ENOVIA Life Sciences Accelerator
for Quality Issues

Product Objective

ENOVIA® Life Sciences Accelerator™ for Quality Issues manages quality issues through a single, global, on-line system, which provides insight into the health of your Quality System. By implementing ENOVIA Life Sciences Accelerator for Quality Issues, companies avoid compliance risk, reduce waste, and increase the ability to leverage quality information for improving related business processes. ENOVIA Life Sciences Accelerator for Quality Issues addresses four critical concerns: Corrective and Preventive Actions (CAPAs), Nonconformance Reports (NCRs), Product Complaints, and Quality Audits.

Product Overview

ENOVIA Life Sciences Accelerator for Quality Issues uses a single enterprise-wide system to manage all quality issues, including CAPAs, NCRs, Product Complaints, and Quality Audits. The CAPA capabilities provide comprehensive management of the quality investigation lifecycle including initial request, root cause analysis, risk assessment, and closure. The Product Complaint capabilities include automation for developing action plans and delivering requisite regulatory submissions to ensure timely resolution. The NCR capabilities provide control over manufacturing nonconformance including containment, bounding investigations, proposed and actual dispositions and verification activities. The Quality Audit capabilities allow an audit team to manage audit requests in real-time to deliver world-class responsiveness and accuracy to auditors.

ENOVIA Life Sciences Accelerator for Quality Issues provides the following benefits:

- Fully integrates the capture and tracking of all quality incidents and the subsequent investigations.
- Far exceeds the CAPA capabilities of a typical quality system suite by integrating across all strategic Product Lifecycle Management (PLM) business processes such as CAPA, Change and Product Design Data.
- Delivers the quality issue processes required for United States Food and Drug Administration (FDA) compliance.
- Includes comprehensive CAPA process control including investigation, root cause analysis, risk assessment, project planning, and effectiveness monitoring.
- Controls the entire complaint process including customer contact, processing, investigation, regulatory submission, and closure.
- Provides capabilities for the electronic submission of Medical Device Report (MDR) forms directly to the FDA eliminating errors due to the creation and delivery of manual paper submissions.
- Tracks product return, decontamination, analysis and replacement related to product complaints.
- Uses a familiar interface and automation to enable quick and accurate complaints processing
- Investigates multiple assignable causes of nonconformances to promote bullet-proof dispositions.
- Identifies trends in nonconformance incidents which can be linked dynamically to the subsequent CAPA investigation.
- Manages auditor requests along with their replies to maximize audit team responsiveness and accuracy.
- Captures and tracks audit findings and their action plans for better visibility and control of open observations to reduce compliance gaps.
- Provides predefined templates and checklists for quality issues to increase consistency and thoroughness.

Key Customer Benefits

- **Deliver Market-Leading Products**
  ENOVIA Life Sciences Accelerator for Quality Issues enables organizations to bring industry-leading products to market more quickly and reliably with real time visibility into downstream problems by linking product design data directly to quality processes.
- **Drive Responsive Execution**
  ENOVIA Life Sciences Accelerator for Quality Issues enables organizations to respond quicker to market opportunities by streamlining product design, and production ramp-up.
- **Achieve Lean Quality and Compliance**
  ENOVIA Life Sciences Accelerator for Quality Issues delivers unmatched CAPA, compliant, NCR and audit management and resolution enabling holistic quality issue mitigation by integrating seamlessly with all other related product lifecycle processes. It improves quality and consistency of quality related processes to dramatically reduce regulatory risk and avoid audit findings. Organizations can satisfy U.S. FDA QSR (Quality System Regulations) and ISO regulatory requirements, move organizational focus from reactive to preventive, and improve customer satisfaction through enhanced process control.

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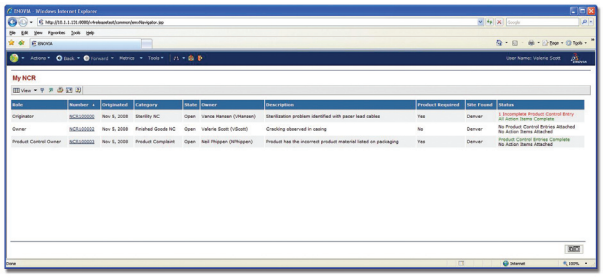
Product Highlights

CAPA Capabilities

The CAPA capabilities provide a central mechanism to investigate and correct the full range of systemic quality issues. A CAPA is managed collaboratively throughout its entire lifecycle including initiation, approvals, root-cause investigation, remediation, and monitoring. The Accelerator provides the CAPA team with a pre-determined set of tasks and deliverables.

