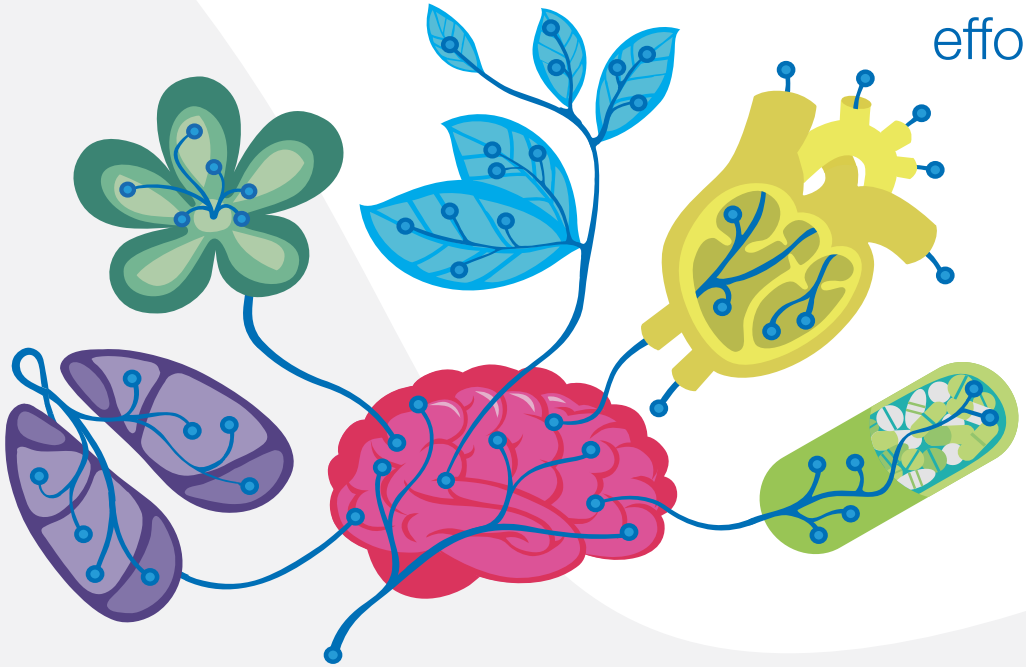
EXTEDO makes **pharmaceutical compliance** an effortless process



EXTEDO

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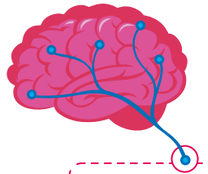
EXTEDO is your trusted bridge between industry and regulatory agencies worldwide. As a leading solutions and services provider in the field of managing regulated information we focus on streamlining our clients' business processes and help them navigate complex regulatory landscapes with ease.

With EXTEDOpulse, we offer a comprehensive, end-to-end solution suite for Regulatory, Quality and Safety Information Management. EXTEDOpulse covers master data management, document management, quality 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.

EXTEDO is the trusted partner of more than 35 regulatory authorities, including the European Medicines Agency (EMA), and around 1,000 maintained customers across 65 countries. With over 25 years of experience, we empower organizations to efficiently manage regulated information throughout the entire drug development lifecycle—ensuring Effortless Compliance™ every step of the way. Operating from our locations in the United States, Germany, and Croatia, and supported by a strong global partner network, we are committed to providing world-class solutions and services to our clients worldwide.

Development, approval and lifecycle process of a new drug

Before reaching patients, medicines undergo a complex development and approval process that requires precise management of data, compliance with diverse regulations, and coordination across varying product specifications—challenges that EXTEDOpulse effortlessly streamlines as a central, reliable source of truth.



Throughout the entire drug development process, master data is managed and provided to all participants globally by **EXTEDOpulse.**

The core product is created and master data is stored in **EXTEDOpulse.** It flows throughout the process.

Discovery and Development

- Pre-clinical development

GLP

Teams use the **Quality Management Hub** to learn and review Standard Operational Procedures (SOPs).

