LAB ICONICS

COMPUTERIZED SYSTEM VALIDATION SERVICES

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Computerized Systems Validation

Computer systems facilitate the daily work of Life Sciences manufacturers. Computers are used more and more in research and development departments, in manufacturing sites, and in storage and distribution and quality control areas. They create, modify, maintain, archive, retrieve or transmit data. Computer systems are a central factor determining work sequences; they are faster and less expensive than manual interventions.

Where a computer replaces a manual operation, there should be no resultant decrease in product quality or quality assurance.

Key challenges

Any computerized system that could influence the safety and quality of pharmaceutical products must be validated.

A validation program must verify whether

- The computer and its applications work as intended and according to specifications and regulatory requirements
- The computer data is protected from unauthorized access and changes, as well as unintended loses
- The quality management system works in sync with the computerized systems with regard to the good practices.

Comprehensive validation assistance

We focus on implementing internationally accepted GAMP 5 guidelines and its current interpretations for validation of computerized systems applying Risk Based Approach and Life Cycle Management Philosophy.

Our validation program covers:

- Validation Master Plan
- Risk Assessment Plan and Report
- User Requirement Specifications
- Functional Specifications
- Design Specifications
- Infrastructure Qualification Protocol and
- Report
- Installation Qualification Protocol and Report
- Operation Qualification Protocol and Report
- Performance Qualification Protocol and Report
- Validation Summary Report
- Traceability Matrix
- Assessment for compliance with regulations pertaining to electronic records and signatures (e.g., 21 CFR Part 11)
- Supplier Assessment Report
  Periodic Review Report

Laboratory Computerized Systems

The validation of computerized systems is required by the OECD (Organisation for Economic Co-operation and Development) principles of Good Laboratory Practice. (Consensus document no. 10).

"All computerized systems used for the generation, measurement or assessment of data intended for regulatory submission should be developed, validated, operated and maintained in ways which are compliant with the GLP principles".

The objective of any chemical analytical measurement is to get consistent, reliable and accurate data. Proper functioning and performance of analytical instruments and computer systems plays a major role in achieving this goal.

Therefore, Laboratory Computerized System Validation (CSV) should be part of any good analytical practice and this is equally important for those working in a regulated and in accredited environment.

We ensure the compliance of your laboratory applications

Lab Iconics provides compliance solutions for building a quality environment for your laboratory applications like i.e., Laboratory Computerized Systems like HPLC, LC, Mass Spectrophotometer, GC, FTIR, KF Titrator, TOC, Stability Chamber etc. We recognize the profound impact of the FDA's 21 CFR Part 11 regulations on the operations of our clients using the laboratory computerized systems. Lab Iconics helps ensure that your instruments meet performance standards at the point of installation through proven performance testing and documentation.

Process Control Systems

Process control systems are used for the automation of manufacturing processes (data collection, data supply, monitoring and controlling of the manufacturing process [PLC], and linking superimposed systems for manufacturing control [MES]. Process control systems encompass a wide range of systems: from small controls, e.g. built into manufacturing devices or equipment, to large, distributed control systems, like those for the operation of plants for manufacturing bulk materials or APIs.

Key challenges

- Determining the critical quality parameters and attributes and having specified instruments for verification of the same
- For large and complex systems, determining the key attributes that affect the quality of product directly/ indirectly

Standardization through GAMP
One of the key benefits of GAMP are the life cycle documents, which have proven their effectiveness as communication tools along the entire validation and life cycle of drug products.

Lab Iconics works with the customer to create a functional specification for the control system, a documented risk assessment to analyze potential hazards and existing mitigations, a design specification for the entire machine, and installation and operational qualification protocols.

We provide validation services for following types of Process Control Systems: -

- PLC + SCADA
- PLC + HMI
- PLC + HMI + Camera System
- Building Management Systems
- Data Logger Systems

Our strength in validating process engineering and control systems can help you achieve the right level of validation. Lab Iconics works closely with you to bring early success and payback from your automation investment.

Infrastructure Qualification

Whether you develop, test, manufacture or deliver active pharmaceutical ingredients, vaccines, or pharmaceutical products, your software applications are based on an infrastructure, including:

- Servers, that host data, databases or files, applications or special services
- Client workstations
- Network components and protocols

The computer infrastructure coordinates and allocates resources to users and applications to enable data sharing, and also provide communication services. Before the computer system can be validated, the infrastructure must be qualified to prove its security, availability, reliability and usability, and to ensure that data is transferred accurately.

Once the validation qualification is available, it can be referenced in all validation programs, and doesn't need to be repeated for each application supported by the infrastructure.

