

# APPLICATION SOLUTION

## QUALITY & COMPLIANCE

### FACTORYTALK® PRODUCTIONCENTRE BENEFITS

- A choice of either rich Java™ client or true HTML thin client technologies
- Solution is designed to help reduce the cost of compliance with 21 CFR Part 11, 21 CFR Part 820, ISO 9000 and ISO 13485
- Fully integrated with non-conformance tracking (Incident Management) and customer complaints (Complaint Handling)
- Drives the CAPA process with role-based, configurable workflows and tasks
- Alerts, escalation, and notification when tasks or process steps are due or overdue
- Seamless access to supplier, production and return/repair records for comprehensive root-cause analysis
- A single location for storing associated documents with automatic versioning control

## CAPA: CORRECTIVE ACTION/ PREVENTIVE ACTION MANAGEMENT



For today's manufacturing enterprise, quality and profitability go hand in hand as consumer expectations and regulatory obligations set requirements for every stage of a product's life cycle.

Increasingly, companies are adopting a quality systems approach to manufacturing. In this approach, the classic elements of a quality assurance program are integrated into the manufacturing and quality control processes to bring a comprehensive approach to meeting quality standards and regulations, including ISO 9000, ISO 13485 and the US FDA 21 CFR Part 820.

This quality systems approach to manufacturing is based on the philosophy that quality should be built into the product and that testing alone cannot be relied upon to ensure product quality. FactoryTalk® ProductionCentre provides core capabilities for manufacturing and quality control on the shop floor as well as off-the-shelf, configurable solutions for quality assurance activities.

QUALITY ASSURANCE PROCESS	SOLUTION
Purchasing	Supplier Management
Control of Non-conforming Product	Incident Management
Corrective and Preventive Actions	CAPA Management
Customer Complaints Servicing	RMA/Repair Management

## CAPA MANAGEMENT

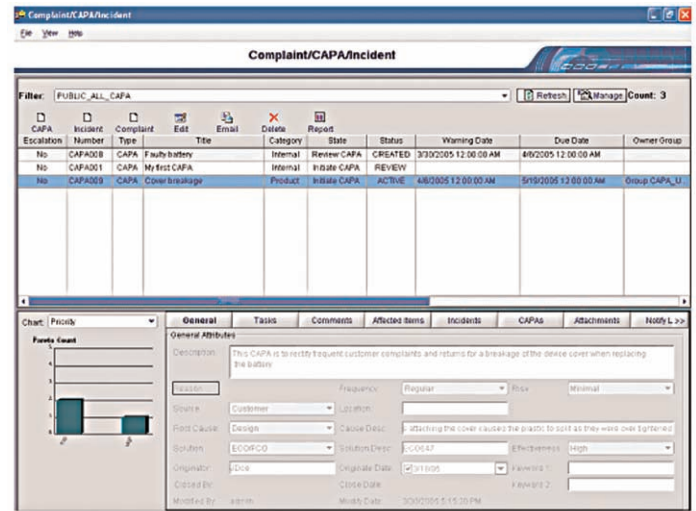
This quality assurance process is responsible for identifying, correcting and eliminating the cause of potential and actual non-conformances, minimizing the risk of poor quality and providing continuous improvement of the manufacturing operation.

## FACTORYTALK PRODUCTIONCENTRE

The FactoryTalk ProductionCentre CAPA Management solution is a comprehensive, closed-loop corrective action application that seamlessly interacts with other quality and manufacturing processes and systems. CAPA Management is deployed as a standalone solution for a single site, or across an enterprise, and can also be integrated with other Rockwell Automation solutions to provide a comprehensive end-to-end quality management system that spans the product life cycle for identifying, monitoring and improving products and processes. CAPA Management is an essential part of a comprehensive quality program to address compliance with voluntary quality standards such as ISO 9000:2000, as well as quality-based regulations enforced in life science industries for Good Manufacturing Practice, such as 21 CFR 820, 21 CFR 11 and ISO 13485.

The CAPA Management solution provides a single tool for creating and managing CAPAs throughout the process, from initiation through plan development, approval, implementation and monitoring. A configurable workflow engine enforces the required process and provides for routing approval of associated documents, which may be secured and placed under change control.

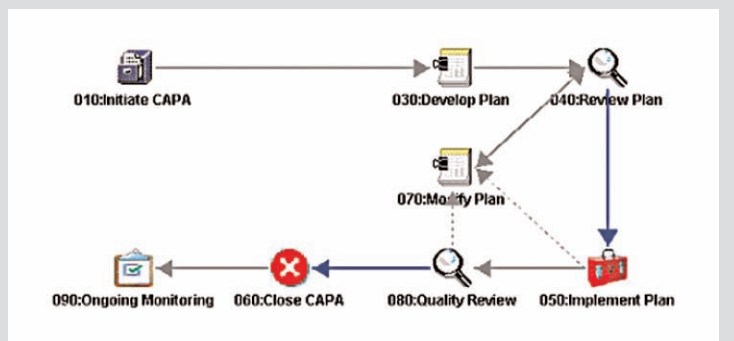
Workflow management is complemented by the Rockwell Automation Integrated Architecture™. Global data management, notification and analytics help manufacturers identify trends, perform root-cause and failure analysis and measure and monitor the results of CAPAs.



CAPA Management can provide site-specific CAPA support or be deployed as a global best practice across the enterprise. The common FactoryTalk data model allows for seamless interaction between CAPA Management, Shop Operations, Complaint Handling, Returns and Repairs and Supplier Management for a complete quality systems approach to manufacturing.