Clinical Trials

- Clinical trial authorization
- Clinical Trial

E2B(R2)/(R3) GCP IDMP CTR No 536/2014 xEVMPD

Regulatory activities are planned within the **Registration Management Hub.**

The Document Management Hub is used to store and manage documents relating to the trials.

Product data is submitted to regulators through the **Registration Management Hub.** Once published, the current status of the regulatory activity can also be monitored.

Adverse events are captured and processed within the **Safety Management Hub.**

All product related master data is managed through **EXTEDOpulse.**

Regulatory Submission and Review

- New drug application
- Application review

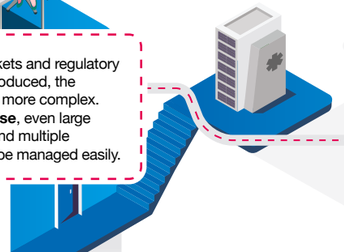
eCTD GVP ePI xEVMPD IDMP

Documentation is created and managed within the **Document Management Hub.**

Reusing the data and documents from EXTEDOpulse, submissions are compiled, published, validated and sent to regulatory authorities through the **Submission Management Hub.**

Submissions are validated and reviewed by the agency using the **Submission Management Hub.**

As additional markets and regulatory authorities are introduced, the process becomes more complex. With **EXTEDOpulse**, even large volumes of data and multiple departments can be managed easily.



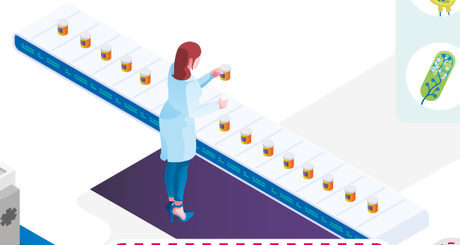
Manufacture

- Drug labeling
- Quality control
- Quality assurance

GMP ePI GLP

Labeling data and variations are managed within the **Document Management Hub.**

Documentation for quality management processes and SOPs is stored in the **Quality Management Hub.**



Master data is available consistently within **EXTEDOpulse** throughout the manufacturing process.

Post Market Monitoring

- Commercialization
- Safety monitoring

eCTD IDMP GVP ePI xEVMPD E2B(R2)/(R3)

The **Registration Management Hub** shares product registration and authorization data internally and with agencies.

Side effects events are captured and processed within the **Safety Management Hub.**

Product master data continues to be centrally managed and available through **EXTEDOpulse.**

Master Data Management

EXTEDOpulse consists of different Business Hubs that cover all the processes needed to achieve Effortless Compliance. Together, they form a comprehensive end-to-end solution that increases efficiency while mitigating risks. The brain of the product suite is the Master Data Management (MDM).

The MDM provides the foundation and a vital resource in which every EXTEDOPulse Hub finds a source of truth for the information it needs. By guaranteeing constant access to up-to-date content and data, the MDM forms a reliable base layer that promotes smooth collaboration. Users additionally benefit from a seamless connection to externally controlled vocabulary repositories such as SPOR. Keeping constant track of all versions of the processed data and documents throughout the system saves precious while mitigating errors. Once created, the core data can be reused at any time for other projects and customized accordingly if needed, for example, adapted to regional requirements.

Document Management Hub

EXTEDO's Document Management Hub 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 DMS** 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.

With **eCTDtemplates** we provide a simple way to create consistent and compliant dossiers in eCTD (electronic Common Technical Document) and other formats. Through a library of over 1300 pre-written Microsoft Word templates, eCTDtemplates deliver a common starting point for all your technical documentation. By ensuring consistent authoring standards, it enables authors to focus on content and automate the style. This reduces common errors and creates a harmonized structure for non-regulatory personnel.

