

# Health Care

## The Client

A major medical technology company that serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public. It manufactures and sells a broad range of medical supplies, devices, laboratory equipment and diagnostic products.

## Business Objective

Diabetes Software was developed for company's new line of blood glucose monitoring products introduced in early 2003. This diabetes management software sets a new standard in ease of use, data management, graphical presentation of glucose and insulin data for pattern management, and provides a patented single-step meter download capability that is truly unique in the industry. Client needed a qualified and flexible IT firm to define the complete verification and validation methodology and prepare the V&V documentation for FDA approval.

## The Solution

Smart IMS helped assess the software for software quality assurance purposes. It defined the complete V&V methodology and executed the approved verification and validation techniques to validate the software according to the customer needs and prepared the complete necessary documentation with detailed verification and validation results from scratch for FDA submission. Due to our documentation efforts the company got the FDA approval in record time. SmartIMS defined Verification and Validation approach that was quick, cost-effective and best suited the problem. The defined Verification and Validation methodology was ideal for the software.

## Results

The client was able to rapidly roll out its software and expand its offering because it did not need to build either the initial infrastructure or the knowledge base for the software quality assurance. The company continues to benefit from reduced complexity, while meeting its customers' needs and expectations.

