Organizational Change Management –
Daiichi Sankyo's Winning Strategy for Global eDMS Implementations

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Overview

Daiichi Sankyo, headquartered in Japan, is a global pharmaceutical company with over 15,000 employees and operations in Japan, the U.S., and the EU. At Daiichi Sankyo, we faced a common industry challenge in balancing the rapid rate of change in technology, increasing regulatory requirements, and the need for improved end user efficiency in the use of information systems to meet the demands of global health authorities.

The company therefore set out to optimize its operations and gain efficiencies in its regulatory submissions globally. A critical component of that optimization was the implementation of a single global information system, a single "source of truth."

This was a major initiative. The system had to support all phases of regulatory document production, including CMC, nonclinical, clinical, labeling, and study-level trial support. It needed to support English and Japanese language submissions in the U.S., the EU, and Japan, as well as in local markets. The processes for producing documents also had to be aligned across regions, with the system configured to support them.

Previously, fragmented systems served one or two functions in a silo and were used by a limited number of countries. But with the implementation of Vault Submissions, we could serve 10-12 functions and span every region worldwide.

Having implemented several global and regional systems in the past, Sobe Good, the head of R&D informatics, knew that end users and executives wouldn't realize the system's full operational or economic value if the organization and business leaders were not fully engaged in both organizational change management and business process engineering. Without this dual focus, an implementation would result in suboptimal configuration, adoption, and use.

> "Companies need to look at optimizing their current business processes in conjunction with helping the organization learn to shift and adopt changes, as part of a holistic approach to system implementations."
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> **Sobe Good, Head of R&D Informatics, Daiichi Sankyo, Inc.**

Informatics – A Specialized Bridge Between Business and IT

At Daiichi Sankyo, informatics plays a critical role in aligning IT and business functions to ensure they understand and support the premise of business transformation as the core of a successful system implementation. Complications arise because IT and business functions essentially speak different languages, and "someone" must translate between these two groups. That "someone" must be in the IT organization, have subject matter expertise, and be able to comprehend business processes so they can serve as the bridge between the two groups. At Daiichi Sankyo, that "someone" is the informatics function within the IT organization.

In our informatics group, a business process engineer always facilitates the process design. Business process engineers work tightly with the business to gather requirements and facilitate the rethinking of the requirements to improve operations. They then translate the optimized business requirements to the technical team for system configuration.

Equally critical to our informatics group is solid management of organizational change. With any system implementation comes process change. These changes must be explained in a manner that allows the business to understand the changes and their value, such that adoption is embraced.

The informatics team also defines and manages a budget to ensure every aspect of the project is given sufficient attention and funding. This includes ensuring that efforts for business process design, system configuration, migration, training, SOP alignment, and change management are all considered upfront as part of the project plan and budget analysis.

Figure 1. The Prosci PCT™ (Project Change Triangle) model illustrates the three elements every project needs to be successful: leadership/sponsorship, project management and change management.

Organizational Change Management – Critical to Successful Implementations

From the onset of our eDMS implementation, we applied a business process engineering and organizational change management (OCM) strategy and framework that provided proven methodologies, tools, and interventions. For this discussion, we focus on the OCM framework, which has several components, each with multiple factors, including stakeholder management, organizational awareness and engagement, global and cross-functional alignment of business requirements, training, and hyper-care.

Stakeholder Management

Stakeholder management is critical to keeping other processes and sub-teams working smoothly. Without continued buy-in from senior executives and alignment with other teams, individual workstreams can go astray or fail to produce. Stakeholder management goes beyond communications and keeping people informed. Instead, it requires deliberate, proactive engagement with thoughtful consideration of what is important to each stakeholder.

In our project, we actively managed relationships with the following four stakeholder groups:

• Executive team: Meaningful communications to senior management.

• Core leadership team: Close communication in weekly team meetings between the informatics and business co-leads with sub-teams, including the business process team, change management team, global representatives, and training services.

