



ENOVIA Life Sciences Accelerator for Change Control

Product Objective

Change is constant. That is why a best-in-class Change Control system is critical for promoting innovation and growth while maintaining a state of control. A Change Control system for document changes, design changes and production and process changes is at the heart of every Quality System and a crucial element of regulatory compliance.

The complex changes common today involve a myriad of elements – specifications, procedures, test methods – that must be carefully coordinated and verified through the change process. Companies must adequately assess and validate the impact of changes, but are hamstrung by poor assessment methods, complex procedures, and inadequate approvals. Moreover, manual steps in executing changes increase the likelihood of error.

Product Overview

ENOVIA® Life Sciences Accelerator™ for Change Control is designed to help life sciences companies manage the change process from request to implementation and closure. It is intended to ensure that the proper process is followed every time and that change activities are completed according to plan.

With the ENOVIA Life Sciences Accelerator for Change Control, life sciences companies can improve the responsiveness of their change process and reduce errors introduced with manual processes:

- Manages modifications to all documents, specifications, procedures and product configurations using a single, flexible, Part 11-compliant electronic Change Control process
- Automatically enforces critical change control business rules to minimize compliance risk
- Enforces required approvals based on a company-defined approval matrix
- Provides dynamic links to related documents and data for improved process visibility
- Aging report provides visibility to the status of the changes and helps identify bottlenecks
- Guides employees through change assessments for regulatory, risk and financial items

Product Highlights

ENOVIA Life Sciences Accelerator for Change Control provides a single, flexible electronic Change Control process to manage changes to all documents, procedures, and specifications throughout an organization. With ENOVIA Life Sciences Accelerator for Change Control, you can easily create a Quality Change Order to manage a change to a broad array of controlled documents, procedures, and specifications.

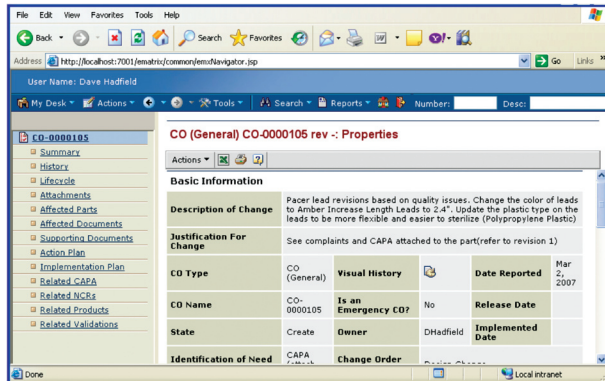
Change Documentation and Impact Assessments

The Quality Change Order is used to control the change to the affected documents from beginning to end. The Quality Change Order captures basic information such as the description of the change and the reason for the change. It also guides the collection of much more detailed information such as risk assessments, regulatory assessments, and cost analyses. ENOVIA Life Sciences Accelerator for Change Control provides dynamic links to related documents and data for improved visibility into related business processes. It also provides standard summary, aging and history reports to improve visibility to the status of the changes and help identify bottlenecks in the process.

Key Customer Benefits

- Deliver market-leading products by linking the Change process to other product related processes such as CAPA, Audit, NCR, Product Development, marketing, and manufacturing
- Drive responsive execution by providing a flexible, ready-to-use business process for managing changes to all documents, procedures and specifications through a single, robust Change Control process
- Achieve Lean Quality and Compliance by automatically enforcing Part 11-compliant approvals for changes based on a company-defined approval matrix to achieve a more reliable change process



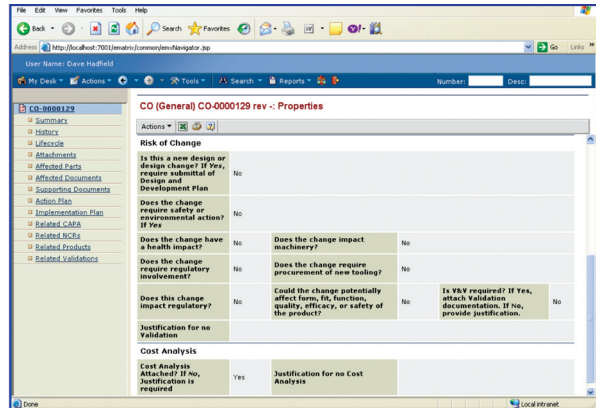


Implementation Action Plans

The Quality Change Order is also used to capture a detailed action plan that is used to assess and, later, implement the change. The action plan can require predetermined action tasks to be completed depending on the type of change or other criteria you define. Alternately, action tasks may also be added manually as needed for that particular change. Until the specified tasks are completed, the Quality Change Order is prohibited from proceeding to the next phase. Action tasks are updated in the system directly by the person assigned to the task, thereby eliminating the burden of tracking action plan execution manually and providing excellent activity traceability.

Process Approvals

When approving a change, ENOVIA Life Sciences Accelerator for Change Control automatically determines the appropriate approvers depending on the types of documents being changed and other criteria you define. The approvals comply with the U.S. Food and Drug Administration's (FDA) Part 11 regulation for access control, security and traceability.



The role of ENOVIA V6 and PLM 2.0

ENOVIA Life Sciences Accelerator for Change Control supports ENOVIA 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.

About Dassault Systèmes

As world leader in 3D and Product Lifecycle Management (PLM) solutions, the Dassault Systèmes group brings value to more than 90,000 customers in 80 countries. A pioneer in the 3D software market since 1981, Dassault Systèmes develops and markets PLM application software and services that support industrial processes and provide a 3D vision of the entire life cycle of products from conception to maintenance. Our offering includes integrated PLM solutions for product development (CATIA®, DELMIA®, ENOVIA®, SMARTEAM®), mainstream product 3D design tools (SolidWorks®), 3D components (Spatial/ACIS®) and SIMULIA®, DS' open scientific platform for realistic simulation. Dassault Systèmes is listed on the Euronext Paris (#13065, DSY.PA) stock exchange. For more information, visit 3ds.com.



For additional information, contact us at:
 Dassault Systèmes ENOVIA Corp.
 900 Chelmsford Street, Lowell, Massachusetts 01851
 978.442.2500 • ENOVIA.com • 3DS.com