MPD manager
powered by cara

EXTEDO
eRegulatory Affairs

Product Information

EXTEDO MPDmanager™ Powered by CARA™

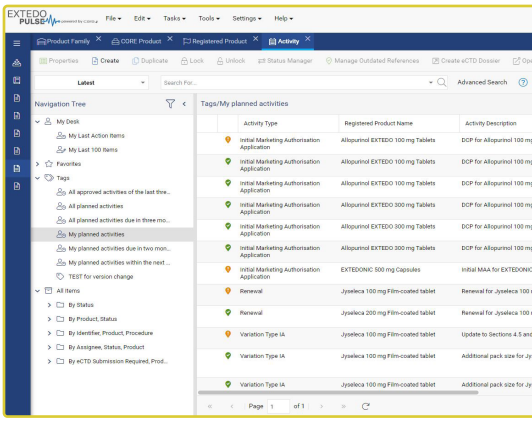
Simplifying the management of IDMP, XEVMPD and other medicinal product information

Different countries around the world each have their own regulations by which every pharmaceutical product must abide by. It is the responsibility of the life sciences company to comply with these regulations, but in a global economy that has different requirements within each region, this is a complex task. Every pharmaceutical product can have multiple registrations within one country, including pack sizes, dosage forms and much more, creating a challenging environment for life science organizations. With employees having to detail every aspect of every product for each country, critical documentation can be duplicated, lost or inaccurate. The imminent introduction of the new IDMP standard means organizations will need to capture and manage significantly more regulatory data for each medicinal product than under the existing XEVMPD requirements.

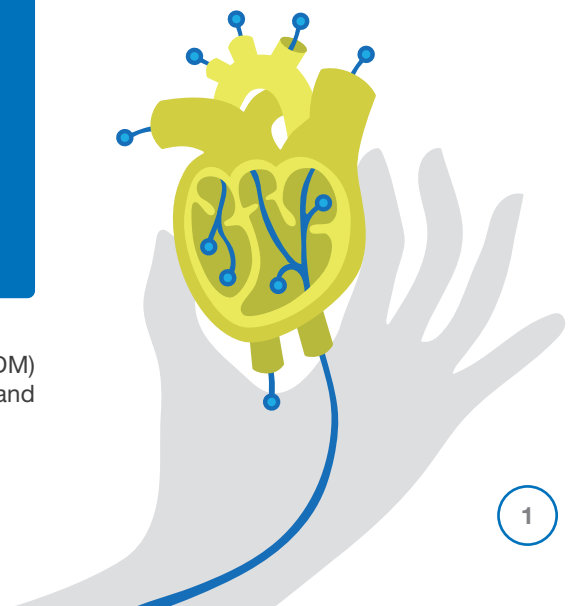
Benefits

- Single application to manage registration and product data
- Can be used as a stand-alone Product Master Data Management (MDM) system or linked to any already existing MDM solution and combined with other Hubs using the EXTEDOpulse platform
- Easy to manage, single source of truth for all your medicinal products
- No technical IDMP knowledge needed to collect and maintain product data
- Assure data reliability and quality via built-in validation
- Works with eDOCSmanager as well as any other DMS
- Supports import of already existing product data from EVWEB, Excel, Access and XEVPRM (XML) files
- Easy to connect/integrate with existing applications
- Can be configured based on individual requirements
- Supports future demands such as multi-gateway functionality and data model changes
- Available as on-premise or cloud solution
- Supports SmPC data extraction
- Regulatory Intelligence Data Collection
- Manage the data of your medical devices
- Keep the overview your registered products by using the comprehensive dashboard

EXTEDO MPDmanager is a comprehensive master data management (MDM) solution that enables you to effortlessly manage all the IDMP, XEVMPD and CORE data relating to your regulated products.



