



ARE YOU READY?

DEVELOPING A PROJECT MANAGEMENT OFFICE (PMO) AT A SMALL MANUFACTURING SITE

CASE STUDY: OPERATIONAL READINESS & EXCELLENCE



Developing a Project Management Office (PMO) at a Small Manufacturing Site

PROJECT OVERVIEW

CAI partnered with a large pharmaceutical company's global network to revitalize project execution for a small manufacturing site. As the site was not prioritized within the organization it needed targeted assistance to ensure it was a fully capable asset ready to produce the division's highest visibility product for global consumption. This product introduction was not the only challenge as the site needed to implement several initiatives to align systems and operations with the parent organization. The site had recently undergone a strategic shift - from being prepped for sale to being assigned the launch of the division's highest-visibility product. However, it lacked a Project Management Office (PMO), making strategic planning and long-term decision-making nearly impossible. CAI was brought in to design and implement a PMO that would transform the site into a high-performing, strategic asset within the network. CAI also recognized the gaps and guided the organization to achieve its goals through comprehensive Operational Readiness.

THE CHALLENGE

The Site Leadership Team (SLT) had been focused on preparing the site for divestiture. As a result, operational excellence had not been a priority, and resources were severely constrained. The site now faced a new reality: launching a critical product while maintaining ongoing operations, responding to global supply chain pressures, and executing a large portfolio of initiatives to avoid material obsolescence. The site's performance was faltering across the board. Company Executive Leadership relied on the site to turn things around - and enlisted CAI to make that happen.



CAI'S APPROACH

CAI applied its integrated Operational Readiness (OR) and Operational Excellence (OE) frameworks, targeting five pillars: Strategy Leadership, Execution Excellence, Workforce Capability, Equipment & Facility Readiness, and Quality Advancement.

KEY INITIATIVES

- 1. Operational Readiness-Centric C&Q Plan:** CAI kicked off the engagement with a one-day OR workshop to define the roadmap for success. The roadmap aligned functional requirements with the global project plan. Armed with a list of objectives and an understanding of timing and interrelationships, the project execution was managed through twice-daily schedule and action reviews. Cross-functional teams rapidly addressed blockers and created recovery plans for off-track activities with maximum focused communication.
- 2. Strategy Alignment across the Organization:** CAI formed a network of divisional PMO Site Leads to share best practices. This led to the creation of a site-wide PMO policy, ensuring all projects aligned with site, division, and company strategies. A multi-year Project Portfolio Matrix (CAPEX and OPEX) was developed and shared with key stakeholders.
- 3. Structured Project Governance:** CAI authored and implemented a project governance procedure approved by the site head. Training and mentorship were provided for project managers handling the site's top ten projects, including the high-visibility product launch.
- 4. Quality Advancement:** CAI led development of an Annex 1 compliance program, integrating individual quality initiatives under a single, site-wide approach. Advisory support was also provided for regulatory filings and CAPA risk mitigation. Updates to the Quality Management System (QMS) were fully embedded in the PMO rollout.
- 5. Workforce Capability Development:** In response to knowledge gaps and portfolio execution demands, CAI led the design of a new organizational structure. Thirty-one new roles were identified across departments, including a second Qualified Professional and additional staff in Maintenance, Engineering roles, QC, and Operations. CAI also introduced a hiring metrics dashboard to track progress and ensure qualification of new hires.



OUTCOMES ACHIEVED

CAI's strategic intervention and Program Management resulted in measurable site achievements and efficiencies:

- **Accelerated Delivery:** The new product achieved FDA approval and was launched globally.
- **Stronger, Quality-Focused Leadership:** Site leaders adopted a quality mindset through coaching and engagement in the PMO and quality programs. The site earned local regulatory approval and successfully expanded its project portfolio.
- **Strategic Contributions to the Network:** Change controls for key raw and packaging materials were implemented. The site's enhanced performance positioned it as a key contributor to global supply chain stability.
- **Sustainable Operational Readiness:** A structured OR approach ensured a smooth handoff from project phase to sustainable operations, securing long-term reliability and performance.

LESSONS LEARNED

- Early alignment between site and global teams under the OR model could have reduced the need for intensive efforts during validation.
- Transparent, real-time project governance is essential for risk mitigation and stakeholder alignment.
- A well-prioritized, resource-aligned project portfolio is crucial for delivering on strategic goals and sustaining success.

CONCLUSION

This engagement highlights CAI's strength in transforming underprepared pharmaceutical sites into high-functioning contributors to global networks. By applying our proven Operational Readiness and Operational Excellence frameworks, CAI enabled this site to meet critical launch timelines, strengthen quality systems, and build a foundation for sustained success.



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