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TECHNOLOGY PROFESSIONALS

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RETROSPECTIVE VALIDATION FOR CUSTOM APPLICATION

Client Profile:

A bio-pharma company involved in drug discovery and moving into pharmaceutical manufacturing.

Technologies Used:

RUP, IEEE Recommended Practice for Software Requirements Specifications, UML, and Rational Rose Modeling Tool.

Project Summary:

The bio-pharma client was using a custom application to automate testing procedures and data analysis. The software had been developed in-house when the organization was a start-up biotech company. The client was fast moving toward commercialization of their first product and needed to have all applications documented and validated per FDA standards. The ASHVINS Group consulted with the client to understand the functional requirements associated with the custom application and to review all existing design and development documentation. By working both with the end-users of the application and with a running model of the application, The ASHVINS Group developed a comprehensive Software Requirements Specification. From there, a Detailed Design Document was developed that included all existing functionality. Finally, the application was fully validated to provide sufficient documentation to support the continued use of the application in an FDA regulated environment. By creating "retrospective documentation" to support the application, the client was able to implement the existing software and use the software as a base-line to support continuing development efforts for the application.