Our experts understand both the technical aspects and the regulatory requirements and help you qualify your computer infrastructure or conduct the complete validation, including:

- Segment GxP and Non - GxP components of the network
- Assist in establishing procedures for: establishing and managing support services, performance monitoring, incident management, corrective and preventive action, operational change and configuration management, repair activity, periodic review, backup and resort, business continuity management, security management, system administration.
- Establish the configuration and specifications of the network and its components

- Qualify the network and its components
- Qualify the data backup, recovery and disaster recovery mechanisms
- Support the ongoing maintenance of the network and its configuration
- Implement recovery plans

ERP Systems

Business systems and applications are increasing in complexity and integration, so that companies can deliver real- time manufacturing, engineering, sales and accounting information across the entire enterprise.

Roles of Enterprise Resource and Planning

ERP systems are widely used by enterprises internally and externally to integrate activities like SCM, inventory management, manufacturing, accounts finance, HRM, quality management, sales, distribution etc. The configuration of an ERP depends on the operational requirements of the business and the software validation requirements are governed by the concerned regulations. Hence validating the ERP system becomes complex and challenging for the enterprises bound by the regulatory pressure.

Key challenges

The most troubling issues while validating the ERP systems are:

- The screening of the key processes for validation of the ERP which are important from the regulatory point of view.
- The extent of validation to be carried out while considering a particular business process

Informed business decisions

Lab Iconics Solutions adheres to a risk management and process analysis strategy which allows enterprises to identify key opportunities to manage and mitigate risks related to long term software validation costs working in accordance with the current GAMP guidelines. We make you understand the risks so that you can make intelligent business decisions while meeting your compliance requirements.

Professionals at Lab Iconics have sound experience of validating wide range of ERP systems. Based on GxP and risk assessment of the processes of ERP systems with respect to the specifications, we deliver to you, the stepwise captured qualification results traceable, point to point, to the specifications.

21 CFR Part 11 Assessment and GAP

Analysis

US FDA 21 CFR Part 11

The US Food and Drug Administration rule 21 CFR Part 11 applies to electronic records and signatures. Key areas of regulation which require attention are:

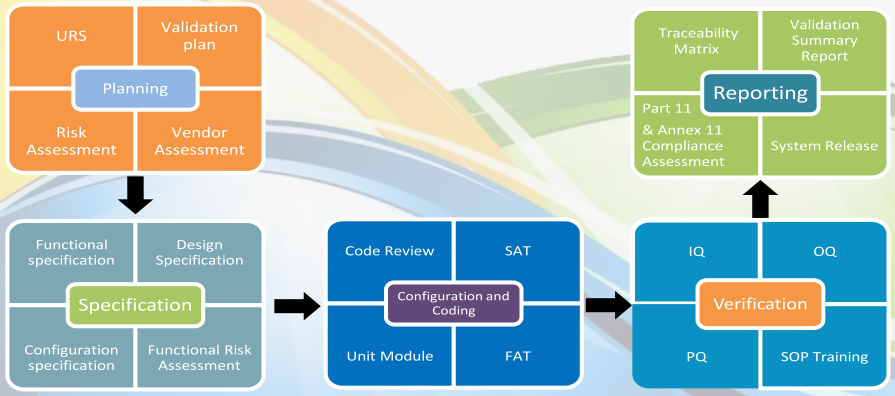
- The definition of an electronic record
- Access control,
- security and data consistency
- Audit Trails
- Electronic copies for inspection
- Retention and maintenance of records
- Application of electronic signatures
- Part 11 makes you put into place both procedural controls (i.e., notification, training, SOPs) and administrative controls, in addition

Solutions for compliance issues

Lab Iconics offers services to assist you, acting as your 21 CFR Part 11 compliance team, we:

- Establish a consistent company-wide Part 11 interpretation
- Integrate Part 11 with corporate policies and guidelines
- Take inventory. Identify and prioritize the systems that are subject to Part 11 for inspection
- Introduce and execute assessment and gap analysis
- Identify non-compliant systems and the tools and solutions for bringing them into compliance

Validation Life Cycle



SPREADSHEET DEVELOPMENT AND VALIDATION

Spreadsheets in regulated industries

Using spreadsheets in a regulated environment for GxP purposes whether as an operator interface, as a data manipulation tool or for data storage, it comes with a lot of responsibility though how so ever simple it may appear to use.

Log-on security for the application and spreadsheets, independent audit trail, electronic signatures, data security, authorizations are the key implications of the rule 21 CFR Part 11.

Warning letters are being sent that cite, for example, a company's "failure to use fully validated computer spreadsheets to calculate analytical results for in-process and finished product testing." Responding to such situations can impact your time-to-market and your manufacturing efficiency.

We customize and simplify

Lab Iconics provides spreadsheet development and validation services to help build authentic spreadsheets which can be used in the regulated environment and generated reliable and authentic data. We provide also you with the documented evidence of their correct functionality.

The process is designed to maximize efficiency and focuses on repeatability of the usage of the spreadsheets and helps its customers build confidence in the spread sheet outputs both for regulatory compliance (21 CFR Part 11) and operational accuracy.

Our validation experts develop your spreadsheets and deliver fully validated applications so you can continue to use the flexibility, familiarity and interconnectivity of Excel.

Contact Us:

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