



## Benefits

- Compliant with all regulatory activities
- Complete overview of drug regulatory activities
- Integrated work-flow engine
- Advanced reporting feature to support information flow
- Simultaneous accessibility
- Reduced costs
- Time efficiency



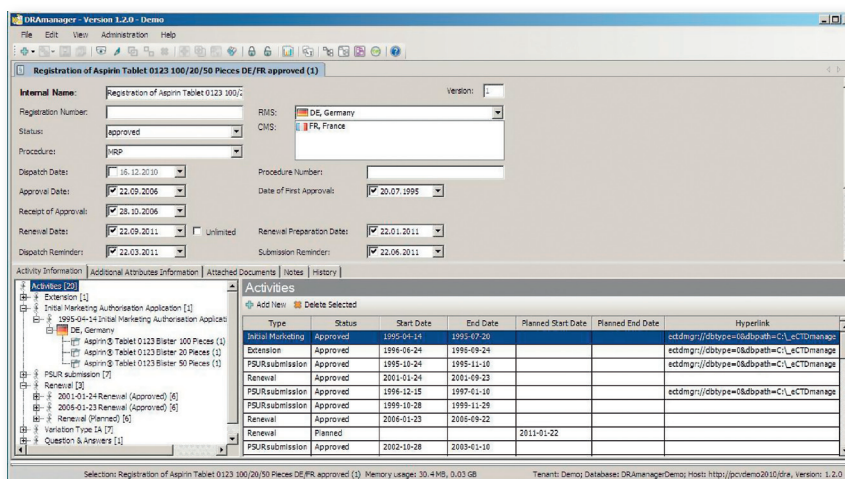
## Product Information DRAmanger™

### Planning and tracking of drug regulatory activities

DRAmanger ensures the fast and smooth functioning of creating and maintaining product and device information and associated activities in accordance with the pharmaceutical, medical and health-related government and regulatory bodies around the world.

DRAmanger is a standardized and open software solution for the management of pharmaceutical product information, me-

dicinal product information, medical device information and associated regulatory tasks. It is designed to provide you with a common overview of whatever aspect of your projects. An integrated workflow engine alerts you about deadlines and open tasks, which you need to process. DRAmanger accurately and efficiently keeps registered products compliant from a submission, labelling, and drug safety perspective.



*Intuitive user interface: managing drug regulatory activities efficiently*



### Total control for you and your team

Once a product/device has been created within DRAmanger, you can easily control the product/device-specific life cycle and all associated regulatory activities at the specific markets, process agency-specific questions, deficiency and approval and efficiently maintain open tasks as well as efficiently manage all processes and deadlines within the scope of the product/device.

Through its reporting features, DRAmanger supports you by sharing all up-to-date relevant information such as regulatory status, deadlines, and the approved production-related packaging or quality requirements with your team. By its design as a client/server architecture multiple users can access simultaneously to edit and process files at different sites and to import files on a central site via a corporate network.

## Functional overview

Important features include the following:

- Lifecycle management of products/ devices with associated registration activities and status information
- Support of all registration procedures including EU (MRP, DCP, NP and CP)
- Automated task processing and integrated workflow management component
- Parallel work is supported, in-house and internationally
- Intuitive user interface with an improved learning curve
- Advanced features for the creation, reuse, tracking, and printing of product/ device information
- Detailed audit trail

DRAManager can map the company's portfolio of products/devices in the repository with their all associated data (product specific information, device specific information, country specific information for both, for example, package information and storage condition for an assigned country).

The system is also supported by MedDRA database for the selection of, for example, the appropriate indications and side effects. This data collection can be reused for any country-specific market presentation by adding relevant information about the actions done in those regions.

All the submitted documents and answers for the questions and reactions from the health authority can be tracked and maintained.

DRAManager can be easily integrated into document management systems such as:

- EMC Documentum™
- NextDocs™
- CSC FirstDoc™, CSC FirstPoint™
- OpenText™
- IBM SCORE™
- Optimal Systems™
- MasterControl™
- QUMAS DocCompliance™
- Microsoft SharePoint™

and others to share data sources or link to certain content objects.

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## About us

EXTEDO is the key software and service solutions provider in the field of Regulatory Information Management. The complete EXTEDOsuite is unique in all that it covers within eRegulatory Affairs:

- Product Registration Planning & Tracking
- Submission Management (eCTD, CTD; NeeS, CADDY, ePRISM, eIndex, eNTA, vNeeS)
- Pharmacovigilance Management (SUSAR, ICSR, PSUR, E2B)
- Labeling Management and
- Document Management

We provide configurable off-the-shelf products, as well as customized and integrated solutions. EXTEDO also provides EURS is Yours, the validation, review and approval software solution for the EMA and more than 25 Regulatory Authorities worldwide.

Today we serve more than 700 customers in 57 countries ranging from small companies with less than 25 employees to large multinational organizations. EXTEDO operates in the following areas of life sciences: pharmaceutical, biotech and biopharma, generics, homeopathics, medical devices, healthcare, and public sector.

EXTEDO is recognized as one of the worldwide leaders in each of our areas of operation.

## Available Modules

### ➤ DMSconnect:



Integration with leading document management systems

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