



VEDANT TECH SERVICES

AN ISO 9001:2015 Certified company

OUR SERVICES:

Computerized System Validation and Automation Solution Provider

❖ Computer System Validation

We provide Regulatory Compliance & Computer System Validation for FDA approved facilities for used in pharmaceutical and Medical devices industries. Having good exposure in process/equipment automation gives us good expertise in validation of the PLC/SCADA/Software based control systems.

Having undertaken several validation projects makes us proficient service provider to take care of regulatory requirements.

We use a Risk based approach for computer system validation. We have good expertise in computer system validation documentation and validation execution as we follow current GAMP 5 guidelines and Medical Devices ISO 13485.

Consultancy to make system 21 CFR Part 11 Compliance

Control System Validation

- PLC/HMI/IPC based control system
- Supervisory Control and Data Acquisition (SCADA) system
- Medical Devices Instrument and Software
- Data Acquisition System (DAS)
- BMS System and DCS System
- Database Systems including ERP such as SAP & LIMS
- IT & Network Qualification.
- Validation Summary Reports and Corrective Actions recommendations.

Plot No. 280, Gopal charan Industrial Hub, Phase-6, Near K.P. Way Bridge, Village-Bakrol (Bujarang), Ahmedabd-382433, Gujarat, India.

Laboratory System Software Validation

- HPLC, GS, UV, Tiamo, stability chamber etc.,
- Clinical Research Software
- PC Software Validation
- Database Software

Medical Devices System Software Validation (ISO 13485)

- Laser Welding Machine, Laser Cutting Machine, Anneling Machine, Lable Printing Machine, Dimension Measurement System, Analysis software, Balloon Farming Machine, Fluting Wrapping Machine, Leak Tester, Hydraulic Pressure Tester, Radial Durability Tester etc.,

Excel Spreadsheet Development & Validation

- Spreadsheet (Excel Sheet) Validation
- Spreadsheet Development
- Predevelopment Spreadsheet
- Macro Development

Our Approach for Computer System Validation

- Validation Master Plan (One Time)
- Gap Assessmet (GAP)
- Initial Risk Assessment (IRA)
- 21CFR Part 11 compliance services (Where ever applicable)
- User Requirement Specification (URS) If Required
- Validation Plan (VP)
- Functional Specification (FS) If Required
- Design Specification (DS) If Required

- Functional Risk Assessment Document (RA)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Traceability Matrix (TM)
- Validation Summary Report (VSR)

❖ **Automation Solution**

We provide Automation solutions to Pharmaceutical Process, Medical Process, Dairy Process and OEM Machine Manufacturing Automation.

We are capable of handling diverse automation requirements from leading vendors including Siemens, Rockwell Automation, Mitsubishi, Delta and Wonderware. Contact us for a primary strategic consulting whereby we evaluate your budget parameters and suggest the best means to execute an automated manufacturing process.

Supply, Installation, Erection, Commissioning and Programming of PLC/HMI/IPC and SCADA based Systems for Pharmaceutical, Medical Device, Dairy Process and OEM Machine

- PLC Systems – Structured way of Programming , Modifications ,Legacy Conversions ,Green field and Brown field jobs
- HMI and SCADA Systems
- DCS Systems
- Manufacturing Production Reporting
- Commissioning & Startup
- Up gradation and Migration Projects
- Regulatory Compliance Consulting
- Machine Up gradation as per 21 CFR PART 11 Compliance and Central SCADA Solution – Line Integration for Life Science
- Utility and Energy Monitoring Systems
- Project Life Cycle Management Solutions
- Professional Resource Augmentation Services

The services provided to various industries are as below:

- Plant/ Section Turn-key Automation
- Retro Automation
- Control System Integration
- SCADA Solutions

CAPABILITIES AND CUSTOMER'S:

Vedant Tech Services team has good exposure and experience working with various Pharmaceutical Manufacturing, Pharma Equipment Manufacturing, Biotechnology and Medical Device Industries companies all over India and abroad. Customer reference can be given based on the request.

Vedant Tech Services is a promoted and managed by Mr. Ritesh Patel; having work experience of about 13 + years in India and Abroad in Computer System validation and Automation field.

VTS is a team of dedicated, talented engineers whom you can trust for your regulatory requirement.

We having experience of more than 13 years of working in the Pharmaceutical automation and validation field. He has worked in Project Leader in reputed Validation and Automation company and pharma machine manufacturer. He has hands on experience in Validation and Automation field for Designing, Developments, Installation and Commissioning. He has expert in CSV Protocol designing and consulting for liquid machinery like ointment, liquid oral plants, fermentation system, SVP and LVP Injectable, gelatin plants and Laboratory System.

Contact Us

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