List of activities in MPDmanager

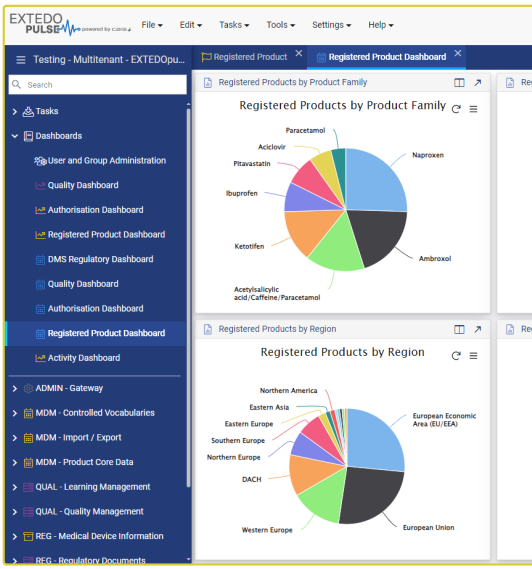


One solution for thousands of registrations

EXTEDO's MPDmanager is a solution for keeping track of thousands of medicinal product registrations worldwide. The application is designed as a Product Master Data Management (MDM) system delivering a single source of truth for the company's product data. Product CORE data can be used as a template for regional product definitions, and only needs to be added to the system once. Identical information such as the formula or composition of one product does not have to be added per market authorization and region. This approach transforms hundreds of hours spent on regulatory administration into a matter of clicks. By also including regulatory activities and correspondence, MPDmanager enables organizations to focus on product development rather than data management and regulation activities.

Extensive dashboard and report functionalities

The intuitive dashboard within the Registration Management Hub provides a user-friendly interface for accessing your registered product information. Based on easy-to-read and precise reports, the user can keep track of the registered products. All registered products can be organized based on various metadata, e.g., by product family, region, country, or even CORE product. From the report, users can seamlessly navigate to the registered product overview or they can make updates to the properties and work with product data directly within the reports.



Overview of the Registered Product Dashboard

Efficiently manage your XEVMPD and IDMP data

EXTEDO's comprehensive XEVMPD and IDMP database enables you to effortlessly manage all IDMP and XEVMPD data. It provides a central product data dictionary that allows you to manage and maintain XEVMPD and IDMP data efficiently whilst complying with current and future regulatory requirements. With the inclusion of region-specific IDMP standards/iterations (e.g. SwissMedic, FDA, etc.), it is the answer for life science organizations who want to keep track of regulatory obligations around the world quickly and efficiently.

Minimal data maintenance

Every change for a particular product must be recorded and its data maintained. Manufacturing, ingredient or production changes could have an impact on the medicinal products involved. This, in turn, affects product approval as different countries have different restrictions, and require various approvals from separate regulatory agencies, creating a formidable administrative task. With MPDmanager, users can see authorizations for any changes and the products affected throughout your system. The user simply changes the data in the core product and this change is then automatically also added to all related products. This saves time, prevents duplicate data maintenance and creates clarity throughout the compliance process.

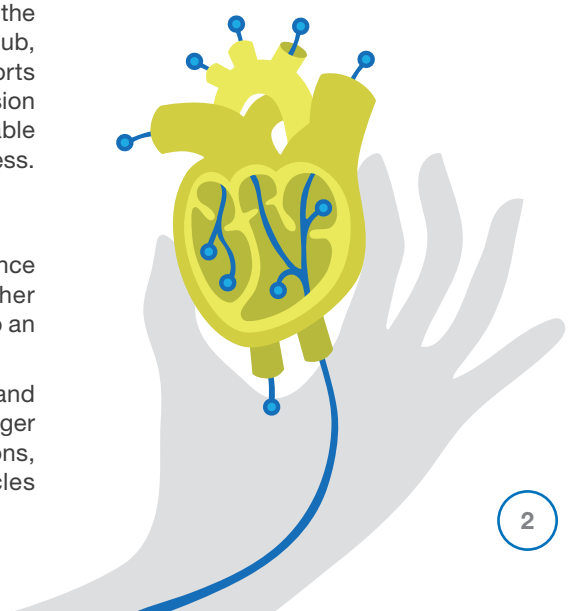
Integrated part of the EXTEDOpulse platform

EXTEDO's MPDmanager works as a stand-alone Registration Management solution or can be combined with other EXTEDOpulse hubs using the same platform. Through its connection to the Document Management Hub, users can store, access, and manage regulatory documents and reports for easy processing. Through its seamless integration with the Submission Management Hub, it can link dossiers to planned activities based on available information in MPDmanager. With EXTEDOpulse, the possibilities are limitless.

