



Case Study

Business Intelligence Solutions: FDA-Compliant BI Server Configuration

CLIENT

This international pharmaceutical company produces and markets targeted therapeutic products based on multiple delivery platforms, with facilities for research, development, manufacturing and operations across the world.



NEED

The company already used SAS to perform regulatory analysis on clinical trials, but needed to evolve from a decentralized, desktop-based approach to a centralized, access-controlled BI Server platform. Further, this system needed to be installed, validated and operating in a manner consistent with regulatory requirements.



SOLUTION

Pinnacle Solutions developed a full set of departmental validation and procedural documentation, including CFR 21 Part 11, to meet FDA regulatory requirements. The SAS BI Server installation and configuration was performed and confirmed under the guidance of this documentation, and ongoing operation and maintenance is being driven by the SOPs created by Pinnacle Solutions.



BENEFITS

- Improved Security
- Enhanced Regulatory Compliance
- Ease of Administration
- Wide Range of Analysis Tools
- Consistent and Standardized Procedures



TECHNOLOGIES

- SAS Enterprise Guide
- SAS OLAP Server
- SAS Web Report Studio
- SAS Integration Technologies
- SAS Microsoft Office Plug-In
- SAS Access to Oracle, ODBC
- Microsoft Active Directory



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