



VEDANT TECH SERVICES

AN ISO 9001:2015 Certified company

OUR SERVICES:

Computerized System Validation and Automation Solution Provide

❖ Computer System Validation

Vedant Tech Services – Excellence in Regulatory Compliance & Validation

Founded in 2017, Vedant Tech Services (VTS) is a trusted leader in Regulatory Compliance and Computer System Validation (CSV) for FDA-approved facilities serving the pharmaceutical and medical device industries.

Our Core Expertise

With extensive exposure to process and equipment automation, VTS brings deep technical proficiency in the validation of PLC, SCADA, and software-based control systems. Our team has successfully executed numerous validation projects, making us a reliable partner for meeting stringent regulatory requirements.

Risk-Based Validation Approach

We follow a risk-based methodology for CSV, ensuring efficient, compliant, and audit-ready systems. Our validation practices are aligned with:

- GAMP 5 Guidelines
- ISO 13485 for Medical Devices
- 21 CFR Part 11 Compliance (where applicable)

Our Services Include

- End-to-end Computer System Validation Documentation & Execution
- Consulting for 21 CFR Part 11 Compliance
- Validation of PLC/HMI/SCADA/IPC-based control systems
- Support for FDA, EU Annex 11, and other global regulatory frameworks

❖ Control System Validation

-  Control System Validation Services – Ensuring Compliance & Operational Integrity
- Vedant Tech Services (VTS) offers comprehensive **Control System Validation** services tailored for regulated industries such as **Pharmaceuticals, Medical Devices, Life Sciences, and Manufacturing**. Our validation methodology ensures systems are compliant, secure, and audit-ready—aligned with global standards including **21 CFR Part 11, GAMP 5, and ISO 13485**.



System Type	Validation Focus
PLC/HMI/IPC-Based Control Systems	Structured Verification, H/W, S/W verification, and compliance documentation
SCADA Systems	Supervisory control validation, data integrity, alarm handling, and audit trails
Medical Device Instruments & Software	Functional and software validation per ISO 13485 and FDA guidelines
Data Acquisition Systems (DAS)	Real-time data capture validation, accuracy checks, and traceability
BMS & DCS Systems	Environmental and process control validation with centralized monitoring
Database Systems (ERP, SAP, LIMS)	Data integrity, access control, and regulatory compliance validation
IT & Network Qualification	Infrastructure qualification including hardware, software, and cybersecurity controls

❖ **Laboratory & Software Validation Services**

❖ Vedant Tech Services (VTS) offers specialized validation services for laboratory systems and software platforms used in regulated environments. Our approach ensures compliance with industry standards such as **GAMP 5**, **21 CFR Part 11**, and **ISO 13485**, while maintaining data integrity, traceability, and audit readiness.

❖ 🔍 **Scope of Validation Services**

❖ **Category Details Laboratory System Software Validation** Validation of analytical instruments and systems including:

- HPLC (High-Performance Liquid Chromatography)
 - GS (Gas Chromatography)
 - UV Spectrophotometers
 - Other lab-based software platforms
- Clinical Research Software** Validation of software used in clinical trials, data collection, and analysis
- PC Software Validation** Ensures standalone or networked PC applications meet regulatory and functional requirements
- Database Software Validation** Validates structured data systems for accuracy, security, and compliance.

❖ **Medical Devices System Software Validation – ISO 13485 Compliant**

Vedant Tech Services (VTS) provides specialized validation services for medical device system software, ensuring full compliance with ISO 13485 and global regulatory standards. Our validation framework is designed to support both equipment manufacturers and healthcare technology providers in achieving safe, reliable, and traceable software performance.



🔍 Scope of Validation Services

We validate system software for a wide range of medical device equipment, including:

- Laser Welding Machines
- Laser Cutting Machines
- Annealing Machines
- Label Printing Machines
- Dimension Measurement Systems
- Analysis Software Platforms
- Balloon Forming Machines
- Fluting Wrapping Machines
- Leak Testers
- Hydraulic Pressure Testers
- Radial Durability Testers
- And other custom or OEM medical device systems

📄 Validation Approach

Our ISO 13485-compliant validation process includes:

- Software Requirement Analysis
- Risk Assessment & Mitigation Planning
- Functional & Design Specification Documentation
- Installation, Operational & Performance Qualification (IQ/OQ/PQ)
- Traceability Matrix and Validation Summary Reports
- 21 CFR Part 11 Compliance (where applicable)
- Audit-ready documentation and support

❖ 📊 Excel Spreadsheet Development & Validation Services

- Vedant Tech Services (VTS) offers specialized services in **Excel-based automation and validation**, ensuring compliance, accuracy, and efficiency in regulated environments such as pharmaceutical, medical device, and manufacturing sectors.

