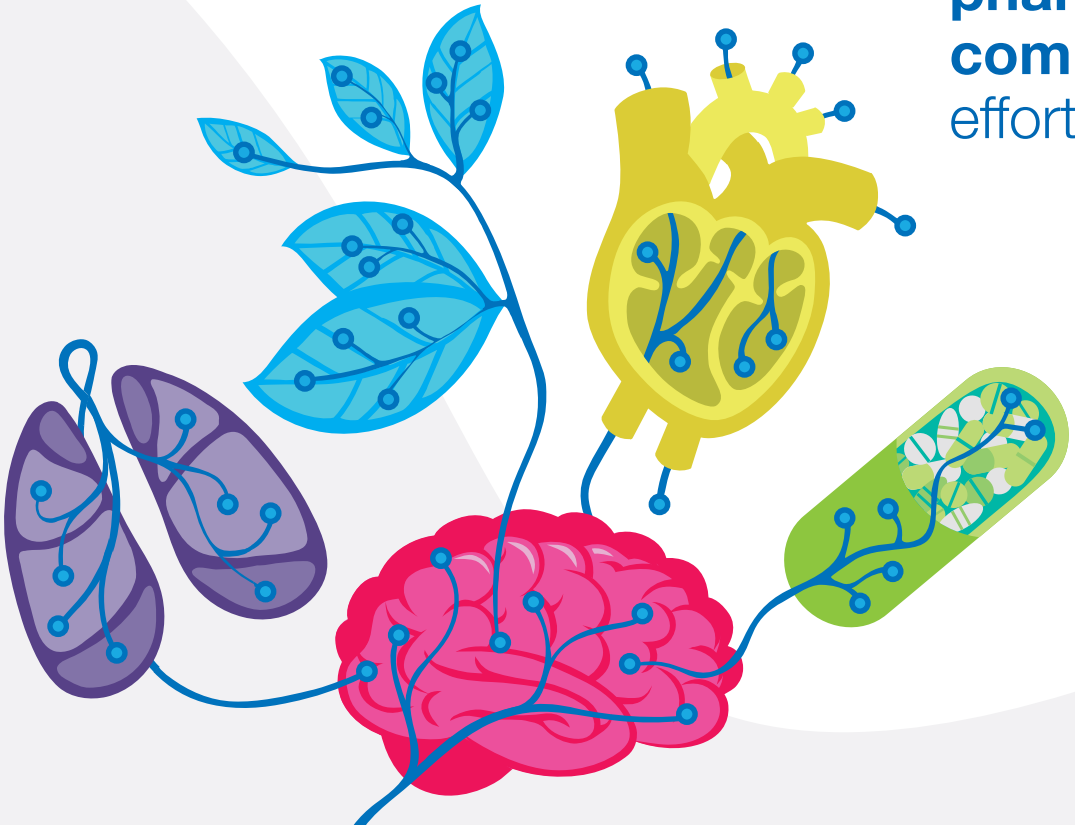
EXTEDO makes **pharmaceutical compliance** an effortless process



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EXTEDO PULSE

EXTEDO is your trusted bridge between industry and agency. EXTEDO has developed and further improved its services and solutions offering in the past years towards an end-to-end Regulatory Information Management System (RIMS) called EXTEDOpulse.

EXTEDOpulse covers master data management, document management, registration management, submission management, and safety management. It provides an integrated, clearer, and better way for life science organizations to achieve their objectives and get their projects off the ground.

Today, we want to introduce you to this new approach and show you how EXTEDO can help you to optimize your eRegulatory business processes. Use the applications individually or use them together based on your requirements and gain additional value.

A single platform

Get to market faster

Eliminate information silos

Connect your team

Adapt applications to your needs

Improve your efficiency

Guarantee compliance

Easy to deploy

Master Data Management Hub

The brain of the EXTEDOpulse platform is the Master Data Management (MDM). Acting as the base layer, the MDM is seamlessly connected to externally controlled vocabulary repositories such as SPOR, while serving as a vital resource for all EXTEDOpulse business Hubs.

