KVS Technologies

YOUR VALIDATION PARTNER FOR GROWTH THROUGH EXPORT

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Computerised System Validation Services

KVS TECHNOLOGIES

YOUR VALIDATION PARTNER

PLC VALIDATION | COMPUTERISED SYSTEM VALIDATION | SAP VALIDATION

Company Introduction:

- KVS Technologies has a strong professional experience of CSV and regulatory services in Healthcare, Pharmaceuticals and Life sciences industries to meet customer expectations. KVS was founded by Mr. Shankar Sapavadiya and Mr. KalpeshKumar Vaghela in Year 2006. Both promoters have 30+ Years of experience in the fields of Instrumentation , Automation and Validation in Pharma Industries. The main area of interest is to provide CSV and compliance services to Life science, Healthcare and Pharmaceutical Industries of India and worldwide.
- KVS Team has 16+ years of experience of Validation of computerised Systems, IT Systems. We build the 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 in the fields of 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 per current regulatory requirements.

Computerised System Validation Services Provided by KVS Technologies

For us at KVS, it's not only about preparing documentation; We are experts in Pharma processes as well as regulatory requirements which enables us to provide perfect solutions. We provide CSV and Regulatory services as per GAMP Guidelines, 21 CFR Part 11 and EU GMP Annex 11 for following systems:

- Automated manufacturing equipment 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 Resource 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 Partner of KVS Technologies, a senior CSV consultant , Mr. Shankar Sapavadiya has an experience of 30+ years in field of Pharma Automation, Instrumentation, Projects and CSV. He started his career from Alembic Pharmaceuticals Limited in 1988 as an Instrumentation and Automation Engineer in Formulation plant. He has 30+ Years of 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 Formulation plants of pharmaceutical 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, Neuland, Mylan, Wockhardt, Ranbaxy, Watson, Sun Pharma, Unison Pharma , Zydus Cadila, etc.

He has a strong track record for SAP Validation, Computer System Validation, PLC, SCADA, DCS and BMS Validation for USFDA, MHRA, WHO GMP, TGA and all the regulatory requirements.

Mr. Kalpeshkumar R. Vaghela

Founder Partner of KVS Technologies, a Senior CSV Consultant,

Mr. Kalpeshkumar Vaghela has 30+ years of experience in field of Pharma Automation, Instrumentation, Projects and CSV. He is an Automation and Software Validation Specialist, Expert Trainer on CSV, Data Integrity, GAMP-5, 21 CFR part 11 Compliance, Annex 11, Risk assessment, Proactive CSV Approach. Since last two decades Mr. Vaghela has been helping Indian and International Pharma Companies achieve compliance by training and motivating professionals for QbD and Right First Time Approach. He has supported clients for many USFDA, MHA, ANVISA, MCC, and TGA Customer Audits as a CSV consultant.

About 11 years of work experience on high-level CSV Validation in India and Abroad has made Mr. Vaghela a Subject Matter Expert in CSV, Data Integrity Audit for Life Science-Medical Device and Clinical Research Industry.

KVS Technologies' Team

KVS Technologies have 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 is meeting to User Requirements Specifications, as well as data integrity and system maintenance. The written documentation must be in alignment with the Industry Standards. Therefore, Computer System Validation (CSV) is an essential part of any good development and manufacturing practice.

Business Benefits of Validation:

There are many major business 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, management and continuous improvement enables innovation and adoption of new technology.
8. Providing frameworks for user/supplier co-operation and 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.

