

CDM Regulatory Manager

Complete overview of the regulatory process

The Regulatory Manager offers you a quick, simple, and complete graphical overview of how your registrations are progressing. The Regulatory Manager module consists of two integrated parts: The product database and the project tool.

The product database

The product database ensures that you have all information of company collaborators, activities and products in the same system. In here, you have a complete list of all your pharmaceutical products, brands, countries, packing, and indications. For a product you can state the MRP number, RMS brand, MA holder, manufacturer, batch releaser, packing sites etc. You can get a complete list of all contacts as well.

The project tool

The project tool is extremely flexible and is used for monitoring the registration process of your products.

Projects are based on project tracks. A project track is a template defined by your organisation that can be used over and over again. You can have as many tracks as you please. Basically, a project track is a list of milestones, checkpoints, and activities. They are usually defined in accordance with the relevant national or EU regulatory procedure.

The milestones are important steps in a project and are used for monitoring the progression of a project. Milestones can be specified with duration, e.g. 90 days. Also deadlines can be defined for selected milestones and monitored by alarms and early warnings. The end date of a project is continuously changed in accordance with the progression of a project.

Integration of your organisation

When sales, marketing, and regulatory professionals use the CDM Life Science CRM solutions, the database will be able to give a consolidated view of company interaction with important doctors, key opinion leaders and authorities. The execution of regulatory projects in the CDM Life Science CRM solutions implies that the organisation can follow the progression of regulatory projects and adjust launch dates and resource allocation accordingly.

Efficient planning and execution of marketing and sales campaigns are the extension of well planned and executed registration projects.

Features

All product information in one system:

- MA numbers
- PSUR
- Renewal
- Withdrawal
- Collaborators
- MRP numbers

Overview of projects in progress:

- Deadlines and alarms
- Milestones

Graphical monitoring of:

- Project progression
- Project deviations
- Drill down from graphical overview

System requirements

Supporting MS operating systems:

- MS Windows 2007-2008-2010

Supporting the following database:

- MS SQL Server 2008 (or later)

CDM

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