



## VALIDATION SERVICES

Computer System Validation is a integral part and perhaps the most critical aspect of regulatory requirement for fundamentally every process in the global health care industry.

At ICS, Validation services are a major part of the offering basket. We have one of the biggest team strength of Experienced Engineers. We provide our best quality services for Computer System Validation in accordance with Guidelines of Good Automated Manufacturing Practices (GAMP 5).

### 21 CFR PART 11

Life Sciences Industries are into manufacturing of Life Saving Drugs/Medicines and thus quality of the medicine is very critical. To ensure a continuous quality product, Manufacturers are more and more inclined to go for the Automated Process using Computers and other latest technologies. The enormous data generated is in electronic forms which is stored for a defined time period. The data generated and stored thus becomes of utmost importance for all the Manufacturers and the Regulatory authorities.

U.S. FDA specifically addresses the generation and Storage of Electronic Records and Signatures through the regulation named as 21 CFR Part 11.

At ICS, we ensure the implementation of 21 CFR Part 11 as a part of Validation activity and comply to the company's quality management system.



### GAMP 5

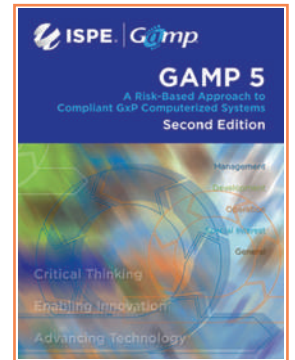
GAMP 5 aims to deliver a cost-effective framework of good practice to ensure that computerized systems are effective and of high quality, fit for intended use, and compliant with applicable regulations.

As per GAMP 5, the software or computerized systems are divided into the following 4 Categories:

Category 1  
Infrastructure and Tools Software

Category 3  
Standard System Components

Category 4  
Configured Components

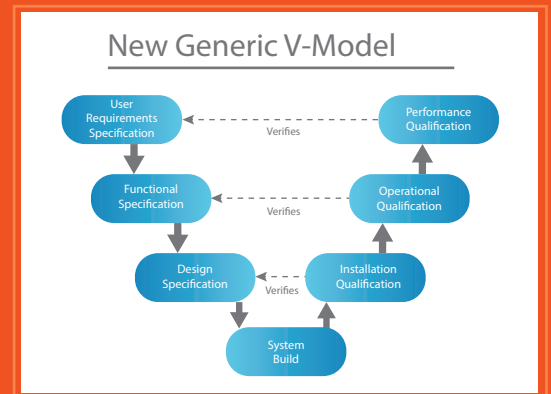


Category 5  
Custom Applications and Components

### V MODEL

GAMP 5 recommends the V-model technique, for carrying out the Validation of the Computer System.

The V-model is an SDLC model where execution of processes happens in a sequential manner in a V-shape. The left arm of the "V" represents the planning / specification phases such as User Requirements Specification, Functional Specification, Detailed Design Specification, and the right arm of the "V" represents the execution-validation phases such as Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) and both the arms converge at the Build and Unit Testing phases at the V-Point.



## OUR USP

- ✔ One of the largest experience team.
- ✔ Working With Big Pharma Major Client.
- ✔ Pan India Presence.
- ✔ Well Trained Team.
- ✔ Following Current Standards.
- ✔ Offering Quality at Reasonable Price.

## OUR SERVICES IN VALIDATION

We offer Validation services as per the regulatory compliances & requirements in Life Sciences industry.

- ✔ PLC/HMI/IPC/ SCADA Validation
- ✔ Laboratory systems Validation
- ✔ IT-Server system Validation
- ✔ Web based Application Validation
- ✔ QMS Application Validation
- ✔ SAP, ERP Validation
- ✔ Standalone system Validation
- ✔ GAP Assessments/Quality Risk Assessments
- ✔ 21 CFR/EU Annex 11 Compliance checklist
- ✔ Equipment Qualification
- ✔ Audit Support
- ✔ SME (Subject matter expert services)

## VALIDATION DELIVERABLES

Some deliverables of validation (Not Limited to)

- ✔ IRA/GxP Assessment
- ✔ Validation Plan
- ✔ User Requirements Specification (URS)
- ✔ Functional Specification (FS)
- ✔ Design Specification (DS)
- ✔ Installation Qualification Tests (IQ)
- ✔ Operational Qualification (OQ)
- ✔ Performance Qualification (PQ)
- ✔ Requirement Traceability matrix (RTM)
- ✔ Reporting (VSR)



## LOCATION / EMAIL

**Head Office**  
33 A Sinhasa IT Park Behind Jagatguru Dattatreya Collage of Tech.  
Opp. Delhi International School, Dhar Road, Indore, MP 453112  
✉ [sales.indore@ics-india.co.in](mailto:sales.indore@ics-india.co.in)

**Chandigarh Office**  
Space No: 223, 2nd Floor, VIP Central, VIP Road, Zirakpur, District:  
SAS Nagar Mohali, Punjab (India)-140603  
✉ [raman.pandita@ics-india.co.in](mailto:raman.pandita@ics-india.co.in)

**Hyderabad Office**  
Cabin: EB-3, Unit 104, 1st floor, Manjeera Trinity Corporate Building, KPHB Hyderabad, Telangana (India)-500072  
✉ [sales.hyderabad@ics-india.co.in](mailto:sales.hyderabad@ics-india.co.in)

**Vadodara Office**  
SF-209, S9 Square, Opp. Lotus Aura, Sama-Savli Road, Vadodara, Gujarat (India)-390008  
✉ [sales.gujarat@ics-india.co.in](mailto:sales.gujarat@ics-india.co.in)

**Mumbai Office**  
Resident Engineer  
✉ [sales.maharashtra@ics-india.co.in](mailto:sales.maharashtra@ics-india.co.in)



Automation

Instrumentation

Electricals

Engineering Services