• Project team: Cross-functional workshops for decision-making and alignment of processes and deliverables, managed through weekly team meetings.

• Vendor team: Working closely with informatics to understand system capabilities, verify that configurations support the defined business processes, and ensure timelines are met.

Organizational Awareness and Engagement

Communications is the core means to organizational awareness and engagement. One-to-many communications provide a broad reach and help generate the awareness that gets people ready for change. We delivered frequent and consistent communications about the project to individuals on every team impacted by the project. Our approach for organizational awareness and engagement included:

• Hiring an external communications expert to coordinate and write a monthly newsletter to keep people informed and engaged. The newsletter covered project timelines, updates on recent activities and decisions, interviews with project leaders and participants, top ten lists on anticipated benefits, user tips, and more.

• Preparing every function for the upcoming changes with active change management by providing demos at functional meetings, providing updates at global town hall meetings, and by equipping leadership with key messages.

"Change is hard, but that doesn't mean communications need to be dry. Taking a light-hearted approach in the writing style established a positive tone overall. Reading a project newsletter is totally discretionary, so if it isn't fun to read, people won't read it."

Cheryl Ressland, Executive Director, Regulatory Operations, Daiichi Sankyo

• Actively managing resistance by proactively working with key stakeholders to bring them along willingly – as this cannot be forced. We worked closely with people resisting change to turn them around and get them supporting the project, and it made a huge difference.

Figure 2. Engaging communications, written with an informative but light-hearted approach, kept a broad range of project stakeholders informed.

Aligning Global and Cross-Functional Business Requirements

Representatives from many different functions were included in the project. Contributions from across the board were valuable, as they ensured all the details were checked, the new processes worked for all functions globally, and there was a proactive drive for adoption.

Recommendations to align global and cross-functional business requirements:

- Keep the full picture in mind. It is easy to lose sight of the goal when working out the details of a sub-process.
- Connect program deliverables, ensuring silos are not created during the project or within the defined processes.
- Be prepared to negotiate to connect all the pieces.
- Be careful with what you set in motion before you put a stake in the ground.
- Empower employees to come up with creative uses of the new system capabilities and share prior experiences.
- Allow for innovative perspectives.
- Leverage lessons learned to avoid prior pitfalls.
- Allocate enough time for all key team members to contribute.
- Accommodate differences in cultural styles. For leaders, it is important to "listen hard" to all contributors.
- Set standards throughout the project to help drive consistency throughout the process. This will require defining rules and managing controversial discussions around those rules.

Designing for the Majority

The team worked collaboratively to design a system that delivered for the majority of participants involved. Requirements that are deemed "outliers" were managed with smaller focus groups after the initial implementation was rolled out. Designing for the majority does not mean designing just for headquarters. To be successful at this, the business must ensure they define a "global business process" that accommodates regional differences to serve as the foundation for the system requirements. Outliers should be considered separately, after the initial implementation, but shouldn't be forgotten otherwise user adoption will suffer.

Training

Training is a critical component of the overall program and should be prioritized from the start. The business processes and system requirements should form the starting point for training materials. If not, critical details will be lost, and training will offer limited value. For large, complex system implementations, try to avoid a "one-size-fits-all" approach. Your training program should be comprehensive enough to accommodate regional differences, varied learning styles, different roles, and different levels of expertise.

Elements of the training program for our Vault Submissions implementation included:

- Instructor-led training: Ensure the instructor is a subject matter expert and fluent in the business process and system use for cross-functional use.

- e-Learning: Verify that the team developing training materials does so based on the business process, and that the materials are detailed enough to provide sufficient value.

- Printed textbook or guide: Create a detailed booklet that explains every aspect of the process and use of the system for individuals and/or cultures that seek a solid understanding of how to complete specific tasks.

"Training is where the rubber hits the road, and it plays a key role in system adoption. If training isn't well-received, people are less likely to use the system."

