



# STAKEHOLDER ENGAGEMENT

**MANAGING STAKEHOLDER EXPECTATIONS  
DURING CHALLENGING SITUATIONS**

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## MANAGING STAKEHOLDER EXPECTATIONS DURING CHALLENGING SITUATIONS

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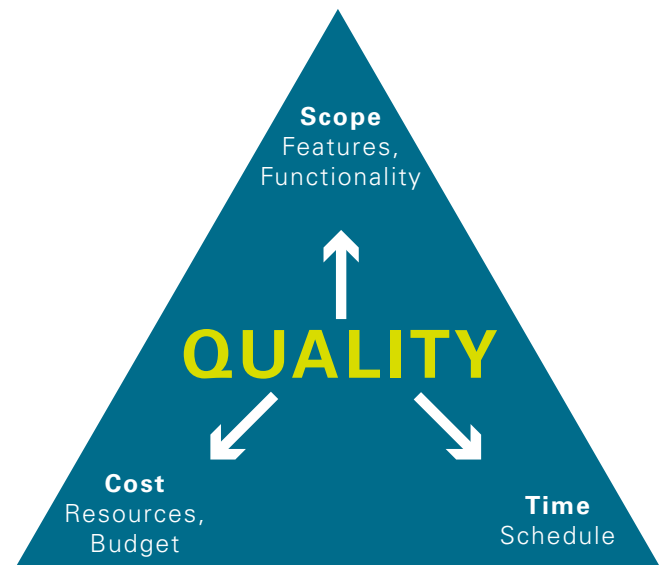
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# STAKEHOLDER ENGAGEMENT

## MANAGING STAKEHOLDER EXPECTATIONS DURING CHALLENGING SITUATIONS

### ABSTRACT

When projects do not achieve stakeholders' expectations and goals are not sufficiently specified and managed, the result can appear to be a failure. With proper stakeholder engagement and when clear, defined objectives are stated at the beginning of the project, you can achieve a successful outcome. Success is not based on all stakeholders getting everything they want in a solution, it is achieved by meeting the triple constraint of Scope, Time, and Budget to produce a quality outcome.





## INTRODUCTION

Stakeholder expectation management is a critical aspect of the successful deployment of a Regulated GxP (Good Manufacturing Practices, Good Clinical Practices, Good Laboratory Practices) software application in the biotechnology industry. This white paper outlines the importance of stakeholder expectation management and provides guidance for capital project managers to effectively engage stakeholders throughout the deployment process.

## PROBLEM STATEMENT

### WHY IS STAKEHOLDER MANAGEMENT IMPORTANT?

Stakeholder management ensures that all parties involved in the deployment process are aligned with the project goals and objectives. This includes end-users, internal stakeholders, and external stakeholders such as regulatory agencies. By engaging stakeholders effectively, project managers can avoid delays, minimize disruptions, and ensure GxP software applications are deployed successfully.

## SOLUTION

### WHO ARE THE STAKEHOLDERS?

Stakeholders can be divided into several categories:

**End-Users:** These are the people who will use the GxP software application on a daily basis. They have a direct impact on the success of the deployment and must be engaged and involved throughout the process.

**Internal Stakeholders:** These are the individuals and departments within the company who will be impacted by the deployment. This includes digital, operations, and quality control.

**External Stakeholders:** These are regulatory agencies and other organizations who must be consulted and informed about the deployment.

Consider the three major activities a project team performs to understand and plan for stakeholders are as follows:

**Stakeholder Identification:** As with risk management, the first step is to know all the potential stakeholders.

**Stakeholder Response Development:** Determine what the stakeholders expect and create a strategy for collaborating with them.

**Continuous Stakeholder Relationship Management:** Engage at the appropriate level with each stakeholder throughout the project.

The approach to stakeholder management is often similar to the way risk management is approached. The parallels to risk management begin with the three-step process stated above. The most important aspect of this undertaking is that following this process means that stakeholder management is a proactive activity rather than a reactive one.



## STAKEHOLDER ENGAGEMENT

**Communication:** Regular and effective communication with stakeholders is key to successful stakeholder engagement. Project managers should establish clear communication channels and provide regular updates on the progress of the development and deployment.

Various communication tools can be utilized to maintain stakeholder engagement:

- Emails (Push Communication)
- Project Charter (Pull Communication)
- Landing page for FAQ
- Team Channels for Asynchronous updates
- Direct communication with stakeholder for document approvals
- Daily Stand-Up meetings (DSU) (Large Team) using Communication and Collaboration platforms (Teams, Zoom, WebEx, Slack, etc.)
- Daily coordination meetings (System Owner (SO), Business Process Owners (BPO), Project Manager (PM))
- End of Day Synchronization meetings (next day's project deliverables)
- Collaboration Tools
- Weekly Flash reports (Push Communication)
- Instant Messaging (IM) Channels
- Bi-daily Critical Deliverables updates and status

**Engagement:** Project managers should engage stakeholders early in the deployment process and involve them in decision-making and planning. This will ensure that stakeholders are invested in the project and that their needs and concerns are addressed and resolved. Having effective stakeholder engagement will allow for effortless transitions during various project phases.

