



NC

Where Will Your Next 483 Come From?

MINIMIZE COMPLIANCE RISK & LIABILITY

21 CFR Part 820.90 specifies controls for non-conforming materials that do not meet quality acceptance criteria and are thereby determined not fit for use. Today's life sciences organizations are increasingly at risk due to poor quality and a lack of control. Does your organization have adequate systems to control the identification, quarantine, disposition, tracking, and trending of non-conforming materials?

The eQCM® NC (Non-Conformance) module delivers a comprehensive set of features that manages and controls the non-conformance quality process from identification through ultimate disposition and tracking.

eQCM® NC - The Integrated Quality & Risk Management

MAXIMIZE COMPLIANCE INTELLIGENCE

eQCM® NC delivers quality and risk management for the control of non-conformances through an easy-to-use, flexible web-based interface. The system is completely configurable and fully automates the routing and approval of integrated userdefined non-conformance forms and triggers corrective actions as needed. Amadeus delivers a comprehensive quality management suite that maximizes enterprise compliance intelligence. As an essential component of the suite, eQCM® NC is tightly integrated with the eQCM® CAPA, eQCM® EDM and eQCM® Audit modules for maximum quality assurance and a closed-loop process. eQCM® NC is used to identify, notify and resolve customer, manufacturer and supplier quality issues during production.

The system is designed to alert all appropriate staff when non-conformances are detected, either at the supplier or the manufacturer level, and facilitates effective team work to contain and resolve the issue in the most appropriate manner and properly dispose of any non-conforming material in accordance with internal and regulatory guidelines.

Integrated Non-Conformance Management

BENEFITS

- Reduced Disruptions
- Decreased Product Quality Costs
- Improved Consistency and Quality
- Optimization of Quality Control and Non-Conformance Management
- Increased Enterprise Collaboration
- Rapid Deployment
- Decreased Regulatory Risk
- Ready To Validate

FEATURES

- Seamless Integration With eQCM® CAPA and eQCM® Audit Modules
- Multi-tier Non-Conformance and Root Cause Categorization
- Management and Tracking of Internal & External Non-Conformances
- Workflow-driven Notices and Reminders
- Configurable Disposition Codes and Product Locations
- Comprehensive NCMR Reporting & Trend Analysis
- Configurable, Integrated Non-Conformance Management Forms
- Rule-based routing of product or process non-conformance
- Determination of Materials Review and Disposition

Product Features

SIMPLIFY NON-CONFORMANCE TRACKING AND MANAGEMENT

SOFTWARE VALIDATION

eQCM® NC is designed exclusively for deployment in highly regulated software environments. Validation of off-the-shelf applications such as eQCM® NC ensures that our software supports your intended use. In recognition of the fact that intended use varies from one company to another, Amadeus International delivers a practical, comprehensive set of validation protocols including Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) to ensure production readiness and accelerate validation requirements. Our validation methodology follows the principles of software validation as defined within the **“General Principles of Software Validation; Final Guidance for Industry and FDA Staff”**. Our professional services team can help you streamline your validation effort thereby reducing time-to-compliance and on-going operational support.

About Amadeus International

Amadeus International is a pioneer and leader in compliance process control solutions. Its flagship product, eQCM®, is a flexible, Web-based integrated suite of applications that allow organizations to map regulated business processes such as CAPA, non-conformances, customer complaints, EH&S, and other related quality and business processes. The application suite is coupled with powerful business intelligence capabilities, enterprise content management, and related technologies that help organizations achieve sustained compliance. Amadeus International's global headquarters are located in Quebec City. Amadeus solutions are distributed across four continents.

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NON-CONFORMANCE PROCESS MANAGEMENT

Feature	Description
Comprehensive Deviation Management Capability	The eQCM® NC system has the ability to help manage non-conforming materials, customer complaints, warranty claims and all other types of quality-related deviations.
Flexible Process Templates	eQCM® NC includes flexible process templates that allow quality organizations to map NC processes quickly and easily. Once process templates are activated, users may initiate new NC events by copying or creating a new event.
Conditional Process Control	eQCM® NC processes templates may include conditional statements that trigger required actions at various steps.
Color-Coded Process Alerts	eQCM® NC includes color-coded process alerts and notifications.
Detailed Task Management	Tasks are embedded within each process template. These tasks are automatically placed in Workload areas for the user.
CAPA Initiation From An NC Event	A CAPA process may be initiated from a source NC report leveraging eQCM® CAPA, keeping the continuity in data between the two events.
Customer Complaint Handling	eQCM® NC includes automated links between issues, CAPA events, and customer complaints. Customer complaint processes can be easily configured and managed within the system.

CONFIGURATION & INTEGRATION

Feature	Description
Comprehensive Security Model	eQCM® NC includes a comprehensive security model that controls access to the various eQCM modules based on user-defined security profiles.
E-Mail Integration	eQCM® NC easily integrates with any MAPI-compliant email system to ensure timely process notifications.
Built-in, Configurable Electronic Forms	Authorized users may customize electronic forms quickly and easily through a built-in electronic forms interface.
Configurable Approval Sequences	Approval sequences are designed to control process tasks. Task progression is controlled at each step in the process.
21 CFR Part 11	eQCM® NC is fully compliant with 21 CFR Part 11.
Site-Specific Event Parameters	eQCM® NC may be easily configured to include site-specific parameters.

NC REPORTING & DISPOSITION

Feature	Description
NC Search & Retrieval	eQCM® NC includes robust search capabilities, allowing authorized users to retrieve all relevant information regarding open and closed NC events.
Status & Metric Reports	St eQCM® NC offers flexible reports that allow authorized users to track status and key metrics of opened and closed NC events.
Material Disposition Management	eQCM® NC system allows authorized users to define issue-critical during the NC initiation and implementation process and generate material disposition reports.

Amadeus
The Step Above
Compliance™