PRODUCT INFORMATION

EXTEDOpulse Submission Publishing

The most comprehensive solution for managing and publishing regulatory submissions across global health authorities.

Managing global submissions with ease

Preparing compliant submissions for global health authorities can be complex and resource intensive. Pharmaceutical companies, biotech organizations, and CROs face the challenge of compiling thousands of documents while ensuring accuracy, efficiency, and regulatory compliance.

EXTEDOpulse Submission Publishing addresses these challenges by supporting dossier assembly, publishing, built-in validation, and lifecycle management in one solution. Available as a standalone solution or integrated with other Hubs of the EXTEDOpulse solution offering, Submission Publishing can be deployed on premises or in the cloud, providing flexibility to match your organization's operating model, IT strategy and collaboration needs. Parameter-based configuration enables alignment with your internal processes and supports rapid deployment without lengthy implementation projects, so teams can standardize publishing quickly and scale efficiently across products and regions.

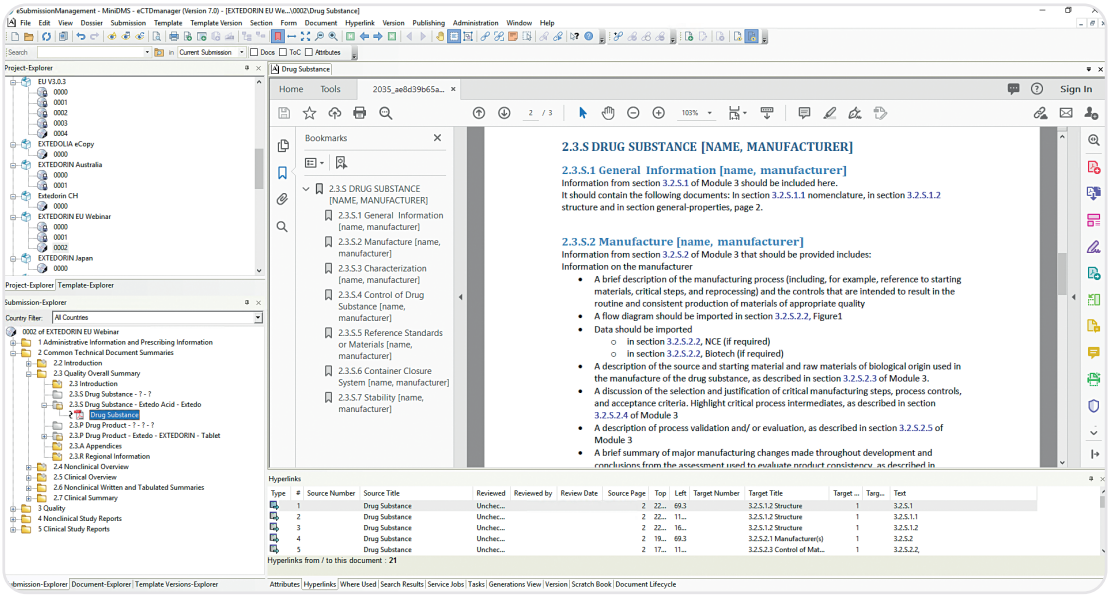
Benefits

- Streamlined and compliant global submissions
- Validation technology trusted by over 35 regulatory authorities worldwide
- Faster approval times and reduced time-to-market
- Cost-efficient submission publishing processes
- Reduced administrative burden & logistics overhead
- Improved document quality and consistency
- Increased value of compliant, submission-ready studies
- Sophisticated management of hyperlinks
- Conforms to ICH and regional file-naming and PDF requirements
- FDA 21 CFR Part 11 and EU GMP Annex 11 compliant
- Rapid deployment, system validation and minimum training

From Planning to Publishing

As part of the EXTEDOpulse ecosystem, Submission Publishing connects seamlessly with your regulatory planning and document processes. Master data is maintained centrally in EXTEDOpulse MDM, regulatory activities are planned in the Registration Management Hub, and submission content is prepared in the Document Management Hub. This integration helps teams initiate and manage publishing activities based on planned regulatory work, reuse content, documents and metadata, and keep stakeholders aligned throughout transparent handovers and clear traceability across hubs.

From the planned regulatory activities, teams can seamlessly initiate dossier and sequence creation in Submission Publishing. The solution auto-compiles the content plan and associated documents, placing them directly into the correct positions within the submission structure while carrying over all relevant metadata. Throughout publishing, progress stays transparent and aligned across hubs: stakeholders can access the linked submission directly from MPDmanager, while in-progress viewing and review can start early in parallel via Submission Viewing—supporting faster cycle times, fewer handovers, and more reliable submission execution.



