

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

With agencies required to produce ever more submissions in electronic formats, the cost and effort involved in converting paper-based documentation into eCTD, and other electronic formats, and publishing them to the authorities can be prohibitive for many smaller life sciences organizations.

Benefits

- › Eliminate the overhead of converting your own submissions to eCTD format
- › Reduce the time taken to convert existing submissions
- › Eliminate effort publishing compliant PDF documentation
- › Data managed in a secure and trusted environment
- › Work performed within a compliant and validated environment
- › Simplify your submission filing process
- › Training and support from regulatory experts
- › Access to EXTEDO's eCTDmanager solution for viewing submissions

In this ever changing, globally regulated environment, thankfully help is at hand. EXTEDO has years of experience working with companies similar to your own. We understand the challenges involved in producing high quality submissions with limited time, budget and resources.

To support your regulatory department, EXTEDO and its partners provide a broad range of regulatory submission publishing and training services.

Outsourced publishing services

Our end-to-end publishing services enable you to effortlessly meet current and future electronic submission requirements. From planning and development of dossier standards, to creation and delivery of eCTD compliant submissions to the agencies, EXTEDO's team will ensure that your applications are handled swiftly and produced faultlessly.

With document publishing tasks, accounting for a significant portion of the time spent on eCTD compilation why not let EXTEDO help. Our team will prepare submission ready documents based on agency requirements (convert your files and take responsibility for activities such as adding bookmarks and checking that external and internal hyperlinks are properly established).

Using EXTEDO's publishing services, you are guaranteed 100% regulatory compliant PDF documents, every time.

Throughout the project, our personal approach ensures that you always work with a consistent team, getting to know the individuals working on your appli-



cation. Using of our own eCTDmanager solution, we will create, validate and publish your application directly to your chosen authorities. If desired, secure access can also be provided to your team to enable them to view and review existing submissions.

Submissions training

Should you be looking to develop your own in-house team of submission experts, EXTEDO also provides personalized regulatory training courses. Built around the specific needs of your business we will introduce you to the details of the electronic submissions standards, help you develop lifecycle management processes, and take you through the steps necessary to publish your first submission through the electronic gateway.

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.



For further information contact your local EXTEDO representative:



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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™.

Microsoft Partner
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