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ENOVIA

DEVICE MASTER RECORD MANAGER

OBJECTIVE

Device Master Record Manager saves companies time and effort by eliminating redundant data entry and validation of medical device procedures and specifications with a single, centralized, secure, digital repository that helps ensure compliance with FDA regulations, ISO quality standards, and other global regulatory requirements.

OVERVIEW

Increasing business, product and process complexities affect operating margins and are driving companies to find business solutions which foster innovation and improve efficiencies. In the Life Sciences industry, the complexity and rate at which new products need to be developed has already out-paced the rate at which many companies can produce them. Furthermore, the rate at which companies need to develop product content is expected to continue to grow faster than the current rate of productivity improvements.

Device Master Record (DMR) is the term used in the Quality System (QS) regulation for all of the routine documentation required to manufacture devices that will consistently meet company requirements and is built up throughout the life cycle of the product. Experienced medical device development and manufacturing teams recognize the significant scope of today's document control requirements and the severe limitations of spreadsheets and paper files to bring innovative devices to market. Engineering, operations design partners, and quality team members must have secure access to a single, unified version of product data to manufacture a compliant product.

Device Master Record Manager works seamlessly with **Manufacturing BOM Manager** to establish a DMR for each manufacturing location and address the following business challenges:

- Automate and efficiently manage the compilation of DMR records
- Save time and eliminate errors caused by existing information silos and redundant systems which manage the Device Master Record
- Enable global product teams to efficiently collaborate, approve and implement device designs, specifications and procedural changes through a common, automated change process

HIGHLIGHTS

Key features and capabilities include:

Access to Latest Product Information

A basic requirement associated with FDA regulation 820.181 is ensuring the DMR is a "living document" that can manage ongoing changes. The DMR will never remain in a steady state. As products mature, manufacturing technology changes, or as product complaints occur, device manufacturers are driven to modify applied methodologies, processes, and procedures. When changes occur, these changes must be captured in the DMR.

To ensure medical device compliance, the DMR should capture every device specification, drawing, work instruction and processing instruction related to the medical device. **Device Master Record Manager** provides users with a single, unified version of documents created with **Product Engineer** and **Manufacturing BOM Manager**. It improves quality and consistency of design controls by dramatically reducing regulatory risk with a single system of record. **Device Master Record Manager** enables users to have multiple views of the DMR as it goes through the product lifecycle from design to each manufacturing plant and the eventual end-of-life. Multiple DMR views at different stages can be stored and compared for differences.

Full Product Traceability

Viewing the DMR throughout the product lifecycle is critical to improve collaboration and achieve compliance with confidence. **Device Master Record Manager** provides DMR views from an engineering perspective before the transfer to manufacturing. Users can view device specifications including appropriate drawings, standard operating procedures, and component specifications with effectivity filtering by date, manufacturing plant, implementing organization, and/or product. When **Device Master Record Manager** is used with **Packaging Copy and Artwork Manager**, it is also possible to view packaging and labeling specifications within the DMR.

With the optional use of Adlib Enterprise, it is possible to package and download PDF versions of the DMR's controlled documents. Regulatory compliant headers, footers, and watermarks are applied to satisfy QSR/ISO regulatory requirements with a full audit trail and signature authentication controls readily available for an FDA investigator.

Key Benefits:

- Transfer finished design output documents into the Device Master Record
- Control changes to product information with a common process that is systemic, automated, traceable, documented and auditable
- Filter the Device Master Record by plants, effectivity dates, and current or pending part revision

Clear Communication of Change Decisions and Assignments

Device Master Record Manager brings all organizations together under one single change methodology to drive a consistent and repeatable change management practice. It provides full change traceability across all impacted organizations, and offers real-time change reports to facilitate decision making. An "Impact Analysis" for a proposed change can be evaluated to determine to understand its full scope. The "Where Used" displays exactly where a part is used across multiple BOMs, which permits users to determine the impact of a single part change and update subsequent changes as needed. Approvals during the change process comply with the CFR 21 Part 11 Electronic Signature regulation.

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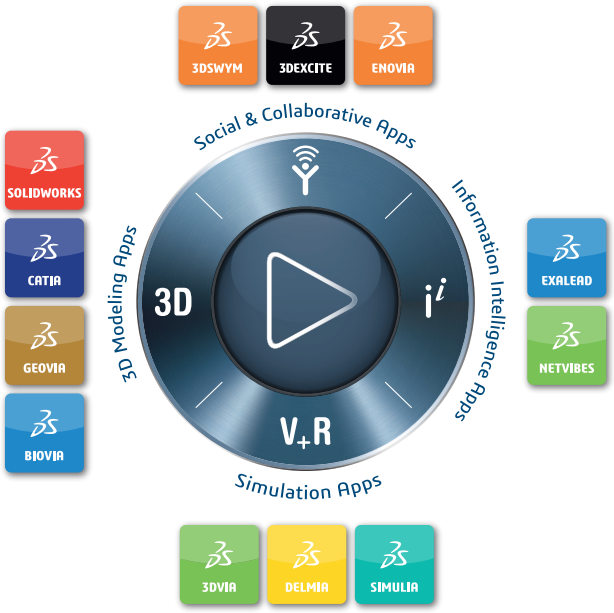

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