REGULATORY AFFAIRS MANAGER

OBJECTIVE

Regulatory Affairs Manager handles global medical device market registration clearance processes, device identification records and publication for product release. It also enables users to evaluate and manage customer reported adverse events with the electronic submission of safety reports to the FDA and manual submission to global health authorities.
OVERVIEW

Gaining the right product approvals and certificates for major markets is fundamental for succeeding and ensuring the safety and effectiveness of every medical device. No one wants to spend all day wading through countless spreadsheets, or digging through file cabinets to locate registration data. Regulatory Affairs Manager is built specifically for the management and tracking of product details needed for product registration and post market surveillance. It provides a quick and easy way to help users prepare, submit, approve and manage submission data seamlessly and efficiently. Regulatory Affairs Manager digitizes and institutionalizes best practices for managing the product lifecycle from planning to market authorization.

Global regulatory bodies have long pointed to incomplete or low-quality submissions as a reason for slowdowns associated with the clearance/approval of new products. By formulating a successful global regulatory strategy and automating the collection of information required in submissions (for example, U.S. FDA 510(k), PMA), medical device companies can bring products to market with greater speed and efficiency.

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Regulatory Affairs Manager handles the medical device identification record and registration processes electronically to the FDA GUID through the entire journey—from review and approval workflows to prevent production errors and product recalls. Safety monitoring and compliance is an integral part of the management of medical devices.

Regulatory Affairs Manager offers a single global solution with powerful automation and productivity tools to meet the challenges of managing your worldwide safety information. It will create, manage and report serious adverse event and product compliance cases for Electronic Medical Device Reports (eMDRs) to the FDA gateway, seamlessly and efficiently, along with other safety reports and submissions globally.

Regulatory Affairs Manager provides a robust set of compliant tools for:
- Dossier Strategy & Submission Management for Market Authorization
- Complete Device Identification Management
- Adverse Event Reporting Management

HIGHLIGHTS

Key features and capabilities include:

Dossier Strategy & Submission Management for Market Authorization

Global regulatory marketing submissions are not simply about document submissions. They are elaborate processes involving end-to-end management, tracking and maintenance. These activities include the initial submission as well as variations, questions, obligations and commitment handling. Regulatory Affairs Manager helps properly defined and prepared market registration submissions, ensuring that the submission contains the appropriate defined information requested by the various regulatory bodies for the specific product classification reducing the likelihood that the submission will be rejected by the regulatory agency for incompleteness and reducing delays in the overall approval process.

Key Benefits:
- Accelerate time-to-market by streamlining and automating the complete regulatory submission and approval process (dossier assembly through end of life).
- Capture the needed submission data and attributes.
- Manage end-to-end DI (device identifier) submission and global regulatory submission tracking for market approval.
- Track reported adverse events and manages them from initial triage through reporting and case closure to meet the complex and varying requirements of global regulatory authorities.
- Perform “where used” analysis to highlight relationships with internal or external complaints.

Regulatory Submission and Calendar Management

Regulatory Affairs Manager drives repetitive execution with the submission content required by regulatory bodies. Regulatory Affairs Manager ensures consistency, accuracy, and on-time delivery through creation of event plans with standard milestones that are fully transparent, across the global organization. Users can define milestones for each submission sequence and track planned vs. actual dates. Users can enable stop and start clocks to meet regulatory deadlines.

Submission Request Management

Regulatory Affairs Manager streamlines the information request process by selecting from predefined types of requests and the needed information. Global coordination and collaboration is improved between departments and affiliates by sharing a common authoritative information source. Regulatory Affairs Manager manages submissions across multiple projects with information that is entered once and replicated as appropriate.

Regulatory Affairs Manager defines the submission plan and dossier to deliver complaint on-time submissions. It defines a new submission program, team and schedule or reuses past project data. It enables users to perform “What-If” analysis and schedule snapshots to compare alternatives and select the best approach.

