

Product Information

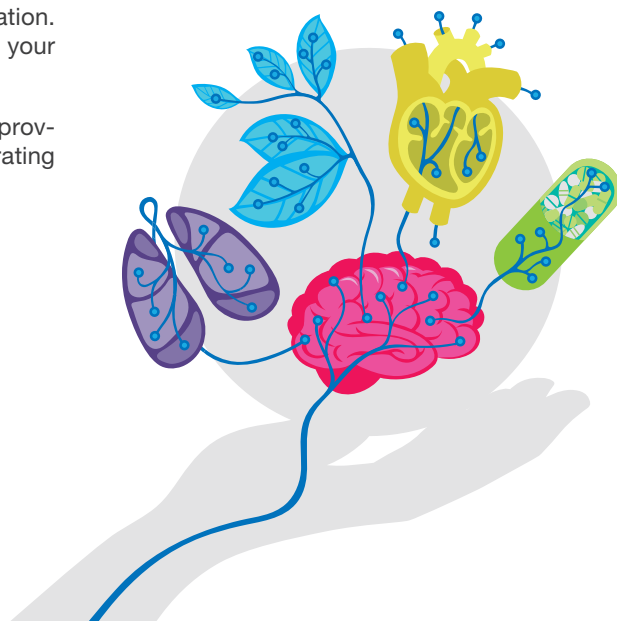
EXTEDOpulse™

Developing pharmaceutical products can be a multi-faceted process, involving input and efforts from across an organization. The complexities of operating within a highly regulated industry only further compound the challenges that a life science organization faces with every release. Having our finger on the pulse of the life sciences anatomy allows us to provide you with great synergy, connection, and innovation for effortless compliance.

EXTEDOpulse has been designed with these aspects in mind to help you connecting the dots throughout the entire lifecycle of pharmaceutical products. With five major hubs covering Planning & Tracking, Document Management, Registration Management, Submission Management and Safety Management, it provides an integrated, clearer and better way to work. Use the applications individually with your existing IT infrastructure or gain additional value by using them together based on your requirements and demands. With EXTEDOpulse, the flexibility for better solutions is in your hands.

5 Reasons to choose EXTEDOpulse for Regulatory Information Management

- EXTEDOpulse makes your life easier by connecting your systems in a way that makes sense for maximum productivity, efficiency and, above all, simplicity. The EXTEDOpulse solutions work with one another, sharing data and information with next level integration.
- EXTEDOpulse gives organizations the freedom to select the applications they need or gain a complete solution for a comprehensive approach. No matter which they decide, organizations are able to fully integrate EXTEDOpulse solutions with their existing IT infrastructure.
- EXTEDOpulse is a complete Regulatory Information Management System (RIMS), including Planning & Tracking, Document Management, Product Registration, Submission Publishing & Lifecycle Management, and Safety Management.
- EXTEDOpulse is flexible and scalable in both security and innovation. By incorporating automation across hubs, EXTEDOpulse optimizes your organization's efficiency.
- EXTEDOpulse includes an even bigger customer focus and customer proven solutions thanks to the EXTEDO influencer program incorporating requirements from global EXTEDO customers.



The Planning and Tracking Hub



The Wrike for Life Sciences app is your key to managing your projects and pushing them towards completion. Oversee the efforts and activities of your team and direct them towards success with this SaaS solution specifically designed for life science projects.

Document Management Hub



The eDOCSmanager app is a secure document management system for Life Sciences organizations. It consists of a number of different business modules including Regulatory, Clinical (eTMF) and Quality to take projects from implementation to quality assurance.



Consisting of a library of over 1500 pre-written MS Word templates, eCTDtemplates is your key to faster, more consistent document delivery. By ensuring reliable authoring standards, eCTDtemplates enable authors to focus on content and automate the style. Using eCTDtemplates in combination with the eCTDmanager app allows automated compilation and effortless compliance.

Registration Management Hub



The MPDmanager app is EXTEDO's registration management system supporting worldwide activity tracking

based on structured product data. It provides a (Product) Master Data Management based on upcoming IDMP as well as on already available XEVMPD that enables you to manage and maintain various data standards efficiently and comply with current and future regulatory requirements.

Submission Management Hub



The eCTDmanager app enables you to readily build, view, validate, and publish compliant submissions based on CTD, eCTD, NeeS, eCopy, IMPD, CTA, VNeS, DMF, ASMF, and other submission structures. Moreover, eCTDmanager allows to plan submissions and the content. With the integrated EURSvalidator app – the de facto standard for eCTD validation – eCTDmanager offers a highly reduced risk of submitting non-compliant submissions.



The EURSvalidator app is used by over 35 authorities worldwide, including the European Medicines Agency to ensure eCTD and NeeS compliance. It enables you to validate medicinal and veterinary electronic submissions easily.



The EURS (EXTEDO Universal Review System) app serves as a complete eCTD validation and reviewing solution used by over 35 authorities worldwide, including EMA. Used with or without automated submission processing it allows evaluations whether any eCTD or NeeS submissions conform to the mandated standards.



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



The eSUBmanager app is the modern, end-to-end industry solution of EURSnext that improves the collaborative review process. Using the eSUBmanager app in combination with the eCTDmanager app planned submission content and respective meta-data can be easily tracked and in-progress submission can be reviewed in parallel to the compilation process.



The PlantOS app is an off-the-shelf submission management and publishing 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.

Safety Management Hub



The SafetyEasy app is a Multivigilance Management Solution supporting the E2B R2 and R3 data standards for pharmacovigilance. It enables you to classify, create, re-view, submit, and maintain vigilance case data for different kinds of products. SafetyEasy is used by industry and agencies.

For further information contact your local EXTEDO representative:



EXTEDO Germany
+49 89 189454-0
info@extedo.com
www.extedo.com

EXTEDO US
+1 (855) 328 3500
info@extedo.com
www.extedo.com

EXTEDO China
request@china.extedo.cn
www.extedo.cn

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 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

