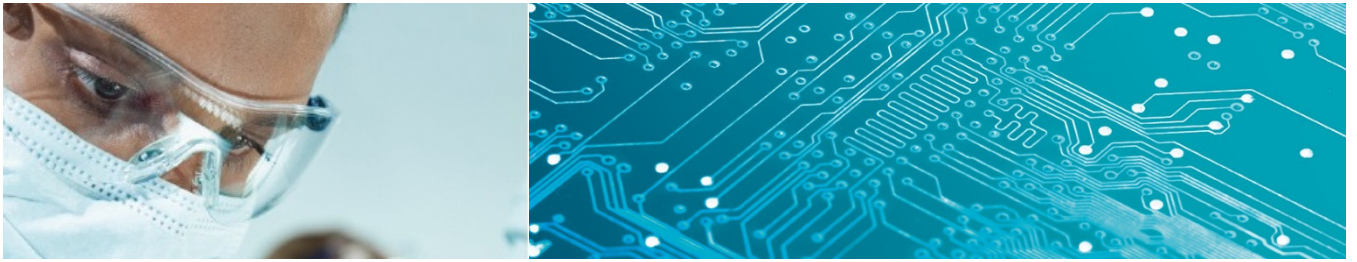




INTEGRATED SCIENTIFIC SERVICES  
A MEDTECH COMPANY



**REGULA™**

**THE REGULATORY AFFAIRS SOFTWARE  
FOR MEDTECH  
AND IVD COMPANIES**










## **REGULA™ - Facts at a glance**

REGULA™ is a database backed application for an efficient management and reporting of worldwide medical device and in vitro diagnostic device regulatory affairs activities. The application is developed, maintained and validated according to ISO 13485 and IEC 62304 standards.

REGULA™ has been developed by RA practitioners for RA practitioners with great dedication to regulatory affairs. The application contains lots of built-in RA expertise and therefore is not just another software.

The goal of REGULA™ is to “reduce your time to market” and increase the efficiency in your daily RA business.

## Features Overview

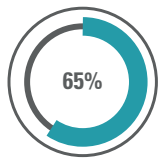
	<b>Submission Management</b>	<ul style="list-style-type: none"> <li>Electronic management of submissions and timelines</li> <li>Centralized management of submission data</li> <li>Guided process for initialization of new submissions</li> </ul>
	<b>Permanent Tracking</b>	<ul style="list-style-type: none"> <li>Approved products (market coverage)</li> <li>Pending registrations (in work)</li> <li>Countries where selling is explicitly blocked</li> </ul>
	<b>Warning Management</b>	<ul style="list-style-type: none"> <li>Expiring registrations</li> <li>Stalled registrations (too long in same status)</li> <li>Document warnings</li> </ul>
	<b>Re-Registration with a few clicks</b>	<ul style="list-style-type: none"> <li>Simple re-registration process</li> <li>Only a few clicks needed</li> <li>Keeping or discarding documents</li> <li>Automatic archiving of old registrations (inactive)</li> </ul>
	<b>Country Templates</b>	<ul style="list-style-type: none"> <li>Recording gained experience</li> <li>Creation of own country templates for future registrations</li> <li>Acquiring templates from ISS AG, Integrated Scientific Services</li> </ul>
	<b>Automatic Reporting</b>	<ul style="list-style-type: none"> <li>Creation of specific management reports</li> <li>Saving of most frequently used reports</li> <li>Automatic and periodic creation and sending of reports to defined people</li> <li>Export of reports to CSV</li> </ul>
	<b>Embedded Task Management</b>	<ul style="list-style-type: none"> <li>Creation of tasks directly in REGULA™</li> <li>Assigning tasks to people</li> <li>Progress control of tasks</li> </ul>
	<b>Simple Submission Compilation</b>	<ul style="list-style-type: none"> <li>Collection of submission documents in a ZIP file</li> <li>Automatic creation of a PDF index, e.g. according to STED</li> <li>Definition of the hierarchy within the ZIP file (flat or chapters)</li> </ul>
	<b>Knowledge Management</b>	<ul style="list-style-type: none"> <li>Placing information and comments on each level</li> <li>Informing colleagues about important issues</li> <li>Summarizing phone calls with brief comments</li> </ul>

## Your advantage using REGULA™



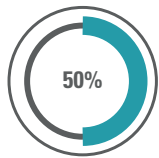
### **Time saving in initial registrations**

- Documents are stored centrally in REGULA™
- Possibility to work with country templates
- Key information about the countries are available



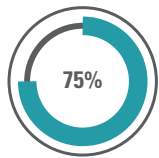
### **Time gaining in re-registration process**

- Keeping products of base registration
- Keeping existing/valid documents of base registration
- Easy replacement of documents/products
- Automatic archiving of the "old" registration



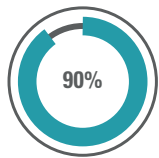
### **Time saving in retrieving documents**

