COMPUTER SYSTEM VALIDATION SERVICES

ABOUT US

QA CAL is your trusted partner delivering sustainable Quality, Regulatory, and Clinical compliance solutions. Computer System Validation (CSV) is a core competency of QA CAL.

FDA guidance defines software validation as "confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled". There is no such thing as "Validated" off the shelf software, since no software is going to match your specific "intended use" (User Requirements). The entire Software Development Life Cycle (SDLC) of a software product may be documented to prove that it functions as designed and may have Electronic Record/Electronic Signature (ERES) and Audit Trail functionality to satisfy 21CFR Part 11, but that still doesn't make it "Validated". Our CSV professionals, following our risk-based approach and leveraging the vendor's testing and documentation, and adhering to your internal policies and procedures, will walk you through documenting your project, from business processes flows and user requirements to developing and executing test protocols which document that the software satisfies your intended use of the system. We will develop customized documentation for your project that is aligned with your risk tolerance, your internal processes and procedures, and leverage accepted vendor documentation to assure your system meets your user requirements and intended use.

We'll develop a customized plan for your project, aligned with your risk tolerance, internal processes and procedures, leveraging accepted vendor documentation to assure that your system meets your user requirements and intended use.

QA CAL CSV practice includes the following services but is not limited to:

- Programmable Logic control
- Control system and software
- BMS (Building management system)
- SCADA (supervisory Control and data acquisition system)
- Manufacturing Execution System
- Analytical Software
- Lab Equipment software validation
- SAP/ERP Software validation
- Laboratory Information Management System Validation
- Excel sheet/ Excel sheet development and validation (as per 21 CFR Part 11)
- Any type Customized software

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Address: - C-8, SF, ELDECO EDEN PARK, JAPANESE ZONE, NEAR CNG PUMP, NEEMRANA, ALWAR, RAJASTHAN-301705 Email ID: info@qacal.in (Web Site: - qacal.in)

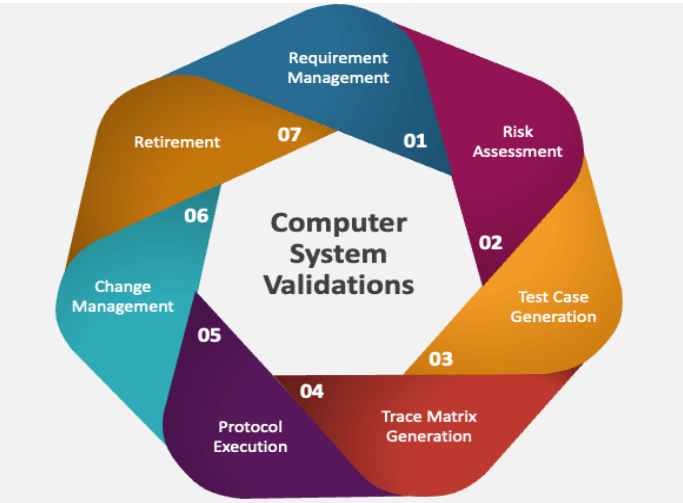
COMPUTER SYSTEM VALIDATION SERVICES:

Computer System Validation is a documented process for ensuring that a computer system can be used in regulated sectors such as pharmaceuticals to accomplish its designated task in a consistent manner. These systems must ensure data integrity, excellent product quality and compliance with GxP regulations. FDA has been using this approach since the publication of the 2003 CSV guideline in addition to 21 CFR Part 11.

Reduce Compliance Risk • Ensure Product Quality • Maintain Data Integrity

Overview: QA CAL offers Computer Systems Validation (CSV) services for laboratories operating in scientific organizations. Computer systems validation is a critical requirement of electronic record and system compliance, as described in the FDA 21 CFR Part 11. The validation process is designed to provide a high degree of assurance that both new and existing computer systems will consistently fulfil their intended purpose by producing results which meet predetermined specifications and quality attributes – accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records. As scientific applications constantly evolve to keep up with the needs of the people and businesses that use them. Life Science companies must perform validation activities on an ongoing basis in order to reduce compliance risk, ensure quality, and maintain data integrity. A “Computer System” in an FDA regulated laboratory is more than just computer hardware and software – it also includes any equipment and instruments linked to the system, as well as the trained staff that operate the system and/ or equipment using Standard Operating Procedures (SOPs) and manuals. Computer system validation requires a comprehensive set of both static and dynamic testing activities that must be conducted throughout the Software Document Life Cycle (SDLC). At QA CAL, we are experts in IT risk identification and management along with regulatory compliance. As such, we understand that computer system validation is not a “one size fits all” process. We work to create CSV processes that are based on FDA regulations and guidance, best practices, and the characteristics of the system being validated. As an FDA regulated company, you don’t just need to do computer system validation – you need it done right in order to assure quality in your regulated business process software, and thereby reduce compliance risk, data integrity concerns, and business liability issues. Our computer system validation professionals provide you with a best practice CSV methodology, along with the peace of mind that comes from knowing your CSV documentation has been produced by experts.

