KVS
Technologies & Automation

KVS Technologies And Automation

YOUR VALIDATION PARTNER

PLC VALIDATION | COMPUTERISED SYSTEM VALIDATION | SAP VALIDATION
PLC – HMI/SCADA Base Software Upgradation

Company Introduction:-

- KVS Technologies and Automation having strong professional experience of CSV and regulatory services in Healthcare, Pharmaceuticals and Life sciences industries to meet the customer expectations. KVS is promoted by Shankar Sapavadiya. Promoters having 32+ Years experience in Instrumentation , Automation and Validation in Pharma Industries. Main area of interest is to provides CSV and compliance services to Life science, Healthcare and Pharmaceutical Industries of India and worldwide.
- KVS Team having 18+ years of experience of Validation of computerised Systems, IT Systems. We build most effective environment for customers on Current updates of 21 CFR Part 11, EU Annex11 regulatory Compliance. KVS has provided CSV and regulatory compliance services to more than 150 companies in India and worldwide to life sciences, Pharmaceuticals, Chemicals, Medical Device, cosmetics.
- **Our Vision** is to be the best partner in Validation of Automated computerised system and IT system and regulatory compliance services for healthcare, pharmaceuticals and life sciences industries.
- **Our Mission** is to provide the most intuitive , Transparent, Economical , Effective CSV and regulatory compliance services to Healthcare, Pharmaceuticals and Life sciences industries as Current regulatory requirements.

Computerised System Validation Services Provided by KVS

KVS provides CSV and Regulatory services as per GAMP Guidelines , 21CFR Part 11 and EU GMP Annex 11 for following system. Its not only about preparing documentation, but We are expert in Pharma process as well as regulatory requirements so provides perfect solutions.

- Automated manufacturing Equipments PLC-SCADA-DCS System
- SAP ECC 6.0 / SAP HANA / SAP HANA Cloud.
- IT Compliance Services and Server based systems
- Laboratory Instruments software Validation HPLC, GC and Laboratory Information Management.
- Clinical trials data management
- Manufacturing Resource Planning(MRP),Enterprise Resources Planning (ERP)
- Building Management System(BMS)/Environment Monitoring System (EMS)
- Document Management System
- Electronic Batch Manufacturing Records (EBMR)
- Stability system software
- Vendor Assessment / Vendor Audit
- 21 CFR Part 11 and EU GMP Annexure 11 Impact assessment.
- Periodic review of Computerised system
- Third party IT Audit
- Deputing CSV /IT work force and Engineers team at site.
- Review of CSV documents , Change control , CAPA and other IT solutions

Mr. Shankar Sapavadiya

Founder of KVS , a senior CSV consultant , Mr. Shankar Sapavadiya having 30+ years experience in field of Pharma Automation, Instrumentation, Projects and CSV. He started his career from well known pharma company Alembic Pharmaceuticals Limited in 1988 as Instrumentation and Automation Engineer in Formulation plant. Having 30+ Years experience for PLC, SCADA, DCS, BMS, Lab instrumentation software, EBMR, ERP software, SAP, ECC 6.0, Pharma cloud , Microsoft Dynamic NAV ,Stability software, Empower 3, Lab solution validation as per GAMP Guidelines, 21CFR Part 11 and EU GMP Annex 11.

He has successfully managed and completed CSV Projects at more than 150 API and Formulations plants of pharma companies. Some of the clients are Abbot, Alembic, Alkem ,Cipla, Dr.Reddy's, Eisai–Vizag ,Glenmark, Gulbrandsen, Lupin, Fresenius Kabi, IPCA , Piramal Health care, Morton Grove USA, Micro Lab , Otsuka, Nuland Mylan, Wockhardt, Ranbaxy, Watson, SunPharma, Unison Pharma , Zydus Cadila.

Strong track record for SAP Validation, Computer Systems Validation, PLC, SCADA, DCS and BMS Validation for USFDA, MHRA, WHO GMP, TGA or any regulatory requirements.

