

# SOLUTIONS

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**Targeted Tips**

- Consider change management at the beginning and throughout the project.
- Ensure consultants are familiar with your industry.
- Define requirements in advance of project—not as the project advances.
- Validation is a process that starts at the beginning of the project.

## FIRST YEAR ON TARGET FOR SOLUTIONS2PROJECTS

In one short year, Terri Mead has demonstrated that a targeted approach to projects in the biotechnology and bio-device industries can lead to faster, more efficient project execution. Key successes include:

- ERP implementation in just 2.5 months

- Accelerated enterprise-wide system implementation at an emerging bio-device company

Both of these contracts resulted in follow-up work including an HRIS implementation and projects to add functionality to ERP and PLM systems.

With projects scheduled through the end of the calendar year, Solutions2Projects is growing and expanding its consultant base to ensure capacity to meet increasing demand for targeted project management within the life sciences industry.

## CHANGE MANAGEMENT: HOW IMPORTANT IS EMPLOYEE BUY-IN?

Change. Many employees fear change. Not because it's necessarily a bad thing, but because there are so many unknowns. Employees can feel left out of the decision-making process, which leads to resentment. Indifference is common, especially when employees don't have a complete understanding of how integral they are to the success of a new system. Keys to reducing fear and resentment associated with major change include:

- Managing expectations
- Providing education
- Ensuring everyone knows the benefits of a new system

Solutions2Projects recently identified the need for corporate-wide buy-in at an emerging bio-device company. They were contracted to assist in validation activities associated with a new product lifecycle management system, but observed that many of the employees who would be using

the system did not understand it and were not interested in it.

Solutions2Projects hired a marketing consultant to create and execute an internal marketing campaign, complete with posters, games, prizes, and parties, all of which coincided with training. At the end of the campaign, when the system went live, there was significant buy-in throughout the company, even by employees who would be using the system infrequently!

While the campaign was a huge success, the company would have been better served if it had begun this process at the beginning of the project, not in the middle. This could have prevented the fear and resentment from which they had to recover.

Bottom line: if a new system is vital to the success of the company, change management is critical throughout the project.

## CONSULTANTS : SHOULD THEY KNOW YOUR INDUSTRY?

What's so different about biotech and bio-device that a consultant needs to specialize? Compliance issues for starters. Other high tech industries may follow ISO or other documentation standards, but when the FDA is involved, it becomes a regulatory issue, not just a marketing tool.

Consultants who specialize in the industry understand the long term effects of compliance and regulatory issues, allowing them to make recommendations based on best industry practices. They understand that time to market is important, but docu-

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**We're on the web!**  
**Solutions2Projects.com**

### Targeted solutions for IT success

*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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## WHY BOTHER WITH SYSTEM REQUIREMENTS?

How do you know when a project is complete? How do you know it was successful? How do you keep it on track? Who needs to be involved? These questions are easy to answer, if you think about them at the beginning of a project.

This may be intuitive, but a lot of companies are too anxious to begin or get too busy to really define a new system's requirements. In some cases, a system is purchased for one purpose, but then applied to an-

other, without redefining the requirements.

When you document requirements ahead of time, you are able to:

- Establish a target: what does a successful end look like?
- Identify cultural and procedural changes: what needs to happen internally for everyone to buy in?
- Prioritize resources: who needs to be involved and do

they have time to participate?

- Control the scope and maintain a schedule: what are the priorities?
- Identify appropriate deviations and minimize time spent resolving issues: what do we need and what can we live with?

Having a clear target at the beginning means you know what you achieved in the end.

## VALIDATION: IT MAKES SENSE

Validation is not only required, it is a logical process: a controlled and documented implementation is a good business practice. Validation proves to an FDA auditor that a company can rely on its system. In biotech, if it isn't documented, it doesn't exist.

System requirements drive validation, meaning the best time to define validation is at the time requirements are identified — at the beginning. Deliverables include a master validation plan, protocols, requirements and configuration documents, and a traceability matrix. Defining

these at the beginning prevents delays during the project and ensures effective testing can be performed.

Effective validation does more than save time and money; it confirms your systems meet your business needs.

## CONSULTANTS : SHOULD THEY KNOW YOUR INDUSTRY?

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mentation and control are even more critical to satisfying industry

and government requirements. And because they understand the terminology, regulatory requirements, generally accepted prac-

tices, and the priorities, they can help companies make the most effective choices for their industry and application.