COMPUTER SYSTEM VALIDATION SERVICES



Our Computer Systems Validation processes typically involve:

- **System inventory and assessment** – Determination of which systems need to be validated
- **User requirement specifications –** Clearly defines what the system should do, along with operational (regulatory) constraints
- **Validation plan –** Defines objectives of the validation and approach for maintaining validation status
- **Risk assessments –** Analysis of failure scenarios
- **Functional requirement specifications –** Clearly defines how the system will look and function or the user to be able to achieve the user requirements.
- **Network and Infrastructure Qualification –** Documentation showing that the network and infrastructure hardware/software supporting the application system being validated has been installed correctly and is functioning as intended.
- **Installation Qualification (IQ) Scripts and Results –** Test cases for checking that system have been installed correctly in user environment
- **Operational Qualification (OQ) Scripts and Results –** Test cases for checking that system does what it is intended to do in user environment
- **Performance Qualification (PQ) Scripts and Results –** Test cases for checking that System does what it is intended to do with trained people following SOPs in the production environment even under worst case conditions
- **Validation Report –** A review of all activities and documents against the Validation Plan
- **System Release Documentation –** Documents that validation activities are complete and the system is available for intended use.

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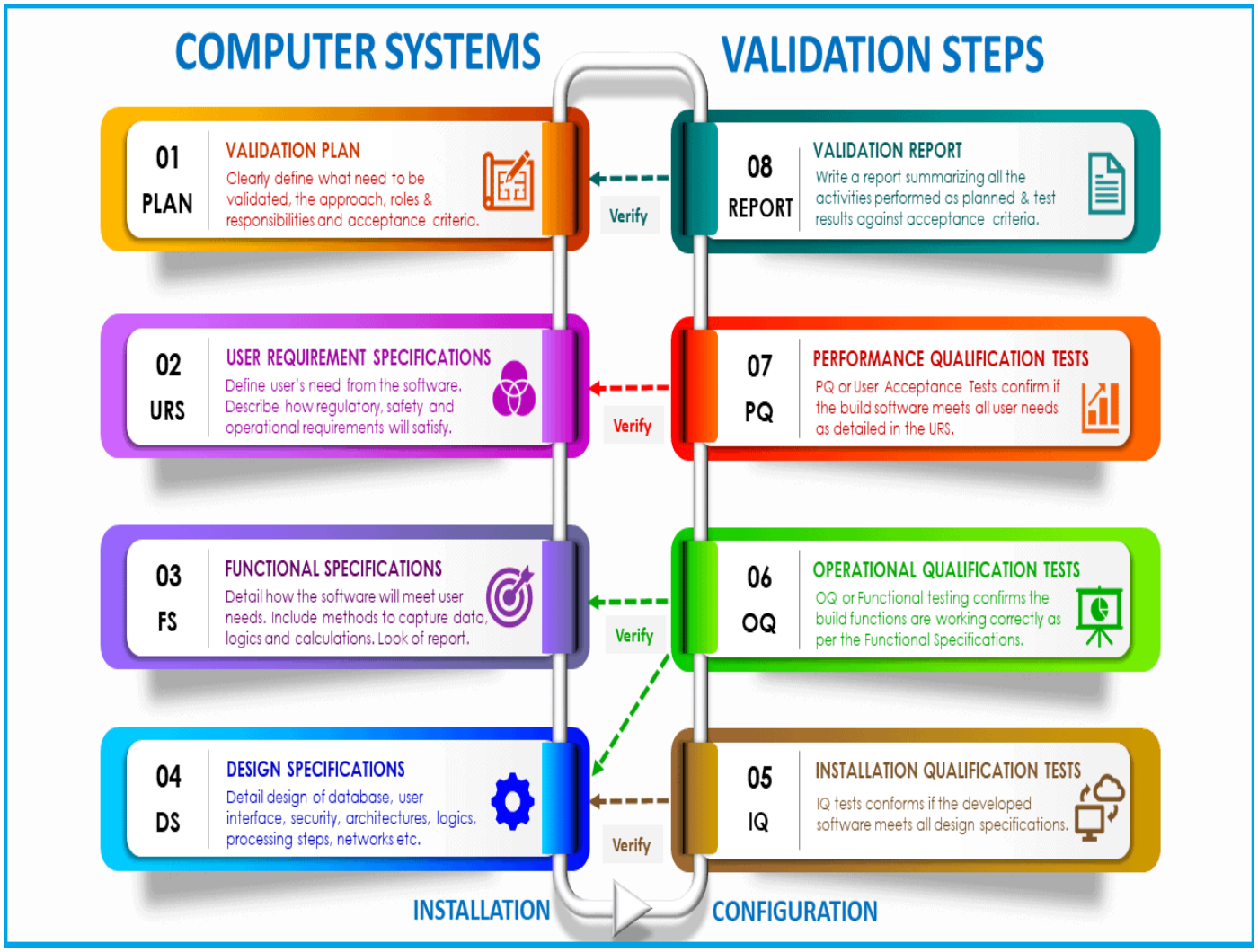
Computer Systems Validation approach:



Good Automated Manufacturing Practice (GAMP) is a set of guidelines and procedures used by pharma companies to validate computer systems to attain compliance with FDA 21 CFR 11. GAMP is not specifically a regulation, but a set of guidelines, which means, companies are not legally bound to comply with it. GAMP however, helps companies comply with global regulations indirectly.

