SPL Success Story

Compliance Management in a Life Sciences Corporation

Executive Summary

Our client is a multinational life sciences and material sciences group. Its global end markets include food and dietary supplements, personal care, food, medical devices, automotive, paints, electrical and electronics, life protection, alternative energy and bio-based materials. Annual net sales are around €10 billion and the company employs more than 25,000 people worldwide.

The group was planning to improve an old Microsoft Access data base system and move it to a centralized Enterprise Quality Management that would manage the company's compliance processes by using one of the industry's leading QMS software. Rather than using a traditional approach, we chose the SPL Way to manage this project. The new system would track Batch Records, tie them back to corporate ERP batch records on an FDA approved system and simultaneously control all changes while providing data in multiple ways and report kinds. Additionally, several new and enhanced reports were put into service during the process to meet recent needs.

Project outcomes resulted in an estimated reduction of 30 % to 40 % in application maintenance costs, less hardware engagement, smooth, timely migration of legacy data, and additional business value of over € 142,000.

Background

For a global player like the €10 billion group, which employs a total workforce of around 25,000, cross-borders business is key to success. To meet customers' need for rapid delivery, the group needs to ensure that its core quality processes are managed with high efficiency while complying with FDA requirements, which mandate that all electronic records, electronic signatures, and handwritten signatures are trustworthy, reliable, and equivalent to paper records. The company decided to implement its Complaint Management system across all its 160 sites worldwide.

Our Solution Delivery organization was chosen to do the job. We typically offer system implementation services (including reporting and analytics services), validation services, data migration services, integration services, and process optimization services.

Project Description and Approach

The purpose of the project was to increase our competitive system by enabling electronic communication, streamlining key processes in regulatory compliance environment, and harmonizing core quality processes across the organization's 160 sites. We realized that we must maintain a flexible approach; employ creative thinking, share information environment, and methodic analysis review throughout the entire project's lifecycle. Our goal was not just meeting the project timelines and budget goals, but also ensure that we are exceeding typical business results and turn this project into a significant business success. We were planning that this would also help our company build stainable long-term relationships with this large customer.

We realized that the traditional project management approach was insufficient to deal with ongoing changes; it also lacks of the role of leadership, which to our opinion, was one of the most critical components of success. We thus made a decision to implement the SPL approach across the entire project portfolio and were prepared to change the way we have managed such projects in the past.

The first and most important thing was to turn project managers into leaders, and made them responsible for the business results. The second thing was to obtain top management support by explaining everyone why we are doing this project, and for what and how we are going to do it. Expectations have been set up in advance, including the business results and other success dimensions for each project stakeholder. The project's vision has then been defined and communicated across all teams to create the right spirit to excite team members and support the creation of competitive advantage.

In order to enhance our operational excellence, strategic focus, and inspiring leadership we have adapted appropriate the organization and processes, which helped us with all execution and monitoring activities.

Additionally, we have also built hierarchical and dynamic plans that were often revised as we moved forward. Strategic project reviews have been conducted in order to reexamine the needs, the strategy and the expectations. All of this helped in creating an on-going learning organization within our project, which helped us winning at the end.

Results

The project was completed on time and within defined budget. Some of the key achievements for the group were:

- Effective, automated quality management solutions
- Estimated 30 % to 40 % reduction in application maintenance costs through system consolidation
- Less hardware required
- Smooth, timely migration of legacy data

- Moving to an Enterprise Quality Management centralized system resulted in an additional business value of over € 142,000

As a result of the successful implementation, the group decided to extend its relationship with us, which led to the establishment of a long term contract for the following 5 years of almost 500,000 € worth.

In Retrospect

One of the main drivers for this amazing success was the fact that managers at all levels have learned a new language to communicate with each other about projects. We have shown executives how to ask the right questions and foresee danger before they make a commitment to the project's steering committee. One of our goals was not just complete the project on time, budget and within performance goals, but also eliminate any "surprises," which might cost thousands of euros. We have set the expectations in advance and ensured that project teams bought-in the "new" mindset, which suggested that deviations from the triple constraint shouldn't always be seen as negative signals that have to be prevented or corrected. Projects teams were often guided in adapting their project management style to the circumstances and environment.

We firmly believe that without using the SPL methodology, tools and processes we wouldn't have had the ability to cope with such a complex and demanding project in a highly regulated environment as well as succeeding in building long term productive relationships with the customer.