

ENGINEERING

ENOVIA Life Sciences Accelerator for Engineering Design



ENOVIA® Life Sciences Accelerator™ for Engineering Design provides robust and flexible management of all enterprise design data such as bills-of-material (BOMs), CAD models and related documentation such as drawings, specifications, procedures and quality standards. It is the “single source of the truth” of product information for all of your product development business processes.

Key Benefits

- Bring industry-leading products to market more quickly and reliably by focusing on the creative aspects of the design process instead of administrative details
- Respond rapidly to market opportunities by streamlining product development and change processes
- Complete projects on time and within budget by facilitating the creation and reuse of product data
- Improve quality and consistency of design controls by dramatically reducing regulatory risk with a single system of record
- Satisfy QSR/ISO regulatory requirements for Device Master Records (DMRs)
- Satisfy FDA Part 11 requirements with a full audit trail and signature authentication controls
- Execute a fully integrated change management process
- Provide a complete DMR in seconds instead of hours

Product Overview

ENOVIA Life Sciences Accelerator for Engineering Design provides a single, integrated system to manage all elements of the Device Master Record (DMR) within accordance of the Food and Drug Administration's Quality System Regulation (QSR) and ISO standards. It provides full audit trails and powerful authentication controls for FDA Part 11 compliance. ENOVIA Life Sciences Accelerator for Engineering Design fundamentally revolutionizes communication and process collaboration between design engineers, manufacturing engineers and software engineers of your company's globally dispersed product development teams and suppliers.

ENOVIA Life Sciences Accelerator for Engineering Design enables organizations to bring industry leading products to market quicker and more reliably by focusing on the creative aspects of the design process rather than administrative details of product data management. It enables organizations to respond more quickly to market opportunities by collaborating more effectively across disciplines, geographies and organizational boundaries therefore streamlining product design and change. As a result, projects are completed on time and within budget by automating product data creation and reuse.

Finally, ENOVIA Life Sciences Accelerator for Engineering Design aggregates all product design data, which helps improve the quality and consistency of design control deliverables to dramatically reduce regulatory risk and avoid audit findings. Organizations can satisfy QSR/ISO regulatory requirements as an automatic byproduct of their usual design processes.

In summary, companies using ENOVIA Life Sciences Accelerator for Engineering Design will:

- Deliver market leading products
- Drive responsive execution
- Achieve lean quality and compliance

Product Highlights

ENOVIA Life Sciences Accelerator for Engineering Design enables the consolidated management of all engineering data and processes in one enterprise solution thus providing a single version of the truth.

Part Management

ENOVIA Life Sciences Accelerator for Engineering Design provides part management capability for both development and production lifecycles for added process flexibility. Parts in ENOVIA Life Sciences Accelerator for Engineering Design can be identified by a unique auto-numbering scheme or by user-entered names. Part revisions can be created for managing the evolution of design and changes for an item if the current part number corresponds to a released part (for tooling or production, for example). Each new part revision must be form, fit, and function ("FFF") compatible with all of its predecessors. "FFF" is a description of an item's identifying characteristics as defined below:

- Form is the shape, size, dimensions, mass and/or other visual parameters which uniquely characterize an item. This defines the "look" of the part or item. Sometimes weight, balance and center of mass are considerations in 'form.'
- Fit is the ability of an item to physically interface or interconnect with or become an integral part of another item or assembly. This relates to the associativity of the part in relation to the assembly, or to other parts, and includes tolerances.
- Function refers to the action[s] that an item is designed to perform. This is the reason for the item's existence, which also includes secondary applications.

If the specifications or criteria, for form, fit and function of a particular item are met, all other attributes, from an engineering design process perspective are moot or extraneous. Interchangeability on an item in a system is mainly determined by physical, functional, and performance characteristics or specifications that uniquely identify a component or device.

Parts can be managed individually or included in a part family, which groups parts into logical families. Parts that are members of the same part family share similar characteristics. Parts within a family can be declared as a master or reference to determine how a common set of specifications is shared. An example could be a set of parts that have the same geometric shape but different colors. The CAD models can be defined once for the “master” part in the part family, and shared between the other “reference” parts in the part family. An auto-naming function allows parts in the family to be named similarly based on customer tailored rules.

