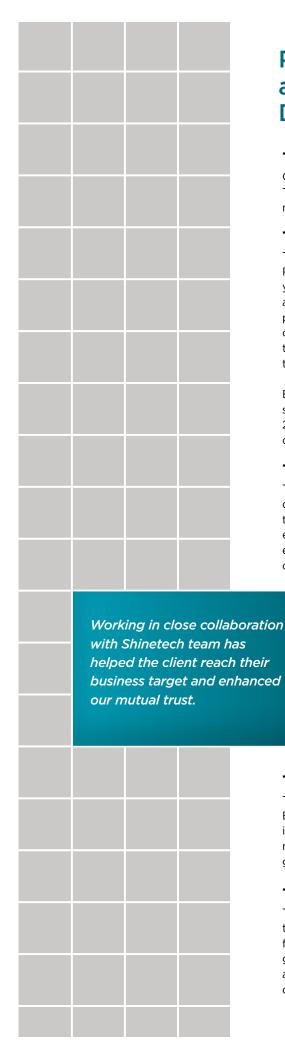


Providing System Maintenance and Support for a U.S. Medical Device Manufacturer

Our client was using three separate systems to manage product registration, inventory, and labeling at their regional headquarters in Hong Kong. When the U.S. Food and Drug Administration (FDA) introduced new labeling requirements for healthcare products, Shinetech took over from a previous vendor to help the client integrate and transform their system to meet the new FDA standards, while adding new functions to increase efficiency.





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The Client

Our client is a Fortune 500 medical technologies firm based in the United States. They manufacture medical devices and medical equipment, which are exported to more than 120 countries.

The Challenge

The client was managing product registrations, inventory and labeling at their Asia Pacific Regional headquarters in Hong Kong using three separate systems, all of which were built years ago on currently outdated .NET 2005 technology. In the meantime, a new U.S. Food and Drug Administration's (FDA) rule required healthcare manufacturers to label their products with unique device identifiers (UDIs) to increase patient safety and help optimize patient care. In order to meet the new requirements, the client had to transform their systems. At the same time, they wanted to take the opportunity to combine their three systems into one, upgrade the technology, and add new functions.

Before working with Shinetech, the client had been outsourcing to a company specializing in ERP development, but the delivery quality had become unsatisfactory. In 2013, the client turned to Shinetech to discuss how to improve and bring the project back on schedule.

The Solution

The client initially planned to transfer the entire project to Shinetech for ongoing development. But considering the critical schedule for development, and the time needed to properly transition the project over to us, we suggested working together with the existing vendor, with Shinetech assuming responsibility for code review and testing to ensure the quality. This arrangement worked out well, and after phase one was completed, Shinetech took over the entire project.

The client has gradually grown the team from three developers to eight, including a leader, five developers, a tester, and a Level 1 help desk support person. The three core technical people have remained part of the team.

Since our collaboration began two years ago, the Shinetech team has often travelled to Hong Kong to work onsite with the client's internal team for one or two weeks at a time. We share and discuss project plans and requirements, and maintain high development efficiency and high-quality deliveries. Our teams are always ready to put in the extra effort to ensure critical milestones are met. This was especially important during one recent project, when we helped the client reach their business target and enhanced our mutual trust.

The Technology

The system we've been working on for two years has been developed in Microsoft .NET. EDI and SSIS are used for data communication with external systems. The main functions include: registration management for markets in different countries; inventory management module, connected with partners' systems and clients' ERP; and label generation and labeling for all products.

The Result

The Shinetech team has successfully completed the integration of the three systems and the transformation required to meet the new FDA standards. In addition, we added new functions including a system admin module; and an approval management module which greatly increases the client's efficiency through an automated approval process. We have a deep understanding of the system and our client's related business logic, allowing us to deal with requirements and tasks quickly and efficiently.