Maintaining stakeholder engagement during project interruptions, such as delays in the delivery of infrastructure or delivery of application development, is imperative for the success of the project. The project team must be informed of adjustments made to the schedules, to account for those disruptions. It is the Project Manager's responsibility to employ agile methodologies in order to determine if efficiency can be gained within timelines to deliver the project on schedule.

**To ensure proper stakeholder expectation management, the following tools should be implemented:**

**Stakeholder Communication Plan:** Outlines the strategies for managing various Stakeholders' expectations and involvement.

**Stakeholder Register:** Will list Stakeholders and their relevant responsibilities to the project.

**Issues Log:** Will track differences and/or unresolved matters to outline plans for resolutions.

**Change Log:** Will document all changes made during the project, along with their impact on the various constraints.

**Action Tracker:** Documents changes required during the project or future enhancements.

Future road-mapping is managed through the implementation of a Continuous Improvement Program. This program will make certain that enhancements to the application are applied in a timely manner to meet the needs of the end users.

## **COLLABORATION**

Collaboration between stakeholders is essential for a successful enterprise application deployment. Project managers should encourage stakeholders to work together to share information and best practices throughout the project.

Coordination within the entire project team during times when key stakeholders are leaving or joining the project is also crucial to project success. Turnover of resources should be anticipated to ensure the project is not delayed. The project manager is responsible for making certain new resources are well informed, having an initial one-on-one meeting to verify they understand the scope of the effort, they are added to the

project communication channels, and are part of the updated organization chart with their role and responsibilities clearly defined.

When a stakeholder leaves the team, the project manager should have a close out meeting to solicit project feedback and lessons learned. The project manager will also verify the status of assigned deliverables, transfer work efforts to other project team members, and update organization charts and communication channels. The departing stakeholder should also be recognized among their peers for the contribution they made to the project effort through rewards and recognition.



## CONFLICT RESOLUTION

Conflicts between stakeholders can arise during the deployment process. Project managers should have a plan in place for resolving conflicts and should be prepared to facilitate discussions and negotiate compromises. You can employ the following methods, individually or in a combination, as the Project Manager in order to resolve differences within the project team.

**Collaboration:** Working together to find a mutually beneficial solution.

**Compromise:** Finding a solution that partially satisfies both parties.

**Accommodation:** Including stakeholders requests where possible.

**Smoothing:** Emphasizing areas of agreement while delaying decisions on areas of conflict until more information is available or the decision must be made to prevent impact to the project.

**Competition:** Making an executive decision based on the perceived best interests of the project.

**Withdrawal/Avoidance:** Moving a request or change to a new project or different project phase.

Each of these methods can be effective in different situations, and it is important for project managers to be able to assess and choose the appropriate method based on the specific conflict they are facing. Project managers can also determine the proper methods to resolving conflict based on what approach is most compatible with the stakeholders involved in the dispute.



# CONCLUSION

Stakeholder expectation management is a critical aspect of the successful deployment of a GxP software application in the biotechnology industry. By engaging stakeholders, communicating effectively, encouraging collaboration, and resolving conflicts— capital project managers can ensure that the deployment is successful. This management style values that software vendors, system integrators, application system owners, client business process owners, validation, and quality are all aligned with the project goals and objectives; encouraging all parties involved in the project to cross the finish line together as a collaborative team.

## ADDITIONAL RESOURCES

1. *Managing Expectations*  
Baker, E. (2006). It's all about ME (managing expectations)! Paper presented at PMI® Global Congress 2006—North America, Seattle, WA. Newtown Square, PA: Project Management Institute.
2. *Stakeholder Management Strategies*  
Verzuh, E. (2005). Stakeholder management strategies: applying risk management to people. Paper presented at PMI® Global Congress 2005—North America, Toronto, Ontario, Canada. Newtown Square, PA: Project Management Institute.
3. *PMBOK® Guide (2021)*.





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Kevin has extensive experience as a project manager leading project in Process Controls Systems, Manufacturing Execution Systems, Compliance & Validation, and Batch Automation for industrial processing implementations. Applying his background and knowledge of S88 batch control standards and S95 MES/Automation control to enterprise integration standards in regulatory environment industries.

Kevin has developed automation, cGMP, GAMP, and CSV business processes. Performed vendor audits,

evaluations and selections, data integrity assessments, and implemented remediation for clients.

Kevin is an organized, energetic, and personable Senior Project Manager with Thirty years of experience covering the fields of Customer Program Management, Resource Management, Portfolio Coordination, Project Management, Information Technology, and Electronics Engineering Technologies. His background includes industries of Biosciences, pharmaceuticals, Manufacturing, and University environments.