BOM Management

Global development teams have a single, persistent definition of new and existing product BOMs, which reduces errors due to time delays in communication and data. BOMs can have an unlimited number of parts and BOM levels and can be specific for a given plant or facility. The BOM assembly structure is updated automatically when new component revisions are released. An integrated structure browser allows users to easily navigate multi-level BOMs. Comprehensive BOM capabilities include the ability to copy parts to and from existing assemblies, and replace, add, remove, and re-sequence parts in the BOM. Time-based BOM effectivity provides clear visibility to the current and pending components of a product. Pending parts automatically replace dispositioned components at the scheduled time. In order to reduce manufacturing downtime and quality issues, a list of engineering approved “alternate” or “substitute” parts can be used by manufacturing in place of the primary engineering part.

BOM Compare

Users can improve part reuse and product quality by comparing BOMs to identify differences. Results are reported in a detailed text format or a visual side-by-side format. Users can compare the BOMs of different parts, different plants for the same part, or different releases of a part.

DMR Management

Companies can manage all elements of the DMR from a single, integrated source. The DMR provides a unified BOM that encompasses the engineering, manufacturing, and process data structures to ensure compliance to FDA regulations. This also enables companies to quickly assess the overall impact of a change to any step or component in the manufacture of a product. Multi-plant routings and work centers capture the process BOM or Bill of Operations (BOO). Routings and work centers can be shared by multiple parts across multiple plants or facilities.

ECR/ECO Management Processes

ENOVIA Life Sciences Accelerator for Engineering Design is delivered with engineering “best practices” from the experience of some of the world’s largest manufacturing companies. These best practices enable standard and repeatable global engineering processes. The change process in ENOVIA Life Sciences Accelerator for Engineering Design supports a seamless process for initial release of a part and the associated specification(s) for production use and to manage and control subsequent changes to current approved part(s) or specification(s) at any point in the life cycle of the item. For any in-work objects (or data), the change is intrinsic to the specification/definition process. In a typical product development cycle, the specification or the implementation of parts is likely to change during their development or integration.

These design changes are commonly referred to as Engineering Change Orders (ECOs). A change can be created directly or it can be created from the Engineering Change Request (ECR) process. If you choose to use the ECR process it can be employed to qualify, analyze, review and approve change requests for released parts, assemblies and documentation before being promoted to an ECO.

ECOs are used to alter the functionality of a design after it has been wholly or partially completed. ECOs can compensate for design errors found during testing or changes that are made to the design specification to compensate for design problems in other areas. ECOs enable the engineering best practice rules of form, fit and function. If a proposed change is FFF compatible then the ECO affected item will be revised. If a proposed change is not FFF compatible then a new part number should be used. A “mass replace” change capability is included in the ECO process to enable the replacement of an existing child part with a new part for all or selected affected parents when a part replacement is required to implement a FFF incompatible change.

In a typical product development lifecycle, the need for change is caused by, one or more of the following conditions:

- Correction of a design error that doesn’t become evident until testing and modeling or until customer use reveals it.
- A change in the customers’ requirements necessitating the redesign of part of the product.
- A change in material or manufacturing method. This can be caused by a lack of material availability, a change in vendor, or to compensate for a design error.
- A proactive change initiated by design or engineering in order to modernize or enhance an existing design.

ENOVIA Life Sciences Accelerator for Engineering Design provides flexibility to split one or many ECRs over one or many ECOs for implementation. It also features streamlined changes where approvals are entered for the ECO and its affected items rather than individual parts or specifications. The configurable approval matrix dynamically selects the necessary approvers based on company specific business rules. Clerical ECOs are also provided to enable document control personnel to correct errors without burdening the engineering and management teams with unnecessary approvals.

Reporting

ENOVIA Life Sciences Accelerator for Engineering Design has reporting capabilities tailored to meet the needs of multiple functional areas. These reports provide valuable product information for cross functional groups to make informed and timely decisions thus contributing to overall product development and planning efficiency and quality. Reports can be formatted in a printer friendly format or exported to Microsoft Excel®.

