

## IMPROVEMENT

### ENOVIA Quality Improvement Central



ENOVIA® Quality Improvement Central™ provides a company with a global, integrated closed-loop system for corrective and preventative action (CAPA) tracking of production and non-production quality issues and audit management for follow-up.

#### Key Benefits

- Seamlessly executes CAPA processes within the change and product design processes
- Includes comprehensive CAPA process controls including investigation, root cause analysis, risk assessment and scheduling of action plan tasks
- Accelerate investigation, review, approval, and closure cycles
- Improves communication and teamwork on quality issues across departments and functional areas
- Improves quality and consistency during the CAPA process to reduce risk dramatically and avoid audit findings
- Provides enterprise-wide visibility into the status of remediation activities
- Eliminates audit errors and inconsistencies with a systematic and workflow driven audit and data collection process across the enterprise
- Maximizes audit team responsiveness and accuracy through management of auditor requests and replies.

## Product Overview

ENOVIA Quality Improvement Central enables organizations to bring industry-leading products to market more quickly and reliably by providing quality management support for CAPA Management and Quality Audits. Its CAPA capabilities provide a closed-loop approach to CAPA process management including tracking the initial request through root cause analysis, risk assessment and closure with effectivity assessment as well. The quality audit capability enables quality departments to structure audits and manage their schedule, response, and closure. Multiple audit teams can manage audit requests and responses in real-time to deliver world-class quality audit management and ensure audit accuracy.

ENOVIA Quality Improvement Central enables organizations to respond quicker to market opportunities by streamlining product design, submissions and production ramp-up. It enables holistic quality issue mitigation by integrating seamlessly with all other related product lifecycle processes and allows companies to reduce internal costs for managing audits. It improves quality and consistency of the CAPA process to reduce regulatory risks dramatically and avoid audit findings. Organizations can satisfy regulatory bodies and move organizational focus from reactive to preventive issue monitoring, and improve customer satisfaction through enhanced process control of product feedback.

ENOVIA Quality Improvement Central is focused at quality departments, which need to manage the CAPA and quality audit processes outside the auspices of typical product development lifecycles. This separation is critical because CAPAs and audits can occur at any time and there are multiple drivers that initiate the process. ENOVIA Quality Improvement Central provides the necessary tools to drive quality throughout an organization with a heavy focus on quality department managers and leads. As part of the CAPA functionality, individual users complete action tasks by providing input and/or results, and managers approve the overall CAPA process. Similarly, the audit process enables quality managers to schedule audits and track their progress and results. Individual contributors can provide responses, enabling the entire team to multi-task and facilitate an in-progress audit. ENOVIA Quality Improvement Central is intended to provide a powerful, yet simple solution for managing quality while maintaining tight process interoperability with other aspects of the product lifecycle.

## Product Highlights

ENOVIA Quality Improvement Central includes these features and capabilities:

### **Corrective and Preventive Actions**

The CAPA capabilities provide a central mechanism to investigate and correct a full range of systemic quality issues. A CAPA is managed collaboratively throughout its entire lifecycle including initiation, approval, root-cause investigation, remediation, and monitoring. ENOVIA Quality Improvement Central provides CAPA teams with a pre-determined set of tasks and deliverables based on the type of CAPA involved, and initiates and tracks all requisite regulatory submissions.

### **Quality Audit Management**

ENOVIA Quality Improvement Central manages both internal and external quality and regulatory audits. Details such as audit lead, audit participants, auditor requests, risk management and audit findings are tracked. When initiating new audits, lead auditors can leverage templates to quickly start new audits. Audit templates are also used to drive standards and best practices into the processes.

### **CAPA and Audit Searches**

ENOVIA Quality Improvement Central has a full-text search capability that allows users to query the entire database based on defined parameters or query for specific CAPA and Audit types. Individual users can also add CAPA and Audits from search results into collections for quick access during future sessions.

## Quality Management Reports

ENOVIA Quality Improvement Central provides managers the ability to run reports and trend analyses on product issues.

The following standard reports are provided to help measure and determine the effectiveness of the CAPA quality process:

- The “CAPA Effectivity Report” calculates the percentage of queried CAPAs that corrected the problem and do not have an adverse effect on the device. It shows whether the CAPA process is truly finding solutions for the underlying causes of a problem rather than just “band-aiding” the symptoms. If the report shows a high percentage of non-effective CAPAs, that would be an indicator that a process that isn’t working.
- The “CAPA Cycle Time Report” measures time elapsed between the team leader’s assignment to the CAPA and its closure.
- The “Investigation Cycle Time Report” measures the time between the team leader’s assignment to the CAPA and Action Plan submittal.
- The “Quality System Report” provides a summary list of all CAPAs from a user-defined search that were categorized as type “Quality System”.
- The “Product and Product Process Report” queries the system based on user entered criteria and provides a summary list of CAPAs that were assigned a CAPA type of “Product Family” or “Product Process”.

The following standard audit reports are provided:

- The “Audit Summary Report” summarizes an audit’s opening and closing meeting, roles, requests, replies, reports, and findings
- The “Audit Dashboard” summarizes an audit’s total number of findings, number of unresolved findings, actual schedule date, location, state and lead auditors

## The Role of ENOVIA V6 and PLM 2.0

ENOVIA Quality Improvement Central 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.



## Delivering Best-in-Class Products



Virtual Product



Information Intelligence



3D Design



Virtual Planet



Realistic Simulation



Dashboard Intelligence



Digital Manufacturing



Social Innovation



Collaborative Innovation



3D Communication

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