DASSAULT SYSTEMES

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REGULATORY AFFAIRS MANAGER

OBJECTIVE

Regulatory Affairs Manager manages global medical device market registration and submissions for marketing clearance, device identification records, and publication for product release. It manages global adverse events including the electronic submission of eMDR (Electronic Medical Device Reporting) to the FDA and manual submission to global health authorities.

OVERVIEW

Regulatory compliance creates unique challenges within the healthcare and life sciences industry and needs to become an integral part of the medical device lifecycle. Gaining the right product approvals and certificates for major markets is fundamental for ensuring the safety and effectiveness of every medical device. No one wants to spend all day wading through countless documents 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.

Regulatory Affairs Manager handles the medical device identification record and registration processes electronically to the FDA GUID through the entire journey— from gathering the data, review to publication. The solution expanded capabilities for DI traceability and submission creates a holistic approach to integrating data across the organization.

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 a company's worldwide safety information. It creates, manages and reports 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.

HIGHLIGHTS

Key features and capabilities include:

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 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.

Regulatory Affairs Manager defines the submission plan and dossier to deliver compliant on-time submissions. It defines a new submission program, team and schedule or it reuses past project data. It enables users to perform "What-If" analysis with schedule snapshots to compare alternatives and select the best course of action.

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, assuring 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.

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

Garner efficiencies in the regulatory approval process and streamline workflows with regulatory requirements set out by FDA and other health agencies. FDA guidance documents are very specific about the format of PDF files required for submissions, including details about hyperlinks, bookmarks, security settings, acceptable fonts, page orientation, page size and margins. Incorrectly formatted PDF files result in frustration and delays at the regulatory agency. These are described within FDA Portable Document Format (PDF) Specifications (v3.1, dated 1/20/2012). Electronic submissions are now mandated and are 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. All PDFs created from Adlib PDF Enterprise perform as is defined in their original documents. Bookmarks and hyperlinks defined in the original documents can still be used. In addition, Adlib PDF has features to add watermarks, headers, footers and other features to created documents. 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.

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.
- Ability to setup a general GTIN format and automatically create GTINs based upon the item reference number.
- Track reported adverse events and manage 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.

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.

Device Identification Management

Regulatory Affairs Manager is a robust solution for creating, transmitting, and tracking GUDID submission data to meet 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 and handling conditions, clinically relevant size, latex information, sterilization, and MRI safety
- Device status and pre-market information

Eliminate Organizational Barriers

Data inaccuracy typically results from the lack of a governance strategy and proper data management. **Regulatory Affairs Manager** automates the business processes necessary to create, track, manage and submit the information required for UDI compliance. Workflow capabilities ensure proper approval processes are followed and an audit trail exists to demonstrate traceability and transparency to regulators. **Regulatory Affairs Manager** integrates data generation and maintenance into existing processes, such as new product introduction (NPI), change control (CC), and quality control (QC).The data reflects product changes, leading to higher quality information. **Regulatory Affairs Manager** ensures that the appropriate data owner is responsible for the accuracy of the data. Manual data management and human intervention is reduced, which then increases efficiency and productivity associated with UDI compliance.

GTIN Generator

GTIN or global trade item numbers are used to identify specific items and are used to comply with FDA regulations requiring assurance of unique device identifiers (UDI) for Healthcare. **Regulatory Affairs Manager** takes inputs from specific fields in the system to automatically generate accurate and unique GTINS for items and parts that comprise medical devices. It has the ability to setup 8, 12, 13, or 14 digit long numbers. Each is constructed in a similar fashion by combining the Company Prefix, Item Reference and calculated Check Digit. **Regulatory Affairs Manager** also associates this number to items and parts for accurate tracking.

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 timely consolidated, global approach adverse events submissions. It automates the process by utilizing decision trees to help drive complaint management investigations and determine regulatory requirements around the world. 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. Any object lifecycle modifications can be formally approved using routes defined by end-users or from standard route templates.

Microsoft Integration

Users can create and access **3D**EXPERIENCE® 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 **3D**EXPERIENCE rather than on users' PCs, organizations are able to create, manage and review product content more securely.

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

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