

## QUALITY

### ENOVIA Product Quality Central



ENOVIA® Product Quality Central™ manages complaints and non-conformance reports (NCRs) so companies can avoid compliance risk, reduce waste and increase the ability to leverage quality information. As a result, product quality improves and the likelihood of product success is achieved.

#### Key Benefits

- Automates and streamlines all complaints and non-conformance reporting across the enterprise to improve product information capture
- Scales to handle a high volume of complaints and non-conformance reports for serialized and non-serialized units
- Shortens cycle time and lowers costs by consolidating disparate systems
- Automates data collection and escalation to increase efficiency and product and process quality
- Achieves lean quality and compliance by executing seamlessly with other related product lifecycle processes
- Controls the entire complaint process including customer contact, processing, investigation, regulatory submission and closure
- Tracks product return, decontamination, analysis and replacement related to complaints
- Investigates multiple assignable causes of non-conformances to promote bullet-proof dispositions

## Product Overview

ENOVIA Product Quality Central enables organizations to respond quicker to market opportunities by streamlining product design and submissions to help prevent recurrence in future processes and designs. It provides a holistic quality issue solution by integrating with other related product lifecycle processes to effectively remove the source of problems. It enables organizations to bring industry-leading products to market quicker with more reliability with real time visibility into downstream problems by linking product design data directly to customer complaints and non-conformances.

The complaints management capabilities enable companies to capture, track, investigate, and take action on field complaints, product inquiries and equipment service requests (ESR). Problems can be escalated between these categories as needed. Users can gather the information necessary to adequately process the complaint, handle contacts and correspondence, and determine risk, impact and reporting status. Complaints can be configured to interoperate directly to corrective and preventative action (CAPA) requests managed in ENOVIA® Quality Improvement Central™.

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The non-conformance management capabilities automate the control and disposition process by identifying issues and tracking the review, monitoring and reporting of follow-up actions. Both product and process non-conformances are managed. The process includes the creation of product disposition records (PCRs), which have a lifecycle including approval, verification, assignable cause analysis, and immediate corrections. Similar to the complaints management process, it can be configured to work with other ENOVIA product development processes. For example, it may be necessary to escalate the non-conformance into a CAPA request.

## Product Highlights

ENOVIA Product Quality Central includes these features and capabilities:

### Capture Complaints

ENOVIA Product Quality Central enables users to capture and manage customer complaints and achieve compliance with FDA regulations such as 21 CFR Part 820. Complaints are usually captured when an adverse event occurs. ENOVIA Product Quality Central uses a simple wizard to automatically capture complaint information and determine the tasks and deliverables required to process complaints. Product complaints are tracked through approvals, investigation, remediation and closure. A complaint is divided and managed into the following sections: Reporter, Event Details, Product Information, and General Complaint Information.

The Reporter section contains information about the person who is reporting the complaint. ENOVIA Product Quality Central provides a default setting for the reporter contact based on information stored about the originator. Therefore, when the originator enters their name and telephone number the remaining reporter information for the contact is completed so follow-up action occurs efficiently.

The "Event Details" section describes exactly what happened when the product was used as well as any medical or adverse events that happened as a result of product use. The Product Information section requires a valid part number so the Product Family and the Product Name can be automatically populated. This allows all complaints in the system to be analyzed by the associated product and determine if there are troublesome trends for particular product types.

After recording the product information, general complaint information and any extra details will be added to the complaint such as additional contacts, correspondence information, hospital information or circumstances surrounding the events. The complaint is then officially captured and registered for processing to decide if it is a valid complaint or should be converted to an equipment service request.

## Complaint Investigation

A valid complaint is submitted to the responsible person to determine if an investigation is required. If an investigation is determined unnecessary, then a reason must be provided and the person who made this decision is recorded with a timestamp for future reference. If an investigation is required, a schedule and action plan is created. The complaint's task assignees can create and submit inquiries for additional information. During the investigation, the following information is captured:

- Reference number of an external risk evaluation
- Investigation Methods - the methods used to investigate the complaint
- Investigation Results - the results of the complaint investigation
- Conclusion Summary - the summary of the investigation conclusion
- Investigation Closed Date - the date the investigation was closed

## Complaint Reports

ENOVIA Product Quality Central provides enterprise complaint reporting to monitor trends to improve management escalation and the complaint process. The following are the complaint reports provided:

- "Complaint Aging Report" contains all data associated with the length of time the complaint has been open
- "Complaint Cycle Time Report" measures the time to close complaints
- "Complaint Loaner Equipment Report" contains data associated with any equipment currently on loan to customers
- "Complaint Products Report" complaint data associated with a single product

## Capture NCRs

ENOVIA Product Quality Central's NCR capabilities allow manufacturers to capture and resolve manufacturing non-conformance easily. Users are guided through the steps necessary for investigating and addressing non-conforming product and processes. The following information is captured for non-conformances:

- Responsible person
- Recommended actual disposition and relevant manufacturing data
- Product name
- Lot/batch number
- Quantity affected
- Non-conformance type and functional area

## NCR Investigation

During the investigation step for each NCR, the responsible person determines if an investigation is required. If an investigation is required, an action plan schedule is created. The following is the information that is captured during the investigation process:

- Results of the investigation
- Severity
- Up to three assignable causes
- Correction records
- Type of correction

## Product Control and Disposition

ENOVIA Product Quality Central has a comprehensive control, review, and disposition process to govern questionable non-conforming products by defining Product Control Records (PCRs). Multiple PCRs can be created to capture separate disposition approaches. This is important to deal with both raw materials and finished goods. All product control records must be complete before an NCR can be formally closed, which ensures all products have been properly dispositioned. The PCR also allows differentiation between an incident that caused a non-conformance and a problem with tolerances.

### **A PCR captures the following data:**

- Entry Type - Differentiates between non-conformance types
- The work order number assigned to the PCR
- The lot code or batch number of material reported in an NCR
- A unique part number or code assigned to material reported in an NCR
- A brief description of the product or material
- The number assigned to a particular production run of a material
- The physical location of material reported in an NCR
- Total quantity of material in a batch or run (both conforming and non-conforming)
- Total amount of defective material found
- The size of the sample taken for quality control
- Defective quantity divided by sample size
- The proposed disposition of material reported in an NCR
- The instructions for the final outcome for the product
- The reason for the final outcome
- The day the PCR was completed

### **Equipment Service Request (ESR)**

ENOVIA Product Quality Central identifies equipment service requests (ESR) required to be performed on equipment that does not allege deficiencies. An ESR is derived from a complaint as an outcome of the evaluation by the original complaint owner. The following information is captured for equipment services requests:

- Product family, part number
- Lot and serial number
- Manufacturing location
- Unit return date shipped/received from customer
- Decontamination details (date sent, received to/from location, decontamination location)
- Evaluation method details (investigation site, evaluation performed, date and summary, failure mode)
- Service information details (warranty status, customer PO number, OEM warranty and extend warranty information, effective dates, warranty owner, labor hours spent on the equipment service request, status of repair)
- Loaner information details (serial number, customer shipped to information, date shipped to/from customer, location shipped to)
- Calibration details (calibration date, frequency and due date)

### **Searches**

ENOVIA Product Quality Central has an advanced search capability that allows users to query the entire database based on defined parameters or query for NCR and Complaints, or subsets of their data such as PCRs, ESRs and complaint product record types using either full text or real time searches.

### **The Role of ENOVIA V6 and PLM 2.0**

ENOVIA Product Quality Central supports PLM 2.0, product lifecycle management online for everyone, and the ENOVIA V6 values: global collaborative 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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