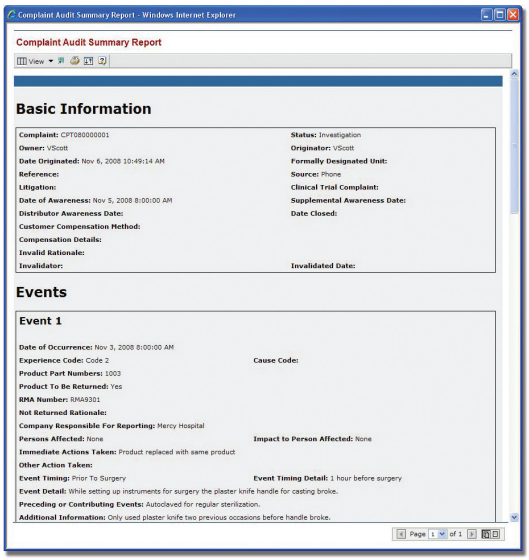


NCR Capabilities

The NCR capabilities allow manufacturers to easily track, investigate, and resolve manufacturing nonconformances easily. ENOVIA Life Sciences Accelerator for Quality Issues guides users through the steps for investigating the incident, dispositioning nonconforming product or material and, if necessary, initiating a systemic CAPA investigation. The product integrates easily with manufacturing systems to ensure production material quarantine status is up to date. The straightforward web-based user interface enables companywide execution of a more consistent NCR process and can be tailored for local needs in a global deployment. Configurable web-based reporting means that NCR trending becomes a reality while role-based access limits sensitive information to certain users.

Product Complaint Capabilities

The Product Complaint capabilities allow companies to capture, track, investigate, and close product complaints. The Accelerator uses an easy to use wizard to automatically determine the tasks and deliverables required to process the complaint. From there, Product Complaints are tracked through approvals, investigation, remediation, and closure. There is special intelligence built in to initiate and track all requisite submissions. Users can automatically generate a completed MedWatch form based on the captured data, which can be published to PDF or electronically submitted directly to the FDA.



Quality Audits

The Quality Audit capabilities manage both internal and external quality and regulatory audits. Quality Audits track all audit details including audit lead, audit participants, auditor requests, and audit findings. This enables fast and accurate audit management. It also provides trending reports of audit results and findings. When Quality Audits are scheduled, notifications are automatically sent to the appropriate people.

All CAPAs, NCRs, Product Complaints, and Quality Audits across the entire organization are managed within a single global on-line system which provides robust reporting for visibility into a single issue or aggregated across a wide range of distinct issues. By implementing ENOVIA Life Sciences Accelerator for Quality Issues, companies will improve customer satisfaction, avoid compliance risk, and encourage more innovative product design.

The Role of ENOVIA V6 and PLM 2.0

ENOVIA Life Sciences Accelerator for Quality Issues supports PLM 2.0, product lifecycle management online for everyone, and the ENOVIA V6 values: global collaboration innovation, single PLM platform for intellectual property (IP) management, online creation and collaboration, ready to use PLM business processes, and lower cost of ownership.

About ENOVIA

ENOVIA is the recognized leader in delivering collaborative PLM solutions. We enable companies from a broad range of industries to dramatically accelerate innovation, time-to-market and revenue generation by collaboratively developing, building and managing products. Our solutions facilitate the sharing of concepts, content and context across product lifecycles and throughout value chains of employees, customers, suppliers and partners.

ENOVIA collaborative PLM solutions help global enterprises bring together people, processes, content and systems to achieve a compelling competitive advantage. Our interoperable solutions unify and streamline processes across the product lifecycle, enabling companies to easily and cost-effectively work on projects within and outside of their enterprises. Our adaptable, scalable technology is built to accommodate the ever-changing marketplace.

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