DASSAULT SYSTEMES

ENOVIA

# QUALITY MANAGER

## OBJECTIVE

**Quality Manager** is a comprehensive quality management solution that directly embeds quality and compliance directly into the product development process. It enables organizations to take control of their global operations, while continuously improving operational performance.

## OVERVIEW

Organizations are consistently struggling to deal with quality issues efficiently and effectively. As the complexity of products and processes increases, this predicament only promises to worsen. By removing departmental silos with the **3D**EXPERIENCE® platform it is possible to enforce common quality processes, while adapting to local regulatory requirements and improving communication.

**Quality Manager** manages the entire event lifecycle from customer event intake through investigation, root cause analysis and closure. This comprehensive solution is designed to help manufacturers expand programs to best capture a wide scope of operations intelligence, which can drive continuous improvement and streamline their quality processes. It provides ease of use at all levels of the organization for managing quality events, corrective and preventive actions (CAPA), product nonconformance, and audits. It is all about collecting the right data, and making it available to the right person, at the right time. This very powerful combination, if done right, can have a profound impact on performance and a pathway to becoming best-in-class.

The challenges of implementing and sustaining an effective CAPA process can vary. There are often too many quality data silos with difficult to view data that hinders access to real time information resulting in poor decisions. A common enterprise-wide quality solution like **Quality Manager** helps companies avoid compliance risk, reduce waste, and improve quality and decision making by improving the interconnection of team members and business processes.

**Quality Manager** is also an effective, consolidated, global approach to managing customer complaints. It improves the management of the complaint handling lifecycle from identification; valuation to closure. **Quality Manager** improves visibility throughout the organization to help reduce delays in identifying, evaluating, and communicating serious events. It automates the control and disposition process of non-conforming products and processes by identifying the nonconformance, tracking its review, and monitoring and reporting the follow-up actions.

For a complete and systematic QMS approach, audits are conducted. After audits are planned, findings are classified and follow-up is assigned to the responsible person. Upon completion of follow-up actions, a final report is issued and routed for complete closure. **Quality Manager** links all artifacts, records, analysis, documentation, and validation results. These artifacts are easily traceable and retrievable for internal or external audits providing added value for engineering, manufacturing and quality teams working on new product programs.

## HIGHLIGHTS

Key features and capabilities include:

### CAPA Management

Today, industries are facing strong pressure from regulatory bodies—government as well as from the industry itself—to focus on quality and, at the same time, the need to increase asset utilization and efficiencies, and lower cost as much as possible. A corrective and preventive action (CAPA) program is one tool to achieve these objectives. As with any program, there are wide variances in program governance, structure, funding and effectiveness. Many CAPA programs have been implemented with few tangible enterprise-wide benefits. Probably the most common reason for disappointing results is the failure to connect and fully integrate CAPA programs with work management strategies and solutions, and other supporting corporate-wide information systems. **Quality Manager** tracks and manages the process of generating and carrying out CAPA process plans using a work breakdown structure Gantt chart. It automates follow-up effectiveness tasks, and, when applicable, closes the loop with the incident record for which the CAPA was created.

## CAPA Templates

Executing CAPA costs money. Before a CAPA can be created, a user must clearly define the problem, source of information and evidence of the problem. A CAPA can result from a complaint, non-conformance, quality issue, or audit finding. Documents and other artifacts are associated to the CAPA as part of its rationale. **Quality Manager** uses templates to institutionalize a structured, repeatable best practice CAPA business process. A template contains pre-defined phases, tasks, folders and content which will be inherited by the CAPA. The template is defined with questions that result in specific phases or tasks to be added to the CAPA.

## CAPA Evaluation Tools

Users determine the CAPA magnitude and potential impact to the organization by entering a type of risk and its severity and occurrence. Risk types include hazard, regulatory, quality and cost. As events come into the system, whether a complaint, a nonconformance, an audit, or any other event, information is gathered and a risk table that includes information such as severity, frequency, or other pre-defined risk elements. These are used to calculate the risk priority number (severity multiple by occurrence). A decision can be made to take immediate action, hold or cancel the CAPA. The "Risk Matrix Cube" display is used to visualize and guide risk assessment using quantitative and repeatable metrics to ensure a consistent method of determining risk and appropriate escalation.

## CAPA Investigation Plan

**Quality Manager** has scheduling tools to schedule the investigation and completion of each activity with assignments of responsibility. Tools exist to collect data, artifacts, and product information in one source and allow users to add objects, such as Change Orders, that are related to the CAPA in a PowerView.

**Quality Manager** can create CAPA Scheduled Baseline, a "frozen" version of the plan, to help determine the overall impact, progress of the CAPA and time needed to close CAPA.

## CAPA Root Cause Analysis

One of the key parts of a CAPA program is root cause analysis, which is utilized to ascertain the source of a problem, non-conformity or defect so that corrective or preventive action can be taken to address the issue. **Quality Manager** captures and documents the root cause analysis approach that was used. Offline approaches include brainstorming, design of experiments, FTA, Pareto charts, and SIPOC. **Quality Manager** also has a fishbone capability to create a visual root cause diagram with associated documents.

## CAPA Planning and Implementation

Users define a plan to address problems based on the analysis that has been performed. For complete traceability the plan is associated to the corresponding root causes. The plan includes the activities and controlled documents that need modifications with direct links to the formal change process. "What-if" analysis can be done to compare different plan alternatives. Team members view their assigned tasks from their personal calendars and related risk. Email notifications are sent to task assignees when task due dates approach. To prevent future reoccurrence of the issue(s) resolved by the CAPA, an effectiveness check can be scheduled.

