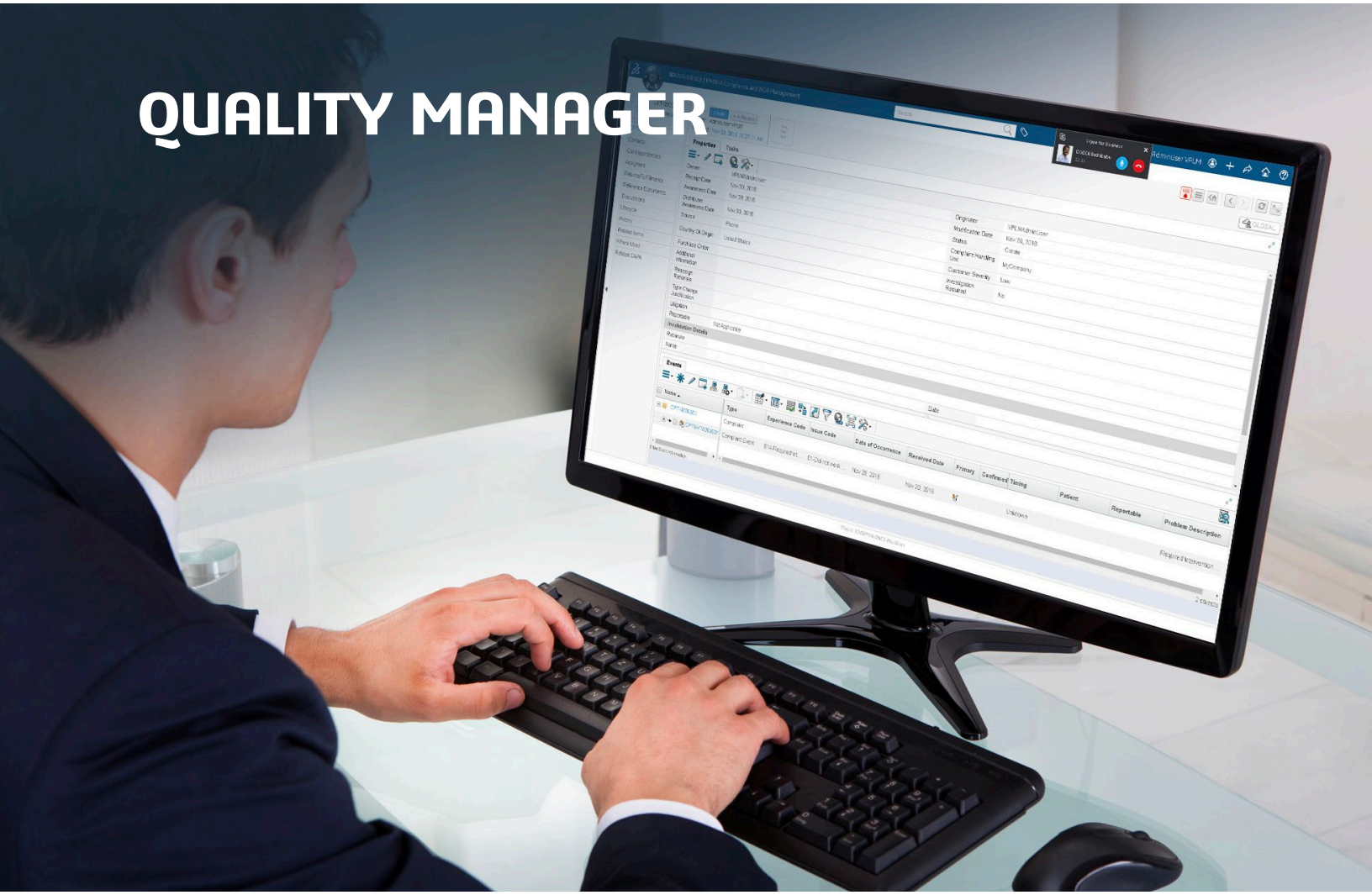
ENOVIA

3DEXPERIENCE®

QUALITY MANAGER



OBJECTIVE

Quality Manager is a comprehensive cross industry quality management solution that embeds quality and compliance directly into the product development process on the **3D**EXPERIENCE business platform. It enables organizations to take control of their global quality operations, while continuously improving operational performance.

DASSAULT SYSTEMES

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

OVERVIEW

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. **Quality Manager** improves visibility 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. **Quality Manager** links all artifacts, records, analysis, documentation, and validation results in a traceable and retrievable format.

CAPABILITIES

CAPA Management

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.

Quality Manager uses templates to institutionalize a structured, repeatable best practice CAPA business process. 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.

Complaint Management

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

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.

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.

Our **3D**EXPERIENCE® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE® Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 210,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.

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