A manager that works with your requirements

EXTEDO's MPDmanager is a dynamic application suitable for all life science organizations. It can be connected to any external DMS or any other Regulatory applications, while used as a Product MDM system or linked to an already existing MDM (such as SAP).

As a stand-alone application, MPDmanager allows you to access IDMP and XEVMPD documents such as SmPCs directly in the system. MPDmanager works the way you want it to. It can be tailored to your own configurations, enabling you to add fields, rename titles, integrate workflows, lifecycles



reports and more. To further assist with adoption, MPDmanager supports the import of existing EVWEB, Excel, XEVPRM and other product data.

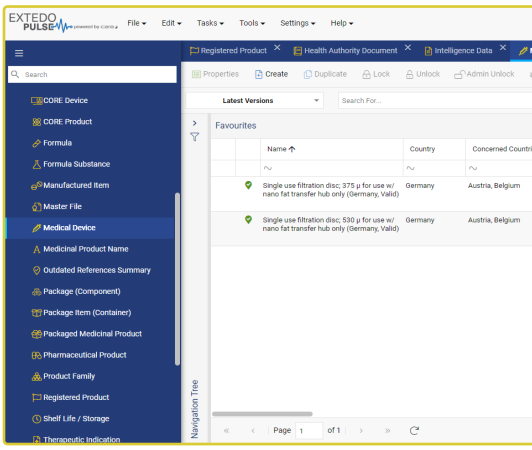
Deal directly with regulatory agencies

MPDmanager's powerful medicinal product database provides a repository for all registrations and the electronic submission of data directly to the authorities. It supports integrated business rules to validate data before submission for all standards based on the latest specifications. The submission itself is delivered through an integrated gateway for direct submission to agencies. Furthermore, MPDmanager uses the EMA SPOR database to work with up-to-date controlled vocabulary and receives agency reports (1st, 2nd & 3rd ACK) in the same application linked to relevant product information.

Navigate the Complexities of your Medical Device Data

MPDmanager allows management of authorization details of medical devices. It is designed to cater to the specific needs of medical device manufacturers and regulatory professionals. It simplifies the management of critical information, including device classifications and essential documentation, all in one accessible location.

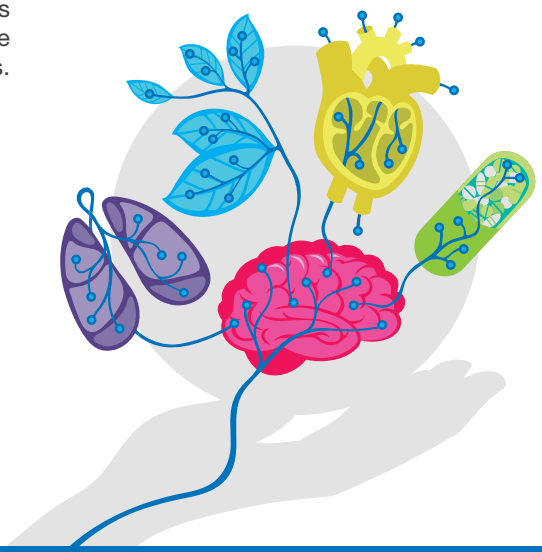
MPDmanager provides peace of mind by guaranteeing that you are fully aligned with the latest regulations, thus minimizing the risk of non-compliance and associated penalties. Furthermore, it optimizes your team's efficiency by automating manual data management and document tracking, allowing them to allocate their time and resources more effectively.



Management of authorization details of medical devices

Simplify Global Regulatory Compliance

MPDmanager's Regulatory Intelligence (RI) Module is a powerful solution, designed to simplify the complex world of regulatory compliance across different markets. This module offers a centralized hub for managing Health Authority Documents and RI Data, making document organization and retrieval effortless. With the RI module you can easily compare Regulatory Intelligence Data, helping you identify similarities and differences across various markets. Integrate all the external information you need and share insights with your team, thanks to seamless import and export functionalities.



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For further information contact your local EXTEDO representative:

EXTEDO
eRegulatory Affairs

EXTEDO Germany
+49 89 189454-0
info@extedo.com
www.extedo.com

EXTEDO US
+1 (855) 328 3500
info@extedo.com
www.extedo.com

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 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

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