

Company Information

EXTEDO Corporate Overview

Our mission & vision

EXTEDO was founded in 2003 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 our EXTEDOsuite 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.



The EXTEDO team at the eRA conference in Munich



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 RIMs solutions

Read further if you would like to simplify and reduce the cost associated with your regulatory controls processes. Whilst essential, these controls form part of our industry, but we would all love to reduce the overheads associated with them.

As the only vendor that provides solutions covering your entire regulatory landscape, EXTEDO helps you simplify these expensive tasks. The EXTEDO-suite combines innovation with compliance, and quality with usability. From product registration planning & tracking, to submission publishing & lifecycle management, to pharmacovigilance management, we are here to optimize your e-Regulatory business processes.

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 DIN (German Institute for Standardization), 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) and delegates for Switzerland and Germany at ISO (International Organization for Standardization). With these memberships and participations we are actively involved in the development of new standards like eCTD 4.0 (RPS) and IDMP.



Trusted and used by the regulatory authorities

Today, EXTEDO enables more than 35 regulatory authorities and over 700 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, our EURS products provide the validation, review and approval technology within the EMA and many other authorities worldwide.

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

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.

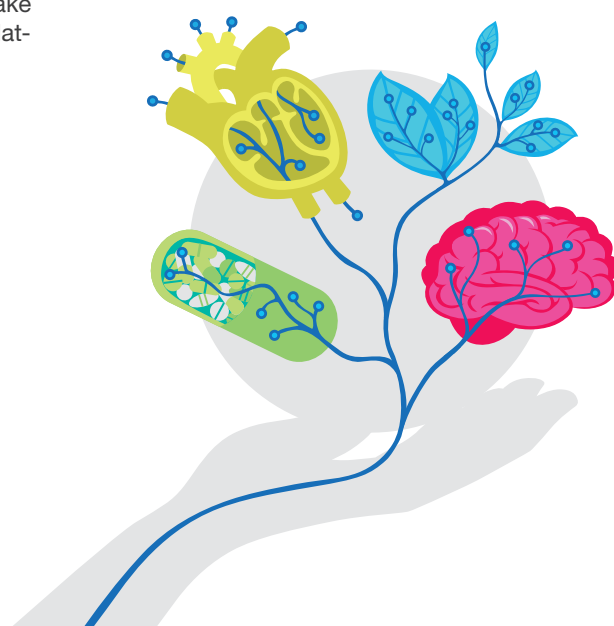
Microsoft Partner

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



18/02

For further information contact your local EXTEDO representative:



EXTEDO Germany

+49 89 189454-0
info@extedo.com
www.extedo.com

EXTEDO US

+1 (855) 328 3500
info@extedo.com
www.extedo.com

EXTEDO China

+86 (0)21 68812608
request@china.extedo.cn
www.extedo.cn

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



Gold Application Development