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ENOVIA Life Sciences Accelerator for Regulatory Affairs

ENOVIA® Life Sciences Accelerator™ for Regulatory Affairs enables users to efficiently submit documentation and improve collaboration in an effort to expedite the premarket approval from global regulatory authorities. The product facilitates communication between submission team members within the organization, and with agencies such as the U.S. Food and Drug Administration (FDA).

Key Benefits

- Meet the mandates of domestic and international regulatory agencies while reducing overall time-to-market
- Manage regulatory mandates to efficiently move a product through the regulatory approval process
- Reduce time-to-market for new products and time required to re-register existing products
- Enable companies to organize regulatory mandates into a clear set of deliverables for each product submission
- Manage and track communications from regulatory agencies to enable faster and more accurate responses to inquiries and deficiencies

Product Overview

In order to market products, companies must provide regulatory agencies with the specific information to prove safety and efficacy of their products. The submission dossier for each market varies by product and region creating a challenge for regulatory administrators. ENOVIA Life Sciences Accelerator for Regulatory Affairs allows users to create custom templates for any type of submission. Regulatory administrators specify the deliverables needed to comply with a market's regulatory requirements. Submission templates ensure successful patterns are repeated and decrease submission assembly time. As changes in regulatory requirements are made, administrators easily can assess the impact on in-process submission with the "where used" feature.

The flexible deliverable structure enables users to add, remove, or waive deliverables as needed for individual submissions. Assignment and read access may be granted for entire submissions or selected deliverables.

Submission deliverables and their content are approved through a 21 CFR Part 11 compliant approval process. Once all deliverables are complete, the content can be exported to a zip file for submission to the agency.

Throughout the submission assembly and review process, communication with the regulatory authority is a critical activity. ENOVIA Life Sciences Accelerator for Regulatory Affairs allows users to track and categorize communications including inquiries, deficiencies, and extensions. In resolving deficiencies, addendums must be submitted to provide the needed information. By revising the submission, new deliverables can be added while maintaining the original revision of the dossier.

Once the submission is assembled, it can now be exported as a PDF. This is required by the FDA for electronic submission. ENOVIA Life Sciences Accelerator for Regulatory Affairs packages all of the submission content and deliverables in the required structure for electronic copy.

When the results of a submission are received, the product codes and classifications for the market are added to the product. All product submissions, codes, and classifications can be tracked with simple navigation. If post-approval activities have been mandated, action items can be created and assigned to ensure activities are completed as required.

Product Highlights

The ENOVIA Life Sciences Accelerator for Regulatory Affairs enables medical device companies to reduce overall time-to-market while efficiently and effectively satisfying FDA Part 814 and Part 807 as well as meet the mandates of international regulatory agencies.

Submission Assembly

Regulatory mandates can be organized into a clear set of deliverables for each product submission. Submission templates automatically generate the necessary workflow structure based on the submission type (e.g. IDE, PMA, 510(k), CE mark). Templates are defined by end users and easily modified when submission mandates change. Deliverable content is displayed clearly under each deliverable, and access to deliverables can be granted to individuals and groups. When delivering submissions to the FDA regulatory body for pre-market approval applications, it can be rendered in a PDF format, which is the preferred format by the FDA. (For PDF rendering support, a company will require the supported version of Adlib Express. Adlib Express is not sold by ENOVIA and can be purchased directly from our partner).

Submission Workflow

To meet product registration requirements and regulatory deadlines, companies must have an organized, traceable workflow. ENOVIA Life Sciences Accelerator for Regulatory Affairs enforces that a submission goes through the necessary workflow steps before it is complete. Audit traceability is maintained compliant with electronic signature requirements (21 CFR Part 11).

Submission and Deliverable Access

To bring new products to market efficiently, collaboration and access to product submission data is critical. Across the company, from marketing to distribution to customer service, controlled access to current submissions and regulatory information is necessary for all divisions and affiliates involved. ENOVIA Life Sciences Accelerator for Regulatory Affairs provides centralized storage to current submission documentation so it is accessible to departments outside of Regulatory Affairs. Cross-department visibility enables Distribution (supply chain) and Marketing to see the current status of a submission.

Communication
ENOVIA Life Sciences Accelerator for Regulatory Affairs manages and tracks communications between a company and regulatory agencies. This includes storage for a variety of communications such as emails, scanned documents, phone call transcripts and PDF documents. The communications can be categorized by topic and type.

Agency Inquiries and Deficiencies
ENOVIA Life Sciences Accelerator for Regulatory Affairs enables faster and more accurate responses to compliance inquiries and deficiencies by leveraging the issue management capabilities of ENOVIA® Live Collaboration. Throughout issue resolution, inquiry and compliance issue data is tracked such as date received, team member assignment, current status, and completion date.

Request Management
ENOVIA Life Sciences Accelerator for Regulatory Affairs streamlines the information request process for Regulatory Affairs associates and affiliates. Users can create request types and define the items that may be selected for each type. In order to route requests to appropriate responders, requests are placed in queues according to a set of user-defined rules. Once a request is accepted from the queue, the items selected by the requester are automatically converted to action items for assignment and completion.

Submission Reporting
ENOVIA Life Sciences Accelerator for Regulatory Affairs provides detailed information on submissions including submission type, countries submitted to, relevant dates, product details, submission cycle times and status. Reports within submissions can be grouped by region, country or submission type.

The Role of ENOVIA V6 and PLM 2.0
ENOVIA Life Sciences Accelerator for Regulatory Affairs 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.

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