## BENEFITS

- Flexible and configurable workflow that provides out-of-the-box CAPA process control
- Defect and non-conformance tracking
- Reduction in cost and reduced risk of regulatory compliance with readily available, validated electronic records of CAPAs



Build a flexible, responsive infrastructure that will allow you to increase production and maintain the high quality required by regulatory agencies and your customers.

Doc Audit Time	Save Key	Tab	Field	Action	Previous Value	Current Value
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## BENEFITS

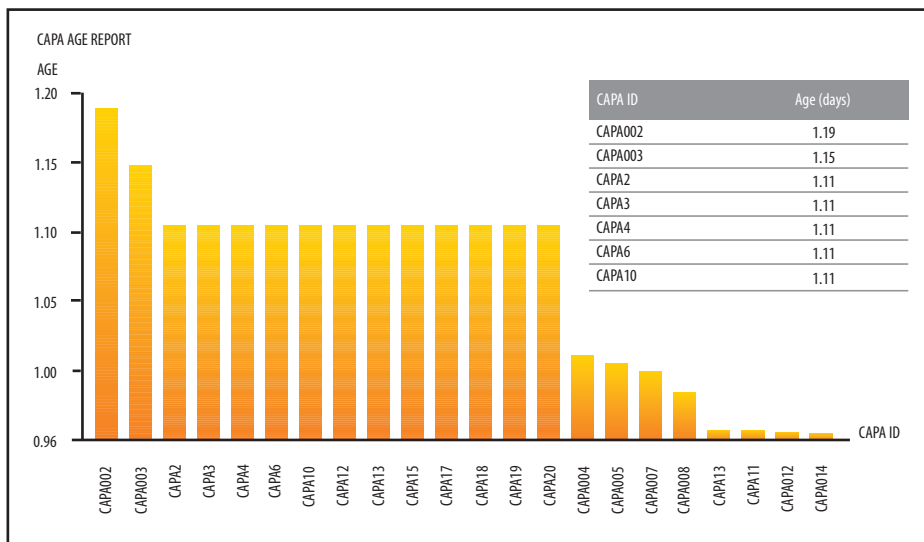
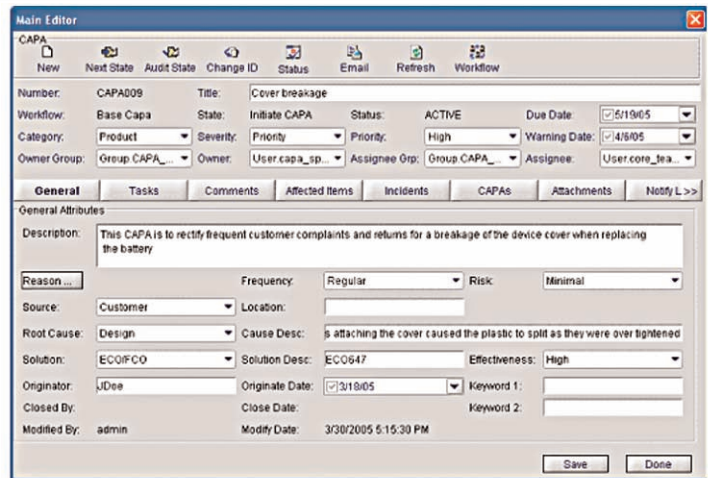
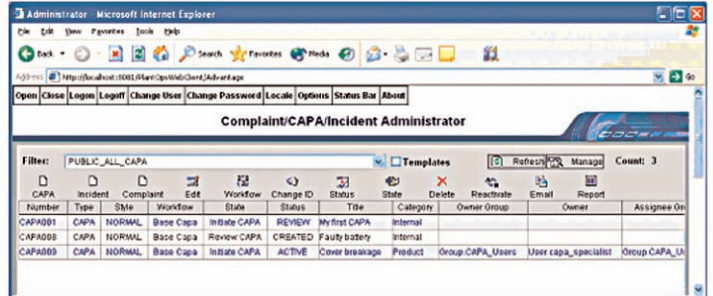
- Enterprise- and site-wide visibility and control of CAPAs for better decision making, continuous process improvement and the application of best practices.
- Accurate and rapid failure and root-cause analysis based on customer complaints, service records, supplier information and manufacturing data.
- Rapid implementation (out-of-the-box configurability, no scripting), with minimal deployment and validation time and costs for a faster ROI.

## FEATURES

- Includes 10 standard reports for analysis and monitoring.
- Produces analysis of CAPA metrics such as aging, average turnaround time and severity count.
- Templates for document and task creation.
- A complete audit trail of CAPA events, including fully authenticated electronic signatures for approvals and modifications.

## PLATFORMS

The FactoryTalk ProductionCentre CAPA Management server runs on a variety of operating systems, including Microsoft® Windows® 2000, Windows 2003, Linux, Sun™ Solaris™, and HP-UX. CAPA Management clients require Microsoft® Internet Explorer® and Microsoft Windows 2000 or Windows XP.



## ABOUT ROCKWELL AUTOMATION

Rockwell Automation is a recognized leader in enterprise software solutions that help global manufacturers achieve predictable product supply through a quality-based approach to manufacturing operations. Headquartered in Milwaukee, Wisconsin, Rockwell Automation serves customers in medical device, pharmaceutical, electronics, automotive, telecommunications and other industries.

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