



## **ARIAD Pharmaceuticals Successfully Deploys Datafarm's S-Cubed® to Establish Electronic Submissions for its Investigational New Drugs**

### **COMPANY PROFILE**

ARIAD Pharmaceuticals, Inc.'s mission is to discover, develop and commercialize small-molecule drugs to treat aggressive cancer in patients where current therapies are inadequate. The company has two Investigational New Drugs (INDs) currently under evaluation; one product candidate is in Phase III development and the other is in Phase I. ARIAD adopted Datafarm's S-Cubed to streamline its regulatory compliance submission process using the FDA's preferred electronic Common Technical Document (eCTD) in preparation for its New Drug Application (NDA) in 2010.

### **CHALLENGE**

Regulatory submissions remain extensive and laborious for many Life Sciences companies that remain paper-based in their regulatory submissions. Charles Deeck, Director of Regulatory Operations for ARIAD and a ten-year veteran in regulation operations, is very familiar with the challenge.

"As a regulated industry, Pharmaceuticals remain entrenched in paper," said Deeck. "We lag behind other regulated industries like Financial with fairly ubiquitous electronic processes in place to move and track money."

Prior to joining ARIAD, Deeck led three other pharmaceutical companies in their transition from paper-based regulatory submissions to a streamlined eCTD process.

ARIAD brought Deeck into its organization to help lead the regulatory affairs division through the same conversion during a critical period in the company's evolution. ARIAD expects to be filing an orphan drug NDA application in 2010 for ridaforolimus, its late-stage cancer-inhibiting compound under development with Merck & Co., and must complete the filing in a compliant electronic format. Both Ridaforolimus, and its other oncology IND currently in Phase I development, had been fully maintained in paper.

"If our drugs are approved, ARIAD will go from an R&D organization to a commercial organization. We simply had to make this happen and needed an eCTD solution to do it."

### **SOLUTION**

After extensive review of multiple electronic regulatory submission solutions from leading providers, Charles Deeck and ARIAD selected Datafarm because it offered the broadest, most intuitive solution offerings without being cost-prohibitive.

Additionally, having gone through the process three times before, Deeck knew that the ease of integration with content management platforms like Documentum was critical to avoid a complicated deployment process.

“When an eSubmission solution is too dependent on Documentum, a tight integration is a logistical nightmare to deploy,” said Deeck. “One of Datafarm’s biggest assets as a solution provider is simplifying the deployment process for its customers by not integrating too tightly with Documentum, but by providing a reliable connection.”

ARIAD adopted the following Datafarm e-submission products:

- **S-Cubed® eCTD:** Facilitates conforming submissions to the current ICH and regional requirements for delivering eCTD submissions to the US, EU, Canada, Japan, swissmedic and Taiwan regulatory agencies
- **S-Cubed® NeeS:** Enables the non-eCTD electronic submission of any other PDF-based electronic submissions
- **S-Cubed® Publisher:** Produces print ready paper volumes from eCTD and NeeS with Table of Contents and tab sheets as required by the agencies that still require paper as official submission format
- **eCTD GateKeeper™:** An eCTD validation module designed to provide your company with a secondary validation process
- **a-Pulse®:** Combines PDF publishing automation with intuitive maintenance and task management functions.
- **S-Cubed® Templates.** Easy-to-use document templates reduce the time manual formatting requires, allowing you to create consistent, industry compliant documents
- **eCTDViewer® Web Edition,** enables permission-based online review of eCTD and NeeS applications/submissions from anywhere in the world.

## RESULTS

The Datafarm Regulatory Services Group completed two pre-submission sequences on behalf of ARIAD for its upcoming NDA in 2010 prior to the completed deployment of Datafarm’s S-Cubed and submitted through the Datafarm Gateway. These included meeting requests and a briefing book.

These sequences have since been imported into ARIAD’s S-Cubed system, fully deployed and in use across ARIAD’s regulatory affairs. These pre-submission sequences will be included in the future eCTD for their NDAs. With the company’s two INDs, its oral ridaforolimus now under evaluation in Phase III and the Phase 1 oncology drug, along with a promising early stage compound expected to enter clinical development next year – all applications will be converted to eCTD formats in early 2010.

Charles Deeck reports several benefits of the company’s transition to eSubmissions with Datafarm:

“We now have an appropriate electronic document management system for our submission documents in which multiple authors and reviewers collaborate and track modifications on one document. The document management system coupled with Datafarm’s S-Cubed will bear obvious resource savings and an increase in compliance. We also like the simple, intuitive tool bars of S-Cubed and the great user-guide documentation and instruction that simplify the process of making a compliant document.”

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