QAvalid™ CAPA Solution

In most industries companies need to have a Corrective Action Preventive Action (CAPA) program to handle non-conformances understand the problems and resolve them. To be efficient a CAPA program must be able to solve issues quickly, and more importantly prevent them from recurring (Preventive Action). Implementing an effective CAPA program is far from simple with today's IT systems. Generally companies rely on a hybrid system - paper forms combined with electronic documents or a simple database generating CAPA forms. They must still be updated manually, causing delays, mix-ups and compliance problems.

QAvalid is designed to automate the process of managing CAPA, while integrating it with other processes essential for regulatory compliance (change control, SOPs, audits). Using the QAvalid system to handle corrective and preventive actions accelerates the process, and makes it more simple and cost-effective.

Some of the Common Problems Are:

- Disconnected Data Collection: A corrective action may be triggered by different factors like deviations, non-conformances, impending internal or external audits, adverse events, or customer complaints. Using manual and hybrid document management systems, data collection is slow and often incomplete. When quality data is dispersed across different departments, facilities, and repositories, implementing a correction can be a difficult process. For companies using manual systems, it means digging through files, hauling-off boxes of paperwork, and making sure nothing is missing: a slow, manual and error prone process.

- Fallible Reporting: When customer complaints, deviations, and adverse events are collected manually, there is no guarantee that all the critical information will be captured. It can be easily misplaced. Paper reports are time-consuming to update. In a hybrid system, re-entering data from a hard copy into an electronic system might be required just to generate a report. And when data re-entry is delayed or performed poorly, you will get an inadequate report.

- Missed Deadlines: Some quality systems impose strict deadlines. Manual and hybrid systems are, by nature, inefficient and are unlikely to help close corrective actions promptly.

- Hidden Costs: Paper may be inexpensive, but the cost in man-hours spent maintaining manual or hybrid systems can be tremendous. Every hour spent by an employee in tedious and inefficient data collection, reporting, and analysis is an hour away from work on other important tasks.

- Lack of Control: A company must track corrective actions over time to prevent the same problem from recurring. A quality assurance manager has to go to different departments or facilities to collect information, plough through piles of forms, and has countless phone calls to make and e-mails to follow up.

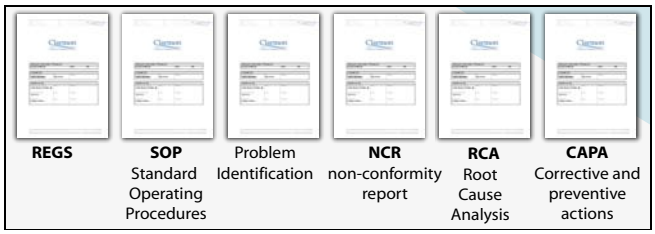
- Inconsistency: A company may be able to devise a corrective action with a manual/hybrid system the first time. What about the second time? When key employees leave will the others be able to repeat the process? Consistency is the key to successful CAPA programs.

The QAvalid Solution

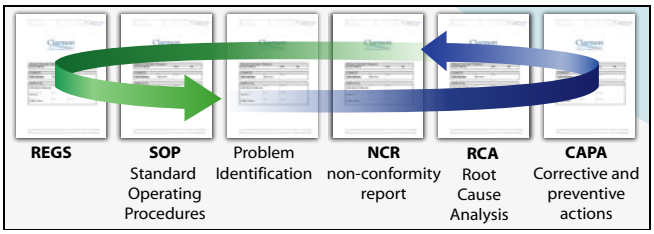
QAvalid is the solution designed to help companies manage corrective action processes that are critical in maintaining compliance. QAvalid collects data from multiple sources, manages trends, connects and automatically triggers sub-system processes to solve production issues.

Electronic managing CAPA streamlines the process by improving root cause detection, solution reporting and resolution. The result is documented and will produce evidence of quality improvement.

QAvalid CAPA initiation can occur either from within your web browser or from Microsoft Word. The QAvalid toolbar appears in Word and helps you manage the document efficiently.



