

Equipment, systems or instruments that may impact product quality or patient safety need to be controlled and evidence of such actions provided.

Despite strong determination and efforts from QA professionals, the equipment inventories in most regulated companies are out of date. When was the equipment last qualified? Were all regulatory requirements (i.e. EU and FDA) met? How were the impact or risk assessments established? Where are the specification and qualification documents? What other documents should be modified when one is changed? How do we come up with the equipment baselines? These questions help identify some serious faults in the way the equipment inventory and related documents are managed.

Why is equipment compliance information difficult to manage?

- Because the equipment inventory and the qualification documents are disconnected and manual updates are always required
- Because users are seldom aware of the change impact. As a result some documents always fail to be updated
- Because disconnected documents are difficult to identify and retrieve
- Because change management is not properly implemented

QValid

The equipment inventory and qualifications, impact assessments, specifications, SOPs, etc are linked. The inventory information can thus be more reliable and the needed documents are easier to retrieve.

Traceability across all documents reveals change impact and highlights out of date documents ensuring a compliant stage is maintained.

Changes are routed through change control workflows while all configuration baselines are saved and linked to the change requests.

The system supports re-qualification and re-calibration schedules, sending tasks whenever an activity is scheduled.

*A new generation solution, QValid saves **40% to 60%** of the time spent documenting compliance!*

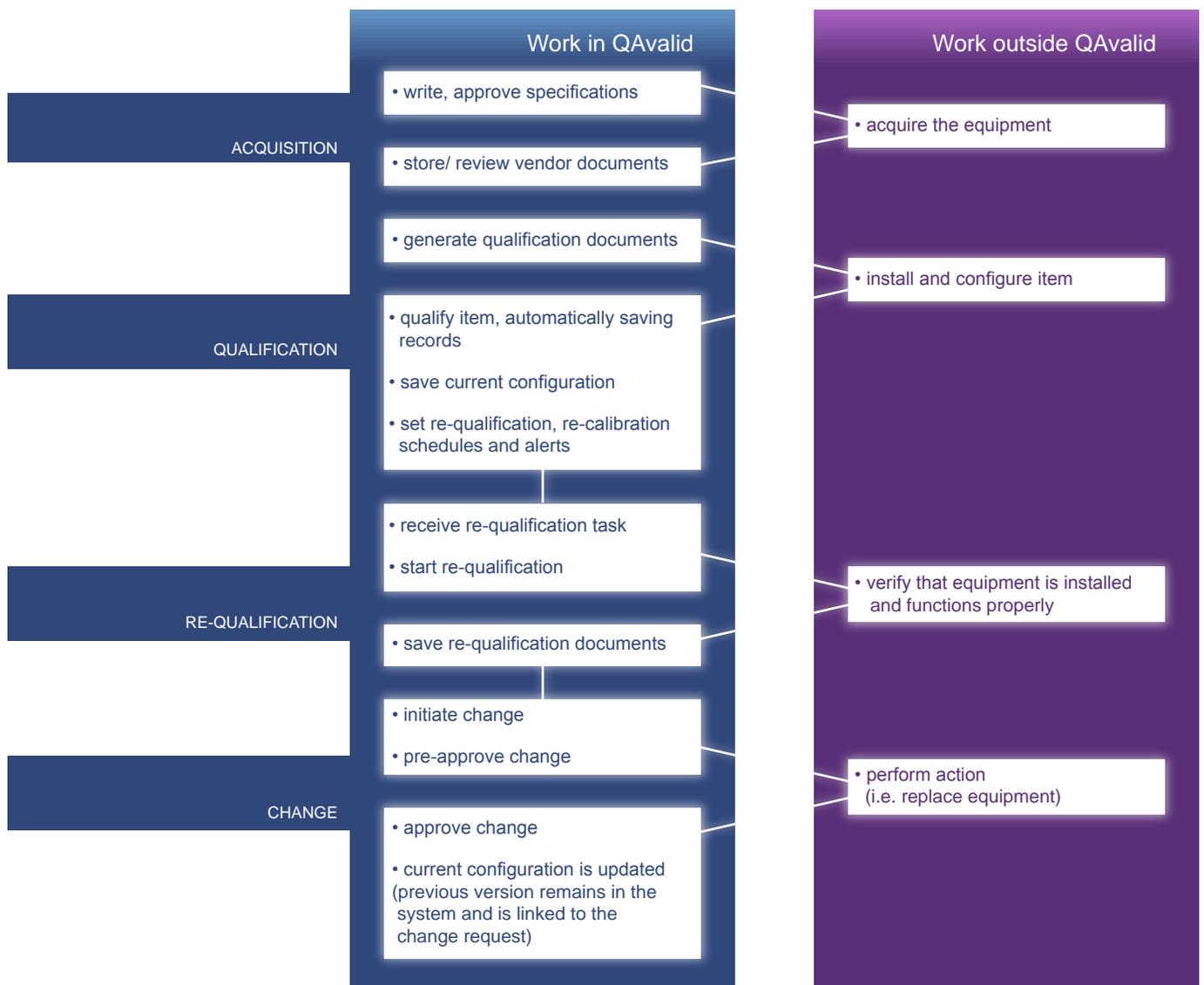
A lifecycle perspective to equipments management

From acquisition to retirement equipment needs to be controlled and documented evidence provided. Uniquely identifying each item, servicing, calibrating, qualifying or validating are processes that can not be performed efficiently using manual methods. The effort to maintain a compliant stage throughout the lifecycle is directly influenced by the number of items that have to be controlled and thus becomes difficult to manage with current systems.

