RI manager

EXTEDO eRegulatory Affairs

WERUM KÖRBER SOLUTIONS

Product Information

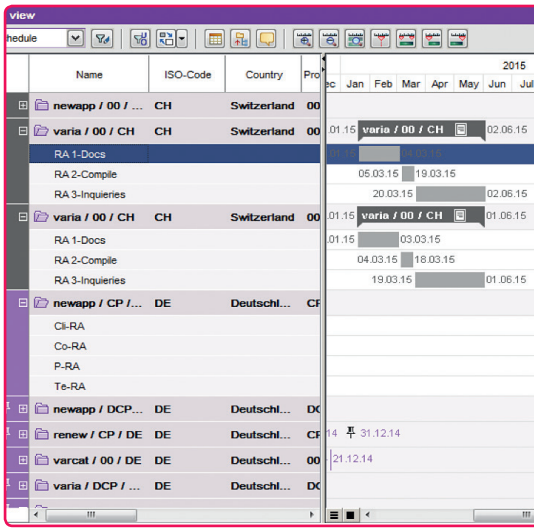
# RImanager™

## A centralized Regulatory Information Management System (RIMS) to manage your company assets

RImanager is a master data driven solution, which provides organisations the capability to manage its product portfolio with effortless compliance. It allows you to plan & track all your registrations across departments on a global scale. With RImanager you will have all your regulatory affairs activities transparent at anytime and anywhere.

### Benefits

- Confluence of Regulatory and Technology to make your life easier
- Manage master data for your products
- Single source of information for your regulatory product maintenance
- Developed and supported by the leaders in manufacturing execution and regulatory affairs software
- Regulatory Activity planning – made easy
- Powerful Project Management functionality
- Assign tasks and responsibilities to relevant people
- Readily generate management reports
- Reduce time and effort creating product documentation and regulatory submissions
- Access current and legacy product data from a single interface




Regulatory Activities Overview

Regulatory departments are the brains within the pharmaceutical industry, you are ultimately responsible for the life of your company's assets. Not only do you have very high standards of regulations that must be followed, you also have to coordinate complex activities with multiple stakeholders to ensure medicines can be assessed effortlessly for quality; efficacy and patient safety.

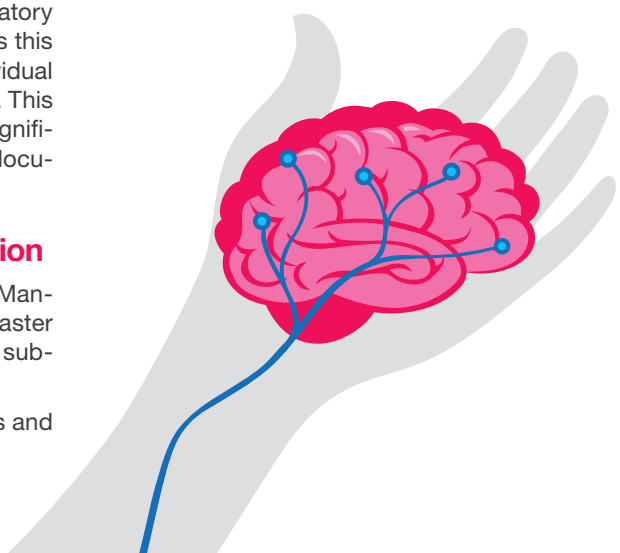
We live in a world where there is an expectation that relevant stakeholders have the most accurate information at a click of a button. Time is limited and standards like IDMP must be adhered to, tracking registration deadlines, planning maintenance submissions and keeping control of related projects can quickly become unachievable. However, failure to manage this effectively can result in compliance gaps and potential risk to patient safety.

Within many companies these processes rely on intensive manual effort, supported by Excel and other disconnected IT solutions such as regulatory product databases and manufacturing execution systems. Not only does this require significant IT effort to maintain, but more importantly the individual silos create disconnects between operational and regulatory information. This makes the alignment of the registration and manufacturing processes significantly more complex and increases the opportunity for errors within documentation and submissions.

## Your single solution for managing Regulatory Information

EXTEDO / Werum RImanager is a centralized Regulatory Information Management System (RIMS) that enables you to efficiently manage your master data well as plan and track related regulated data, activities, processes, submissions and commitments.

Regulatory Activity becomes the central trigger for all impacted changes and RImanager opens up transparency within your company.



## Functional Overview

- Manage Master Data for your product portfolio
- Powerful project management tools to plan and track regulated activities; tasks and resource
- Structured data driven system that supports IDMP exchange to authorities
- Connection to MPDmanager to allow for effortless transmission to regulatory authorities
- Supports EU and USA regulatory procedures and lifecycle maintenance
- Email alerts – So you dont miss important reminders
- FDA CFR 21, Part 11 compliant
- Structured data to generate labelling and forms (extension module required)

## Available Modules

**MPDmanager**
MPDmanager is EXTEDO's comprehensive XEVMPD and IDMP-ready data base system.

**DMSconnect**
Integration with leading document management systems

**SAPconnect**
Integration with SAP

**Trademark Management**

**Label Content Management**

As a part of the EXTEDOsuite, RImanager ensures that you have a single source of truth for all your regulatory product data. RImanager supports product registration, submission management and pharmacovigilance processes, and its open architecture queried through the same intuitive user interface.

## Connecting your regulatory and production processes

RImanager manages all your product master data. Regulatory activities can be defined that store and track the information related to each product and its related submissions. As RImanager is built upon Werum's PAS-X platform, it can also be integrated tightly into your manufacturing processes. This ensures that information regarding labelling, formulation and drug safety remain in a single repository, allowing instant access for your end-users and providing essential management and regulatory reporting capabilities.

Used in combination with EXTEDO MPDmanager, RImanager supports the transmission of both the XEVMPD and IDMP standard data to regulatory authorities, allowing information to be readily shared without the need for exports or manual re-keying.

## Effectively manage your regulatory projects

RImanager also includes a set of powerful project management tools to help you to structure and control your overall regulatory processes.

Using the built-in task management tools, you can assign specific activities to departments or teams of users. Direct links between tasks and business objects such as manufacturing sites, pharmaceutical products, formulations or submission documents allow quick and accurate access to related objects. For more complex processes, RImanager's workflow engine enables you to assign tasks in sequence to a number of users. The fully audited workflows can also be used to manage review and approval processes. RImanager's real-time email alerts provide instant notification to users about upcoming tasks or activity deadlines.

RImanager also includes version control capabilities that allow you to track and control the status of every object within the system. For example, by making changes to a new "Draft" version of an object, you are able to modify it without affecting the currently published version.

## About Werum IT Solutions

Werum IT Solutions is the internationally leading supplier of manufacturing execution systems (MES) and manufacturing IT solutions for the pharmaceutical and biopharmaceutical industries. Its out-of- the-box PAS-X software product is run by 17 of the world's top 30 pharmaceutical and biotech companies and in about 800 installations. Werum's manufacturing IT solutions help pharma manufacturers to increase efficiency, improve productivity, and meet regulatory requirements. Founded in 1969, the IT company employs about 420 people at its headquarters in Lüneburg, Germany, and at ten other locations in Europe, America and Asia. Werum is part of Medipak Systems, the Pharma Systems business area of the international Körber technology group. Körber unites more than 11,000 professionals in about 50 industry-leading companies, achieving annual earnings of more than two billion euros.

For more information take a look at our website **www.werum.com**.

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For further information contact your local EXTEDO representative
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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™.