EXTEDO

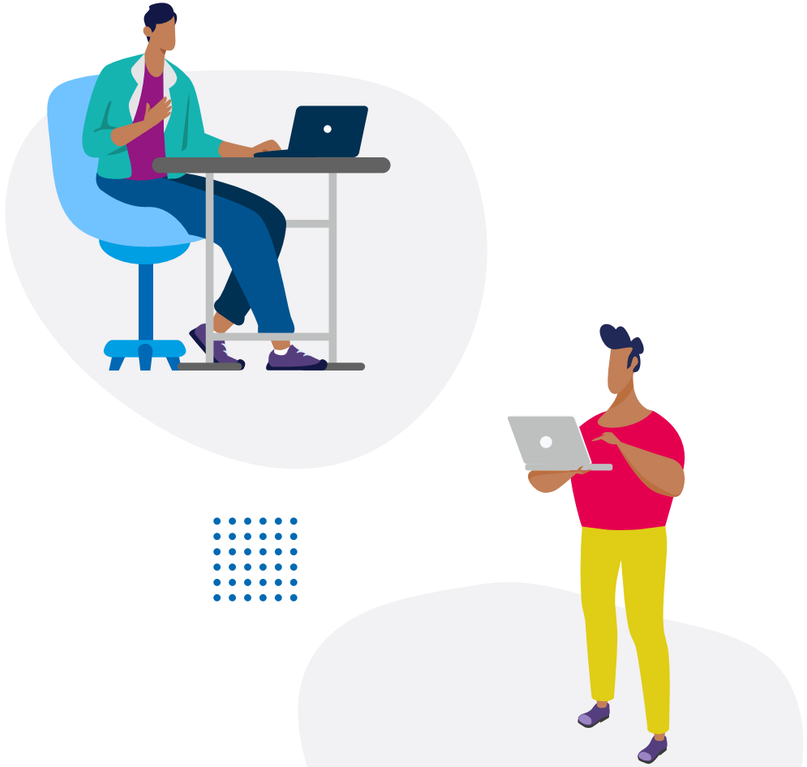
Registration Management Hub

EXTEDO's Registration Management 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 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 Document Management 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 and NeeS. 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.

- **Submission Publishing:** Readily build, view, validate, and publish compliant subimssions.
- **Submission Viewing and Reviewing:** Improve the collaborative viewing and reviewing processes surrounding submission content and metadata.
- **Submission Validation:** Easily validate medicinal and veterinary electronic submissions.
- **EURSnext** is a complete eCTD validation and the next-generation reviewing tool, allowing assessors to access and collaboratively work on dossiers from wherever.

EXTEDO

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. The integrated Artificial Intelligence (AI) functionalities enable you to compliantly process more cases, faster.

All adverse event reports, reviews, regulatory procedures, and other vital processes can be classified, created, reviewed, submitted, and edited from EXTEDO's Safety Management Hub based on the E2B data standards and MedDRA for coding adverse events.

Quality Management Hub

As part of EXTEDOpulse, the Quality Management Hub streamlines compliance, risk management, and quality processes through automation, data integration, and real-time oversight, ensuring efficiency and regulatory success for life sciences organizations.

The **Quality Management Hub** provides life sciences organizations with a seamless solution to maintain compliance, manage risks, and optimize quality processes. By automating workflows, managing quality events, and integrating data across systems, the Quality Management Hub ensures efficiency and transparency in business operations.

The solution offers advanced tools for CAPA management, audits, supplier oversight, and change control, helping organizations stay ahead of evolving regulations. With features like real-time reporting, controlled document handling, and seamless system integration, EXTEDO's Quality Management Hub empowers companies to enhance product integrity, improve operational efficiency, and ensure regulatory success.

