

Optimizing the NMPA Submission Package Preparation Process with Structured Project Management

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ABSTRACT

A structured and disciplined project management approach was implemented to optimize the preparation process for NMPA submission package, achieving significant efficiency gains. Key success factors included clearly defining the roles and responsibilities of sponsors, project leader, and core team, complemented by fostering a shared vision and goal ownership through scope-based team selection, consistent and effective communication. Interdependencies were identified, and critical path analysis enabled the creation of an integrated project plan. The team developed detailed subgroup action plans that linked key deliverables to project objectives. A high-level project timeline with key milestones was established, providing a foundation for monitoring and refining progress through regular reviews. Scope creep was systematically mitigated during regular reviews, ensuring alignment with project objectives.

Through cross-functional collaboration and a disciplined approach to project management, the preparation timeline for NMPA submission packages was successfully reduced from 22 weeks to just 10 weeks. This outcome demonstrates the power of structured methodologies to drive efficiency, enhance team alignment, and deliver transformational results in business processes.

INTRODUCTION

Driving a cross-functional collaborative project is inherently complex and demands robust leadership, clear communication, and meticulous planning. Many organizations face numerous challenges that threaten the successful execution of such projects. Common failure modes include poor project leadership skills, lack of sponsor support, unclear project scope, insufficient team alignment, weak communication processes, and uncontrolled scope creep. These obstacles can significantly hinder progress and jeopardize project outcomes, particularly within organizations operating in highly regulated industries.

This paper focuses on a cross-functional project—optimization of the preparation process for National Medical Products Administration (NMPA) submission packages—a critical and time-sensitive regulatory task. Historically, the preparation process for NMPA submission packages spanned an average of 22 weeks within the author's organization. However, through the application of structured project management methodologies and collaborative team efforts, the timeline was successfully shortened to just 10 weeks.

The purpose of this paper is to analyze the structured approach implemented in this cross-functional project, identify the key principles that contributed to its success, and highlight essential methods to drive team collaboration. By systematically addressing the aforementioned failure modes and fostering alignment across project roles, the team overcame barriers and achieved transformational process improvements. The discussions presented in this paper aim to provide readers with practical insights into effective project execution strategies that can be applied to optimize other complex, cross-functional initiatives.

TEAM STRUCTURE & GOVERNANCE

An effective team structure with clearly defined roles, responsibilities, and accountabilities is foundational to the success of any project. In the context of optimizing the preparation process for the NMPA submission packages, establishing a robust governance framework ensured seamless execution and alignment across stakeholders. This section discusses the team structure adopted for the project and the critical roles that contributed to its success.

TEAM STRUCTURE

The project adopted a dual-layered team structure that balanced continuity and flexibility with one sponsor and one project leader:

- **Core Team Members (CTMs):** These individuals were responsible for specific project deliverables and remained engaged throughout the entire duration of the project. This ensured stability, accountability, and consistent focus on delivering key objectives.
- **Extended Team Members (ETMs):** These individuals were brought in as needed to provide expertise or resources for specific deliverables. They stepped in and out of the project based on their assigned tasks, allowing for scalable resource allocation without overburdening the Core Team.

ROLE OF THE SPONSOR

The Sponsor played a pivotal role within both the project team and senior management. As the chief advocate for the project, the Sponsor had multiple responsibilities that ensured the project stayed on track:

Setting Clear Expectations: The Sponsor provided a clear vision for the project outcomes, emphasizing that the final delivered process must enable submission package readiness within 3 months following the first worldwide submission. The Sponsor also stressed minimizing the gap between readiness and the first worldwide submission to optimize timelines.

Controlling Scope Changes: One of the most significant challenges faced during the project was managing scope creep. During a Steering Committee review meeting, a senior manager proposed expanding the project scope to include additional dossiers, which threatened to delay the deliverables. The Sponsor stepped in, reinforced the project principles, and pushed back the proposal, effectively mitigating the risk of scope creep and preserving project timelines.

Securing Resources: Cross-functional projects like this often require diverse expertise and resources. The Sponsor worked closely with the Project Leader to secure the necessary resources, including budget allocation, personnel assignments, and time commitments. The Sponsor also identified and engaged key functional stakeholders, ensuring their inclusion as Core or Extended Team Members, as appropriate.

Maintaining Communication: The Sponsor maintained open and periodic communication with the Project Leader to provide support for risk mitigation and conflict resolution. This consistent dialogue ensured that challenges were addressed promptly and that the Sponsor remained actively engaged in removing barriers to success.

