



Case Study

Health Care Product Manufacturer

CLIENT

This Health Care Product Manufacturer (HCPM) makes and sells a variety of products for consumers, life sciences researchers, and health care providers. One product line includes glucose monitors, disposable testing strips, a ROM chip [for calibrating meters to the unique chemistry of each strip manufacturing lot], and other diabetes care products for people managing that disease.

NEED

The company uses SAS-based software applications to assess test strip lots and create meter calibrating data for the programmable ROM chips. The applications were decentralized, causing duplication of reports, rising application deployment and maintenance costs, and labor-intensive efforts to ensure 21 CFR Part 11 compliance.

SOLUTION

HCPM had plans to launch a new product to replace the old product line of glucose monitoring systems. The company needed a centralized, integrated, FDA-compliant solution for managing, analyzing, and reporting the calibration data for the new product.

SOLUTION

Pinnacle Solutions designed, developed, and implemented a system which delivers the calibration data HCPM needs in a compliant and cost-effective fashion. The new application, partly driven by modified versions of existing programs, now resides in a single, secured environment. SAS Integration Technologies anchors the application's analytic engine, and a document management system stores output in a globally-accessible secure environment. Audit trails for all transactions and version control of all data, programs, and output are maintained automatically.

Business Intelligence Solutions:

FDA-Compliant Analytics

BENEFITS

- 21 CFR Part 11 compliance
- Global access to data
- Controlled costs
- Centralized & searchable repository
- Enhanced efficiency and productivity

TECHNOLOGIES

- SAS Integration Technologies
- SAS Output Delivery System
- PowerBuilder
- Oracle
- ProductCenter/CMS



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