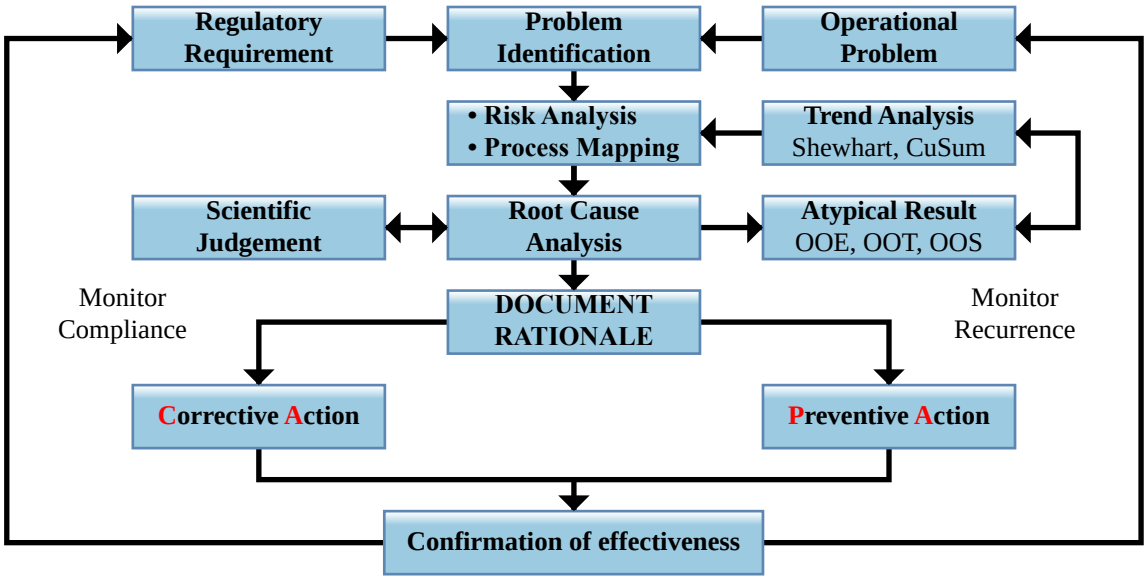
Created with Microsoft Word



Kept Compliant with QAvalid

QAvalid automates the process of managing CAPA and provides best-practice features that prompt users with selected data. It includes a step by step approach to CAPA implementation from team selection through root cause investigation and closing of corrective action.

QAvalid has a secure web-based interface. Employees, customers and suppliers can participate in the CAPA processes like data gathering and verification, document approval, notifications and training from anywhere in the world.



Compliance Features and Benefits

QAvalid can connect all quality subsystems under one quality process for a general approach to problem solving. Management teams will have a proactive view into the entire quality system to better prevent or reduce the number of recalls and returned products. QAvalid tracks quality incidents that can lead to a CAPA.

Reports can be generated with one click allowing managers to gain precious overview of the entire quality system. Managers can also track the actual progress of the tasks they issue. For instance the system will tell you if a CAPA form is “In Progress” or “Completed”.

• Linked Processes

QAvalid CAPA can be integrated with other QAvalid documents to link all corrective action processes with document control and change management. The resolution of a corrective action will trigger an engineering change, a Standard Operating Procedure (SOP) change, and retraining of employees on the new SOP. The software handles the entire life cycle for quality management incidents and changes.

• Audit History

QAvalid maintains a secure, time-stamped audit trail of all changes made to any field on a form and makes them accessible to the appropriate users and departments. Information is automatically captured and secured. Reporting and analytics functionality are provided to track non-conformances, customer complaints, and open corrective actions. Each time a change is made to any field, the system tracks it and makes it available through system reports.

• Document Control

QAvalid can put a stop to unauthorized copies of CAPA reports. Only authorized users can view, edit and print sensitive information.

• Electronic Signature

With QAvalid, you can automatically append signature manifestations to each completed form, including first name, last name, date, time, and meaning of the electronic signature.

• Revision Control

The Project Manager has control of all CAPA form revisions throughout the process lifecycle. With automatic revision control, current form data and form templates will never be overwritten.

• Automatic Workflow

QAvalid has an integrated workflow and individually assigned tasks, like inputting and approving data, are automatically allocated as a form moves through the workflow process, from person to person or department to department. For example, when a CAPA moves through the multi-step process of initiation, team creation, root cause analysis, and change implementation, tasks are automatically connected to each stage of the workflow route.

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

Clarmon Corporation

145-157 St John Street, 2'nd Floor
London, EC1V 4PY
United Kingdom

Phone: +44 (845) 058 2023
Fax: +44 (870) 762 7231
www.clarmon.com

Clarmon
Compliance Management Solutions