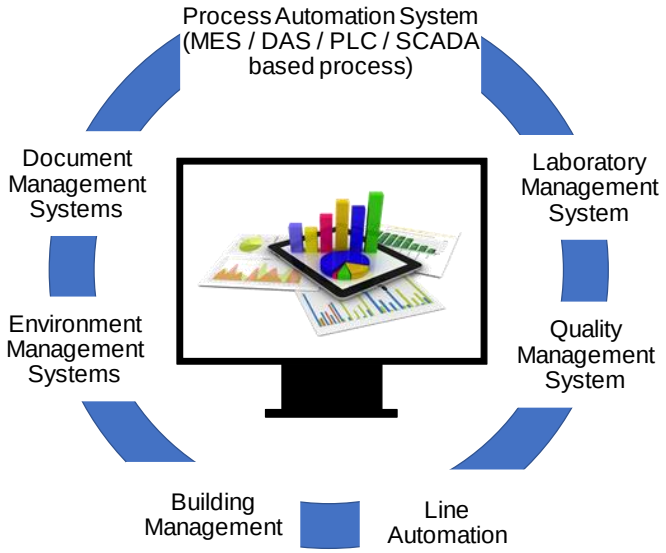
Software Validation Offerings

A robust documentation is the DNA of successful Pharmaceutical Validation project. If a validation process is not documented, it cannot be proved to have occurred.

Our CSV services are comprehensive business offerings driven by:

- Pragmatic and risk-free approach
- End-to-end knowledge of pharmaceutical business and operational processes
- Use of stringent norms, processes, check lists and procedures
- Validation of controlled development and implementation of computer systems



We ensure integrity, reliability, continuous availability of regulated business data, patient safety and enable quality-compliant production environment.

Helping you Comply with regulations | Assuring you about data integrity
Enhance Brand reputation | Save on cost of Quality

Our core expertise for Pharmaceutical Validation

Rich Process Knowledge

- Rich expertise in Integration of SCADA, MES, OPC, LIMS, etc.
- Ability to immediately address industrial automation challenges
- Diligent approach to avoid errors in validation

Domain Expertise

- Pharmaceutical process know-how as per regulatory guidelines
- Trained professionals on 21 CFR part 11, EU annexure 11, GAMP 5, GDP, cGMP guidelines
- Practical understanding of process risks

Operating Procedures

- Complete ownership of Standard Operating Procedures (SOPs)
- Well defined qualification templates and checklists
- Comprehensive validation master plan as per the compliance requirements

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