



## BORLAND CASE STUDY

# Rosetta Biosoftware



### FAST FACTS

#### COMPANY

Rosetta Biosoftware is a leading provider of informatics solutions for life science research

#### INDUSTRY

Pharmaceutical

#### GEOGRAPHY

US

#### CHALLENGES

- Meet changing industry and customer needs
- Support FDA Voluntary Genomics Data Submission Program
- Potentially help reduce drug costs for customers

#### SOLUTION

- Borland® CaliberRM®
- Borland® StarTeam®
- Borland® Together®
- Borland Services

#### RESULTS

- Reduced rework
- Improved application quality
- Increased predictability and visibility

### EXECUTIVE SUMMARY

Rosetta Biosoftware develops informatics solutions and provides services that enable research organizations to efficiently and effectively conduct life-saving discoveries and develop drugs. The Rosetta's Resolver® system, developed using the Borland Application Lifecycle Management (ALM) technology, offers life science researchers an analysis and data management framework for gene expression which can minimize costly and time-intensive downstream drug development. Life science research organizations that have licensed the Rosetta Resolver system include many of the top pharmaceutical companies in the world, as well as premier academic institutions and service providers. In August 2005, the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) licensed the Rosetta Resolver system for gene expression data management and analysis. The CDER will use the Rosetta Resolver system in the Voluntary Genomics Data Submissions (VGDS) program to analyze microarray data from any organization engaged in drug development. The FDA's use of the Resolver system will enable the agency to better understand the role genomics data submissions could play in the drug discovery process and enable them to understand the technology being used by drug companies to develop safer drugs more quickly.

### COMPANY

Established in 1997, Rosetta Biosoftware develops informatics solutions and provides services that enable research organizations to efficiently and effectively conduct life-saving discoveries and develop drugs. The company's mission is to be the premier provider of scalable software solutions to empower research that improves the quality of human life. Rosetta Biosoftware provides value to discovery and development efforts by offering customizable informatics solutions and services that are adaptable to each organization's needs. Rosetta Biosoftware is a customer-driven organization with the scientific expertise to effectively complement internal informatics groups or serve as an informatics resource. Rosetta Biosoftware is a business unit of Rosetta Inpharmatics LLC, a wholly owned subsidiary of Merck & Co., Inc.

### CHALLENGES

It takes years and costs nearly a billion dollars to develop and approve a blockbuster drug in the U.S. To reduce the rising costs and develop safer drugs, faster, pharmaceutical companies, or sponsors, are seeking more innovative technology solutions. For example, gene expression data analysis is playing an increasing role in pharmaceutical and biotech drug development pipelines in areas such as toxicogenomics, clinical studies and molecular diagnostics. There is no question that genomics data opens new windows into understanding diseases and developing safer drugs more quickly. Rosetta Biosoftware's Resolver system offers life science researchers an analysis and data management framework for gene expression, which can minimize costly and time-intensive downstream drug development.

Rosetta Biosoftware's customers which include pharmaceutical companies, premier academic institutions, service providers and the U.S. Food and Drug Administration's Center for Drug

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Evaluation and Research (CDER) with its Voluntary Genomics Data Submissions (VGDS) program must have confidence in the accuracy and reproducibility of the analysis results produced by the company's software. This confidence is needed not just in the software, but in Rosetta Biosoftware's methods for developing and validating the software. To support these needs, early on, Rosetta Biosoftware realized it needed a comprehensive application lifecycle management (ALM) solution one that integrated and documented requirements creation and management, source code control, requested changes, and validation—to help its team:

### MEET CHANGING INDUSTRY AND CUSTOMER NEEDS

The life sciences industry rapidly changes as information technology is applied to more areas of research. Rosetta Biosoftware must be able to deliver quickly new features and functionality that meet the rapidly changing software needs of its customers. Therefore, Rosetta Biosoftware's development methods needed to follow suit. On one hand, they must be well-defined, predictable, well-documented and capable of producing high-quality software. On the other hand, they must also be lean and agile, enabling Rosetta Biosoftware to quickly adjust to the changing industry and to customer needs. Rosetta Biosoftware required a complete ALM solution to achieve these goals.