- The **Master Data Management (MDM)** serves as the central repository for maintaining reusable data at a single point of truth
- Based on a strict single-source principle, the MDM offers not only CV Management but also an essential Core Product Data Management component
- With this approach the MDM is an innovative all-in-one product solution that simplifies the process of assembling country-specific (registered) products. This allows you to reuse existing core data seamlessly and if necessary, customize it to specific regional requirements
- This strategy empowers you to keep track of all versions and their reusability throughout the system
- Access content and data across various Hubs within the EXTEDOpulse platform to promote seamless collaboration, discovery, and traceability across your organization

Document Management Hub

EXTEDO's eDOCSmanager Powered by CARA addresses all needs of life science companies and can be adjusted to your individual business processes. The Document Management Hub facilitates the influx of documents critical to regulations so that you can manage, organize and (re-)use them effectively as well as properly archive them.

- The **Regulatory Module** ensures you achieve consistent, effective regulatory submission results. In combination with the submission applications, you benefit from adding documents quickly and easily with drag-and-drop functionality and maintaining quality with version control
- The **Quality Module** includes all standard document and SOP creation, review, approval, sign-off, and publishing features for your team to make your quality control processes more efficient
- Additional enhancements of the DMS Hub like the **Clinical Module** or the **Labeling Module**, will include a template-based approach for fully configurable document creation. For the Clinical Module, the eTMF structures and a Clinical Trial Master File System (CTMS) are part of the standard out-of-the-box solution. Within the labeling management, you will be able to manage and reuse information across different documents like product information and Company Core Data Sheet (CCDS)

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Registration Management Hub

EXTEDO's Registration Hub Powered by CARA enables you to keep track of thousands of medicinal product registrations worldwide by acting as a single, easily managed source of truth for all your medicinal product data.

- The **Registration Hub** simplifies the management of IDMP, XEVMPD, and other medicinal product information
- The application is designed to work with the platform-inbuilt Product Master Data Management (MDM), delivering a single source of truth for the company's product data, for an enhanced more detailed resource and task planning/tracking
- Its powerful medicinal product database provides a repository for all registrations and the electronic submission of data directly to the authorities while supporting integrated business rules to validate data before submission for all standards based on the latest specifications
- Through its connection to the DMS Hub, users can store, access, and manage regulatory documents and reports for easy processing
- Use its seamless integration with the Submission Management Hub, to link dossiers to planned activities based on available information. With EXTEDOpulse, the possibilities are limitless

Submission Management Hub

EXTEDO's Submission Management Hub makes publishing, validating, viewing, and updating of regulatory submissions quick and easy. The Hub covers all global standards like eCTD, NeeS, or CADDY-XML. The Submission Management Hub within EXTEDOpulse is designed to maintain a comprehensive overview of your submission statuses across many products within multiple different geographic markets.

- **eCTDmanager** enables you to readily build, view, validate, and publish compliant submissions
- **eSUBmanager** improves the collaborative viewing and reviewing process surrounding submission content and metadata in readiness for transmission to the publishing system
- **EURSvalidator** enables you to validate medicinal and veterinary electronic submissions easily
- **EURSnext** is a complete eCTD validation and the next-generation reviewing tool, allowing assessors to access and collaboratively work on dossiers from wherever

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Safety Management Hub

EXTEDO's Safety Management Hub is designed to streamline your pharmacovigilance, medical device vigilance, cosmetovigilance and nutrivigilance processes quickly and effectively. Understanding the risks and benefits associated with pharmaceutical products brings with it the need for more efficient and effective pharmacovigilance solutions.

- EXTEDO's **Safety Management Hub** is ideal for medicinal product developers, marketing authorization holders, and clinical investigators
- This single, easy-to-use solution has everything a life science professional needs to ensure pharmaceutical products' safety
- It provides options for pharmaceutical companies to monitor critically important data to protect public health and to adhere to stringent regulations
- All adverse event reports, reviews, regulatory procedures, and other vital processes can be classified, created, reviewed, submitted, and edited from EXTEDO's drug safety management solution based on the E2B data standards and MedDRA for coding adverse events

At EXTEDO, we understand the challenges associated with ensuring industry compliance and maintaining the level of quality and consistency of your submissions. In this ever-changing, globally regulated environment, thankfully help is at hand with EXTEDO's years of experience working with companies similar to your own.

