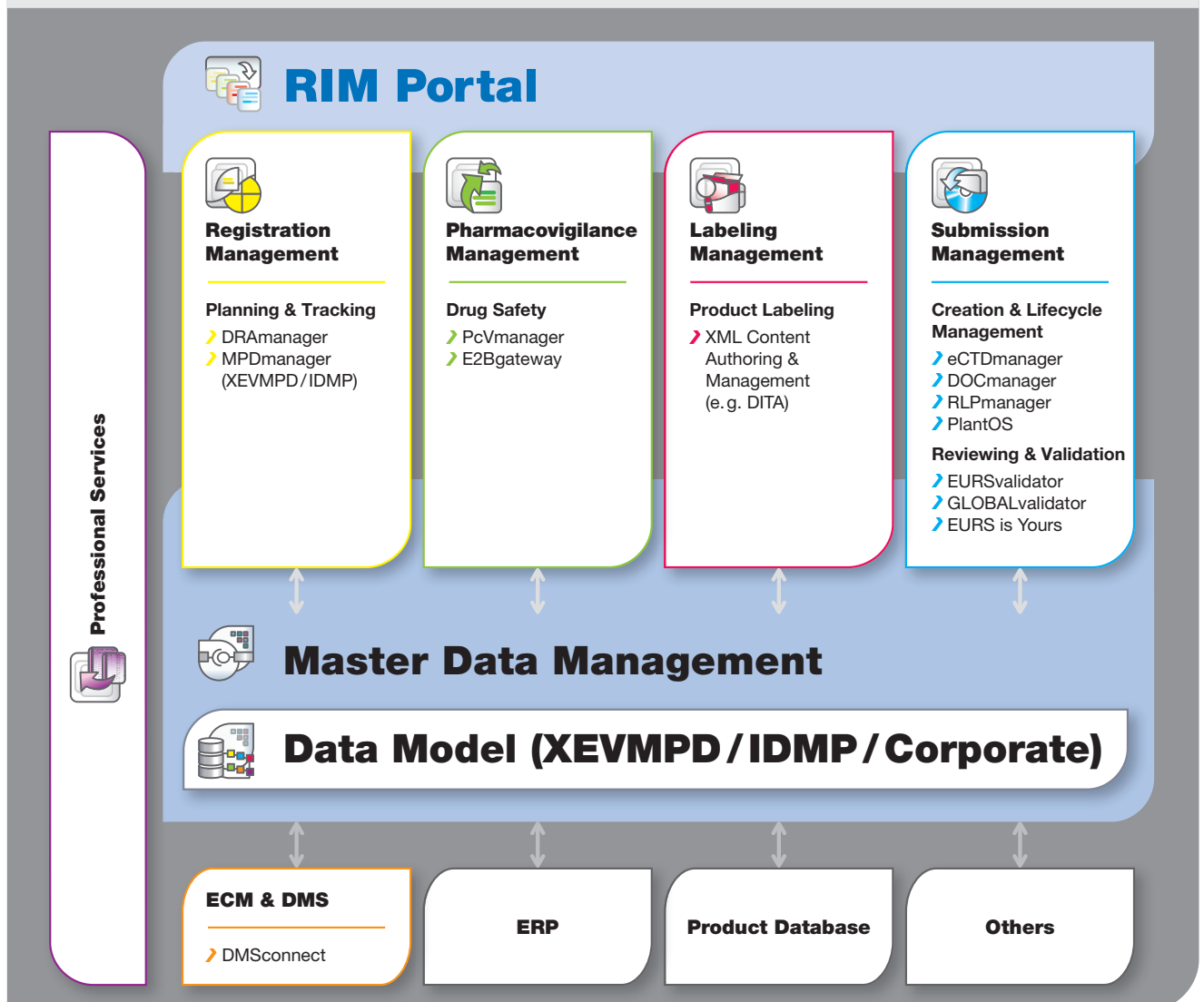


5 Reasons to choose the EXTEDOsuite for Regulatory Information Management

- Provides a complete range of products and services, designed to work both as standalone solutions, as well as integrated pieces of the suite, streamlining the entire product lifecycle within eRegulatory Affairs and reducing the time to go to market.
- Supports the critical relationship between industry and authorities by ensuring a compliant and efficient product registration and maintenance process.
- Solutions can be rapidly deployed. Installation, validation & training take minimal time. The user interface is intuitive, further reducing time to implementation.
- Integration with leading technology platforms from vendors such as Microsoft, EMC, CSC, NextDocs, and QUMAS greatly reduces your total cost of ownership.
- EXTEDO achieves compliance with the rapidly changing regulatory landscape by maintaining a leadership role in defining and promoting standards through participation in various organizations such as HL7 and IRISS.

EXTEDOsuite – Modular Concept



Products within the EXTEDOsuite

Registration Planning & Tracking



DRAManager

DRAManager is a planning and tracking solution that enables you to manage regulatory tasks associated with medicinal product and medical device development. DRAManager accurately and efficiently keeps registered products compliant from a submission, labeling, and drug safety perspective.



MPDmanager

MPDmanager is a standardized database that allows the guided entry and automated imports of all regulatory data requested by XEVMPD and IDMP. For the management of additional product attributes, it enables you to comply with corporate standards.

Pharmacovigilance & Drug Safety



PcVmanager

PcVmanager is a drug safety management solution that enables you to classify, create, review, submit, and maintain pharmacovigilance data and adverse event reports in accordance with E2B and Med-DRA standards.

Submission Creation & Lifecycle Management



eCTDmanager

eCTDmanager enables you to easily build, view, validate and publish compliant submissions based on CTD, eCTD, NeeS, IMPD, CTA, eNTA, VNeS and other submission structures.



DOCmanager