### Key Benefits:

- Standardize the development of a closed-loop, holistic approach to CAPA activities and management.
- Manage complaint handling processes from identification and product evaluation, to closure.
- Manage deviation/nonconformance identification, reporting, disposition and resolution with explicit documentation to ensure quality standards and compliance.
- Manage audit activities and processes from scheduling to execution to ensure quality assurance and quality systems are working as defined and approved.

## Complaint Management

Complaints can indicate a serious safety issue, but effectively handling the complaint can improve overall product quality and initiate new product development. **Quality Manager** digitizes and streamlines the complaint-handling process. Users from Quality and R&D departments use **Quality Manager** to investigate causes for customer reported events.

Complaints are captured and managed from intake through investigation, remediation and closure. Users capture all pertinent information about the reported customer complaint whether it is a real defect or just an inquiry or request for more information. The source of the event and the related product model information and return material authorization (RMA) is recorded for complete traceability. All correspondence and documentation related to the complaint is also saved. If a complaint is reopened, the number of times this occurs is recorded.

Finally, users have personalized work queues to facilitate and manage assigned complaints.

## Complaint Triage and Evaluation

The initial assessment of a complaint includes clarifying missing or ambiguous information in order to determine whether to invalidate it, close it if it is a duplicate or move forward with an action plan, which includes the method, results and root cause of an investigation. If no investigation occurs an e-Signature is required. Complaint evaluation can include determining the CAPA requirements by either referencing the existing CAPA or starting a new CAPA. Complaints cannot be closed until all of the tasks are complete including product evaluation, returns and fulfillments. Throughout the process, all reviews are captured with electronic signatures. A report is available to summarize all activity.

## Nonconformance Management

**Quality Manager** allows manufacturers to easily identify and record non-conformance for processes and products that do not meet requirements. It has a comprehensive control, review, and disposition process to govern questionable non-conforming products. **Quality Manager** enforces quarantine and final disposition of non-compliant products and process. Detailed information about the non-conformance or unexpected observation contrary to the standard requirement is recorded by type and with a detailed description. A responsible person is identified, and for product, non-conformance, the lot/batch number and affected quantity can be entered. To define the containment or corrective action, users enter a recommended disposition, relevant manufacturing data, and the severity of the issue. Users can manage a personalized list of assigned non-conformances.

## Nonconformance Investigation

Production managers investigate all reported non-conformances and assign responsible people to conduct an investigation for assignable causes and results. Corrective actions can be planned or it can be determined to not further investigate the nonconformance.

## Nonconformance Controls and Closure

Users determine the fate for a nonconforming product by creating a product control record. It records the part number or code assigned to material, the lot code or batch number, physical hold location, entry type (incident or bounding) and work order number. The run details include the total quantity in the batch or run, total amount of defective material identified, size of the sample taken, and a calculation of the percent defective. For disposition, users must enter a proposal, instructions and rationale for the final outcome. In order to close a nonconformance, all assigned tasks and product control records must be complete.

## Audit Management

**Quality Manager** ensures that the full audit process is executed so that findings are resolved in a timely and effective manner. It can manage both internal and external quality and regulatory audits. Details such as audit lead, audit participants, auditor requests, risk management and audit findings are tracked. A powerful process management engine automates all steps in the audit lifecycle including scheduling of tasks and tracking communications and CAPA progress.

## Audits

The regulatory authorities also expect organizations to have robust internal audit functions capable of providing a genuine challenge to management and driving improved governance, risk management and internal controls. An Internal audit has always been a valued part of any organization as an opportunity to consistently strengthen the organization through strategic, proactive measures—such as best practices, employee training, complaint management workflow processes, etc. **Quality Manager** can be used to schedule audits for the appropriate team members to collaborate. It saves time and ensures consistency by creating audit templates with as little or as much flexibility as standards and corporate policy dictate. It reduces risks and increases audit efficiency and visibility by enforcing consistent and harmonized processes and procedures across the organization. Auditors can associate requests with the audit template and files and other data entries depending on the area of focus and type of audit.

## Collaboration and Approvals

Users can benefit from a wide range of capabilities for global enterprise collaboration. Those capabilities include the ability to manage and organize shared documents and structured product data; they also enable the creation of digital workspaces for virtual teams to work together. Users can easily raise issues, organize meetings and track decisions. Any object lifecycle modifications can be formally approved using routes defined by end-users or from standard route templates.

## Microsoft Integration

Users can create and access **3D**EXPERIENCE® data from the most popular Microsoft applications: Word®, Excel®, PowerPoint®, Outlook®, Windows Explorer, and Windows Desktop Search. This capability enables enterprise-level collaboration while not disrupting the established productivity of end-users. With product content being managed in **3D**EXPERIENCE rather than on users' PCs, organizations are able to create, manage and review product content more securely.



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**Americas**
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

**Europe/Middle East/Africa**
Dassault Systèmes
10, rue Marcel Dassault
CS 40501
78946 Vélizy-Villacoublay Cedex
France

**Asia-Pacific**
Dassault Systèmes K.K.
ThinkPark Tower
2-1-1 Osaki, Shinagawa-ku,
Tokyo 141-6020
Japan