

## CASE STUDY

# Middleware/Data Management Solution to significantly streamline LABORATORY WORKFLOW

**With a very rich history our Client built its place on the market on a company culture oriented toward customer satisfaction and the quality and reliability of their solutions. Our customer's extensive client portfolio of large companies has driven the need for numerous interfaces for most laboratory information systems and instruments available on the market. The Middleware/Data Management software enables clinical labs to consolidate test information from various instrument systems and manage data in real-time.**

## The Client

Our Client is a software company that develops value-added solutions in data management for clinical laboratories. Our Client is experienced in the most advanced Microsoft and Internet technologies.

## The Idea

With a very rich history our Client built its place on the market on a company culture oriented toward customer satisfaction and the quality and reliability of their solutions. Our customer's extensive client portfolio of large companies has driven the need for numerous interfaces for most laboratory information systems and instruments available on the market. The Middleware/Data Management software enables clinical labs to consolidate test information from various instrument systems and manage data in real-time.

## The Challenge

For manufacturers and clinical laboratories, software is the premier cause of postponements of instrument launches. The software that causes most delays is the one that mediates interactions between laboratory instruments and the laboratory information system (LIS) middleware.

In order to speed up instruments go-to-market times, the middleware solutions needed to feature in a highly customizable workflow, an entire range of functionalities like: multi-disciplines, multi-sites, multi-LIS, multi-instruments, multi-users, multi-languages, automatic results validation, delta checking, reflex testing, quality control, results editing, and archiving and restoring.

The solution also needed to comply with the strict regulatory framework in the area of clinical related operations like 21 CFR Part 11, FDA approval or CE marking. On top of this, our client's own standards and certifications implied total quality control over the development process to fully contribute to products destined to become homologated for the U.S. and European markets.

## The Solution

OSF Global Services partnered with the Client building a mixed team with his own staff, working from the client's own specifications to build tools and framework elements. The use of open standards and service-oriented architectures (SOA) to build the middleware was selected to embed the digital library information sources in the technical frameworks, thus obtaining an open, reusable middleware that can bridge the complex functionality of the LIS with the instruments interfaces.

Running off a desktop station, the middleware system views, tracks, and manages from one location all laboratory instruments, to enable automatic validation and reporting of normal results, according to rules programmed into the software. With reporting modules such as regulatory provider, audit and auto-validation, quality control interface, and up to 50 instruments driver development, the middleware system developed provides a versatile response to a variety of issues.

Heavy quality control documentation, testing and process maturity procedures were implemented all throughout the development of the project to ensure compliance with all quality standards to integrate with client's own processes and procedures as well as the challenging clinical environment requirements.

## Technologies

.Net 2.0, C Sharp, Dev Express, engine reporting, code covering tools

## The Results

Our Client's middleware critically improves the integration of the instrumentation, the automation system, the lab's data management component, and the LIS. The data management system that OSF Global Services contributed to helps streamline laboratory information processes for maximum efficiency interfacing timely, accurate and reliable clinical test results, eliminating LIS bottlenecks, and enabling lab operations in a cost-effective manner.