SERVICES INFORMATION

eCTD Services

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.

With regulatory standards such as ICH eCTD version 3.2 and the future version 4.0, 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.

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 software 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 Submission Management Hub 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 Submission Management Hub 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.

Benefits

- Ensure compliance with eCTD submission requirements
- Simplify and streamline your eCTD submission data
- Streamlined business processes and improved compliance
- Optimized software configuration and processes

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
- Submission readiness assessments
- Conversion of submissions from NeeS to eCTD
- Non-eCTD region submission template creation
- 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
- Validate and repair eCTD/NeeS submissions to receive agency approval
- Migrate 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 readiness workshop

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

For further information contact your local EXTEDO representative:

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