ROLE OF THE PROJECT LEADER

The Project Leader was fully accountable for leading the team and ensuring the delivery of the final project objectives. Their responsibilities included:

Team Alignment & Motivation: The Project Leader worked to align and motivate team members, fostering a collaborative environment where all contributions were valued. Regular recognition of team efforts was integral to sustaining morale and engagement.

Relationship Management: Managing the relationship with the Sponsor was a critical aspect of the Project Leader's role. Regular progress reviews with the Sponsor ensured alignment on objectives, resource needs, and risk management priorities.

Establishing Roles & Responsibilities: Within the team, the Project Leader collaborated closely with members to define clear roles and responsibilities, ensuring that everyone understood their accountabilities and how their contributions tied to the broader project success.

Progress Tracking & Risk Management: The Project Leader proactively tracked and assessed progress, ensuring the project remained on schedule. They also led the team in identifying, mitigating, and managing risks to navigate challenges effectively and avoid delays.

TEAM ALIGNMENT

Team alignment is a continuous process that focuses on building commitment and accountability within the team and the organization towards shared goals. Effective alignment is not a one-time activity but

rather a sustained effort that promotes a shared vision, ownership of goals, mutual trust, and a clear understanding of roles and responsibilities. Furthermore, alignment is instrumental in protecting the team from scope creep by continuously realigning expectations, objectives, and project constraints. This section discusses how the project team achieved alignment and the principles, methods, and timing that made it successful.

HOW TO ALIGN

Achieving team alignment requires both structured conversations and intentional interpersonal engagement. The following practices proved critical in fostering alignment during the project:

Do's:

Prepare and Drive Meaningful Conversations: The Project Leader and Sponsor prepared thoroughly for alignment discussions by addressing doubts and highlighting shared values. This proactive approach mitigated uncertainties and reinforced alignment on core project objectives.

Connect Individually: Regular one-on-one interactions via face-to-face meetings, phone calls, or video conferences were prioritized over emails or texts. These personal connections helped explore individual emotional commitments and business interests, building trust through human interaction.

Listen Neutrally: The team emphasized understanding each member's perspective and motivations without judgment to create an atmosphere of collaboration.

Confirm Understanding and Summarize Agreements: Frequent check-ins ensured that all team members shared the same understanding of objectives, actions, and progress. Agreements were summarized and confirmed to reinforce alignment.

Conflict Resolution: The Project Leader actively sought opportunities to resolve conflicts, maintaining harmony and focus within the team.

Don'ts:

Avoid Shutting Down Discussions: Open dialogue was encouraged even when differing opinions arose. Disagreeing or feeling uncomfortable with the message did not hinder meaningful discussions.

Do Not Assume Alignment Based on Silence: Silence was not treated as agreement. The Project Leader ensured that all team members explicitly conveyed alignment to avoid ambiguities.

Remain Vigilant for Changes: Early alignment was not assumed to persist; instead, the team remained agile to adapt to the dynamic nature of the project.

WHAT TO ALIGN

Three key elements were prioritized during the alignment process to ensure the shared focus and successful execution of the project:

Project Scope: Defining the boundaries of the project—what is included and what is not—was critical in avoiding scope creep. The Sponsor and Project Leader refined the scope by collecting input from Key Stakeholders. When scope changes were requested during the project lifecycle, these were treated as proposals rather than mandates and evaluated collaboratively within the team. The Sponsor retained the ultimate authority to approve or reject changes, ensuring that any modifications did not compromise the project timeline or objectives.

Final Project Objectives (FPOs): Specific and quantifiable goals were aligned with the team before execution to define success using SMART criteria: Specific, Measurable, Achievable, Relevant, Time-bound. FPOs served as the "contract" between the Core Team and Sponsor, guiding decision-making and tracking performance throughout the project. By providing clear metrics of success, FPOs reinforced accountability and cohesion within the team.

Key Deliverables: Key Deliverables represented specific accountabilities assigned to Core Team Members, aligned by function and project phase. These deliverables ensured that all critical tasks were assigned and tracked, empowering each team member to take ownership of their commitments. Even

when work was delegated to Extended Team Members, the responsible Core Team Member maintained their overall accountability.

WHEN TO ALIGN

The Kick-off Meeting was the most significant alignment event in the project journey, serving as the foundation for building a unified team. During this meeting, the Sponsor, Core Team Members, Functional Managers, Key Stakeholders, and Extended Team Members came together to achieve alignment on the following:

Project scope and Final Project Objectives.

Key Deliverables and individual accountabilities.

Communication channels and expectations for collaboration and reporting.

