DASSAULT SYSTEMES

ENOVIA

CHANGE

ENOVIA Life Sciences Accelerator for Change Control

ENOVIA® Life Sciences Accelerator™ for Change Control manages modifications to all types of Quality System Regulation (QSR) and International Organization for Standardization (ISO) regulated documents, procedures and specifications—throughout an organization with previously unattainable levels of automation and control. It provides a single, flexible electronic change control process that enables enterprise-wide collaboration to improve operational efficiency and enforces critical business rules to minimize compliance risk. Using ENOVIA Life Sciences Accelerator for Change Control, companies will attain U.S. Food and Drug Administration (FDA) Part 11-compliant access control, security and traceability as demanded for this mission-critical business process.

Key Benefits

- Bring industry-leading products to market more quickly and reliably by focusing on the creative aspects of design instead of administrative details
- Enable product teams to collaborate easily with various contributors and stakeholders to plan changes, expedite documentation, and deliver new products
- Enable organizations to respond more quickly to market opportunities by streamlining their change process
- Complete changes on time and on budget by automating change execution
- Improve the quality and consistency of document deliverables to dramatically reduce regulatory risk and avoid audit findings
- Satisfy QSR/ISO regulatory requirements and achieve Six Sigma objectives through enhanced process control, metrics and real time reporting

Product Overview

Change is constant. That's 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, 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 throughout 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 to execute changes increase the likelihood of error.

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 processes are followed every time and that change activities are completed according to plan.

With 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 help 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 (QCO) to manage a change to a broad array of controlled documents, procedures and specifications.

Change Documentation and Impact Assessments

The QCO is used to control the change to the affected documents from beginning to end. The QCO captures basic information such as the description and the reason for change. It guides users through the collection of required 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. Summary, aging and history reports are provided to improve change status visibility and help identify process bottlenecks.

Implementation Action Plans

The QCO is used to capture a detailed action plan that for assessing and later, implementing the required change. The action plan can require predetermined action tasks to be completed depending on the type of change or other defined criteria. Alternately, action tasks can manually be added as needed for that particular change. Until the specified action tasks are completed, the QCO 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 manually tracking the action plan execution and providing 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 defined criteria. The approvals comply with the U.S. Food and Drug Administration's (FDA's) Part 11 regulation for access control, security and traceability. With ENOVIA Life Sciences Accelerator for Change Control, customers find that the time to execute a change often shrinks significantly and lost sales due to launch delays are avoided.

The Role of ENOVIA V6 and PLM 2.0

ENOVIA Life Sciences Accelerator for Change Control 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.

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