Don Costello, Senior Director
Medical Writing, Daiichi Sankyo

eLearning Modules
Users in the West

Instructor-led Training
For champions

Textbook Training
"Read & Understood" training for users in the East

Initial Training
Reinforcement / Reference

Training & Reinforcement Methods

Learning Labs
In-person tutorial sessions driven by business needs

Quick Reference Cards
Step by step instructions for frequent tasks

Mobile App
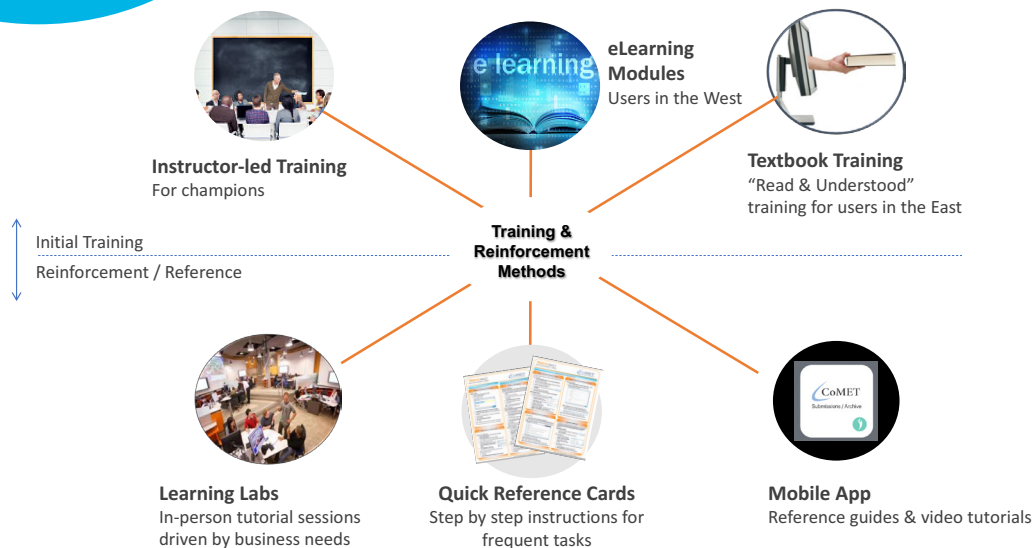Reference guides & video tutorials

Figure 3. A broad range of training materials and formats were provided to accommodate different learning styles and different phases of the learning process.

"Hyper-care" is a critical period of support immediately after go-live that ensures everything (people, process, and technology) runs smoothly. Organizational change management does not end when the project ends. Instead, reinforcement is critical immediately after the implementation to help people use the system optimally.

A hyper-care plan is defined early in the project and should be included in the budget. An effective hyper-care plan continues beyond system go-live and should consider functional and regional needs throughout the process steps.

When making significant changes to process or technology, additional assets or programs are needed during hyper-care to address the breadth of questions and requests that arise. Daiichi Sankyo's hyper-care plan included:

• A help hotline to address technical and business process-related inquires.

• A mobile app to provide quick tips and job aids that help users at the point of need.

• In-person tutorial sessions called "learning labs" for different groups according to their specific business needs.

• Champions from each functional area. These individuals were intensively trained before the system went live. During the implementation, the champions kept their colleagues informed on the progress of the system implementation and expected benefits. After roll out, they answered user questions and served as the go-to person for their functional area.

• New governance committees with defined roles to support all functions and regions with the process and system moving forward.

A Continuous Transition

Making sustainable process improvements is the goal of most system implementations. To achieve this, we invested in business process engineering and organizational change management throughout all three phases of the implementation lifecycle: project start to go-live, hyper-care to stability, and continued evolution with on-going releases. As a result, we completed our implementation of a global enterprise system in under nine months.

We hope the recommendations we've shared will help you succeed with your own initiatives.

This document was derived from a white paper authored by Sobe Good, Cheryl Ressland, and Don Costello at Daiichi Sankyo along with the system implementation provider, Pyxa Solutions