

Regulatory Submission Publishing Services

Better manage the cost and effort involved in publishing your regulatory submissions

Whether you're submitting to a new regions, preparing your first electronic submission, or simply need extra support due to limited internal resources, having a reliable partner by your side can make all the difference. Our team supports life science companies of all sizes with expert publishing services, helping you navigate unfamiliar requirements and ensure timely, compliant submissions without the need to build in-house expertise.

In today's dynamic and globally regulated environment, our team understands the pressure of delivering high-quality submissions under tight deadlines and limited budgets.

To further support your regulatory department, EXTEDO and its trusted partners offer a comprehensive range of publishing and training services tailored to your specific needs.

Outsourced publishing services

Our end-to-end publishing services enable you to effortlessly meet current and future electronic submission requirements. From planning and developing dossier standards, to the creation and delivery of eCTD-compliant submissions to agencies, EXTEDO's team guarantees that your applications are handled swiftly and produced without errors.

Document publishing tasks account for a significant portion of the time spent on eCTD compilation—why not let EXTEDO assist you? Our team will prepare submission-ready documents based on agency requirements, converting your files and managing tasks such as adding bookmarks and ensuring internal and external hyperlinks are properly established.

By using EXTEDO's publishing services, you are assured 100% regulatory-compliant PDF documents, every time.

Throughout the project, our personal approach ensures you work with a consistent team, getting to know the individuals handling your application. Using our own submission

Benefits

- Ensure timely and compliant eCTD submissions instead of the existing one
- Eliminate effort publishing compliant PDF documentation
- Expert-managed data handling in a secure, validated and trusted environment.
- Simplify your submission filing process
- Receive training and support from regulatory experts
- Reduce the time required to convert existing submissions

publishing solution, we will create, validate, and publish your application directly to your chosen authorities. If needed, we can also provide secure access for your team to view and review submissions throughout the process.

Submissions training

If you're looking to develop your own in-house team of submission experts, EXTEDO offers personalized regulatory training courses tailored to the specific needs of your business.

We will introduce you to the details of electronic submission standards, help you develop lifecycle management processes, and guide you through the steps necessary to publish your first submission via the electronic gateway.

With teams based in Pennsylvania (USA) and Munich (Germany), we offer both in-house and remote training options.

Based in Pennsylvania (USA) and Munich (Germany) our teams are able to offer both in-house and remote training possibilities.



In addition the EXTEDO team also provides the following regulatory pushing services:

- Submission publishing, including document (eCTD) and report-level publishing
- Support with paper/NeeS to eCTD conversion
- Dossier planning and strategy development
- Submission filing (media or electronic submission gateway)
- Business process consulting
- SOP/work practices documentation
- Training to support core document and submission publishing techniques

Whether you need someone to publish and submit your submissions, or you want to learn more about managing the processes yourselves, EXTEDO is here to support you throughout your regulatory journey.

I am so sorry –
I don't get this in
1 page :-(

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