Our services cover the entire regulatory landscape to ensure industry conformity, improve the quality and consistency of your submissions, as well as to reduce the time & resources associated with system installation, implementation, and compliance.

Together with our partners, EXTEDO's services team is well-equipped with knowledge and experience to support you in the area of the following business services:

- **Business Process & Regulatory Consulting**
- **Technical Consulting**
- **Validation Services**
- **Training and Education**
- **Regulatory Publishing Services**

Professional Services

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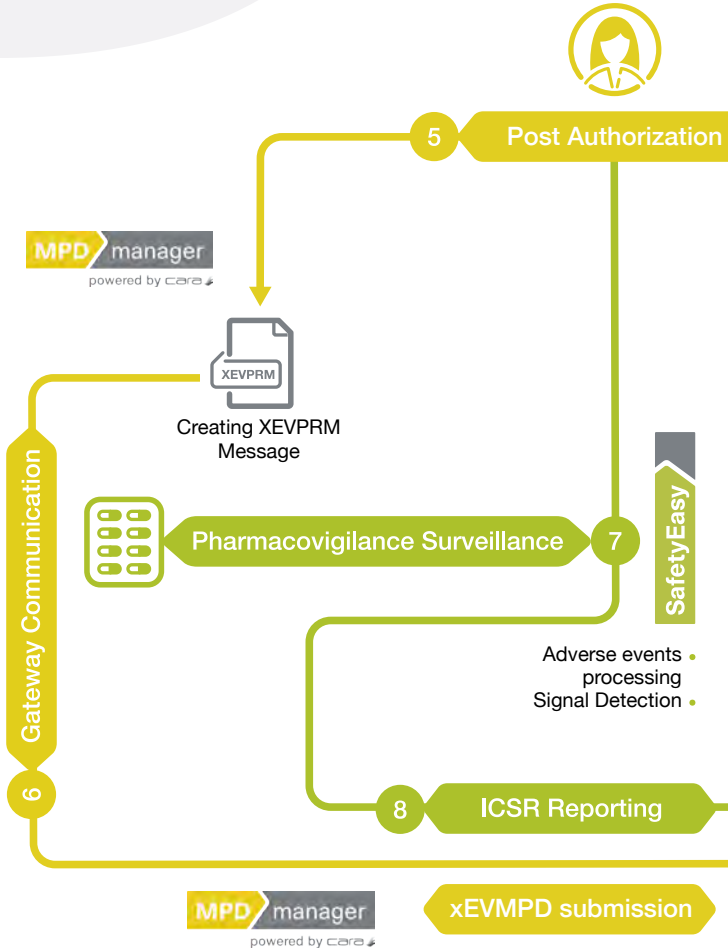
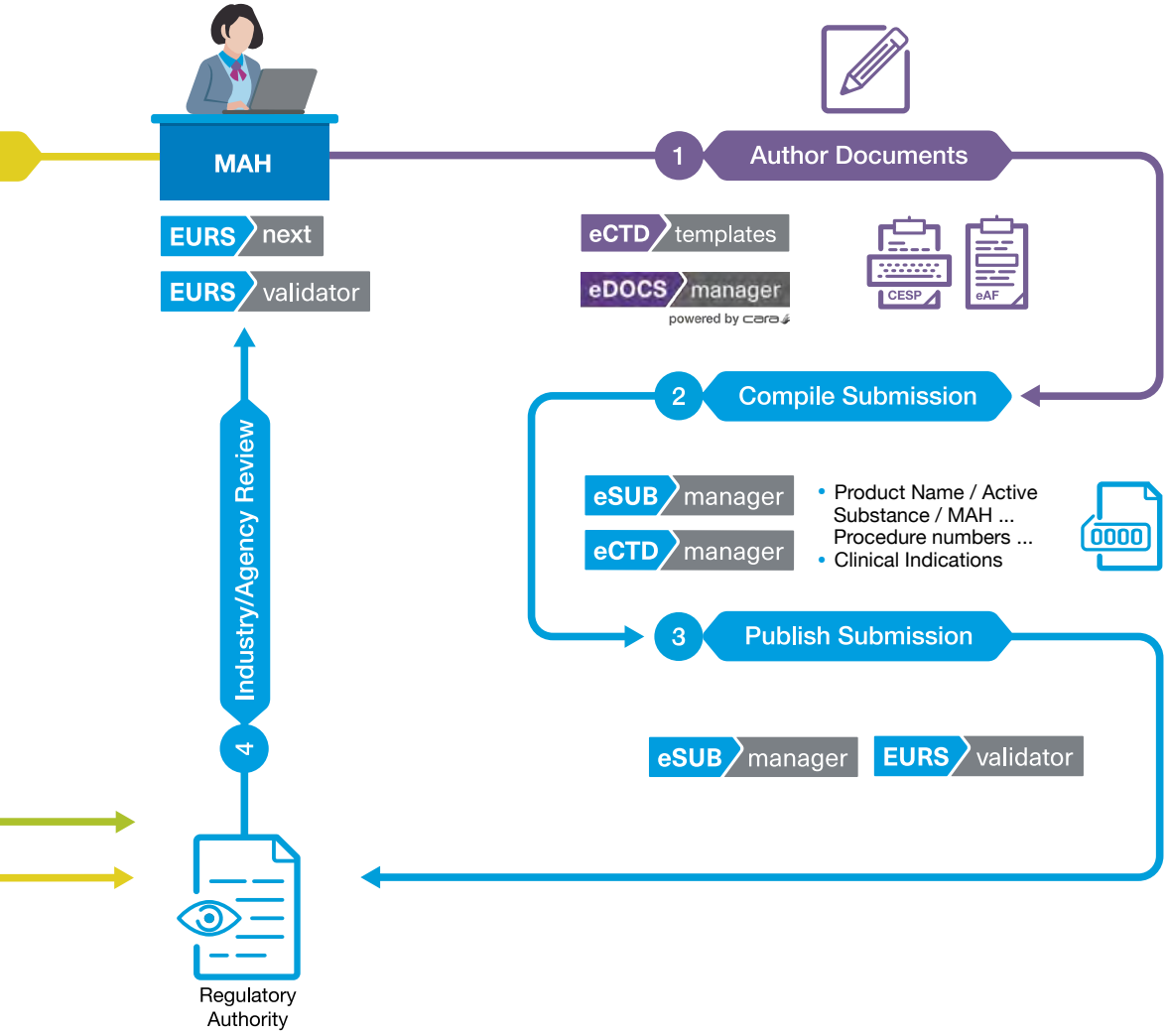
Business Optimization with EXTEDOpulse

EXTEDO understands the complexities of the regulated pharmaceutical product journey. From drug development to market launch and pharmacovigilance surveillance, EXTEDOpulse is the right solution from the start, for every step:

- All hubs of EXTEDOpulse combine into a complete Regulatory Information Management System (RIMS) and address every step of pharmaceutical product development
- Use the applications individually or gain additional value by using them together based on your requirements
- EXTEDOpulse is created from direct feedback and the needs of life science organizations
- EXTEDOpulse introduces next-level automation to optimize your team's productivity across every aspect of development

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.





End-to-End RIM Platform

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Your reliable partner

for the pharmaceutical industry…

- Manage regulatory information effortlessly
- Navigate intricate regulations for multiple products across regions
- Minimize compliance risks and accelerate time-to-market

…and for regulatory agencies

- Streamline submission validation and review
- Foster collaboration and seamless interactions with industry stakeholders
- Improve efficiency by relying on a tool that is trusted by the agency world

Choose EXTEDO - Your Trusted Bridge between Industry and Agency

Unlock the synergy, connection, and innovation for Effortless Compliance for all of your projects with EXTEDOpulse.

If you would like to find out more, contact EXTEDO today. Stay updated with the latest news by following us on LinkedIn, and visit our website at **www.extedo.com**

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