

CDM Flexible Regulatory Manager



Actavis: Viewing worldwide Marketing Authorizations using one click

The world leading generic pharmaceutical company uses the CDM Regulatory Manager in 65 countries for managing regulatory activities. Through the unique pharmaceutical-specific product database, which forms an essential part of this system, Actavis is able to gain a comprehensive, international overview of the regulatory registrations for their large portfolio of products.

Replacing local databases, this overview saves a lot of time and efforts for Actavis in their daily management of regulatory processes. Furthermore the likelihood of a successful launch on Day 1 after patent expiry is increased – an essential success factor in the generic pharmaceutical industry.

In 2005, Actavis implemented the CDM Medical system with the Regulatory Management module with the purpose of managing regulatory approvals. Since then the system has grown alongside the company, which today, following an explosive growth, is one of the world's largest suppliers of generic pharmaceuticals.

Project Manager Nina Thorsdottir: "The CDM Regulatory Manager is one place to look for data in a fast way. You can find all marketing authorizations for Actavis worldwide by using one click. [...] It saves a lot of time and thus costs."

Regulatory overview

Not only does the Regulatory Manager save time, it also gives pharmaceutical companies an important competitive edge as it smoothes the road to market for pharmaceutical products through the overview provided by the system.

An essential overview provided by the system is that all necessary regulatory information of all pharmaceutical products in all countries can be viewed centrally. This truly improves the process of getting pharmaceutical products ready to be marketed and sold.

In Actavis this overview is gained through the registration of all obtainments of Market Authorizations, handling withdrawal dates, and generally registering regulatory activities on a product level such as submissions, procedures, variations and renewals.

Ms. Nina Thorsdottir: "The system stores data about planned, submitted and approved applications for Marketing Authorizations for each product for all markets. Furthermore, information about variations and other activities for each product can easily be found. This gives you an overview of the registration status in each country, for example the number of submissions or approvals for a given period on a country or regional level."

About Actavis

Actavis is one of the world's leading players in the development, manufacture, and sale of first-class generic pharmaceuticals. Founded in 1956, the Company has led an assertive programme of expansion, making more than 25 acquisitions in the past seven years while maintaining strong organic growth. The Group has approximately 11,000 employees operating in about 40 countries around the globe. Actavis' headquarters are in Iceland.



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Access to data – no matter the location

The overview provided by the CDM Regulatory Manager revolutionized Actavis's way of executing regulatory processes by centralizing information to a central database. This revolution made visible as the introduction of the system obliterated the previously arduous work of maintaining data, stored and managed in multiple locations.

Ms. Nina Thorsdottir: "Previously our regulatory data was managed through local databases – Lotus Notes in some countries and in Excel sheets for most other markets. Now we have a mutual database where every market can access data for the country no matter the location. All data is stored at one place and you do not have to send an e-mail to ask if the country has this product registered or not."

Actavis' Regulatory Managers very positive

As the management of regulatory processes is executed locally in each of the 65 countries, the CDM Regulatory Manager is deployed in, it is important that all the local country Regulatory Managers becomes active users of the system.

As all important information is made readily available to the users and is helpful in the everyday regulatory work routines, the application offers a natural incentive for usage. This helped Actavis overcome the challenge of user adoption.

Ms. Nina Thorsdottir "Everyone was very excited and happy to have a database that holds information for all markets and we have had very positive feedback from all Actavis employees. Now people have a place to enter important dates, and it is very easy to find information. You can get an overview for your country for different information."

Good solutions to regulatory problems

The adaption of the Regulatory Manager module to Actavis' specific needs has been worked out in cooperation between CDM and Actavis. This process was helped by combination of the flexibility of Actavis and the technological competence and pharmaceutical know-how of CDM.

Ms Nina Thorsdottir: "We've had an open and easy going cooperation on developing the system with CDM. They have had good solutions to problems that arose and good ideas of how to make the use of the database easier."

About CDM

CDM A/S is a Danish owned software company and Microsoft Gold Certified Independent Software Vendor (ISV) Partner. The core business of CDM is to sell and develop industry specific CRM solutions that support and optimize regulatory, sales and marketing processes. Our main focus is the life science industry.

Sales Excellence Systems
Optimize Processes / Maximize Sales