CSV

CSV is a computer validation systems. CSV is a documented process for assuring that a computer systems does what it is designed to do.

What is Computer System Validation (CSV)?

Computer Systems Validation (CSV) – have paved the way for organisations to implement the international legal requirements for product quality & data integrity. Which in turn plays a vital role to patient safety in the pharmaceutical and medical sector.

Our CSV as a service will ensure to tick all the boxes required by EMA & FDA for your organisation to be compliant with the guidelines set out by industry regulators.

Our accredited experts are able to take on the full burden of validating your organisations computer systems, or can work collaboratively with your IT department.

We provide a proven methodology in the delivery of CSV, which consists of:

- High specification consultancy
- Internal audits of systems/Compliance checks
- CSV Framework that reviews your current validation process and implementing an improved framework that covers complete documentation for validation purposes
- Assessments of current systems and data integrity
- Provide a development and risk plan to meet new regulatory requirements
- Development of testing strategies, data migration and validation strategies
- On site/remote coaching on your organisations internal IT team

Benefits of Computer System Validation (CSV)

Computer system validation is a critical tool to assure quality of computer system performance. CSV enhances the reliability of system, resulting in fewer errors and less risk to process and data integrity. It also reduces long term system and project cost by minimising the cost of maintenance and rework.

Benefits of effective computer system validation:

Ability to provide all required documents readily by FDA, other regulatory agencies and your customers.

Maximize the value of the computer system and the employees that use it.

Reduce labor cost by enhancing employee efficiency and effectiveness.

Effective project management are scheduled on time and budget.

Save money and time by discovering defects at early stage.

Reduces risk, legal liability, not regulatory, is often the most important reason to perform validation.

Promotes continual process improvement.

Together, we can build the best IT environment for your business.

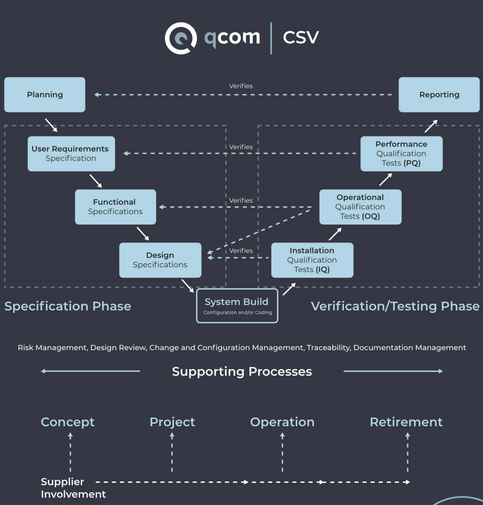
Why Do We Need CSV?

The pharmaceutical and medical device industries are regulated, meaning that what goes on inside the factory walls are subject to the law of the land. In the 90s, the regulatory authorities for these industries took the decision to replace paper records and handwritten signatures with electronic records.

CSV is a process that creates an indelible electronic data trail that allows us to treat the regulated data and electronic signatures captured in drug discovery, drug trials, manufacturing, distribution and storage as the legal equivalent of paper records and handwritten signatures and have the equivalent level of confidence in their accuracy, reliability and data integrity.

As you can see, the computer system validation process is time-consuming and expensive but necessary in order to keep data quality safe, accurate and secure.

How do you Validate a Computer System?



The lifecycle of CSV to help you through the entire process.

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