

Product Information

Rlmanager™ Starter Package

Statistics show that organizations who follow a structured implementation approach typically reap a faster return on their investment than those who don't. EXTEDO's packaged solutions provide you with a best practice approach including pre-defined configurations, consulting and training. Our approach ensures a quick and cost effective implementation.

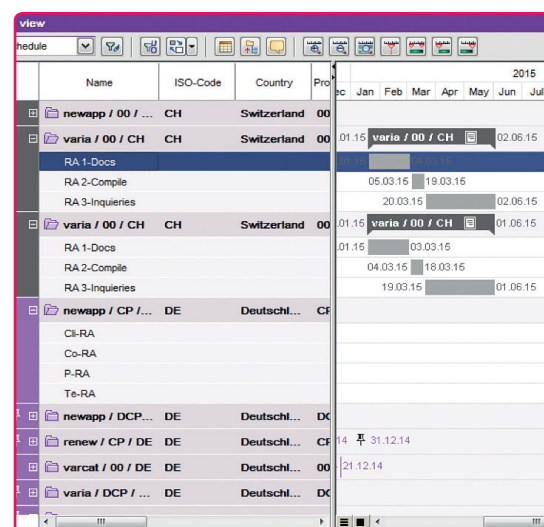
Benefits

- Reduced requirement for in-house expertise to get up and running
- Faster implementation time, without the requirement for expensive customization
- Installation and configuration services are fully documented and performed by EXTEDO's expert consultants
- Simplify the path to validation through use of EXTEDO's proven implementation methodology
- Ensure compliance with the latest industry standards
- Our packages include pre-defined configurations that have been extensively tested
- Complete documentation, IQ test scripts and end-user training material

The Starter Package includes EXTEDO's Rlmanager software as well as an expert team to guide you through the implementation. Rlmanager enables you to efficiently manage your master data as well as plan and track related regulated activities, processes, submissions and commitments. Rlmanager covers the entire lifecycle of your product and supports development, product registration, submission management, maintenance activities and pharmacovigilance processes.

To guide you through your initial installation, training and implementation, the Rlmanager Starter Package includes the following services and configurations:

- Installation and setup of a ready-to-use Rlmanager as a test and production environment
- Configuration of users and groups for your organization
- Comprehensive training including:
 - Business and technical training for administrators and end-users
 - Train the Trainer course for in-house experts
- Configuration of data and processes within your system, including:
 - Pre-defined filters to enhance your internal reporting
 - master data based on controlled vocabularies from the EMA SPOR implementation
 - addresses of regional agencies
 - regulatory activities / phases / procedures for EU/EEA and US
 - country profiles for EU/EEA and North America including pre-defined language settings for documentation
- Documentation
 - Rlmanager user manual
 - "Train the Trainer" in-house training material
 - IQ scripts



Name	ISO-Code	Country	Pro	Calendar
newapp / 00 / ...	CH	Switzerland	00	01.15
- RA 1-Docs				02.06.15
- RA 2-Compile				05.03.15 - 19.03.15
- RA 3-Inquiries				20.03.15 - 02.06.15
- RA 3-Inquiries				01.06.15
- RA 1-Docs				01.15 - 03.03.15
- RA 2-Compile				04.03.15 - 18.03.15
- RA 3-Inquiries				19.03.15 - 01.06.15
newapp / CP / ...	DE	Deutschl...	CF	
- Cl-R				
- Co-R				
- P-R				
- Te-R				
newapp / DCP...	DE	Deutschl...	DC	
renew / CP / DE	DE	Deutschl...	CF	14 31.12.14
varcat / 00 / DE	DE	Deutschl...	00	21.12.14
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Functional Overview

- › Manage Master Data for your product portfolio
- › Powerful project management tools to plan and track regulated activities, tasks and resources
- › Structured data driven system that supports IDMP exchange to authorities
- › Connection to MPDmanager enabling effortless transmission to regulatory authorities
- › Supports EU and USA regulatory procedures and lifecycle maintenance
- › Email alerts – So you don't miss important reminders
- › FDA CFR 21, Part 11 compliant
- › Structured data to generate labelling and forms (extension module required)

Further Support

Beyond our standard package components, EXTEDO's consultants are able to provide additional business and technical services tailored around the requirements of your business. These include:

- › Regulatory consulting and training
- › Advanced / bespoke product training for end-users and administrators
- › Business specific platform configurations
- › Development and integration with other 3rd party solutions
- › Data import and migration
- › Validation support services

About Werum IT Solutions

Werum IT Solutions is the world's leading supplier of manufacturing execution systems (MES) and manufacturing IT solutions for the pharmaceutical and biopharmaceutical industries. Its PAS-X software product is run by the majority of the world's top 30 pharmaceutical and biotech companies and also by many mid-sized manufacturers. Werum's manufacturing IT solutions help pharma manufacturers to increase efficiency, improve productivity, and meet regulatory requirements. Founded in 1969, Werum is headquartered in Lüneburg, Germany, and has many locations in Europe, America, and Asia. Werum is part of Medipak Systems, the Pharma Systems business area of the international technology group Körber. Körber unites around 11,500 professionals in industry-leading companies worldwide, achieving annual earnings of 2.3 billion Euros.

www.werum.com.

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

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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™.