The efficient way to manage equipment documentation using QValid

QValid supports significant improvements in the way equipment documentation is managed. The major benefits consist in reducing the effort needed to retrieve documents, to change and maintain them up-to-date, or to manage recurring equipment related tasks (i.e. qualification).

The equipment inventory and related information (specifications, qualifications, SOPs, etc) are managed in QValid as controlled documents. Microsoft Word can be used to write, change and approve documents, while content is centrally controlled. Equipments can be maintained compliant with less effort using re-qualification schedules. Automated workflows supported by audit trails and integrated change management form a second layer of features that improve efficiency and support compliance. Proprietary Linksense™ technology allows knowledge capture and traceability, connecting related documents or sections. Thus, change impact is always available, making it easier to maintain up-to-date documentation.



Routine equipment operations; activities in QValid / outside QValid

From Requirements to Retirement

QValid manages equipment information starting from the specifications phase, before the item is acquired. Specification documents can be written in Word by using the QValid Word Add-In toolbar or via the web interface. Automated workflows accelerate reviews and approvals, while the document is saved in a centralized repository.

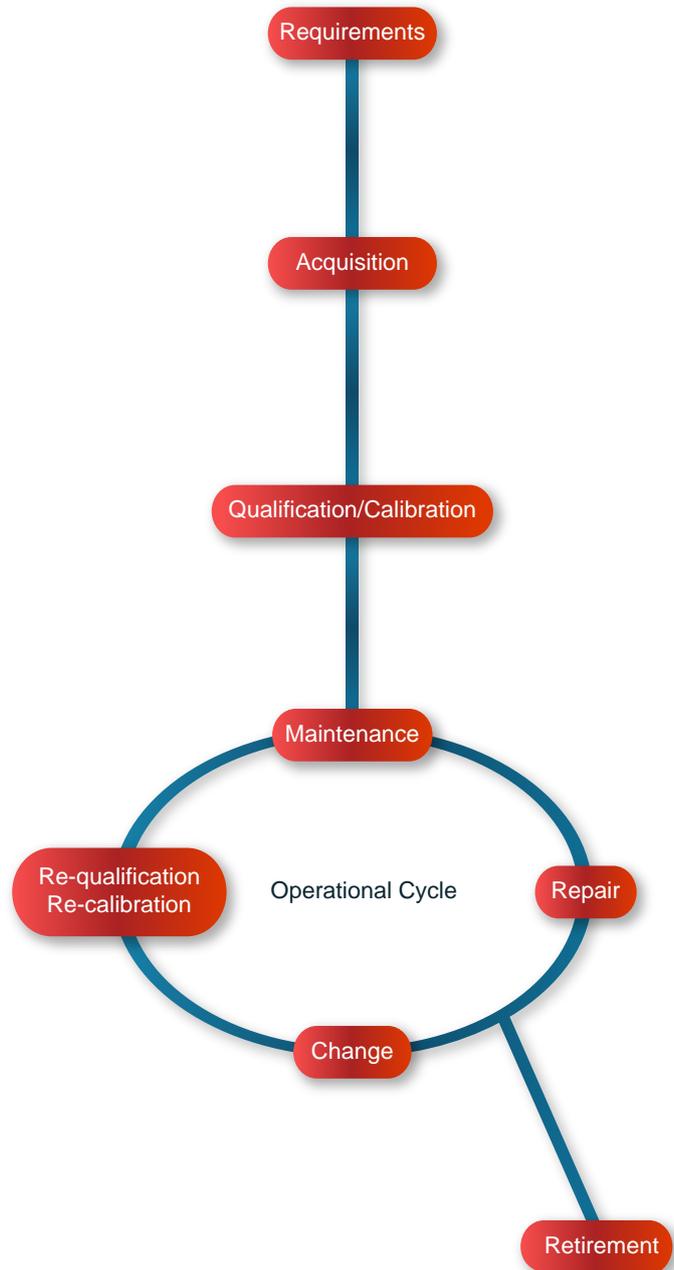
One of the problems associated with the acquisition phase is ensuring that the selected item meets the predefined specifications. This is simple to demonstrate in QValid, as the specifications are linked to the equipment configurations, becoming readily available.

Qualification is electronically managed, and the qualification documents are linked to the configurations. This ensures that the qualification status is up-to-date and that it can easily be justified by retrieving the relevant documents.

By using re-qualification (re-calibration) schedules and the integrated change control system, a planned, structured approach can be shown to the inspectors. While in the past, equipments were re-qualified and re-calibrated whenever there was time, now there is a frame that guarantees these tasks are carried out at set intervals.

In addition to qualification and calibration, other activities and documents that relate to equipment can be centrally managed in QValid. Using the special Linksense™ technology that supports knowledge capture, maintenance records and SOPs may be linked together with configurations, specifications or qualification protocols. By knowing the impact of any document or section change, the system can be maintained compliant using less resources. A traceability matrix can be generated instantly to display the links to and from specific documents. Moreover, inside one document users are able to see if another related document has been changed without updating the current one. QValid supports a risk based approach. Risk assessments can be generated for a selected group of items from the equipment inventory and can be automatically linked to each equipment.

To ensure compliance is maintained, modifications are implemented through a change control workflow supported by automatic audit trails. Linking to the change requests, all configuration baselines are stored in QValid and accurately present the item's history: what changed, why and who approved it.





Who we are

Clarmon Corporation is a privately owned company founded in 2004.

Clarmon is established and 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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