Product Development

A FOCUS ON COLLABORATION

Gets CMC Back on Track, Increases Efficiency, & Solidifies a Round of Funding

The product development timeline for a new pharmaceutical is fragile. If one link in the chain breaks, it delays everything else, including clinical trials, regulatory approvals, and getting life-enhancing therapies to patients. And a delay can negatively affect company reputation and investor interest as well.

For example, a startup biopharma company had fallen behind on its clinical manufacturing goals prior to a Phase 3 study. If it couldn't meet the clinical study deadlines, it would be hard-pressed to launch on time. The company was at risk of losing its next round of funding for its lead asset as well as the reputation it was trying to build. And patients in need of a life-saving drug for a liver disease would go without.

WHAT WENT WRONG?

First, the company did a lot of things right, including hiring knowledgeable and experienced staff. As in many startups, however, a lot of the talented people were also inexperienced communicators. They built a culture that didn't share robust information.

The information they did share was a timeline housed in a massive MS Project document. However, at more than 2,600 lines, the timeline was too big to be useful. There was little confidence the milestones were achievable because there were no risks or assumptions documented. People stopped looking at the timeline, and nobody was tracking progress.

Because they didn't communicate with each other, teams worked in silos. The experienced employees in chemistry, manufacturing, and controls (CMC) did good work but didn't collaborate with other functions. They didn't consider other teams or their impact on the timeline. Add to the equation the timing: It was during the height of pandemic-related supply chain problems. If the active pharmaceutical ingredient (API) team was struggling to get a raw material, they weren't letting the drug product team know, impacting manufacturing resources and contracts. The outcome: CMC delayed clinical trials because they didn't have the clinical drug supply ready in time.

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A 'SOFT' APPROACH TO HARD DEADLINES

The company enlisted Integrated Project Management Company, Inc. (IPM) to get manufacturing back on track so it could meet its development timelines. (And so the company could retain the confidence of its investors.)

The first order of business was to build relationships among the different functions. IPM found the teams had the right expertise, so its program manager started building connections. To get people sharing information and working together, he created healthy communication channels. For example, he led weekly team meetings with CMC functions, adjacent functions, and senior management. The meetings created transparency and alignment on key milestones and began to shift the culture to one of collaboration.

To make the timeline more useful, the program manager broke it down into multiple (but integrated) timelines, such as clinical operations and regulatory. He also developed an integrated process map to show how functions impacted each other. Together, the team pressure-tested the timeline.

IPM's program manager developed processes and tools to capture risks, issues, and assumptions. This drove accountability and ensured that the team analyzed assumptions and identified and mitigated any risks. (In the past, the company had only considered the best-case scenario. When there was a problem, there was no Plan B. For example, manufacturing was contracted out to a company in China, which risked product availability.) The program manager led the team through several scenario planning sessions.

Risk management and scenario planning gave CMC more confidence in the accuracy and achievability of the milestones. It also built confidence among management and other stakeholders. In fact, the team's scenario planning helped the supply chain director with forecasting and helped build the relationship between CMC and purchasing.

Brainstorming workshops helped to develop new workflows to achieve objectives. Weekly sprints helped to accelerate deliverables, focus on priorities and accountability, and bring the project back on track. With everyone working with the same information and goals, they were able to make better and faster decisions.

GETTING THE JOB DONE

Established collaborations and communications—as well as customized tools for more effective execution—improved team efficiency. Durations between critical milestones, such as ordering raw materials to drug product readiness, were reduced by 60 percent. CMC was out of the critical path and no longer hindering progress.

Developing trust and mutual respect removed the silos within the company and helped CMC transform into a high-performing team. The department evolved into a dependable partner to other functions within the company. And, importantly, the company successfully manufactured the drug product on time to support Phase 3 clinical trials.

IPM left the company with robust processes and procedures in place for CMC to meet current and future demands of the company's vision. Collaborative work, brainstorming sessions, and scenario planning workshops have become a norm in the department and continue to improve decision making and efficiency. As of press time, the liver disease drug development is still on track and its investor funding is secure.