Mr. Nirav Patel : Having 8 Years Experience in filed of PLC – SCADA Automation , control system , Calibration and Validation. And he Manage and executed PLC, SCADA , Lab Instruments software , ERP projects in different site all over India. are trained for GAMP Guidelines , 21 CFR Part 11 , EU GMP Annex 11, cGMP Requirements , GDP requirements , Instrumentation and Engineering aspects.

Mr. Amit Patel : Having 12 Years Experience in filed of Instrumentation design Automation , control system , Calibration and Validation and Project monitoring , execution. Development and manufacturing experience of micro controller based system.

KVS Team :

KVS has well trained , experienced team of 18-20 Engineers. All are trained for GAMP Guidelines , 21 CFR Part 11 , EU GMP Annex 11, cGMP Requirements , GDP requirements , Instrumentation and Engineering aspects.

What is Validation :

Validation is "Establishing **documented evidence** that provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes."

What is Computer System Validation?

Computers are widely used during Product development ,Product Testing , Analysis and Manufacturing. Proper functioning and performance of Automated system software and computer systems play a major role, reliability and accuracy of product output. Computer System Validation is the process of documented evidence for verification of system functions and the performance are meeting to User Requirements Specifications, as well as data integrity and system maintenance. And the written documentation must be in alignment with the industry standards. Therefore, computer System validation (CSV) should be part of any good development and manufacturing practice.

Business Benefits of Validation:

There are major business benefits and compliance benefits of qualification and validation.

1. Delivers systems that are fit for intended use, on time, and within budget.
2. Systems that are well defined and specified are easier to support and maintain, resulting in less downtime and lower maintenance costs.
3. Specific benefits to regulated companies and suppliers include:
   Systems that are fit for intended use, on time, and within budget.
4. Reduction of cost and time taken to achieve and maintain compliance.
5. Early defect identification and resolution leading to reduced impact on cost and schedule.
6. Cost effective operation and maintenance.
7. Effective change and management and continuous improvement, enabling of innovation and adoption of new technology.
8. Providing frameworks for user/supplier co-operation assisting suppliers to produce required documentation.
9. Promotion of common system life cycle, language, and terminology.
10. Providing practical guidelines and examples.
11. Promoting pragmatic interpretation of regulations.

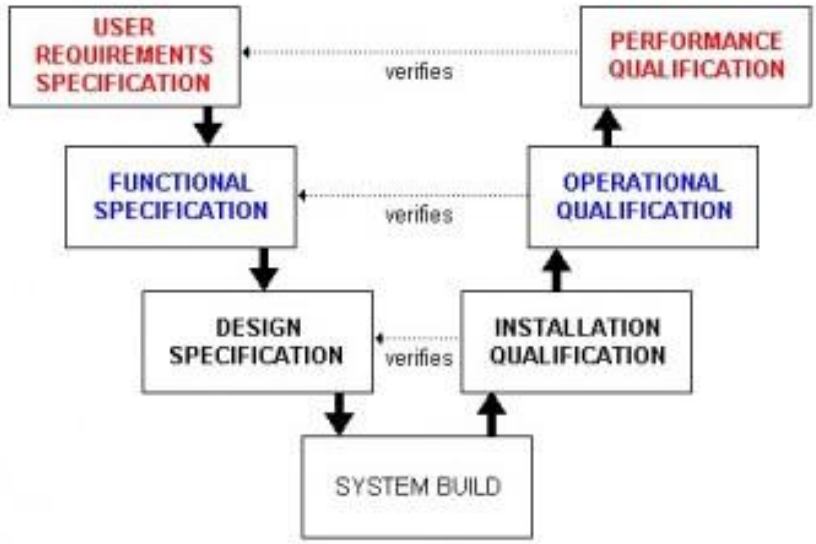
GxP Compliance:

