MPD manager

EXTEDO eRegulatory Affairs

Product Information

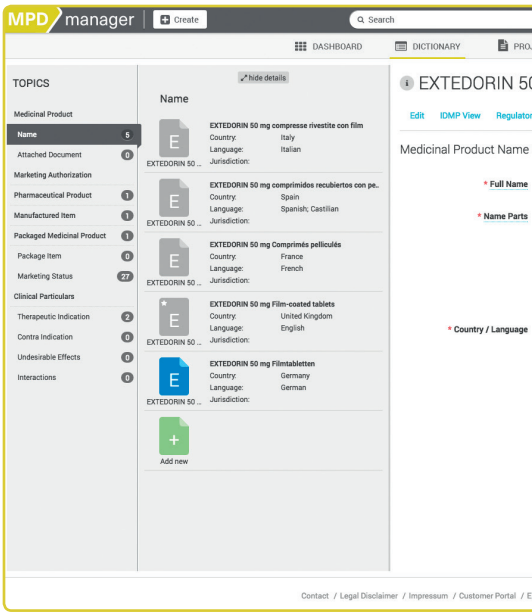
MPDmanager™ for IDMP

Simplifying the management of IDMP and other medicinal product information

With the imminent introduction of the new IDMP standards, organizations will need to capture and manage significantly more regulatory data for each medicinal product than under the existing XEVMPD requirements. Data management for multiple medicinal products registered in numerous different regions involves significant effort, which can be a time consuming and costly process.

Benefits

- No technical IDMP knowledge needed to collect and maintain IDMP data
- Guided dictionary maintenance through standard regulatory activities
- Multiple internal and external users can maintain multiple medicinal products at the same time
- Assure data quality via business validation, technical validation and four-eye principle
- Increased transparency and productivity via user friendly and modern interface
- Global IDMP and CFR Part 11 compliance
- Product dictionary provides a single source of truth for all your medicinal products
- Supports future demands such as multi-gateway functionality and data model changes
- Integration with EXTEDOsuite and other third party products to provide a total RIMS solution
- Reuse your data from source systems to improve data quality and save time
- Full system validation support reduces validation effort to a minimum
- Well established in operation management services, which takes over IT infrastructure services, application management services including maintenance of controlled vocabularies, pre-validated software releases and video tutorials on new features

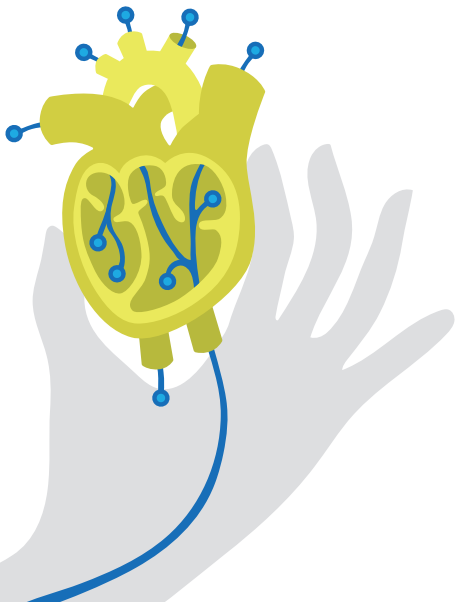


Editing of a Medicinal Product

EXTEDO's MPDmanager simplifies the process of maintaining IDMP submissions, delivering a single source of truth for all IDMP data. By providing a repository for all registrations and enabling the electronic submission of data directly to the authorities, MPDmanager's powerful medicinal product database enables you to efficiently fulfill regulatory requirements surrounding the management of product data

Simplifying IDMP registration maintenance

MPDmanager's clear and concise user interface is specifically designed to make data collection, maintenance and IDMP compliance straight forward. The integrated authoring guide provides you with the information needed to understand and collect your data. It also includes the knowledge to maintain activities with predictive regulatory activity selection. The system guides the user through each maintenance activity in a step-by-step mass update wizard until all changes have been executed. When you are ready to submit an update, MPDmanager's built-in validation engine provides a quick and easy quality check to ensure that all changes remain compliant with ISO and other regional specifications.



MPDmanager is the perfect solution for any company size

Standalone solution – for CROs, small to mid-sized corporations

As a standalone tool MPDmanager provides simple IDMP compliance for CROs and small to mid-sized corporations. Out-of-the-box, its capabilities enable you to efficiently submit and manage IDMP registrations with the EMA

Functional Overview

- Integrated Authoring Guide, written by regulatory experts, describes all IDMP elements and relations to source data.
- System suggests maintenance activities based on provided standard regulatory activities
- The system guides the user through a step-by-step wizard while supporting individual and bulk updates.
- Multiple users can maintain one medicinal product at the same time
- View your product history related regulatory and maintenance activities
- Full multi-gateway functionality with automated communication between industry and authority
- Medicinal product history related to maintenance and regulatory activities
- Dashboard provides the user most essential information that is needed to maintain medicinal products on a daily basis
- Identify medicinal product by message and data record life-cycle states
- Quick and advanced search to find data records quickly and efficiently
- Create medicinal product based on pre-defined templates
- View your IDMP data in a SmPC like structure
- Reduce your medicinal product data set to iteration I via content filter
- Automated data pull from MedDRA, Snomed /GInAS, EMA and other sources managed by EXTEDO
- Connect a single source system, RImanager or MDM (Master Data Management)
- Web based, deployed as SaaS (subscription) and in-house (license)
- Validation documentation package
- Protection of intellectual property via user and rights administration
- External security and privacy audits including penetration tests

and other regional authorities. While its easy-to-use interface allows you to browse data without requiring a detailed knowledge of the IDMP data model. Additionally, innovative dashboards and notifications provide you with up-to-date information about the status of your registrations. MPDmanager also enables you to query live data through quick and advanced search forms, allowing your users to manage medicinal products efficiently.

Integrated RIM and MDM – for medium to large-sized corporations

For larger corporations, MPDmanager can be implemented as part of an integrated Regulatory Information Management solution. Full multi-gateway functionality and automated communication between industry and authorities are supported and its plugin architecture enables you to connect to tools such as EXTEDO's RImanager or Master Data Management (MDM) systems. This approach means that data can be reused, improving data quality and saving time.

Simplifying the move from XEVMPD to IDMP

MPDmanager is your perfect companion for handling the transition from XEVMPD to IDMP. The ability to access submission data without requiring a comprehensive understanding of every detail makes your transition smoother and ensures that your business continues to remain compliant into the future. EXTEDO MPDmanager provides Effortless Compliance™ with IDMP medicinal product data management regulations. It improves your data quality, increases operational efficiency, and delivers better-automated communication channels between your departments and with the authorities.

Available Modules

Report Module

Configurable map and charts showing medicinal products with authorization status. 3rd party application for custom specific reports.

National Authority Gateway Module

Send messages to other national HL7 authorities once the respective implementation guides become available.

MPDconnect

Connect your source system to MPDmanager. MPDconnect is a state of the art standardized interface giving full access to the MPDmanager functionality and supports a 2-way communication with any source system. Available with SaaS, extended SaaS and in-house solutions.

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About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 700 maintained customers across 60 countries to deliver Effortless Compliance™.