# Avoiding the Biggest Pitfalls When Managing Complex Pharma Projects <sup>1</sup>

### Shannon Keenan

When we think of being successful in the pharmaceutical and biotech industries, we immediately think of the need for strong scientific or technical capabilities. And that's certainly a big piece of the puzzle. But to bring an idea to reality in these sectors also requires exceedingly strong project coordination and execution skills.

Each step of the way—from early discovery to product launch—mission-critical projects typically involve cross-functional teams spanning business and therapy areas. I've seen this firsthand over the past 25 years, leading countless pharma and biotech programs and projects. Project management may seem fairly straightforward, and most people think they know how to do it. But in reality, it's an intricate dance that requires a focus on much more than simply executing deliverables on time and on budget. The high degree of regulation and complex global matrices in these industries only increases the complexity of managing these projects.

Let me give an example. We were brought in to help a pharma client prepare for a significant regulatory meeting encompassing various therapy areas. This meeting was pivotal, as it involved discussions with governmental agencies regarding the approval of several medications. Also critical was how that information coming back from the regulators was conveyed to the various stakeholders in the company.

There were multiple therapy areas represented at the meeting that collectively had more than 100 stakeholders. The challenge lay in ensuring that each representative accurately conveyed the details of the meeting to their respective therapy areas without succumbing to the pressure of delivering information hastily and incompletely. With multiple stakeholders involved, we also ran the risk of inconsistencies in reporting and communication.

It was clear that we needed a highly structured approach to managing this project. While each stakeholder had their own priorities and perspectives, it was crucial to align everyone towards a unified goal in how the information was disseminated.

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We implemented a comprehensive communication plan that delineated roles, responsibilities, and timelines for each stakeholder. We established clear expectations and standardized reporting templates to ensure consistency across the board.

By adopting this structured approach, we were able to minimize the chaos and confusion that often plague such high-stakes meetings. Our efforts not only enhanced the efficiency of communication but also mitigated potential stress and confusion among team members.

I've encountered a myriad of challenges when it comes to managing complex projects. Whether you're leading drug discovery or preparing a market launch, you'll need seamless coordination across diverse teams and disciplines. Here are some of the major pitfalls to watch out for:

#### **1.** Communications Breakdowns: Bridging the Gap

I've seen too many times how disjointed discussions across various meetings can lead to confusion and inefficiencies. That's why I stress the significance of establishing clear communication protocols from the outset. By defining objectives, identifying stakeholders, and implementing a unified communication strategy, teams can ensure alignment and foster a collaborative environment conducive to success.

This is an especially acute concern today in the era of virtual and hybrid work, when we have more options at our disposal for communicating than ever. Some of us prefer email, some swear by IM, some need face-to-face interaction in a meeting. Make sure you understand what communication style works for those around you, and plan accordingly to bridge gaps to reduce the risk of misunderstanding. In today's environment, it's almost never a bad idea to err on the side of overcommunication.

#### 2. Scope Creep: A Silent Threat

The gradual expansion of project objectives beyond the initial scope can easily send complex projects veering off course.

It's essential to rigorously define the project at the outset and actively manage change requests to prevent scope creep from wreaking havoc. Through robust change control processes and ongoing stakeholder engagement, teams can prevent protracted timelines and adhere to the original objectives. One way to flag potential distractions is to refer back to Day One and remind the team: What's our overall goal here? What does success look like? Does this contribute to that outcome?

#### 3. Failure to Develop a Mitigation Plan: Anticipating Challenges

Risks are inevitable. But failing to anticipate and mitigate these risks can have dire consequences. That's why I advocate for the development of a comprehensive mitigation plan.

For example, a new regulation or an audit from a regulator can impact the charter or timeline. Creating a risk log, or "raid" log (risks, actions, issues, and decision), and categorizing the type of risk and the escalation procedures is a great way to prioritize and address the mitigating actions.

Whether you're working with teams of 20 or 200, navigating complex pharma and biotech projects requires more than just technical expertise—it demands clear communication, vigilance against scope creep, and proactive risk-mitigation plans. Only with those pieces in place can project managers lead successful initiatives.

## About the Author



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