Simplifies the Dossier Preparation and Assembly

Regulatory Affairs Manager streamlines the global regulatory submission assembly with a tool flexible enough to adapt to changing regulations. It executes submission plans that include document placeholders prior to authoring, uses visual cues to determine easily the submission documents that are out of date, and automatically synchronizes documents to the submission dossier.

eCopy Submissions

Electronic reporting is an imperative to ensure proper collaboration. Regulatory Affairs Manager creates multiple submissions in multiple regions using comprehensive built-in templates. It enables users to create an eCopy submission dossier via a package that is exported to PDF. The PDF can contain bookmarks, insert or overlay headers, page numbers, logos, and addresses. Email notification is sent when rendering is complete. Users can easily manage subsequent amendments, supplements and variations within the context of the full application.
Interactive Review Process

Regulatory Affairs Manager captures the eCopy submission “sent date” and regulatory body “received date”, and manages and tracks communications between a company and all regulatory agencies. It captures and manages regulatory correspondences, assigns tasks to requests, tracks the status of the regulatory commitments and correspondence required to keep products on the market. Regulatory Affairs Manager easily manages subsequent amendments, supplements, and variations within the context of the full application.

Manage Registration Activities

Regulatory Affairs Manager provides greater visibility into registration activities and product detail information through robust querying and dashboard reporting. It includes market authorization information results (approved/clearance and registration and expiration dates), and registration license number. Regulatory Affairs Manager supports creation of a submission project for post-initial marketing commitments, and subscribing to events to monitor the submission process.

Complete Device Identification Management

Regulatory Affairs Manager is a robust solution for creating, transmitting, and tracking GUDID submission data to meet the U.S. Food and Drug Administration’s (FDA’s) new UDI rule. It is able to leverage both submission-only technology and data staging technology. Regulatory Affairs Manager provides unique data management and synchronization capabilities to automatically keep GUDID submissions current as product attributes change, which is one of the key requirements of the FDA UDI rule.

Capture Device Identification

Regulatory Affairs Manager captures, collects, reviews and submits data in a standardized workflow. It includes:

- Device information such as its product line, model, and product name
- Device specific packaging and secondary DI Information
- Device characteristics for storage & handling conditions, clinically relevant size, latex information, sterilization, and MRI safety
- Device status and pre-market information

Manage DI Records

Regulatory Affairs Manager uses an enterprise process workflow to assign tasks to different parties to provide information from across your organization.

Submit and Publish DI record to FDA GUDID database

Regulatory Affairs Manager generates compliant XML files (HL7 SPL) that contain the pertinent DI data for submittal to the GUDID. It receives acknowledgement from the GUDID database when a submission is successful or rejection notices for an invalid DI record submission.

Device Identification Record Search and Report

Regulatory Affairs Manager publishes the state once the system receives the success ACKs (acknowledgements) from the FDA. All ACK files will be stored along with submission XML file and a traceability audit trail for submission and acknowledgements to GUDID are automatically maintained.

Adverse Event Reporting Management

Regulatory Affairs Manager enables fast and timely adverse events submissions. It creates consistency and full traceability in managing an adverse event by providing the ability to expedite the process of submitting electronic reports. This eliminates the need for faxing or mailing the report, which further reduces the costs associated with paper, shipping, resources, repetitive data entry, and errors. Regular Affairs Manager submits safety reports directly to the FDA, EU, Health Canada, Japan, and Australia. All receipt acknowledgements from the FDA are lined up automatically with the corresponding submission and a PDF file will be auto-generated.

Collaboration & Approvals

Users can benefit from a wide range of capabilities for global enterprise collaboration. Those capabilities include the ability to manage and organize shared documents and structured product data; they also enable the creation of digital workspaces for virtual teams to work together. Users can easily raise issues, organize meetings and track decisions while any object lifecycle modifications can be formally approved using routes defined by end-users, or to simplify and facilitate a repeatable approval process, standard route templates.

Microsoft Integration

Users can create and access 3DEXPERIENCE data from the most popular Microsoft applications: Word®, Excel®, PowerPoint®, Outlook®, Windows Explorer, and Windows Desktop Search. This capability enables enterprise-level collaboration while not disrupting the established productivity of end-users. With product content being managed in 3DEXPERIENCE rather than on users’ PCs, organizations are able to create, manage and review product content more securely.

Our 3DEXPERIENCE® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the 3DEXPERIENCE® Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes’ collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 190,000 customers of all sizes in all industries in more than 140 countries. For more information, visit www.3ds.com.