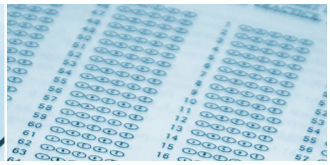
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY



Some references of REGULA™

REGULA™, SOFTWARE FOR SUBMISSION MANAGEMENT

REGULA is a database-driven application for an efficient management and reporting of Medical Device and IVDD regulatory affairs activities. This software package supports regulatory affairs managers in each stage of a submission and provides transparency through structured reports of registrations. With few clicks important information, e.g. market coverage and submission status, can be obtained. Specially developed functions such as "Warnings", "Specific reports" and "Country templates" simplify the administration of regulatories.

Your Advantage

Management, Marketing & Sales
Automatically delivered reports or active queries via browser allow an overview of the worldwide status of your product registrations at all times.

Much implicit knowledge about registration procedures is stored in this application. That reduces the dependency from individuals and ensures that important deadlines (such as renewals of certificates) will not be forgotten.

Responsibility for Regulatory Affairs
As a regulatory affairs manager you will have optimal support in each stage of your submission. All relevant documents are available immediately. The documents are optionally stored on the database or linked to your DMS by a specific interface. The launch of further products in one of your already developed markets will be simplified remarkably.
The clear breakdown of all products and markets will enable you to react fast and competent to requests. Periodical management reports will automatically be generated and distributed.
You will automatically be notified about expiring registrations in advance. REGULA™ automatically generates the contents for your dossiers (e.g. FDA, TGA, etc.) and merges the complete content of a submission in a ZIP-file, e.g. for emailing.
The different levels of authorisation ensure that each user is only able to modify as much as considered appropriate.

Customer Statement
Dr. Christian Münster, Global Regulatory Affairs of Carl ZEISS: <<Thanks to the good preparation of all parties and the structured execution of the workshop through ISS, the REGULA™ project proved to be extremely productive. The collaboration with ISS was pleasant and a friendly working environment was created, which helped the project to go swiftly and smoothly. REGULA™ gives us a true advantage in our daily business.>>

Our Services

You do not buy just a software package only. We assist you in establishing an efficient management of your regulatory affairs. This includes:

- Analysis of your processes and product structures
- Customizing if needed: Requirements engineering – Development of a prototype
- Installation of the software on your operating system
- Application Training for Super Users
- Regular functionality updates
- Technical and regulatory support
- Support in regulatory activities in your targeted markets

Your contact

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