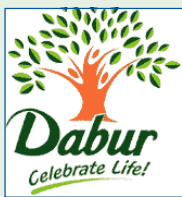


# PharmaReady™



## PharmaReady Case Study Submitted by Dabur Pharma Limited

Now after PharmaReady's implementation, we can manage all our documents online, and the submission size has reduced drastically from tons of paper to a CD ROM...amazing, isn't it?

### COMPANY PROFILE

Dabur Pharma Limited is the leading Indian company for cancer research and anticancer products. The company is a global player in oncology formulations providing high quality products supported by superior level of customer services, at highly competitive prices.

Dabur Pharma Limited, a public limited company incorporated in March 2003, is an associate company of Dabur India Limited, a US \$ 250 million healthcare company founded in 1884. Dabur Pharma Limited operates in Europe and in some other markets through its fully owned subsidiary - Dabur Oncology Plc.

The fully integrated pharmaceutical business of Dabur Pharma Limited covers the oral & injectable finished dosage forms and active pharmaceutical ingredients (APIs) & intermediates.

Dabur's finished dosage forms are manufactured at most modern manufacturing units in Bordon (UK) and Baddi (India), while the APIs are manufactured at Kalyani (India).

Dabur has overseas offices in the UK, Malaysia, Russia, Thailand and Philippines. Offices are also being set up in Brazil and US.

Dabur has obtained marketing approvals for oncology products in several key highly regulated and less regulated markets across the globe.

### BUSINESS PROBLEM

Being a company with vision for the future, we had sensed well in advance that the future belongs to electronic submissions based on the developments of ICH M2 ESTRI working group. Hence, we wanted a comprehensive regulatory compliant electronic content assembling product integrated with document management abilities.

To ensure compliant electronic submissions and to facilitate seamless document management, we did a lot of market research in order to find a product which meets both ours and regulatory requirements. Some products provided document management and others solutions for eCTD and SPL. They all

were really just application silos and not truly integrated solutions. However, our requirement was 21 CFR Part 11 compliant integrated solution which could satisfy all our electronic submission requirements.

We finally found our solution in the fully integrated PharmaReady suite, which offered eCTD, DMS, TRMS and SPL...yes, all in one. A fully integrated compliant and costeffective system... What more we could have asked for?

Before the implementation of PharmaReady, we used to struggle with handling and managing data worth tons of paper. Now after PharmaReady's implementation, we can manage all our documents online, and the submission size has reduced drastically from tons of paper to a CD ROM... amazing, isn't it?

### BUSINESS DRIVERS

Dabur Pharma being a global player in Oncology formulations, its key business drivers include providing high quality products supported by superior level of customer services, at highly competitive prices. The company strives to make available quality and low cost oncology treatment to patients across the globe.

To make this possible, penetrating different markets across the globe is imperative. For this, obtaining marketing authorizations through submissions in these markets is crucial. Here we count on support from Take Solutions via their effective tool PharmaReady. PharmaReady has helped us not only in complying to and meeting the expectations of various regulatory agencies but also handling and managing the data for submissions in a faster and simpler way. It will also help in shortening the review cycle, as it is reviewer friendly, thereby obtaining faster approvals. These product approvals across the global markets will help us achieving our business drivers, as we have a rich pipeline of potential products and have aggressive expansion plans across the globe to become a leading oncology player. An attractive portfolio of drug candidates for liver disease. Our goal is to add value by confirming efficacy in preclinical studies and demonstrating activity in human clinical trials in a defined patient population.



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## SOLUTION

We purchased the entire PharmaReady Document Management, Training Records Management, Structured Product Labeling and eCTD Publishing Solution Suite in the year 2006. Dabur was one of the first of Take Solutions clients where the entire PharmaReady suite was implemented.

We had a very structured implementation and exhaustive training programme from Take Solutions.

The implementation and training schedule included the following steps:

- 1) Preparation for installation, where we (our users and our IT team) had detailed telecons with Take Solutions team. Our IT team acquired hardware and software for installation and our users planned for intended use of the products.
- 2) Software installation at our facility, where Take Solutions team installed all the three products.
- 3) Training, where Take Solutions team provided exhaustive Admin, Document Management and Reader training on the DMS application and User training for SPL and eCTD. Training was provided at our research centre (for DMS, eCTD and SPL) and manufacturing unit (for DMS).
- 4) Validation, where validation of the DMS and SPL systems including execution of the OQ documents, etc was carried out across the globe.

## BUSINESS VALUE

Currently, we are using PharmaReady for our ANDA and DMF submissions and subsequent life cycle maintenance in the US FDA and ANDS submissions in Health Canada.

Initially we submitted our sample DMF and ANDA and sample ANDS to USFDA and Health Canada respectively, which passed the respective agency's validation successfully.

After that there was no turning back. We have filed our original submissions for DMF and ANDA in the US FDA using PharmaReady. We have also filed amendments to ANDA using PharmaReady. In fact, we recently submitted our DMF created with PharmaReady version 4.0, which also passed the FDA validation.

We are now ready for electronic submissions in the UK MHRA and plan to implement the same as soon as the agency is ready for accepting eCTD in early 2009.

Successful electronic submissions using PharmaReady and excellent round the clock support from the Take Solutions team has boosted our confidence. We are so excited to realize the fact that we can achieve compliance and hassle free submissions at the same time. eCTD submissions using PharmaReady have not only given us freedom from difficult to manage paper submissions, but also made us compliant with respect to the future expectations of the regulatory agencies.

Currently, we are managing all our DMF and ANDA eCTD submissions to the US FDA using PharmaReady which has given triple advantage:

- 1) It benefits us, given the ease of compilation. Also, it has reduced handling and managing data at our end drastically – from tons of paper to a CD ROM.
- 2) It also simplifies the review process at the regulatory agency, being so reviewer friendly and
- 3) Not to forget our valuable possession – our Environment. It saves the environment, as it saves paper.

## Ready for more?

Visit [www.pharmaready.com](http://www.pharmaready.com) to take a look at PharmaReady. If you've looked at other regulatory information management products, we think you'll like what you see.

Learn how your organization can benefit from the most cost-effective, EDMS solution on the market today by calling: **877-320-3626** or visit: [www.pharmaready.com](http://www.pharmaready.com).



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