DOCmanager is an add-on for eCTDmanager that allows the creation and maintenance of many child dossiers based on one parent dossier and reduces update times for variations.



PlantOS

EXTEDO PlantOS 3 is an off-the-shelf solution that manages the assembly and compilation of electronic dossiers. The following digital standards for regulatory affairs in Crop Science are supported and can be exported from one single data collection (based on the OECD CADDY table of contents):

- e-PRISM (USA)
- e-Index (CAN)
- CADDY.xml (EU)

Submission Reviewing & Validation



EURS is Yours

EURS is Yours serves as a complete eCTD validation and reviewing software solution. It reports whether a submitted eCTD- or NeeS-based application conforms to the official format.



EURSvalidator

EURSvalidator supports you in validating medicinal and veterinary eSubmissions. The validator is used by the majority of European National Authorities including EMA to ensure eCTD and NEES compliance.



GLOBALvalidator

GLOBALvalidator is an add-on for EURSvalidator that provides enhanced functionality and additional validation sets.

About us

EXTEDO is the key software and service solutions provider in the field of Regulatory Information Management. The complete EXTEDOsuite is unique in all that it covers within eRegulatory Affairs:

- Product Registration Planning & Tracking
- Submission Management (eCTD, CTD; NeeS, CADDY, ePRISM, eIndex, eNTA, vNeeS)
- Pharmacovigilance Management (SUSAR, ICSR, PSUR, E2B)
- Labeling Management and
- Document Management

We provide configurable off-the-shelf products, as well as customized and integrated solutions. EXTEDO also provides EURS is Yours, the validation, review and approval software solution for the EMA and more than 25 Regulatory Authorities worldwide.

Today we serve more than 700 customers in 57 countries ranging from small companies with less than 25 employees to large multinational organizations. EXTEDO operates in the following areas of life sciences: pharmaceutical, biotech and biopharma, generics, homeopathics, medical devices, healthcare, and public sector.

EXTEDO is recognized as one of the worldwide leaders in each of our areas of operation.

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