Ensure that your NCA is eSubmission-ready today and for the future

Is your agency ready for the expected increase in volume of submission related data?

Are all your submission administration processes optimized and ready for future changes?

Are all of your legacy eSubmissions stored in your reviewing system?

Is your agency prepared for eCTD 4.0 / RPS?

As the trusted vendor to over 35 regulatory authorities, EXTEDO's services team comes well-equipped with the knowledge and experience required to support your agency. At EXTEDO we understand the detail, including the technical challenges and procedural dependencies that are required to make your agency a successful regulatory business.

Benefits

› Reduce the time and resources associated with the setup, administration, integration and use of your reviewing tool
› Ensure data quality via business & technical validation
› Simplify and streamline your submission data
› Guarantee effective EURS maintenance
› Reduce downtime and increase effectiveness

When engaging our services, our technical and regulatory consultants provide you with an in-depth analysis of your existing processes and technologies. The result is an accurate assessment of the changes your agency needs to make in order to future proof your regulatory department and ensure ongoing success.

Tailored services for EURS: from submission receipt to review

EXTEDO's business process, regulatory and technical consulting services are tailored specifically to the needs of regulatory agencies. 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 EXTEDO Universal Review System (EURS) implementation approach for your specific submission flows – from receipt to review.
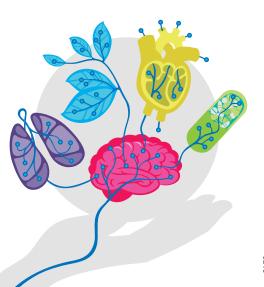
Our time-tested approach is designed to help you plan your regulatory work-flows; simplifying and structuring your processes and communications to align them with your system configuration and IT environment. EXTEDO's team will help you to identify gaps in your business and regulatory processes and develop the appropriate strategies to eliminate them.

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

› Development of business processes to plan and handle regulatory processes

› Manage internal and external communications in a structured way

› Setup of a regulatory management reports

› Structure business processes and implement associated workflows using EURS stand alone or integrated with your tools.

› Ensure your business meets all relevant business requirements (e.g. time lines)

› EURS update service

Our team provides the following services:

› Business process consulting to improve and optimize the use of EURS

› Regulatory consulting to make your NCA successful using existing and new standards

› Gap analysis of data, storage and archiving

› Strategies for systems implementation, integration, e.g. connection with CRM, document management systems, data tracking and other control systems

› eSubmission data migration strategies

› Legacy submission data import to bring any of your existing submissions into your EURS reviewing system

› Validation issue interpretation to provide better qualified rejections to the applicants

› EURS portal integration service

› EURS update services to provide qualified updates to your EURS production system – even on weekends and on business holidays

› Agency-to-industry workshops to help you introduce your new agency standards and regulations to the industry

Whether you need help to install your EURS solution, or advice surrounding future challenges, such as data volume growth, new standards or optimizing process flows, 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