- Many filter possibilities
- Well thought out search feature (e.g. to which countries has a specific document been submitted)
- Clear history through versioning and comments



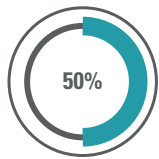
### **Reduction of questions to RA department**

- Creation of specific management reports
- Automatic and periodic creation and sending of specific reports to defined people
- Viewer rights for selected people



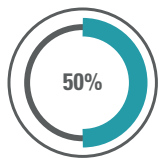
### **Risk reduction of missed deadlines**

- Warning about expiring submissions
- No submissions fall unintentionally into oblivion



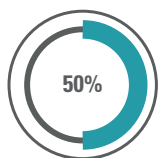
### **Simplification of the labor division**

- RA task management directly in REGULA™
- Notification about the progress via email
- Comments and information can be placed on each level



### **Improvement of project management**

- Overview of responsibilities
- Overview of market priorities
- Creation of project specific reports



### **Time saving in getting submission information**

- What is the current market coverage
- Which submissions are currently in work
- Where is a specific product approved in the world
- Etc.

## Six reasons for REGULA™



### **Reduction of time to market**

Approve your products earlier on the market by using REGULA™. Be faster than your competitors in getting market presence.



### **Reduction of business risks**

No submissions fall unintentionally into oblivion  
Permanent tracking of submitted documents  
People are informed at any time  
Products are only sold to countries where selling is permitted



### **Increase of turnover**

The earlier you receive market access, the faster you can generate revenue



### **Improvement of efficiency**

Your daily business will be more efficient  
REGULA™ supports a structured working method



### **Enhancement of transparency**

Get a better and transparent overview of your regulatory affairs activities. With REGULA™, the traceability is ensured and the information is available.



### **Standardization of your RA Structure**

The introduction of REGULA™ can also be an opportunity to analyze the company-wide RA structures and processes and to standardize them.

## Introduction process

Each REGULA™ introduction is considered as a project and for each introduction we work through the following steps together with you:



As we are owner of the source code, customizing according to your wishes is possible.

The duration of a REGULA™ introduction phase strongly depends on the complexity, the resources and the general situation in your company.

➔ Lead time: 3-9 months

REGULA™ will be installed on your own IT-infrastructure.  
 REGULA™ allows data interaction via interface to third-party systems.

Visualization:



## System requirements

The system requirements are depending on the complexity of your existing RA structure, the number of users and the data volume to be handled in REGULA™.

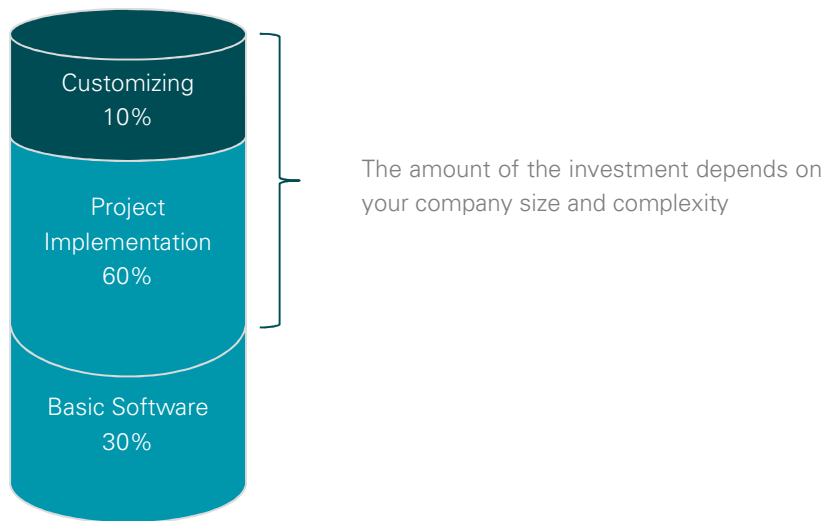
The installation of REGULA is done on a dedicated server (Windows or Linux). Detailed server requirements and the installation process are defined during the introduction project in collaboration with you.

REGULA™ is accessed via web browser. For an unrestricted use of REGULA™, JavaScript needs to be activated in the browser.

## Your investment

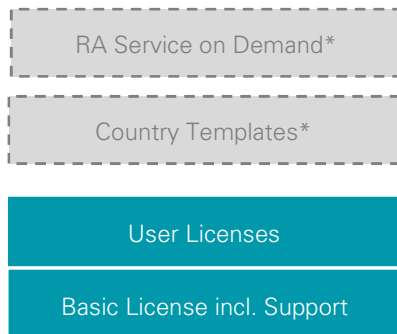
REGULA™ is not just a software, it is a project.  
Based on the experience of former projects, the costs are comprised as follows:

### Initial cost



### Recurring costs

The recurring costs are calculated based on the initial investment as well as on other factors:



\* optional

## Your contact

Are you interested in more information about REGULA™ or do you wish a live presentation of the application?

Please contact:



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