### SUPPORT FDA VOLUNTARY GENOMICS DATA SUBMISSION PROGRAM

Rosetta Biosoftware customers use the Resolver system in conjunction with their gene expression profiling or microarray studies. Microarray technology, in terms of gene expression analysis, allows scientists the ability to interrogate tens of thousands of genes at one time. The ability to perform gene expression profiling with such tools as the Resolver system has increased the industry's overall understanding of disease mechanisms and potential therapeutics. This knowledge has helped to improve the ability of pharmaceutical and biotechnology institutions to bring lifesaving therapies to market.

Gene expression data analysis is playing an increasing role in pharmaceutical and biotech drug development pipelines, and the FDA continues to try to better understand how genomic data figure in a drug company's submission for a new drug. Therefore, in 2005, the FDA began requesting that sponsors who are part of a drug development program voluntarily submit

genomics data when such data are normally not required under the regulations, as part of a new program called the Voluntary Genomics Data Submission (VGDS) program. The Center for Drug Evaluation and Research (CDER), which is responsible for the VGDS program, selected the Rosetta Resolver system as one of the technologies they would use to help support the VGDS program.

Specifically, the CDER would use the Resolver system to replicate analyses performed by sponsors who voluntarily submit these data. Additionally, the CDER would use the system to conduct its own independent analyses. According to the FDA, voluntary submissions of genomic data are a novel way to share information with the FDA, and a greater understanding of the issues surrounding the use of these data may prevent delays in reviews of future submissions where genomics are an integral part of specific studies in a drug development program. To meet the needs of the FDA and other large pharmaceutical customers, Rosetta Biosoftware needed to ensure its development and validation methods were well-documented and reproducible, and supported the creation of high-quality software.

### POTENTIALLY HELP REDUCE DRUG COSTS FOR CUSTOMERS

For the FDA, voluntary genomics submissions today can benefit both the industry and the FDA in a general way by providing a means for sponsors (e.g., pharmaceutical companies and academic institutions) to ensure that regulatory scientists are familiar with and prepared to appropriately evaluate future genomic submissions. This understanding should expedite processes and lead to lower overall development costs, and possibly to reduced costs for consumers.

According to the FDA, for the participating sponsors, voluntary submission to the FDA of genomic data offers a number of specific potential benefits:

- It creates an opportunity for early informal meetings with FDA pharmacogenomics experts
- It offers flexibility in review and meeting process
- Sponsors receive and benefit from informal peer-review feedback on issues and/or questions
- Sponsors gain insight into current FDA thinking that may assist in reaching important strategic decisions

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“Now everyone throughout the product lifecycle—from project managers to analysts to architects to developers to testers—has access to the same information at the same time, enabling teams to communicate more effectively, which prevents costly errors and rework... In addition, we are assured of our ability to support the regulatory compliance requirements of our customers.” —JIM PEARSON, MANAGER OF QUALITY ASSURANCE AT ROSETTA BIOSOFTWARE

- It offers time- and cost-savings by familiarizing both parties early with novel approaches avoiding future delays in review
- It provides an opportunity for sponsors to impact FDA’s thinking and help build consensus around future standards, policies and guidances

To help its customers achieve these benefits, Rosetta Biosoftware needed a comprehensive ALM solution that would help the company ensure it was delivering the highest-quality software, on time, within scope and on budget.

### SOLUTION

Rosetta Biosoftware selected the Borland ALM solution to better manage critical software development processes, including requirements management, change and configuration management and visual modeling, with the goal of delivering more defined, predictable, well-documented and high-quality software.