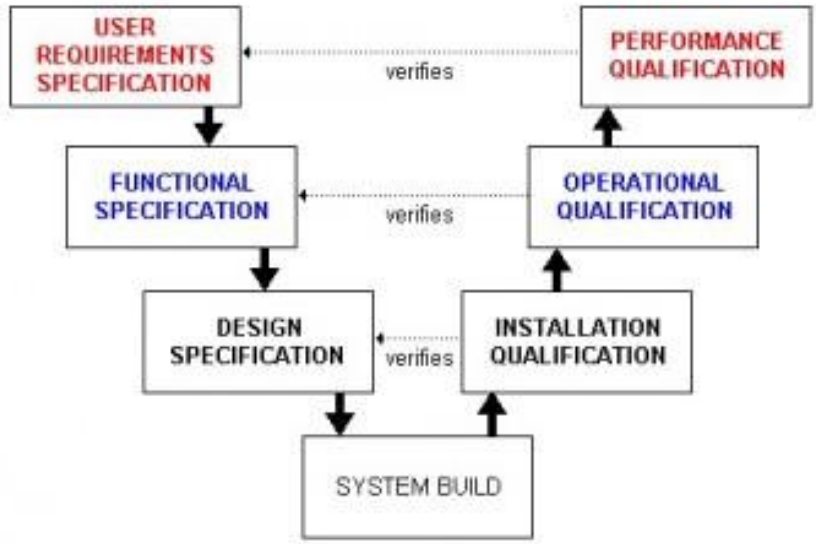
GxP Compliance

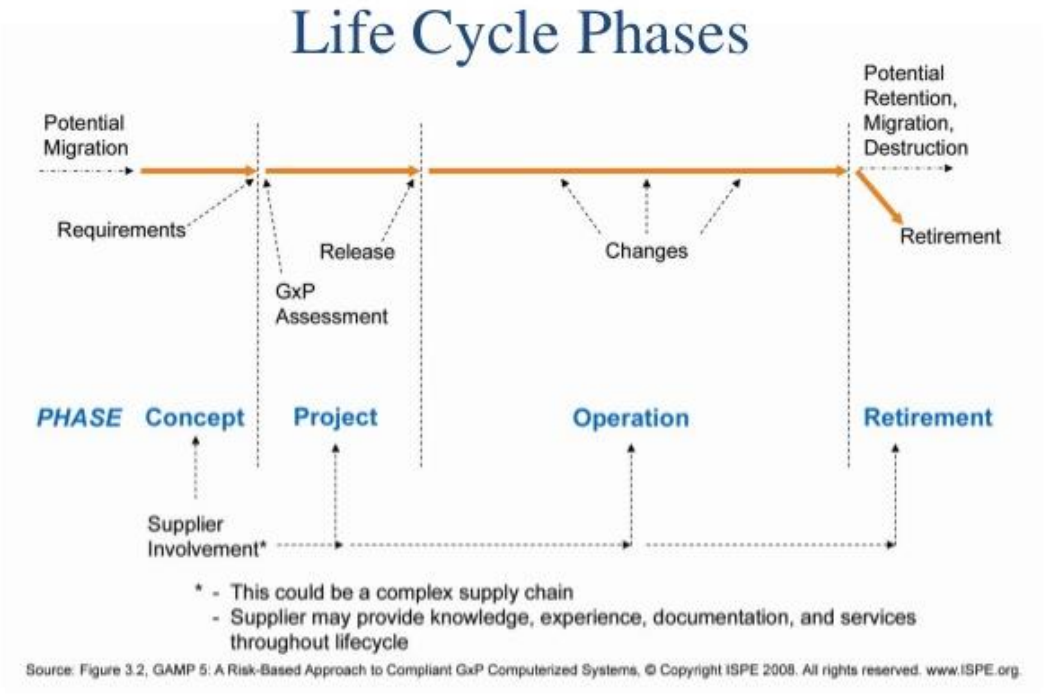
Meeting all applicable pharmaceutical and associated life-science regulatory requirements.

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	• IT Infrastructure • Server & Data centre • SAP(ECC 6.0)and HANA • 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

➢ Client List

- ACG Associated Capsules Pvt. Ltd.
- Abbott Healthcare Pvt. Ltd.
- Alkem Laboratories Ltd.
- Adept Engineers
- Alembic Pharmaceuticals limited
- Astral Pharmaceuticals Industries
- Apothecon Pharmaceuticals Pvt. Ltd.
- Apicore Pharmaceuticals Pvt. Ltd.
- Avantika Medex Pvt. Ltd.
- Baroque Pharmaceuticals Pvt. Ltd.
- Bectochem Laboratories
- Cadila Pharmaceuticals Ltd.
- Cipla Pharmaceuticals Ltd .
- Centurion Laboratories Ltd.
- Dr. Reddy's Laboratories Ltd.
- EISAI Pharmaceuticals India Pvt. Ltd.
- Exemed pharmaceuticals Ltd.
- E.I.D Parry India Ltd.
- Elysium Pharmaceuticals Ltd.
- Emcure Pharmaceuticals Ltd.
- Escientia Advanced Sciences Pvt. Ltd.
- Famy Care Limited.
- Fisher Biopharma Services (Pvt.) Ltd.
- Flamingo Pharmaceuticals Ltd.
- Fresenius Kabi Oncology Ltd.
- Gulbrandsen Technologies India Pvt. Ltd.
- Glenmark Pharmaceuticals Ltd.
- Glenmark Generics Ltd.
- Globela Pharma Pvt. Ltd.
- Golden Cross Pharma Pvt. Ltd.
- Intas Pharmaceuticals Ltd.
- J B Chemicals & Pharma Ltd.
- Johnson & Johnson Pvt. Ltd.
- Jubilant Life Sciences Ltd.
- Lupin Ltd.
- Liva Pharmaceuticals Ltd.
- MAC-CHEM Products India Pvt. Ltd.
- Mylan Laboratories Ltd.
- Micro Labs Ltd.
- M.J Biopharm Pvt. Ltd.
- Marksans Pharma Ltd.
- Macleods Pharmaceuticals Ltd .
- Morton Grove Pharmaceuticals Inc.
- Murli Krishna Pharma Pvt. Ltd.
- NGB Laboratories Pvt. Ltd.
- Nabros Phrama Pvt. Ltd.
- Navin Fluorine International Ltd.
- Naprod Life Sciences Pvt. Ltd.
- Neuland Laboratories Ltd
- Orchev Pharma Pvt. Ltd.
- Otsuka Pharmaceuticals India Pvt Ltd.
- Oxalis Labs
- Praj HiPurity Systems Ltd.
- Piramal Health care Ltd
- Ranbaxy Laboratories Ltd .
- Raks Pharma Pvt. Ltd.
- Raptim Research Pvt. Ltd.
- Rusan Pharma Ltd.
- Shasun Pharmaceuticals Ltd.
- S Kant Health Care Ltd.
- Soham ERP Solutions Pvt. Ltd.
- Sun Pharmaceutical Industries Ltd.
- Syngene International Ltd.
- Sudeep Pharma Pvt Ltd
- Swiss Parenterals Pvt. Ltd.
- Stallion Laboratories Pvt. Ltd.
- Securus Records Management Pvt. Ltd.
- Thermolab Scientific Equipments Pvt. Ltd.
- Troikaa Pharmaceuticals Ltd.
- Teva Pharmaceutical Ltd.
- UCB India Pvt. Ltd.
- Umedica Laboratories pvt. Ltd.
- Unichem Laboratories Ltd.
- Unimed Technologies Ltd.
- Unison Pharmaceuticals Pvt. Ltd.
- VHB Medi Sciences Ltd.
- Watson Pharma Pvt. Ltd.
- Wockhardt Limited
- Zenara Pharma Pvt. Ltd.
- Zydus Cadila Health Care Ltd.

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