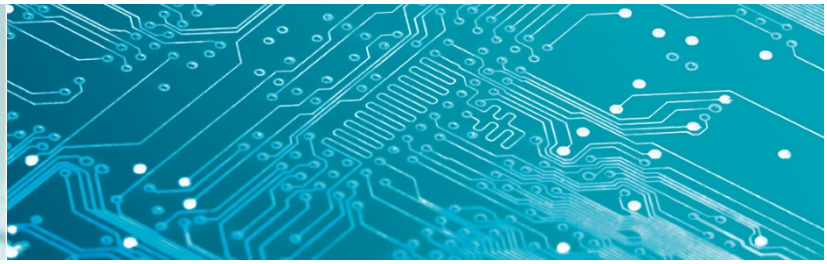
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY



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

Submission Management	Electronic management of submissions and timelines Centralized management of submission data Guided process for initialization of new submissions
Permanent Tracking	Approved products (market coverage) Pending registrations (in work) Countries where selling is explicitly blocked
Warning Management	Expiring registrations Stalled registrations (too long in same status) Document warnings
Re-Registration with a few clicks	Simple re-registration process Only a few clicks needed Keeping or discarding documents Automatic archiving of old registrations (inactive)
Automatic Reporting	Creation of specific management reports Saving of most frequently used reports Automatic and periodic creation and sending of reports to defined people Export of reports to CSV
Embedded Task Management	Creation of tasks directly in REGULA™ Assigning tasks to people Progress control of tasks
Simple Submission Compilation	Collection of submission documents in a ZIP file Automatic creation of a PDF index, e.g. according to STED Definition of the hierarchy within the ZIP file (flat or chapters)
Knowledge Management	Placing information and comments on each level Informing colleagues about important issues Summarizing phone calls with brief comments

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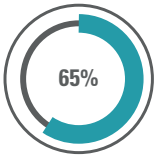
Your advantage using REGULA™

Time saving in initial registrations

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

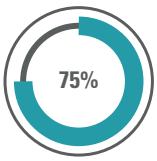


Time gaining in re-registration process

- ➔ 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

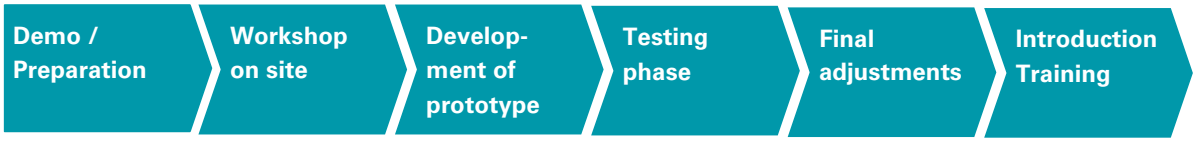
Get a better and transparent overview of your regulatory affairs activities. With REGULA™, the traceability is ensured and the information is available.

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™.

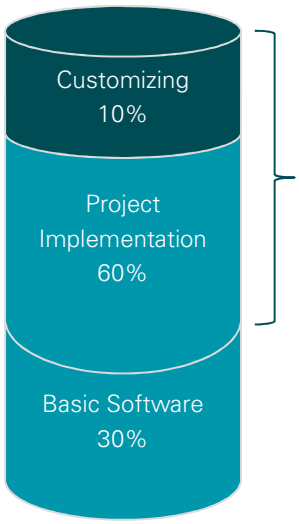
The installation of REGULA is done on a dedicated server (Windows or Linux). Detailed server requirements and the installation process are defined during the introduction project in collaboration with you.

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:

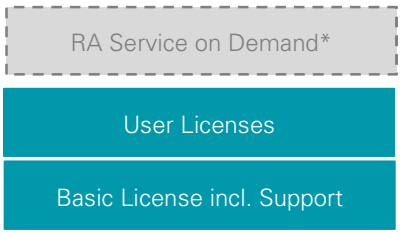
Initial cost



The amount of the investment depends on your company size and complexity

Recurring costs

The recurring costs are calculated based on the initial investment as well as on other factors:
Die wiederkehrenden Kosten berechnen sich auf Basis der initialen Investition sowie anderer Faktoren:



* optional

Your contact

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

Please contact:

Hansjörg Riedwyl
CEO

Phone: +41 32 513 6766
hansjoerg.riedwyl@iss-ag.ch