Clarmon
Compliance Management Solutions

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Facility Commissioning and Qualification using QAvalid™

Pharmaceutical companies typically expend significant resources (time, money, specialized personnel or consulting) to validate a current Good Manufacturing Practice (cGMP) facility.

The lion's share of these large costs can be attributed to inefficient practices and tools used in this effort. The lack of control and of a structured way to create and manage documents is the main source of stress for the managers in charge of such projects. Traditional electronic systems provide limited improvements, while the actual users are left to struggle with complicated interfaces.

QAvalid™ is the solution that manages all the commissioning and qualification (C&Q) documents as electronic records, while at the same time managing the relationships between them. This facilitates control across all phases of the project and ensures that relevant information is kept up to date and compliant.

Designed to support an integrated approach to C&Q, QAvalid essentially eliminates repetitive efforts and automates recurring tasks, without changing the way users actually work. The familiar Microsoft Word® environment is the primary interface when creating/changing content, while all documents, tasks and requirements can be managed from any location through the web interface.

Why QAvalid?

- Provides a simple, structured way to write documents and to manage them
- Ensures that regulatory requirements are met substantially faster than with current systems
- Allows constant control over project progress
- Provides unique content level linking between documents to reveal change impact
- Automatically updates documents (i.e. the Validation Master Plan always contains the current inventory list with the associated status)

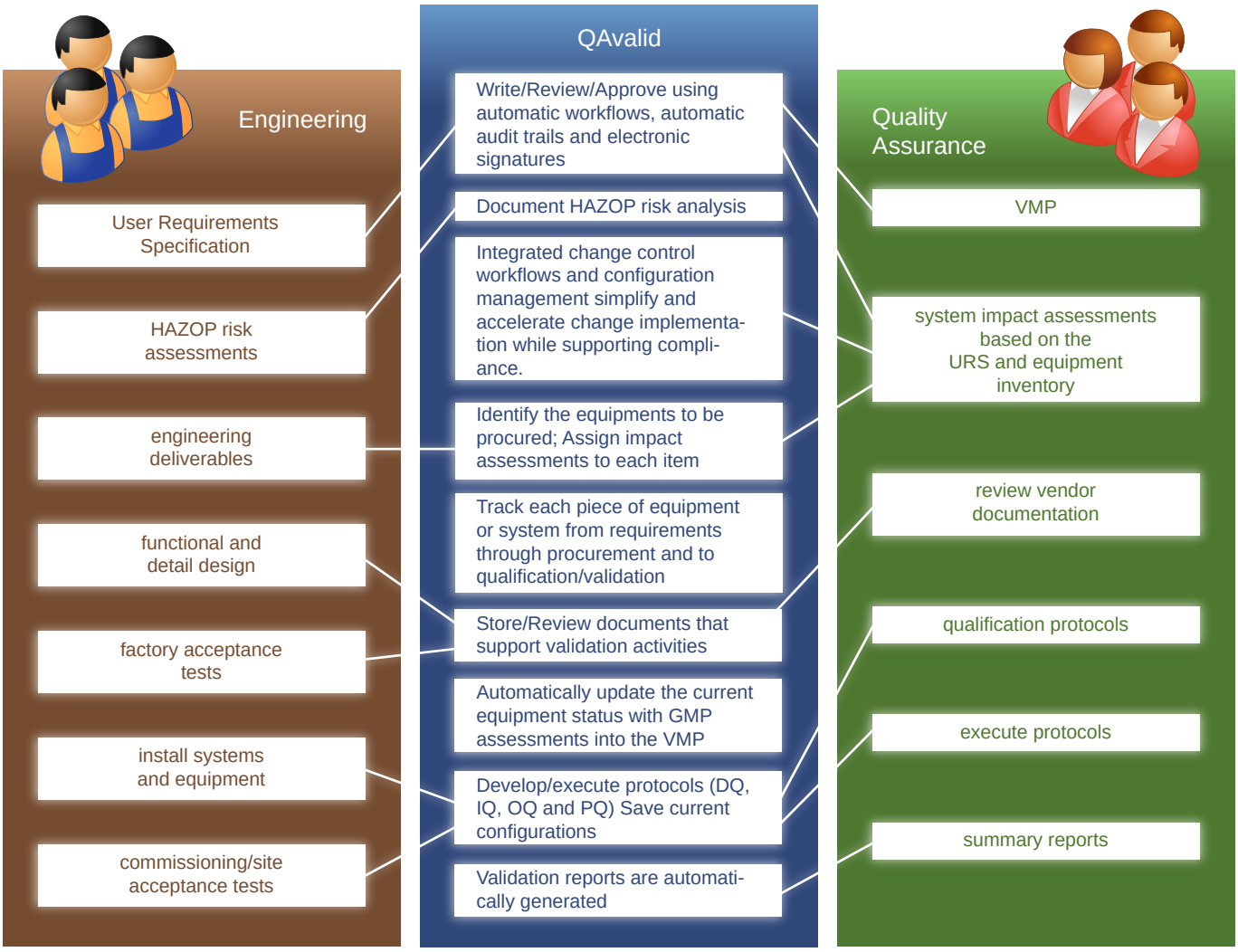
The lifecycle approach to C&Q that is internationally accepted follows a structured method to plan, design, implement, test, operate, change and/or retest systems. In practice, user requirements specifications (URS), risk assessments, plans, procedures, test protocols (IQ, OQ, PQ), reports and other related documents have to be created and maintained to meet cGMP requirements and pass inspections.