EXTEDO

Professional Services

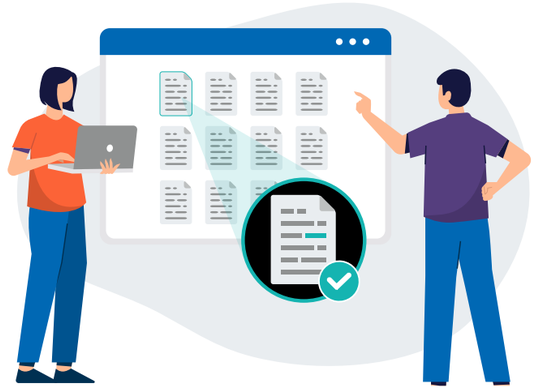
At EXTEDO, we understand the challenges associated with ensuring industry compliance and maintaining the level of quality and consistency of your submissions. In this ever-changing, globally regulated environment, thankfully help is at hand with EXTEDO's years of experience working with companies similar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

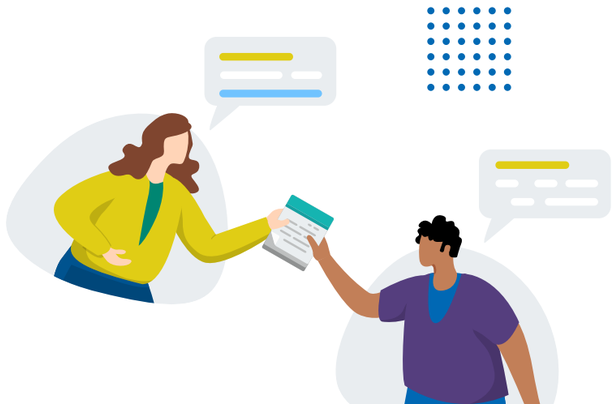
Our services cover the entire regulatory landscape to ensure industry conformity, improve the quality and consistency of your submissions, as well as to reduce the time & resources associated with system installation, implementation, and compliance.

Our **Regulatory Submission Publishing Services** provide everything you need for successful submissions - from document preparation to submission publishing. Whether you're just starting out or seeking to streamline your process, we've got you covered with our publishing teams in the US and Europe, providing regulatory excellence 14 hours a day.

Together with our partners, EXTEDO's services team is well-equipped with knowledge and experience to provide additional support by:

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





EXTEDOpulse for Agencies

EXTEDOpulse for agencies is the comprehensive solution suite designed to support health agencies in streamlining regulatory processes. It ensures efficiency and compliance at every step of the agency assessment by providing solutions for submission reviewing and validation, submission lifecycle tracking, master data management, document management, and more.

A dedicated agency portal facilitates bi-directional collaboration, enabling seamless communication between regulatory authorities and stakeholders. With integrated decision-making and reporting tools, EXTEDOpulse for agencies improves transparency, accelerates approvals, and allows full control over regulatory workflows.

As a trusted partner in regulatory excellence, EXTEDO provides solutions and services tailored to the evolving needs of health agencies. Our deep expertise is reflected in long-term collaborations with leading regulatory bodies. We proudly support the majority of European agencies, including the EMA, and are the trusted choice of over 35 regulatory agencies worldwide. With EXTEDOpulse, agencies can embrace a smarter, more connected approach to regulatory management.

EXTEDOpulse for Agencies

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.

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

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**

cormeo – Smart Information Lifecycles for a Healthier Tomorrow

Since April 2025, EXTEDO is proud to be part of cormeo, a Bertelsmann company (www.bertelsmann.com). Uniting key players in their fields, cormeo builds the trusted bridge between the life science industry, authorities, healthcare professionals, and patients worldwide.

cormeo is shaping the future of life science information management, advancing health outcomes and fostering the highest standards of patient care by creating a seamless end-to-end process – from product development to the patient.

Three specialized brands, one unified vision:

- **Docuvera –** Information Creation through AI + Structured Content Authoring
- **EXTEDO –** Information Management through Streamlined Regulatory, Safety and Quality Workflows
- **Rote Liste Service GmbH –** Information Distribution for Informed Decision Making

For more information visit **www.cormeo.com**

Benefit from an end-to-end solution

Get to market faster

Eliminate information silos

Connect your team

Adapt applications to your needs

Improve your efficiency

Guarantee compliance

Deploy easily

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