EXTEDO
eRegulatory Affairs

# Regulatory Intelligence Services

## Optimize your regulatory data management and processes with RImanager

Like products themselves, regulations are subject to continual maintenance and updates. When this happens, regulatory departments are directly impacted and are responsible for implementing the change within their business as well as communicating them to other key stakeholders.

### Benefits

- Ensure compliance through a full understanding of current, future and planned regulations
- Simplify follow-up activities through efficient communications between health authority and internal teams
- Optimize business processes and workflows through personalized implementation of RImanager
- Deliver instant management reports through pre-defined templates
- Fulfill legal requirements through a complete understanding of IDMP and IDMP data collection specifications

EXTEDO understands the complexities associated with the lifecycle of a regulated product. The management of Marketing Authorizations relies on an equal balance of data accuracy, streamlined change control procedures and effective communication between multiple stakeholders. The use of defined processes is essential.

With regulatory standards such as xEVMPD and the future IDMP, it is also necessary to ensure that you have the necessary data captured and managed for each product. With data coming from many different sources the challenge is collecting, structuring and migrating it correctly. So how do you manage that?

## Tailored services for RImanager

EXTEDO's Business Processes and Regulatory Consulting services are tailored specifically to the needs of regulatory and related stakeholders. Through a series of workshops, our team of experienced consultants will establish your business needs, understand your processes, and help you to define the most appropriate implementation approach for your individual RImanager solution.

Based on many years of experience within the Life Science industry, our time-tested approach is designed to help you properly plan your regulatory activities; simplifying and structuring your processes and communications to suitably align them with your RImanager configuration and overall IT environment. EXTEDO's team will help you to identify gaps in your business and regulatory processes and develop the appropriate strategies to eliminate them.

At EXTEDO we are dedicated to helping you meet and exceed your business objectives. We regularly assist organizations with:

〉 Development of business processes to plan and handle regulatory activities

〉 Manage health authority and internal communications in a structured way

〉 Setup of a regulatory management reports

〉 Structure business processes and implement associated workflows using RImanager

〉 Ensure your business meets regulatory requirements such as xEVMPD / IDMP

Our team provides the following services:

〉 Business process consulting to support RImanager

〉 Gap analysis of data, e.g. for IDMP (IDMP readiness)

〉 Definition of data migration strategies

〉 Strategies for systems integration, e.g. connection with ERP, document management, publishing, pharmacovigilance, MES, and change control systems

〉 IDMP training

Whether you need help to install your RImanager solution, or advice surrounding future regulations such as IDMP, EXTEDO is here to support you throughout your journey.

# 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™.

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