By focusing on alignment early in the project lifecycle, the Kick-off Meeting established the shared understanding and mutual trust essential for success. However, team alignment was continually reinforced throughout the implementation phase, particularly during Steering Committee reviews, where adjustments were made to expectations, objectives, and plans as new challenges were uncovered.

SUBGROUP PLANS AND INTEGRATED PROJECT PLAN

To ensure the success of any complex project, translating high-level objectives into actionable, detailed plans is essential. In the NMPA submission package preparation project, the implementation of structured action plans at the subgroup level—combined with the development of an Integrated Project Plan—played a critical role in aligning efforts, identifying interdependencies, and maintaining focus. This section discusses how these two levels of planning were implemented, their interrelation.

SUBGROUP ACTION PLANS

At the core of the project's execution was the development of subgroup action plans by each subgroup. Core Team Members (CTMs), who is also the leader of subgroup, took ownership of their respective Key Deliverables by creating detailed plans that outlined the tasks needed to achieve these deliverables. Each action plan included:

Task Breakdown: Clear identification of individual tasks required to complete the Key Deliverable.

Timelines: Start dates, end dates, or task durations for each activity were carefully defined.

Dependencies: CTMs identified interdependencies between their tasks and those of others, ensuring alignment with related deliverables.

Risk Mitigation: Each team member proactively outlined potential risks and proposed mitigation strategies specific to their deliverables.

By empowering CTMs to own their action plans, accountability was embedded directly at the subgroup level. This approach also allowed for the delegation of specific tasks to Extended Team Members (ETMs), where applicable, without compromising the CTMs' overall accountability for completion.

This decentralized planning approach ensured that the project's progress was driven collaboratively while reducing bottlenecks often associated with top-down task allocation.

INTEGRATED PROJECT PLAN

Following the completion of individual subgroup action plans, the Core Team worked collaboratively to develop an Integrated Project Plan (IPP). The IPP was a holistic schedule that mapped the project's critical path and interdependencies between Key Deliverables. The development of the IPP included the following stages:

Consolidation of Action Plans:

The Project Leader facilitated a workshop where all Core Team Members reviewed their subgroup action plans collectively. Tasks were sequenced to establish predecessor-successor relationships, visualizing the flow of work across the team.

Identification of the Critical Path:

The IPP identified the longest sequence of dependent tasks (the critical path), which ultimately determined the project's total duration. Critical path analysis helped prioritize tasks and identify high-stakes deadlines that needed close monitoring.

Adjustment of Schedules:

Based on insights from the critical path analysis and interdependency mapping, task durations and deadlines were refined. Aligning timelines across all functions ensured that no task delay would cascade into broader disruptions.

Periodic Updates:

As the project progressed, the IPP served as a living document that was continually updated to reflect ongoing changes, emergent risks, or newly surfaced dependencies. Regular reviews of the IPP allowed the team to remain agile and responsive to challenges.

INTERPLAY BETWEEN SUBGROUP PLANS AND THE IPP

The subgroup action plans served as foundational building blocks for the IPP. While action plans focused on delivering specific Key Deliverables, the IPP provided the macro-level view needed to ensure cohesion and integration across all project activities. This two-tiered system created a structured yet flexible framework for project execution:

The action plans ensured task-level transparency, accountability, and ownership.

The Integrated Project Plan enabled the team to monitor interdependencies, identify risks at a higher level, and make timely adjustments.

This dual approach bridged detailed execution with strategic oversight, ensuring alignment between individual efforts and the overarching project objectives.

COMMUNICATION AND EXECUTION

Effective execution is the synthesis of meticulous planning, structured communication, and disciplined team coordination. In the NMPA submission package preparation project, two key practices—clearly defined communication channels and structured Core Team Meetings—were integral to maintaining focus, addressing challenges, and delivering results. This section highlights these execution practices.

COMMUNICATION CHANNELS

Clear and effective communication was a cornerstone of the project execution strategy. Well-defined communication channels were established across various relationships within the project team to ensure information flowed seamlessly and the right messages reached the right people at the right time. Key communication processes included:

Sponsor and Core Team Members: The Project Leader (PL) served as the primary channel of communication between the Sponsor and the Core Team. This ensured that the Sponsor's input and guidance were conveyed to the team efficiently while escalating relevant issues, risks, or approval requests to the Sponsor for resolution.

Core Team Members and Extended Team Members: Each Core Team Member (CTM) was responsible for relaying project updates, expectations, and action items to their respective Extended Team Members (ETMs). This ensured proper collaboration while maintaining accountability at the Core Team level.

External Stakeholders: Defined communication channels with external stakeholders, such as regulatory or functional groups outside the immediate team, ensured that outreach was timely and appropriately managed by the designated team member.