Specifically, Rosetta Biosoftware is deploying the ALM solution to better manage critical software development processes, including:

**REQUIREMENTS MANAGEMENT:** Rosetta Biosoftware leverages the tightly integrated and customizable Borland® CaliberRM® technology to automate its specific requirements processes and to track requirements from elicitation through final delivery. For example, after business, technical, functional, and operational requirements are entered into the Borland CaliberRM repository, stakeholders across the organization can collaborate more effectively, including quality assurance team members who can immediately begin building test cases to ensure requirements meet specifications, so that Resolver system releases and upgrades are high-quality and delivered on time. “Using Borland CaliberRM to define, prioritize and track requirements throughout the project lifecycle, our Rosetta

Resolver development team is better able to respond rapidly to ever-changing requirements without jeopardizing project success,” explained Jim Pearson, Manager of Quality Assurance at Rosetta Biosoftware.

**CONFIGURATION AND CHANGE MANAGEMENT:** A robust platform for coordinating and managing the entire software delivery process, Borland® StarTeam® promotes team communication and collaboration within the Rosetta Biosoftware development team through centralized control of all project assets and time stamping. With Borland StarTeam, every member of the Rosetta Biosoftware development team is able to rely on a single repository for integrated requirements management, change management, defect tracking, file versioning, threaded discussions, and project and task management for all of its development projects. Rosetta Biosoftware also enables its customers to leverage the ALM solution to automatically enter escalation and enhancement requests for the Resolver system, and then dynamically extract web pages to view the progress of their change requests.

“For internal use, the Borland StarTeam repository is being used to house a variety of Rosetta Biosoftware documents, from policies and standard operating procedures to project specific documentation history, and more,” said Pearson. “Borland StarTeam delivers version control and change management capabilities to help manage these documents to regulatory compliance standards.”

**VISUAL MODELING:** The Rosetta Biosoftware team is using Borland® Together® to help bridge the gap between business and IT stakeholders using a common set of visual best-of-breed modeling languages to help define the next release of the Resolver system. With support for business process modeling, data modeling, application modeling and visualization, and

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comprehensive audits and metrics for both models and code, the visual modeling technology helps the Rosetta Biosoftware development organization accelerate the delivery of its high-quality software solutions.

Rosetta Biosoftware is also working with Borland Consulting and Borland Education Services to ensure the successful rollout of the Borland ALM solution.

### RESULTS

Across the Rosetta Biosoftware development organization, team members have experienced increased efficiencies from the Borland ALM system, including:

#### REDUCED REWORK

By documenting all processes and providing a standard repository for every artifact and asset, Rosetta Biosoftware has reduced rework within its development organization. “Now everyone throughout the product lifecycle—from project managers to analysts to architects to developers to testers—has access to the same information at the same time, enabling teams to communicate more effectively, which prevents costly errors and rework,” said Pearson.

#### IMPROVED APPLICATION QUALITY

By driving more effective development and delivery processes throughout the entire application lifecycle, the development team has been able to improve application quality. According to Pearson, “We have leveraged the Borland tools to develop an entire ALM process that is well documented and well-designed, and enables the development team to be more agile.”

#### INCREASED PREDICTABILITY AND VISIBILITY

The Rosetta Biosoftware development team has increased predictability and visibility into the application by improving code traceability, thereby delivering greater control of and visibility into the entire software delivery lifecycle. “In addition, we are assured of our ability to support the regulatory compliance requirements of our customers,” concluded Pearson.

Rosetta Biosoftware’s customers and the FDA have also directly benefited from the documented, defined ALM methodology. For example, a recent situation occurred when a VGDS program participant submitted a large amount of research data to the FDA. The FDA successfully reproduced the research analysis with one minor discrepancy. In attempting to understand this anomaly, Rosetta Biosoftware teams were able to review the software development documentation to help to explain the discrepancy to the satisfaction of the VGDS program participant and the FDA.

Voluntary Genomic Data Submissions are a novel way to share information with the FDA, and this program with FDA’s CDER is the first of its kind. At the current time, most pharmacogenomic data are of an exploratory or research nature and FDA regulations do not require that these data be submitted to an Investigational New Drug application or that complete reports be submitted to a New Drug Application or Biologic License Application. However, voluntary submissions are becoming more prevalent as a result of this voluntary program.

### ABOUT BORLAND

Borland Software Corporation is a global leader in platform-independent solutions for Software Delivery Optimization. The company provides the software and services that align the people, process, and technology required to maximize the business value of software.



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