🔍 Our Capabilities Include:

Service	Description
Spreadsheet Validation	Ensures spreadsheets meet regulatory standards, including audit trails and data integrity
Spreadsheet Development	Custom-built Excel tools tailored to client-specific processes and reporting needs
Predevelopment Spreadsheet	Initial design and planning to align spreadsheet logic with functional requirements
Macro Development	Advanced automation using VBA macros for streamlined workflows and data processing



❖ Our Approach for Computer System Validation

- **Vedant Tech Services – End-to-End Validation Documentation & Compliance Services**
- Vedant Tech Services (VTS) offers a comprehensive suite of **Computer System Validation (CSV)** services tailored to meet global regulatory standards, including **21 CFR Part 11** and **EU Annex 11**. Our structured approach ensures full lifecycle compliance, risk mitigation, and traceability for regulated industries.
- **Validation Documentation Portfolio**

Document / Service	Purpose & Scope
Validation Master Plan (VMP)	One-time strategic blueprint for all validation activities
Gap Assessment (GAP)	Identifies compliance gaps and improvement areas
Initial Risk Assessment (IRA)	Evaluates system risks prior to validation
21 CFR Part 11 & Annex 11 Compliance	Ensures electronic records and signatures meet regulatory standards
User Requirement Specification (URS)	Captures functional and regulatory expectations <i>(if required)</i>
Validation Plan (VP)	Defines scope, responsibilities, and timelines for validation execution
Functional Specification (FS)	Details system functionalities <i>(if required)</i>
Design Specification (DS)	Describes technical architecture and design <i>(if required)</i>
Functional Risk Assessment (RA)	Assesses risks associated with system functionalities
Installation Qualification (IQ)	Verifies correct installation of hardware/software
Operational Qualification (OQ)	Validates system performance in real-world scenarios
Traceability Matrix (TM)	Maps requirements to test cases for complete traceability
Validation Summary Report (VSR)	Final report summarizing all validation activities and outcomes

❖ Automation Solution

Vedant Tech Services – End-to-End Automation Solutions Across Industries

Vedant Tech Services (VTS) delivers cutting-edge automation solutions tailored for the Pharmaceutical, Medical Device, Dairy, and OEM Machine Manufacturing sectors. With deep expertise and strategic insight, we help clients streamline operations, ensure regulatory compliance, and achieve scalable growth.



Strategic Automation Consulting

We offer primary consulting services to evaluate your budget, process needs, and compliance goals—recommending the most efficient and cost-effective automation strategies.

Core Capabilities

We specialize in the Supply, Installation, Erection, Commissioning, and Programming of:

- PLC/HMI/IPC and SCADA-based Systems
- DCS Systems
- Manufacturing Production Reporting
- Utility and Energy Monitoring Systems
- Project Life Cycle Management Solutions
- Professional Resource Augmentation Services

Technical Expertise

Our team is proficient in handling diverse platforms from leading vendors:

- Siemens, Rockwell Automation, Mitsubishi, Delta

We support:

- Structured PLC Programming, Modifications, Legacy Conversions
- Greenfield and Brownfield Projects
- HMI and SCADA Development
- Commissioning & Startup Services
- System Upgrades and Migration Projects
- Regulatory Compliance Consulting
- Machine Upgradation aligned with 21 CFR Part 11 and Central SCADA Integration for Life Sciences

Industry-Specific Services

We provide tailored automation solutions for:

- Plant/Section Turnkey Automation
- Retro Automation Projects
- Control System Integration
- SCADA Solutions
- Custom Software Development



❖ Manufacturing in Medical device Machinery

⚙️ EP-SS: Advanced Vertical Electro Polishing Machine by Vedant Tech Services

Vedant Tech Services (VTS) proudly introduces its Fully Automatic PLC and HMI-based Vertical Electro Polishing Machine, model EP-SS—a breakthrough solution designed specifically for medical device surface enhancement.

🌟 Key Highlights

- Precision Engineering: EP-SS is purpose-built to deliver advanced surface therapeutics for medical devices, with a focus on next-generation stents.
- Material Compatibility: Capable of producing ultra-smooth, high-shine finishes for stents made from L316LVM and L605 alloys.
- Regulatory Compliance: The system is fully aligned with medical device guidelines, covering:
 - Secure login/logout protocols
 - Comprehensive reporting features
 - Alarm systems and safety interlocks
 - Recipe management for various stent types

📄 Documentation & Demo

- Functional Design Specification (FDS) and Technical Design Specification (TDS) are available for review.
- A demo unit of the EP-SS machine is ready at our facility. Interested clients are welcome to visit and experience the machine in action.



CAPABILITIES AND CUSTOMER'S:

Vedant Tech Services – Trusted Partner in Pharma Automation & Validation

Vedant Tech Services (VTS) is a highly experienced and reliable team of engineers specializing in **Computer System Validation (CSV)** and **Automation** for the **Pharmaceutical, Biotechnology, Medical Device, and Pharma Equipment Manufacturing** industries across India and abroad.

Industry Exposure

Our team has successfully collaborated with leading organizations in:

- Pharmaceutical Manufacturing
- Pharma Equipment Manufacturing
- Biotechnology
- Medical Device Industries

Customer references are available upon request.

Leadership

VTS is promoted and managed by **Mr. Ritesh B. Patel**, a seasoned professional with **20+ years of global experience** in the field of Computer System Validation and Automation. His expertise spans:

- Project Leadership in reputed validation and automation firms
- Hands-on experience in **Design, Development, Installation, and Commissioning**
- Specialized consulting in **CSV Protocol Design**

Our Strengths

- A dedicated team of talented engineers committed to regulatory excellence
- Proven track record in delivering compliant, efficient, and scalable automation solutions
- Deep understanding of global regulatory standards and validation protocols

Contact Us

VEDANT TECH SERVICES

504- Rashmi Growth Hub, Opp. Shreeya Residency,
S.P. Ring Road, Odhav, Ahmedabad-382415,
Gujarat, India.

Contact Person: Mr. Ritesh B Patel

Mob: +91-9913685696

Email: info@vedanttechservices.com / vedanttech2017@gmail.com

Web Site: www.vedanttechservices.com