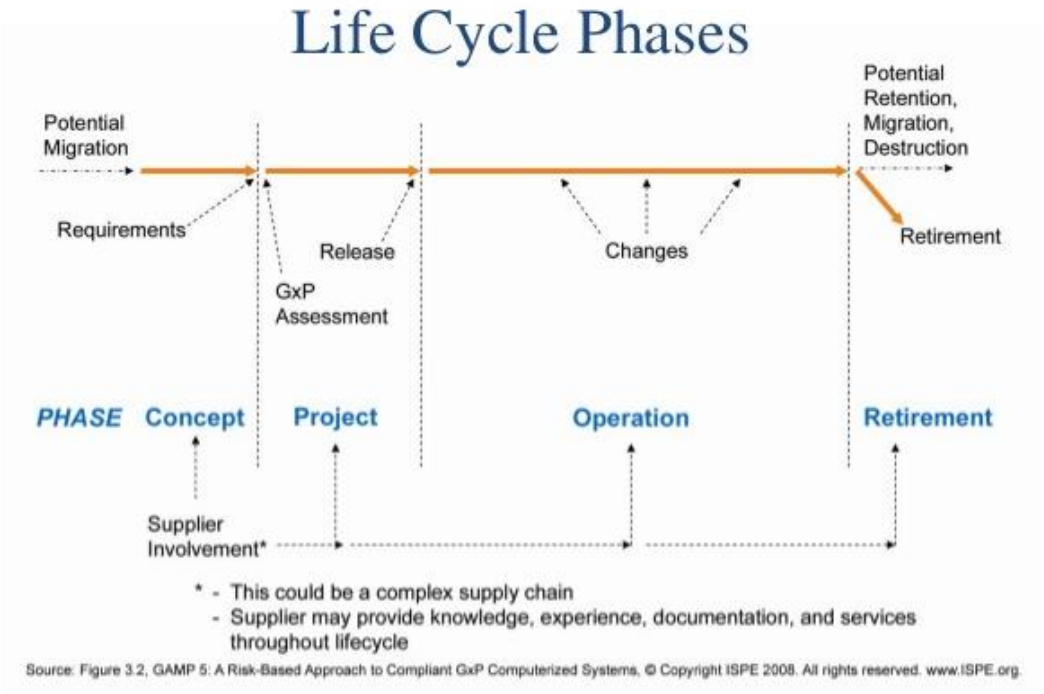
Meeting all applicable pharmaceutical and associated life-science regulatory requirements

GxP Regulated Computerised Systems:

Computerised systems that are subject to GXP regulations. The regulated company must ensure that such systems comply with the appropriate regulations.

- **GAMP-5 V Module – Life Cycle Approach**





CSV Services Provided by KVS Technologies:

Validation of System	IT System/ ERP	Lab Instruments
• PLC- SCADA System • DCS based System • BMS – EMS System • Track and Trace system • Vision system • Access control system • Equipment Qualification • API process plants • Purified Water system • Medical devices	• SAP(ECC 6.0)and HANA • IT Infrastructure • Server & Data centre • Pharma cloud ERP System • E-BMR Software • Document Management System • CAPA and Change Control Management Software • Training management software	• HPLC, GC System • Empower software • Lab Solution software • LIMS Validation • Non- Chromatography System • Stability chamber software • Clinical research software

➢ Compliance Services :

- GAP Analysis of Software/System
- 21 CFR Part 11 and EU GMP Annex 11 Impact assessment.
- Standard Operating Procedure Preparation and Review
- Compliance Audit/Third Party IT Audit
- Vendor Assessment / Vendor Audit
- Periodic review of Computerised system
- Deputing CSV /IT work force and Engineers team at site.
- Review of CSV documents , Change control , CAPA and other IT solutions

➢ Industries where KVS Provides Services

- Pharmaceuticals Industries
- Medical device
- OEM Machine manufacturer
- Clinical Research Organisation
- Food Industries
- SAP and ERP implement partners
- IT Industries
- Healthcare and Hospital

➢ **Office :** 450/2/A , GIDC , Makarpura , Vadodara – 390010-Gujarat India.

➢ **E mail :** niravs.patel@kvstechno.com Kvs.niravs@gmail.com shankar.sapavadiya@kvstech.com, sps1.kvs@gmail.com

➢ **Mobile :** +91 7567123647, 9375969719.