Improve and optimize your electronic submission management and processes

In order to maximize profitability, modern pharmaceutical organizations need to be able to register products as quickly as possible whilst ensuring compliance with a variety of global regulations. With the high costs associated preparing regulatory submissions it is essential that the compilation and publishing processes are fully optimized.

Benefits
> Ensure compliance with eCTD submission requirements
> Simplify and streamline your eCTD submission data
> Streamlined business processes and improved compliance
> Optimized eCTDmanager configuration and processes

With regulatory standards such as ICH eCTD version 3.2 and the future version 4.0 (RPS), it is also necessary to ensure that you have the correct data captured, the documents available in an appropriate format, and your business process updated.

So, how do you achieve all this?

Tailored services for eCTDmanager

Tailored specifically to the needs of regulatory and related stakeholders, EXTEDO's business process and regulatory consulting services are designed to support you during and after your eCTDmanager implementation. Through a series of workshops, our team of experienced consultants will establish your business needs, understand your processes, and help you to define the most appropriate implementation approach for your specific eCTDmanager usage.

Based on many years of experience within the Life Science industry, our time-tested approach is designed to help you properly plan your submissions; simplifying and structuring your processes and communications to ensure that they align with your eCTDmanager implementation. EXTEDO's team will help you identify the gaps in your business and regulatory processes and support to develop the appropriate strategies to eliminate them.

At EXTEDO we are dedicated to helping you meet and exceed your business objectives and assist organizations with:

> Developing submission lifecycle processes to ensure effective management of regulatory information
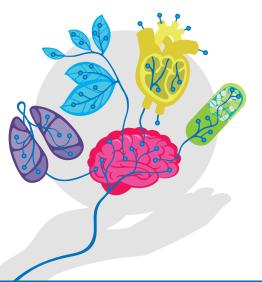> Establishing document lifecycle processes that guarantee eCTD-ready documentation

- › Regulatory best practice workshops to provide you with an understanding of global requirements across the US, Canada, EU, Switzerland, Gulf Countries, South Africa, Australia and Thailand
- › Submission readiness assessments to evaluate your organization's readiness to submit regulatory applications
- › Conversion of submissions from NeeS to eCTD in order to meet the required timeline for the mandatory eCTD format
- › Non-eCTD region submission template creation

Our team provides the following services:

- › Business process consulting to improve your submission publishing processes and optimize the use of eCTDmanager
- › Gap analysis of data, structure and documents to achieve eCTD readiness
- › EXTEDO workshops: How to move from paper/NeeS to eCTD
- › Conversion services: Bring your existing NeeS submissions into eCTD
- › eSubmission quality service: Validate and repair eCTD/NeeS submissions to receive agency approval
- › Standard migration service: Import any NeeS/eCTD submissions into eCTDmanager
- › eCTD training and individual workshops for existing eCTD regions
- › Critical submission support (24/7 regulatory support from our regulatory competence center during your critical submission phases)
- › eCTD 4.0/Regulated Product Submission (RPS) readiness workshop
- › Development and implementation of any non-eCTD region submission template to be used/re-used in eCTDmanager

Whether you need help in building eCTD submissions or advice surrounding future regulations, EXTEDO is here to support you throughout your journey.

24/03

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
Gold Application Development