

Company Information

# EXTEDO Corporate Overview

## EXTEDO enables you to bring new drug products to the market faster and safer

EXTEDO started its business in 1996 as a department of IABG with a simple vision: to help life sciences organizations ensure Effortless Compliance™ with industry standards and regulatory requirements. Over the years EXTEDO has become one of the leading names in the field of Regulatory Information Management (RIM). With EXTEDOpulse and expert consultants, we are on a mission to enable agencies, CROs and life sciences organizations around the world to bring new products to market faster and safer.



*EXTEDO is a great example of a company that really understands the requirements of the market*

Director Business Development, Technical Operations and International Business of Genericon

## Innovative eCTD and Regulatory Information Management solutions

Read further if you would like to simplify and reduce the cost associated with your regulatory processes. We would all love to reduce the overheads associated with them.

EXTEDO helps you simplify these expensive tasks. EXTEDOpulse combines innovation with compliance, and quality with usability. From document management, to product registration planning & tracking, to submission management, to pharmacovigilance management & drug safety, we are here to optimize your regulatory business processes.

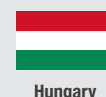
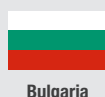
## Trusted and used by the regulatory authorities

Today, EXTEDO enables more than 35 regulatory authorities and over 850 maintained customers across 60 countries to deliver Effortless Compliance™. Our clients range from small CROs to large multi-national pharmaceutical organizations.

As the trusted partner of the regulatory authorities, we implemented the eCTD standard in many countries. Our EURS products provide the validation, review and approval technology within the EMA and a lot of other authorities worldwide.



## Some of the regulatory agencies using or recommending EURS / EURSvalidator:



## Our people develop the standards

Our people make EXTEDO who we are. Whether you are looking for the detail beneath an industry standard, or local implementation advice our consultants are all experts in their chosen fields. With innovation and openness being part of our culture many also play leading roles within local standards committees and the ISO group, as well as national competent authorities (NCAs), helping to define standards worldwide.

EXTEDO experts are members in many associations like SNV (Swiss Association for Standardization), BPI (Federal association of pharmaceutical industry in Germany), MEGRA (Middle European Association for Regulatory Affairs), IRISS (Implementation of Regulatory Submission Standards), HL7 (Health Level 7), TOPRA and delegates for Switzerland at ISO (International Organization for Standardization). With these memberships and participations we were actively involved in the development of major standards like eCTD and IDMP.

## Reliable professional services and partner network

Bringing together the right people is what makes any relationship a success, and at EXTEDO we chose our partners with care. Through our trusted partner network, we provide regulatory affairs knowledge and technological expertise to our global user community. Whether you need support with project management, regulatory business consulting, implementation or system validation EXTEDO, or one of our select local business partners, has the skills you need.

Through Effortless Compliance™ we ensure that you get to spend more of your time doing the things you want to do, rather than the things you have to do.

If your business operates within the life sciences industry, then EXTEDO should be your partner of choice.

### ISO 9001 certified Quality Management System

EXTEDO GmbH has established and applies a quality management system for design, implementation and distribution of document management systems, IT-solutions and associated services for life sciences organizations.



[www.tuev-sued.de/ms-zert](http://www.tuev-sued.de/ms-zert)

### Microsoft Gold Partner

By achieving Gold Certified Partner status EXTEDO has achieved the highest level of the Microsoft partner program, which provides software vendors with the right resources to build and support leading edge solutions that take full advantage of Microsoft platform technologies.

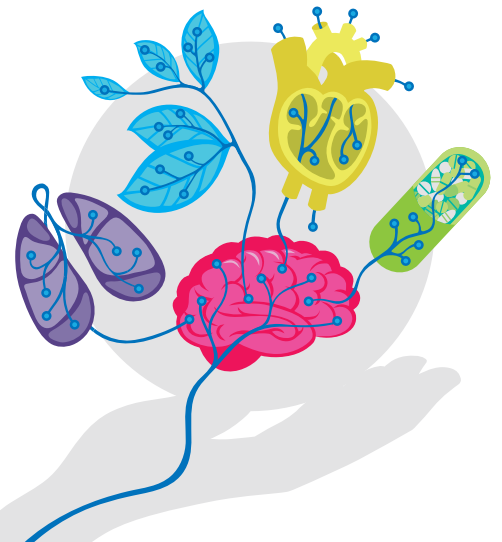
### Microsoft Partner

Gold Application Development



*After the implementation of EXTEDO's DOCmanager and due to the parent-child-concept, expenditure of time for an international dossier rollout has dropped from 6 months to 1-2 months.*

Director, Regulatory Informatics and Submission Management of Merck Serono



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 850 maintained customers across 60 countries to deliver Effortless Compliance™.