Escalation Processes: Escalation mechanisms were clearly outlined, allowing team members to raise issues or potential risks at the appropriate level. Escalation processes minimized delays in decision-making and ensured all issues were addressed by the right stakeholders without creating unnecessary bottlenecks.

By establishing these channels, the project avoided common breakdowns in communication, such as misinterpretation of messages or delayed escalation of issues. This structured approach maximized efficiency, minimized duplication, and preserved team cohesion.

CORE TEAM MEETINGS

Core Team Meetings (CTMs) served as the central hub for project coordination and were critical to ensuring alignment among all team members during the execution phase. Led by the Project Leader, these meetings were regularly scheduled and properly structured to address multiple aspects of project progress. The main objectives of these meetings included:

Communicating and Tracking Progress of Key Deliverables:

The team discussed the progress of Key Deliverables and addressed the impact of interdependencies on individual action plans. This promoted transparency and helped ensure all tasks stayed on schedule.

Capturing Follow-ups:

Previous follow-ups were revisited to verify completion, and new follow-up actions were identified and assigned as necessary. This ensured accountability for all outstanding tasks and next steps.

Reviewing Project Objectives:

The overall health of the project was evaluated through high-level status updates. Metric reviews—comparing actual progress against planned targets—provided insights into potential variances and areas requiring additional focus.

Communicating Risks and Mitigation Status:

Identified risks were discussed, along with mitigation actions and their implementation status. This forum enabled proactive risk management and continuous refinement of the project execution strategy.

To maximize the efficiency and effectiveness of Core Team Meetings, the following best practices were implemented:

Structured and Routine Format: Meetings adhered to a standardized structure, including a pre-defined agenda, a tracker for follow-ups and commitments, and detailed meeting notes. This format kept the discussions focused and promoted accountability for deliverables.

Agenda and Notes Accessibility: Agendas, participation trackers, and meeting notes were shared as inline content in emails (rather than attachments). This practice made it quick and easy for participants to access critical updates and commitments at a glance, boosting efficiency and engagement.

Facilitation Discipline: The Project Leader emphasized time management, guided discussions to remain on-topic, and ensured follow-ups were systematically tracked. Without such discipline, meetings could have descended into unorganized discussions, undermining progress and the credibility of the Project Leader.

By following these practices, the Core Team Meetings became a reliable mechanism for ensuring alignment, driving progress, and resolving problems in a timely manner.

CONCLUSION

Effective execution of cross-functional projects requires a combination of strategic planning, robust governance, alignment across stakeholders, and disciplined execution methodologies. In the case of optimizing the NMPA submission package preparation process, the project team successfully reduced the timeline from 22 weeks to just 10 weeks by implementing structured project management practices. This remarkable achievement highlights the importance of adhering to key principles, fostering collaboration, and maintaining focus on clearly defined objectives.

At the foundation of the project's success was the establishment of a well-structured team with clearly defined roles, responsibilities, and accountabilities. The Sponsor's active involvement in setting expectations, controlling scope changes, and securing resources proved instrumental in maintaining alignment and protecting the project from scope creep. The Project Leader's ability to motivate the team, manage relationships, and proactively tackle risks ensured smooth execution.

Team alignment was a continuous effort throughout the project. By fostering a shared vision, accountability, and trust, the team was able to navigate challenges collaboratively. Regular alignment on the project scope, Final Project Objectives (FPOs), and Key Deliverables provided a clear roadmap for success while defending against potential disruptions, such as scope creep.

The implementation of detailed action plans by individual team members, followed by the creation of an Integrated Project Plan, created a tightly linked execution framework. This ensured precise task-level accountability while enabling holistic oversight of interdependencies and the critical path. The Integrated Project Plan became a dynamic tool for tracking progress, mitigating risks, and maintaining momentum.

Finally, disciplined execution practices—such as clear communication channels and well-structured Core Team Meetings—ensured that the project team operated with transparency, efficiency, and agility. Proactive communication processes minimized misalignment and facilitated timely escalation of issues, while the routine Core Team Meetings provided a platform for progress tracking, risk mitigation, and collaborative problem-solving.

The success of this project demonstrates that cross-functional collaboration, when supported by structured methodologies, can lead to transformational results. By addressing common failure modes, fostering alignment, and emphasizing execution discipline, the team was able to overcome complex challenges and achieve ambitious goals. This paper provides insights into best practices for managing cross-functional projects and showcases the tangible benefits of a structured project management approach. These lessons serve as a valuable reference for future initiatives, particularly in time-sensitive and high-stakes regulatory contexts..

CONTACT INFORMATION

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