SOLUTIONS

Targeted Solutions for IT Success

SOLUTIONS2PROJECTS

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Targeted Tips

- Consider getting processes under control when trying to satisfy compliance requirements.

- Increase internal adoption of new systems through "behavior modification" campaigns

- Get management to communicate project priority to project participants when trying to achieve an aggressive timeline.

- Always consider the core goals and objectives when balancing cost, time and scope.

Solutions2Projects Continues to Exceed Expectations

Someone once said that the reward for doing good work is more work, and that certainly holds true for Solutions2Projects!

Consistent success has led to a steady stream of requests for our services. To handle the increased load, we are adding new consultants to our team at Solutions2Projects.

Go to the website for updates on this thrilling new expansion - and what it could mean for you!

Good Business Practices Can Satisfy Compliance Requirements

A recent project with a client demonstrated how good business practices can prepare a company for compliance.

Our client determined that they had to get their IT processes under control - a good business practice that would also help them satisfy their Sarbanes-Oxley (SOX) requirements. They decided to leverage a Product Lifecycle Management (PLM) program they had recently purchased and implemented elsewhere in the company. They brought Solutions2Projects in to drive and manage the project, with a very aggressive timeline - design, implementation and validation in just 10 weeks!

As the PLM program was not designed for this application, Solutions2Projects worked with the application consultant to configure the program's workflow to support the company's IT processes. We then worked with the IT group to gather all of the required data, enter it into the system, and validate both the data and the newly configured application.

One part of this exercise required a close examination of the dependencies and relationships between IT objects. The Bill of Materials (BOM) structure within the PLM program was utilized to show these relationships. This would be useful when performing impact assessments, a requirement for future change requests.

While the catalyst for this project was a centralized repository for SOX objects and SOX compliance evidence, the GMP and financial systems also benefit from the company's ability to control IT processes. Additionally, the ability to track system deviations means the company can investigate and document resolutions for future reference and metric reporting.

When the SOX consultant came in to perform the initial walkthrough, she was impressed with the system and the progress achieved in such a short period of time. She saw how easy it was to retrieve evidence, confirm approvals and demonstrate control over policies, procedures, project logs, network topology, and other documentation.

The ability to easily demonstrate compliance revealed that process control isn't simply a good business practice, it's a requirement.

What Does It Take To Meet An Aggressive Timeline?

During project execution, there are three components that can be adjusted: cost, time, and scope. (Historically, quality has been considered an aspect of scope, although it is starting to emerge as a discrete component).

When time is the most critical factor, and cost secondary, there are ways to adjust scope and still achieve success.

- Focus on the most critical outcomes; consider minimizing details to save time. In the SOX compliance case, the initial scope included all IT documents within a BOM structure. Due to time constraints, we planned a multi-phased approach, initially focusing on process flow

Out and About

At Solutions2Projects, we believe that the best way to implement systems in a regulated environment is to establish reasonable processes and adhere to them We understand that every company is different and at varying stages of the drug development lifecycle requiring different levels of formalized processes. We tailor our services to meet individual client needs.

Solutions2Projects offers targeted solutions in:

- *Project Management*
- *Corporate Compliance*
- *Computer Validation*
- *Other services that augment companies' current capabilities*

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Increase Adoption Through "Behavior Modification" Campaigns

What do you do when a new business practice benefits the company and/or a small group within the company, but requires compliance by all employees?

Solutions2Projects encountered this question when our client planned to implement an online timesheet program that would replace an existing system. Both upper management and the employees perceived this new system as a benefit to the accounting department only. The client was concerned that the employees would not enter timesheets consistently, thus jeopardizing the benefits of the new system.

Solutions2Projects determined the best way to address this potential issue was with an internal "behavior modification" campaign.

One week before timesheets were due, we began the program by placing note card reminders, along with a small, edible treat, on each desk. We repeated the reminder again on the day before timesheets were due. Supervisors were given reminders on the day they needed to approve the timesheets. The reminders were bright, quirky, and attractive; the messaging was simple and consistent.

We provided training and individual help when employees had problems entering hours.

This program continued for approximately 8 weeks. The final note card reminder included a small keepsake to encourage continued participation.

The accounting department reported that compliance increased immediately, and has remained higher than the previous timesheet entry program.

Success for this program was attributed to the smart, consistent messaging, immediate issue resolution for new users, as well as supervisor accountability, all of which contributed to and resulted in the newly desired behavior.

What Does it Take to Meet An Aggressive Timeline?

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and BOM structure, leaving the remaining documentation for later.

- Get top priority from management and minimize obstacles for project participants.   In the SOX case, we had IT management communicate the project priority to the team and we worked with participants in a way that worked for them.

- Engage strong project management to keep the focus and priorities on the core objectives and goals. In the SOX case, we ensured that the priority remained on the project and that the team stayed focused on completion.

While setting priorities can seem like a sacrifice, maintaining focus on the core objectives can help ensure the company objectives are met within existing constraints.