Computer System Categorization According to GAMP 5

Category 1: Infrastructure software, tools, and IT services

Category 3: Standard system components/ Non configured functions

Category 4: Configured components

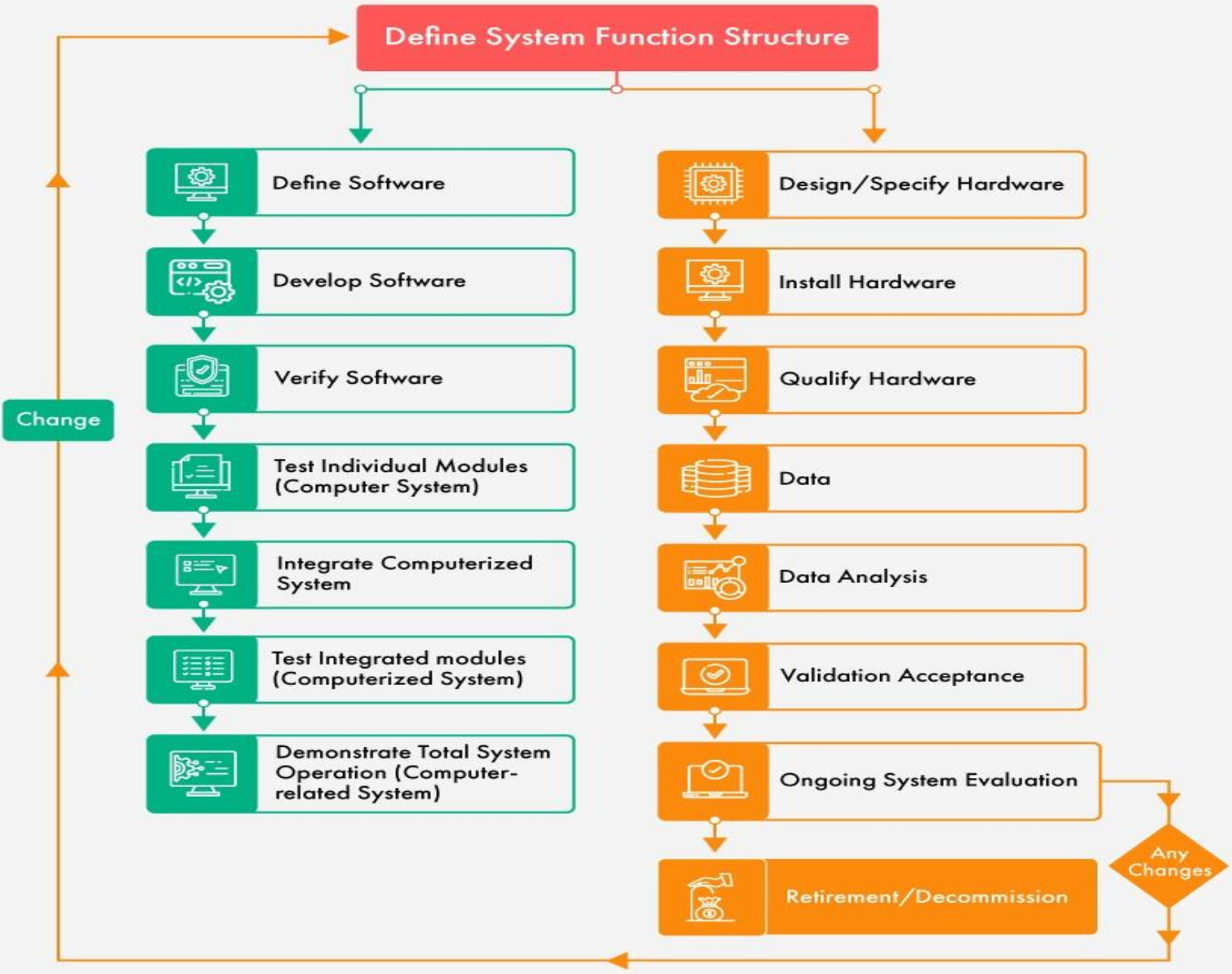
Category 5: Custom applications and components

COMPUTER SYSTEM VALIDATION SERVICES

COMPUTER SYSTEM VALIDATION (CSV)

A DEFINITIVE APPROACH FOR COMPLIANCE

Computer system defects can be difficult to recognise and may result in severe problems if not detected until the issue arises. Are you wondering how to avoid/reduce these defects? Here is a definitive approach you can bank on.



Above all this, for end-to-end compliance, one should follow a progressive Computer System Validation (CSV) as per the USFDA, EU, PIC/s, GAMP 5, ICH, WHO, 21 CFR Part 11 and EU Annex 11.

Are you adept with all the compliance procedures? Evaluate right away!

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