Intuitive user interface: handling of pharmaceutical submissions without the knowledge of XML-technology

Core Capabilities

EXTEDOpulse Submission Publishing provides a streamlined environment for regulatory dossier assembly and publishing—without requiring XML expertise. It supports major global submission formats, including eCTD v3 and v4, NeeS, ACTD, IMDP, PIP, VNeeS, DMF, ASMF, Clinical Trial Applications, and other regional formats, ensuring broad compatibility for global submissions.

Built-in technical validation helps ensure submissions meet current authority requirements, while comprehensive lifecycle management tracks updates and changes—supporting accuracy, transparency, and compliance throughout the product lifecycle.

Reliability is further enhanced by the module's powerful hyperlinking and bookmarking engine which continuously checks references. If a target document is missing, the hyperlink is removed, and once the correct target is added, the link is automatically resolved—ensuring submission integrity and technical compliance at all times. For FDA electronic submissions, sophisticated Structured Product Labelling (SPL) capabilities streamline data entry and product information maintenance, keeping submissions complete, accurate, and fully compliant.

Through EXTEDOcloud, Submission Publishing minimizes validation time and costs through shared cloud-based validation. The system is Installation Qualified (IQ), Operationally Qualified (OQ), and Performance Qualified (PQ), fully validated under FDA 21 CFR Part 11 and EU GMP Annex 11 Volume 4, with all necessary validation scripts and documentation provided to ensure regulatory compliance for every submission.

eCTD v3 to eCTD v4 Transition Support

As health authorities move forward, EXTEDOpulse Submission Publishing also supports a smooth transition from eCTD v3 to eCTD v4. The solution helps your team navigate new metadata structures, lifecycle changes, and forward-compatibility requirements, ensuring submission remains compliant during this critical transition. Automated tools and controlled vocabulary help your team reduce the risk of errors and maintain efficiency during this transition, so global submissions stay compliant and on track without disruption.

AI Capabilities Across the Submission Management Hub

The EXTEDOpulse Submission Management Hub includes AI-supported review to help teams work more efficiently with complex dossiers. Within Submission Viewing, the GenAI Reviewing Assistant enables users to ask

questions in natural language and receive clear answers based on the submission documents—together with direct links to the supporting source documents for fast verification. Submission Publishing complements this by ensuring submission content is structured and consistent—so review and verification in Submission Viewing remains transparent and reliable across the hub.

Integrated Regulatory Publishing Solution

EXTEDOpulse provides an end-to-end solution covering the entire submission lifecycle — from dossier assembly, compilation, and document management, to validation, lifecycle management, and compliant publishing for worldwide health authorities.

Additional Modules of Submission Publishing

RLPmanager

Designed to simplify the creation and publishing of clinical and non-clinical study reports, RLPmanager optimizes pre-publishing work and supports clinical study departments. With intuitive drag-and-drop functionality, reusable templates, and automated publishing capabilities, it ensures your study reports are eCTD-ready, complete with hyperlinks, bookmarks, and metadata.

DOCmanager

Developed to simplify the creation and maintenance of multi-region product dossiers, DOCmanager optimizes the management of global submissions through its parent-child dossier concept. Changes made to the parent dossier are automatically inherited by child dossiers, eliminating revalidation and reducing duplicate effort. With support for country-specific templates, regional adjustments, and lifecycle updates, DOCmanager ensures consistency, compliance, and efficiency across all your submissions worldwide.

Functional Overview

eCTDmanager is equipped with various functions for critical submission support, including:

- Support of parallel submissions (MAA, NDA, BLA, NDS and IND)
- Time-sensitive tracking functions for dossiers, which prevent the delays in filling
- Sophisticated management of hyperlinks and bookmarks, including automated text to hyperlink functionality supporting most technical writing standards
- SPL data entry and management
- Incremental publishing and export capabilities
- Support for Critical Submissions
- Supported regional eCTD standards include EU, US FDA, AU, CA, CH, GCC/KSA, JO, JP, TH, ZA, EAEU, as well as other submission standards like IMPD, CTA, NeeS
- Integrated validator for US FDA, EU (EMA approved) and many more
- DMS integrations available for BIOVIA, Generis, MasterCotrol, Microsoft SharePoint, OpenText/Documentum, Veeva, and additional document management systems
- Multilingual User Interface
- Support of grouped submissions for US FDA
- Automated compilation support

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

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