



## **ENOVIA Life Sciences Accelerator™ for Quality Issues**

The process of dealing with Quality Issues, such as Corrective and Preventive Actions (CAPAs) and Product Complaints, is the single greatest source of regulatory risk for Life Science companies today. And, the reason is simple. The process gets bogged down in the minutiae of documentation and fails to adequately address the critical issues regarding risk, root cause and remediation. Despite its apparent simplicity, Life Science companies still consistently struggle to deal with Quality Issues efficiently and effectively. And as the complexity of products and processes increases, this predicament only promises to worsen. Meanwhile, Life Science companies are not getting the strategic value they should from the vast resource of valuable feedback collected in their Quality Systems.

To improve QSR/GMP/ISO compliance while eliminating non-value-added waste, your organization needs an effective and efficient means to manage Quality Issues. The **ENOVIA Life Sciences Accelerator for Quality Issues** helps give Life Science companies this ability.

### **The Solution**

#### **Overview:**

The ENOVIA Life Sciences Accelerator for Quality Issues manages all Quality Issues through a single, global, on-line system which provides insight into the health of your CAPA process. By implementing ENOVIA Life Sciences Accelerator for Quality Issues, companies will avoid compliance risk, reduce waste and increase the interconnectedness of team members and business processes.

The ENOVIA Life Sciences Accelerator for Quality Issues addresses two critical concerns for Life Science companies: Corrective and Preventive Actions (CAPAs) and Product Complaints.

#### **Corrective and Preventive Action (CAPA):**

The CAPA solution provides a collaborative means to track, investigate and correct a wide variety of systemic Quality Issues according to established regulatory conventions and industry best practices. Each CAPA progresses through a series of stages including initiation, approval, root-cause analysis, remediation and, finally, effectiveness monitoring.

*With the ENOVIA Life Sciences Accelerator for Quality Issues, Life Science companies can improve the results of their Quality Issue investigations and reduce regulatory risk while eliminating much of the waste*

- Provides a flexible, ready-to-use business process for managing Quality Issues such as Corrective and Preventive Actions (CAPAs) and Product Complaints
- Interacts seamlessly between the CAPA and Product Compliant Processes and other ENOVIA PLM business processes such as Change Control, Product Development, Supplier Control
- Verifies that quality investigations are executed properly and that all critical deliverables are completed resulting in greater regulatory compliance.
- Automates the routine aspects of your quality investigations, reducing waste and focusing attention on the truly critical issues of risk, root cause and remediation
- Addresses Quality issues in the context of similar previous issues reducing duplicate or worse, conflicting results
- Make the leap to a proactive Quality System that unleashes the power of the information you already have locked away on paper
- Compatible with ENOVIA's V6 global collaborative platform, offering greater flexibility, scalability and openness with a lower total cost of ownership

## The Solution (continued)

The system automatically determines the particular set of tasks and deliverables required for successful completion of each distinct type of CAPA you may encounter. Specifically, the CAPA solution allows you to:

- Ensure your CAPA process is under strict control leading to greater consistency and compliance
- Automate the tedious aspects of your CAPA process allowing your team to reduce waste and focus on the critical issues involving risk, root causes and remediation
- Define and track the participation of all functional roles on your CAPA team including Quality, Regulatory, R&D and Operations
- Provide a global collaboration platform for team members to complete assignments directly in the CAPA system
- Promote best-practices for risk assessments in order to support a truly robust risk-based approach
- Identify root causes via a thorough investigation and target each individually with an appropriate remediation action plan
- Capture critical feedback about products and processes for use towards continuous improvement and Lean Six Sigma programs
- Transition seamlessly between the CAPA process and related business processes such as Change Control, Product Development and Supplier Control
- Elevate the visibility of monitoring plans to confirm the effectiveness of completed CAPAs.

## Product Complaints:

The Product Complaint solution allows companies to track, investigate and disposition field complaints, product inquiries and service requests. Each Product Complaint progresses through a series of stages similar to the CAPA process, but tailored to the needs of a complaint investigation. The system uses a wizard-based process that further fine-tunes the required set of tasks and deliverables. Specifically, the Product Complaints solution allows you to:

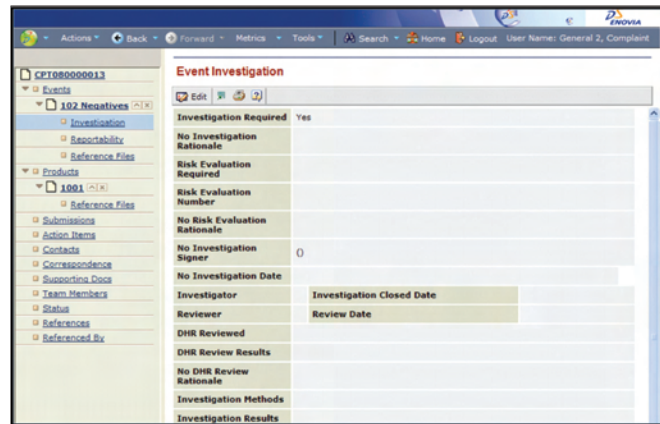
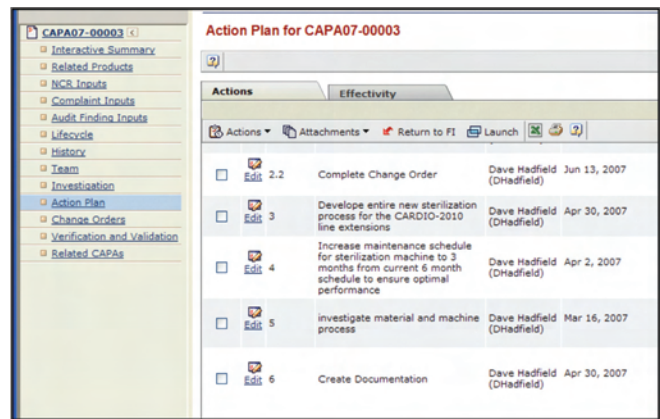
- Manage all of the distinct aspects of the Product Complaint process including customer communications, incident criticality assessments and investigation, product dispositions and regulatory submissions
- Leverage the generic CAPA capabilities to automate routine tasks, establish a team collaboration platform and encourage consistency and compliance
- Automatically determine all required regulatory submissions, generate finalized MedWatch MDR forms and track correspondence with regulatory agencies
- Assess and disposition product returns and equipment service requests
- Maintain management control and ensure timeliness with Cycle Time Reports

## Proven Business Value:

In use at some of the world's largest Life Science companies, the ENOVIA Life Sciences Accelerator for Quality Issues is a proven solution for one of the most highly scrutinized processes in your Quality System.

With the ENOVIA Life Sciences Accelerator for Quality Issues, customers find that the costs of operating your CAPA system decrease while dramatically improving the quality, reliability and timeliness of the results.

For more information on the business value achieved by medical device companies, refer to ENOVIA's BVA Value Discovery Program.



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