Specific EBOM reports include:

Multi-Level EBOM

Any number of Engineering Bills of Material (EBOMs) levels can be expanded and included in the multi-level EBOM report.

BOM Comparison

This report improves part reuse and product quality by providing the ability to compare EBOM differences. The report has many comparison options including basis of comparison, attributes to display when a difference occurs, and BOM levels to compare. Results can be displayed in either a printer friendly table or in a graphical side by side format. When ENOVIA® X-BOM Manufacturing is also implemented, users can compare any combination of EBOMs or manufacturing BOMs.

Part Whereused

The “whereused” report provides a part’s single or multi-level parent usage, which is very useful in analyzing the scope and impact of engineering changes.

Consolidated EBOM

This report improves purchasing response time and reduces errors by providing a quantity roll up of parts from multiple levels of an EBOM.

Engineering Effectivity

The engineering effectivity report provides the ability to view an EBOM based on an historical date. This report enables the user to see the “effective” EBOM at a select date in the past.

Electronics Approved Vendor List (AVL) BOM

This report improves communication and reduces data errors internally and with electronic contract manufacturers by providing EBOM views and data packages with optional location specific preferred suppliers and component parts.

View EBOM in Expanded Format

The EBOM view can be “expanded” by displaying each reference designator value as a single EBOM record. This is particularly useful for consistently displaying electronic or location-specific items in the EBOM. For example, an EBOM record with a reference designator value of R1-R3 and a quantity value of 3 would be expanded to display three separate EBOM records with reference designator values R1, R2, R3 and with a quantity of 1 for each. The inverse view can also be calculated where an expanded view can be consolidated.

Specific change process reports include:

ECR/ECO Summary Reports

ECR/ECO summary reports are generated automatically and refreshed during the change process lifecycle and can be stored in HTML or PDF format. These reports provide a synopsis of the change so change board members can quickly review and approve complex pending changes.

ECR/ECO Metrics Report

These reports can be generated to capture lifecycle date and time metrics for ECR or ECOs. These reports are useful to determine trends in change process throughput.

ECR / ECO Late Approvals Report

Late approval reports provide engineering management with a list of change review or approval tasks that are late by the resource assigned. Late approval reports are useful to manage resource tasks and as input to resource load balancing.

Document Management

Any document type, including Microsoft Office, can be managed independently or associated to parts. This improves inter-department communication and company knowledge capture such as best practices and industry standards. Documents can be connected to parts, specifications or change objects as reference documents or supporting documents as needed.

Interoperability with Cross-Functional Product Development Processes

ENOVIA Life Sciences Accelerator for Engineering Design is designed to make sure other enterprise business processes can work with the bills-of-material defined with ENOVIA Life Sciences Accelerator for Engineering Design. Examples include:

- Define plant-specific manufacturing BOMs with ENOVIA® X-BOM Manufacturing
- Capture and track part materials compliancy data with ENOVIA® Materials Compliance Central™
- For custom and low-volume medical device manufacturers, define and maintain the as-built BOM with ENOVIA® X-BOM Unit Tracking
- Capture part cost elements with ENOVIA® X-BOM Cost Analytics

ERP Integrations

Customers can choose to extend their ENOVIA Life Sciences Accelerator for Engineering Design capabilities by licensing the following products to integrate seamlessly with leading Enterprise Resource Planning (ERP) systems:

- ENOVIA® X-BOM for Oracle Manufacturing
- ENOVIA® X-BOM for SAP
- ENOVIA® X-BOM for JD Edwards EnterpriseOne
- ENOVIA® X-BOM for QAD MFG/PRO

When used with the above ERP integrations, the ECO release process automatically updates the associated ERP system(s). This automatic synchronization process eliminates redundant, error-prone manual data entry.

The Role of ENOVIA V6 and PLM 2.0

ENOVIA Life Sciences Accelerator for Engineering Design supports PLM 2.0, product lifecycle management online for everyone, and the ENOVIA V6 values, which are:

- Global collaborative innovation
- Single PLM platform for intellectual property (IP) management
- Online creation and collaboration
- Ready to use PLM business processes
- 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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