Today's challenges

- As information is commonly stored in "physically separate documents", it becomes difficult to manage change in the overall system. Professionals with different expertise have to work together through design, commissioning, procurement and qualification phases.
- Not only do the documents have to be written by different people but they also need to be approved and updated or changed in a compliant manner.
- As integration between engineering/commissioning and qualification activities is reduced, documents are needlessly recreated causing delays and inconsistencies when transferring data between different phases.
- Control is very limited with traditional documentation systems-it is almost impossible to check the validation status of all equipment or systems in real time, or to promptly identify and fill the gaps in documentation.

Tomorrow's solutions

QAvalid supports a unique approach to ensure success in facility validation. It manages information inside documents (the content) and the relations between documents. Commissioning and qualification activities can be seamlessly integrated in a controlled manner so data is written once and project time is decreased.



Commissioning and qualification activities integrated by QAvalid

QAvalid Benefits for Facility Commissioning and Qualification

Constant Control

- An up-to-date status is always available for each piece of equipment or system.
- The items can be easily grouped and traced according to GxP impact.
- Integrates with Primavera® and similar solutions enhancing control and efficiency.
- QAvalid tracks the compliance status for each item and exposes what has been written inside each validation document. This creates an image of documentation gaps in real time, and allows managers to tightly control every aspect of large scale validation projects.

Accelerated Reviews/Approvals

- QAvalid provides configurable electronic workflows to accelerate collaborative documentation tasks.
- Email notifications instantly deliver assignments to the next user. Simultaneously, the task appears on the main page of the web interface for the appropriate person.
- GxP approval, deviation or change control workflows, which are integrated within the application support time efficiency and compliance (automatic audit trails are always available).

Documents are Connected, Change Impact Always Available

- Plans, vendor documents, specifications, qualification protocols, or configurations are among the related documents that have to be managed to achieve facility validation. QAvalid captures the relations between separate compliance documents and makes them available as live links. Through the live links it is thus possible to see when a related document has been changed without modifying the current one.
- The traceability matrix can be automatically generated to reveal the documents that would have to be updated when changing a certain section.

Use Microsoft Word® to Write/Change Documents

- Facility validation documents can be written, reviewed or approved in Microsoft Word®, while the relations between them are captured and the system is centrally managed. QAvalid provides a Word Add-In toolbar to achieve this.

Fully Electronic Computerized System Validation

- Electronic validation is accelerated by automatically creating and linking test scripts from requirements.
- When an incident occurs, the system automatically generates and links an incident form to the original test eliminating the issues that arise when these documents are lost.
- All approved document versions remain stored in QAvalid and all changes are made through electronic change control workflows.

Real time equipment tracking and reporting

- Equipment information is centrally managed and controlled throughout all project phases (i.e. specifications, P&IDs, procurement, impact assessments, and qualification).
- As IQ, OQ and PQ are completed, the equipment status is updated into the VMP to demonstrate compliance.
- Relevant electronic information connected to each piece of equipment is readily available (i.e. vendor documents, IQ, OQ, SOPs).

Continued compliance after the project ends

- QAvalid is uniquely suited to manage the ongoing compliance documentation challenges. Re-qualification and re-calibration activities supported by e-mail notifications and change management will reduce the effort needed to maintain compliance.

Who we are

Clarmon Corporation is a privately owned company founded in 2004.

Clarmon was established and is sustained by people with extensive experience in Compliance Management, Quality Assurance and CSV. They have been brought together by the belief that documentation processes can and should be simple and automated.

We are headquartered in London with a highly experienced development and consultancy team in Bucharest, supported by sales staff in Dubai and Singapore and by a number of global partners.

What we do

We provide configurable software solutions to solve your documentation problems efficiently.

We support solutions for:

- Computerised System Validation
- Change Control and Configuration Management
- Equipment Inventory Management
- Corrective and Preventive Actions (CAPA)
- Audit Management
- Facility Validation Management

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