



ENOVIA Life Sciences Accelerator for Product Introduction

Product Objective

ENOVIA® Life Sciences Accelerator™ for Product Introduction provides advanced project management capabilities for Life Sciences companies to institutionalize best practices in executing new product introduction projects.

Product Overview

Project managers are provided with advanced visual project tracking reports to maximize management visibility and control. By implementing ENOVIA Life Sciences Accelerator for Product Introduction companies improve time-to-market, avoid regulatory risk, and improve operational excellence. ENOVIA Life Sciences Accelerator for Product Introduction dramatically increases the productivity and coordination of globally distributed users by executing project activities with real-time information that updates automatically through direct links to tasks, documents, deliverables and other data sources. This automatically completes Design Control deliverables for the resulting Design History File (DHF). These automatic updates allow project managers to focus on high value activities rather than tracking down status.

ENOVIA Life Sciences Accelerator for Product Introduction:

- Manages any number of new product development projects, activities and deliverables.
- Embeds compliant best practices and Critical-To-Quality drivers into standard, repeatable project templates.
- Provides highly visual dashboards of deliverables, phases and functional area responsibilities to enable on-time completion of all design control activities.
- Automatically generates the structure of the DHF.

Product Highlights

ENOVIA Life Sciences Accelerator for Product Introduction key features and capabilities include:

Business Goals

Managers can define a business goal hierarchy to help identify which projects to approve and fund based on how they impact strategy.

Resource Management

Organizations can define enterprise wide business skill hierarchies to perform project planning based on resource competency and experience along with resource utilization reports to optimize productivity and improve resource allocation decisions.

Management Dashboards

Management can leverage advanced visual project tracking dashboards to maximize visibility and control of all product introduction projects. Swim lanes provide a birds-eye view of each project organized according to functional responsibilities. Managers can view different sections of the project to understand individual tasks and deliverables.

Key Customer Benefits

Deliver Market-Leading Products

- Bring industry-leading products to market more quickly and reliably by focusing on the creative aspects of design rather than administrative details.
- Increase collaboration with various contributors and stakeholders to plan projects, develop designs, expedite documentation, and release new products.
- Increase executive visibility across all projects and institute clear accountability across all project teams.

Drive Responsive Execution

- Respond more quickly to market opportunities by streamlining product design, submissions, and production ramp-up.
- Complete more projects on time and budget by automating project execution, visibility to dependent projects, reusing available information, and avoiding unnecessary setbacks.

Achieve Lean Quality and Compliance

- Improve quality and consistency of document deliverables to reduce regulatory risk dramatically and avoid audit findings.
- Satisfy Quality System Regulation (QSR)/ ISO regulatory requirements and achieve Six Sigma objectives through enhanced process control, metrics and real time reporting.



Project Templates

Project managers can develop process standards and enhance predictability by driving repetitive project execution throughout the organization. The project template consists of work breakdown structures defined by responsible roles, folder structures, questionnaires, document templates, and bookmarks.

Work Breakdown Structure

Project managers can decompose complex product development activities into smaller manageable sub-projects. Project leaders can then define schedules to organize global project teams into individual groups that take into consideration an assigned project member's role and non-working days. ENOVIA Life Sciences Accelerator for Product Introduction supports all phases of development, including the ideation phase in which organizations evaluate the likely value and feasibility of all potential new projects. Once each concept is approved, it is updated to a formal project and can be planned in detail. ENOVIA Life Sciences Accelerator for Product Introduction provides a bi-directional integration to Microsoft Project® for project managers that prefer using a Microsoft Project user interface for editing schedule information.

Task Deliverables

As tasks are assigned and being worked, task deliverables should be associated and managed in the context of the task. As a deliverable is promoted through its lifecycle, the system updates the task status automatically. After the tasks are completed, project folders store and categorize the deliverables for access controls and increased visibility. To keep task deliverables on schedule, project leaders can configure automatic reminders of upcoming or late tasks that project members will receive in their company email.

Product Line Management

ENOVIA Life Sciences Accelerator for Product Introduction organizes and manages a company's product portfolio and executes development projects related to the planning and introduction of future products. Product lines and model hierarchies organize a company's family of products. Model hierarchies represent specific products available to customers. Product managers can associate product releases with development projects and organize them into portfolios. A portfolio provides visibility into a product line's road map, product release dependencies and a real time status of strategic project milestones to share with other organizations.

Schedule Product Builds

Prototype and production builds represent key milestones of the product development process. Multiple builds can be identified and planned for a particular product, and then their completion can be tracked through the project schedule.

Project Content

All project content and deliverables are managed and stored securely within controlled and uncontrolled folder and subfolder structures. Security is established on a per project basis. Project owners and project leads determine individual access rights.

Within a project, each folder and file maintains additional levels of security. Lifecycle controls establish folder content baselines as a means of measuring project performance and historical references. Team members can establish a single environment for managing and sharing all project information—not just documents. By subscribing to document events, members can become informed immediately as changes and additions occur. Reports provide a consolidated list of project-related content either from the work breakdown structure or from the folder structure.

DHF and Product Dossier Tracking

ENOVIA Life Sciences Accelerator for Product Introduction automatically tracks the activities and deliverables to generate the resulting DHF in accordance with U.S. Federal Drug Administration (FDA) Code of Federal Regulations 21 CFR 820.30(j). Project deliverables can be viewed according to a number of configurable criteria to show only those deliverables that are most important to you. The DHF provides dynamic links to related documents and data for improved visibility into related business processes.

Team Collaboration

A project manager can institute standard reviews for project members using routes or workflows to circulate tasks, projects and files. The entire project team can be kept informed of important project information with online discussions. All team members can subscribe, view and comment on the original discussion topic or any of the subsequent responses.

Issue / Risk Management

Issues are real incidents, inquiries or problems that impact a project negatively, and risks are anything that can potentially impact a project negatively. Issue management provides a context for capturing, tracking and closing issues in the context of a project. Issues are identified, captured, classified and assigned to project members for resolution. Risk management enables project teams to identify, quantify, analyze and mitigate project risks. During the analysis process, risks need to be assessed and quantified in two dimensions. These two dimensions are impact and probability with ranges from 1-5. These dimension values help minimize these potential negative impacts by determining each risk priority and clarifying which project risks need mitigation.

Project Meeting Traceability

Project or program managers can capture meeting details to maintain artifacts for historical references. Managers can define meetings, and track who was invited and who actually attended. Agenda topics can be added to meetings with time durations allocated for each topic and associated document attachments for discussion. Issues that need further follow up and recorded decisions are stored as an outcome of the meeting.

The Role of ENOVIA V6 and PLM 2.0

ENOVIA Life Sciences Accelerator for Product Introduction 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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