EXTEDO suite

EXTEDO eRegulatory Affairs

Product Information

EXTEDOsuite™

Planning & Tracking (P & T)	Registration Management	Submission Management & Publishing	Submission Validation	Submission Viewing & Reviewing	Pharmacovigilance Management
Activity & Content › RImanager	**Product Dictionary** › MPDmanager	**Application & Publishing** › eCTDmanager › DOCmanager › RLPmanager › miniDMS › PlantOS	**Industry** › EURSvalidator	**Health Authorities** › EURS › EURSnext **Industry** › eSUBmanager	**Drug Safety Database** › SafetyEasy › PcVmanager **ICSR Triage** › iTap
Supports: *IDMP*	*Supports:* *XEVMPD, IDMP*	*Supports:* *eCTD, ASMF & DMF, NeeS, vNeeS, eCopy, CADDY-xml, …*	*Supports:* *US, EU, CH, CIS, AU, ZA, GCC, CA, JP, JO …*	*Supports:* *eCTD, ASMF & DMF, NeeS, vNeeS, eCopy, CADDY-xml, …*	*Supports:* *E2B (R2), E2B (R3)*

Global Master Data

Services	ECM & DMS Connectors	Integration via Standard APIs	Gateways
› Business Process and Regulatory Consulting › Technical Consulting › Education and Training › Installation and Validation › Extended Support › Solutions Hosting › Submission Publishing	› Agatha › Alfresco › Aurea › BIOVIA › OpenText / Documentum › MasterControl › Sharepoint › Optimal Systems › Veeva Vault › …	› EDC › ERP System › LIMS › Master Data Management › Product Dictionary (external) › Product Labeling › …	› CESP › Common Repository › EMA & NCAs eSubmission › E2B (IDMP, XEVMPD, ICSR, PSUR, SUSAR, …) › National Portals › …

EXTEDO RIMS Solution (Cloud & in-house)

EXTEDOsuite

› EXTEDO understands the complexities of the regulated pharmaceutical product journey. From drug design, to market launch and pharmacovigilance surveillance, the EXTEDOsuite is involved right from the start. Our EXTEDOsuite modules can be implemented separately or as a part of a unified Regulatory Information Management Solution. They act as building blocks that enable companies to manage the business critical processes that are essential to maintaining medicinal products.

5 Reasons to choose the EXTEDOsuite for Regulatory Information Management

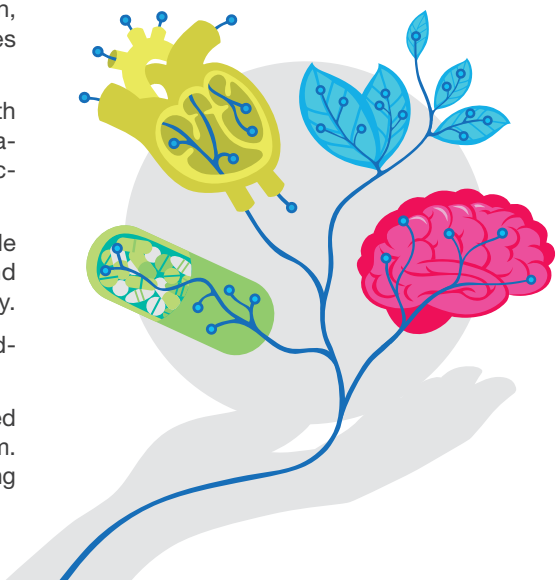
› Through Effortless Compliance™, the EXTEDOsuite ensures a healthy relationship between industry and the authorities. It provides critical validation, review and approval capabilities to the EMA and many other authorities worldwide.

› EXTEDO products combine innovation with compliance and quality with usability. Our products can be rapidly deployed and installed, with validation & training taking minimal time. An intuitive user interface further reduces time to implementation.

› The only Regulatory Information Management System (RIMS) to include Planning & Tracking, Product Registration, Submission Publishing and Lifecycle Management, Pharmacovigilance Management and Drug Safety.

› Comprehensive support for current and future industry standards including IDMP, eCTD 4.0 / RPS

› Designed to work both as a standalone solution or as part of an integrated platform with vendors such as Microsoft, BIOVIA and OpenText / Documentum. The EXTEDOsuite streamlines the pharmaceutical product lifecycle, shortening time to market and greatly reducing the total cost of development.



Planning & Tracking

RI manager

RImanager is a centralized Regulatory Information Management System (RIMS) that enables you to efficiently plan and track the regulatory activities, processes, submissions and commitments related to your entire portfolio of products.

Registration Management

MPD manager

MPDmanager is EXTEDO's comprehensive XEVMPD and IDMP database system delivering a single source of truth for all IDMP data. It provides a central product data dictionary that enables you to manage and maintain XEVMPD and IDMP data efficiently and in compliance with current and future regulatory requirements.

Pharmacovigilance Management

SafetyEasy PV

SafetyEasyPV is a drug safety management solution based on the E2B and MedDRA industry data standards. It enables you to classify, create, review, submit, and maintain pharmacovigilance data and adverse event reports.

Submission Management & Publishing

eCTD manager

eCTDmanager enables you to readily build, view, validate and publish compliant submissions based on CTD, eCTD, NeeS, eCopy, IMPD, CTA, VNeeS, DMF, ASMF and other submission structures.

DOC manager

DOCmanager is an extension to eCTDmanager that enables users to re-create dossier templates for different submission requirements with a "parent/child" concept. It significantly reduces the time require to update variations.

RLP manager

RLPmanager is EXTEDO's advanced report level publishing solution. It is designed to optimise pre-publishing activities and support clinical study departments in managing and publishing clinical and non-clinical study reports that later become part of eCTD or NeeS submissions.

PlantOS

EXTEDO PlantOS is an off-the-shelf solution for regulatory affairs within Crop Sciences. It manages the assembly and compilation of electronic dossiers. It supports the e-PRISM (USA), e-Index (CAN), CADDY.xml (EU) standards.

Submission Validation

EURS validator

EURSvalidator is used by over 35 authorities worldwide, including EMA, to ensure eCTD and NEES compliance. It enables you to easily validate medicinal and veterinary electronic submissions. EURSvalidator is available in several versions providing functionality and validation sets tailored to your region.

Submission Viewing & Reviewing

EURS

EURS (EXTEDO Universal Review System) serves as a complete eCTD validation and reviewing solution used by over 35 authorities worldwide, including EMA. It evaluates whether any eCTD- or NeeS-based submission conforms to the mandated standards.

EURS next

EURSnext is designed to simplify the view and review of eCTD and NeeS-based submissions within authorities. It features state-of-the-art web-based technology and is easy to deploy.

eSUB manager

eSUBmanager provides a modern, end-to-end solution that improves the collaborative review process surrounding submission content and metadata in readiness for transmission to the publishing system.

19/05

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 850 maintained customers across 60 countries to deliver Effortless Compliance™.