Bridge the gap between Computerised Systems and Validation

empowerment
quality engineering

Computerised Systems Test and Quality Assurance

Welcome

The Pharmaceutical industry is ever more dependent on increasingly complex computerised systems. With this comes a greater responsibility to ensure that such systems are thoroughly validated.

EmpowermentQE combine Quality Assurance and Technical Testing to ensure that the demands placed by the modern computerised system on compliance can be met. These powerful disciplines, when applied throughout the computerised system life cycle, will yield "Right First Time Validation"; reduce the risk of technical failure; greatly enhance quality and patient safety; and substantially reduce computerised system costs.

Talk to us to find out about applying a holistic approach to the implementation, verification and validation of computerised systems.

Benefits

Reduce:

Computerised system implementation, operation and maintenance costs.

Computerised system failure rates.

Unnecessary duplication of verification activities.

Patient Risk.

Increase:

Awareness in computerised system implementation.

Computerised system reliability.

Innovation.

Early defect detection leading to reduced schedule and cost impact.

Ensure:

Computerised system life cycle process improvement.

Wholly traceable computerised system artefacts and activities.

Continuous improvement and sensible change management.

Staff well being.

Independence.

Identify:

How to provide a fluid computerised system life cycle and procedures.

How to ensure compliance of unfamiliar computerised system approaches.

Gaps in supplier's approaches.

Cost effective operation and maintenance.

Case Studies

Establishing an independent test team alongside an established computerised systems implementation team.

A global pharmaceutical company needed to improve the quality of their computerised system deliverables. The company had an established computerised system implementation team. The following summarises the main activities undertaken:

- Performed an audit of the previous computerised system project to identify the strengths and weaknesses of the implementation approach.
- Identified and implemented quick win procedures: configuration management procedure, document management procedure, project change control procedure, metrics procedure, inspection and review procedure and testing guidelines.
- Templates, project plans, quality plans and testing plans were defined. These were used to detail: schedules, roles, responsibilities, approaches, tools, test environments, defect management, quality criteria, project reviews and so forth.
- Introduced an independent technical test team.
- Devised an "incremental" approach to implementation and testing in order to facilitate a "test *more*, test *sooner* and test *smarter*" policy.
- Re-prioritise the implementation schedule in order to deliver the highest risk software earlier into the test environment.
- Enforced technical inspections of the user requirements, functional requirements, design and test specification documentation in order to ensure testability, uniqueness, business value add, risk (quality, business and technical) and their subsequent priority.
- Participated in the code review: ensured that the coding layout standards were followed and traceability occurred.
- Devised strict entry criteria into the test environment. Performed seven iterations of testing, ensuring the build, release and installation instructions were refined and correct prior to OQ.

Outcome:

- "Right First Time Validation".
- Earlier defect detection, which reduced system cost and reduced schedule impact.
- The technical inspections of the requirement specification resulted in 87 defects being captured by the test team, of which 34 were deemed priority 1 and priority 2 issues - all before a piece of code was written.
- An improved life cycle, providing effective change management, facilitated innovation and improvement, which reduced the time and cost to achieve compliance.

"EmpowermentQE added enormous value to the project. Their ability to get up to speed, spot gaps and communicate information back in a supportive manner is something that I will now endeavour to harness throughout the entire company".

"I have found EmpowermentQE to take a very professional and structured approach towards their work, with a dedication for success."

An automatic Clinical Trial project management and drug supply management system.

This was a complex integration project with a 3rd party IVR solution provider to provide a HIV clinical trials drug distribution and re-ordering system.

Main project aspects:

- Devised the integrated quality approach, the implementation methodology, verification activities and validation activities.
- Identified technical and business risks in tandem with the quality risks.
- Devised a bespoke computerised system approach to manage the implementation, technical test and validation tasks in order to mitigate against the identified risks.
- Inspected the requirements from a software engineering" and "technical test" perspectives to ensure that the technical risks of the project were managed.
- Collated "project" metrics to facilitate process improvement activities on the new approach.
- Devised the project visioning, configuration management and change control approach.
- Managed the user acceptance test specification for the end client and for the validation approach.
- Devised a computerised system QMS to manage the newly created procedures and guidelines.
- Managed internal audit of the computerised system approach for QMS compliance and process improvement.
- Managed and participated in all functional, design and code reviews.
- Devised, managed and implemented the technical test approach.
- Managed the technical test environment.
- Prioritised and managed defects.
- Designed and wrote a bespoke automated test harness to facilitate real time testing between the integrated systems and the IVR.

Outcome:

- Achieved a timely delivery, within budget - achieving "Right First Time Validation."
- Enabled a cost effective operation and maintenance.
- Enabled innovation, with the introduction of a new technology and implementation approach.
- Ensured wholly traceable documentation and enabled a least burdensome approach for Validation activities.

"Dependable, quality and client focused. They performed their engagement efficiently and delivered on their commitment. Always willing to go the extra mile."

tested by empowerment
quality engineering

Service Offerings

- Computerised System Consultancy.
- Computerised System Managed Service.
- ISO Based 3rd Party Supplier Audits.
- Computerised System Methodology Creation.
- Computerised System QMS Creation and Management.
- Computerised System Process Improvement.
- Computerised System Quality Assurance Training.
- Defect Prevention and Defect Detection Training.
- Computerised System Test Management.
- Holistic Risk Based Verification and Validation Strategies.
- Cloud Testing Strategies.
- Computerised System Change Control, Revision Control and Configuration Management.
- Customised Off the Shelf Tool Selection, Implementation and Verification Strategies.
- Computerised System Test Environment Creation and Management.
- Building Computerised System QA Teams.
- Computerised System Project Management.
- Computerised System Estimation Training.
- Computerised System Project "Fire-Fighting".
- Computerised System Knowledge Transfer (Hand-over into Operation).
- Technical Testing:
- Static; Manual; Automated; Performance; Vulnerability and Fault Tolerant Testing.
- Non Graphical User Interface Based Testing.
- 21 CFR Part 11 Testing.
- Hardware Testing.
- Test Design Techniques.

empowerment
quality engineering

Omagh Business Complex | Great Northern Road | Omagh | N. Ireland | BT78 5LU

t: +44 (0) 28 82 25 19 50
m: +44 (0) 77 80 43 29 53

w: www.empowermentqe.com/pharma
e: ciara.mcmanus@empowermentqe.com