OPERATIONAL READINESS

THROUGH THE LENS OF CAPITAL PROJECT MANAGEMENT

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A CAI E-Publication

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EXECUTIVE SUMMARY

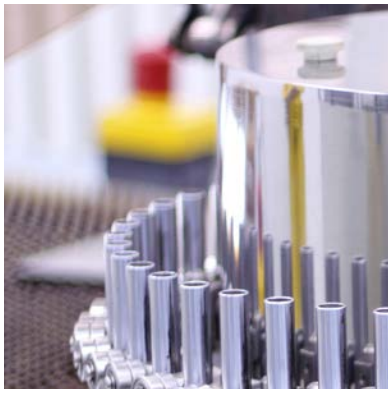
Achieving Operational Readiness on any Capital Project is a milestone event and should be integrated into every aspect of the Lifecycle of Project Delivery. Historically, Capital Project Management focuses on the delivery of the facility, the equipment, and supporting infrastructure. A good Project Manager will manage the five stages of Project Management (Initiation, Planning, Execution, Monitoring and Controlling, and Closeout) to deliver the project on time, on budget, within scope, and with high quality. An excellent Project Manager understands what the facility needs to achieve Operational Readiness and engages the team to identify the activities necessary to be at full scale production when the "go" button is hit.

INTRODUCTION

In the Pharmaceutical Industry, managing the various stages of a Capital Project is not for the faint of heart. Whether the project is to replace all of the light bulbs in the facility from incandescent to LED, or building a new 250,000 sqft Manufacturing Facility, navigating the complex web of planning and execution requires an understanding of a multitude of aspects in the lifecycle of project delivery.

As a Project Manager, one approach that can greatly aid in wrangling a "hair on fire" team in to a cohesive and collaborative unit, is to focus on achieving Operational Readiness once the project is complete. One definition of Operational Readiness is "the state of preparedness attained by an organization when they can safely and efficiently startup, achieve design throughput with the design timeframe, and operate that process in control, in a sustainable and environmentally friendly manner"[1].

Breaking down that definition and translating it to actual Project Management practices is not as daunting as it may seem. When the team is in the initial throws of the Initiation and Planning processes, if the focus on the desired outcome is Operational Readiness, and not solely on the delivery of the facility, equipment, and supporting systems, many aspects of the project that typically lie on the periphery will come to light.



CAPITAL PROJECTS – DEFINING SUCCESS

Historically, success of a Capital Project is defined by meeting a budget and schedule, while meeting specific scope and quality requirements. These are all very good metrics with which to measure a successful project. However, it is critical to ensure that when the project is complete that it meets the intended purpose. If a new facility or manufacturing space is built, and there is no one qualified to operate it, no maintenance program in place, or no supply chain established to support production, the facility is useless.

As a Project Manager, it is essential to bring the team together to address all aspects of Operational Readiness during the project lifecycle, ultimately resulting in a fully functional facility when the "go" button is hit! However, this requires commitment to Operational Readiness from a multitude of key stakeholders within the organization. "Buy-in" is essential throughout all levels of the project team, the leadership, and the entire organization. This "buy-in" sometimes requires a "shift" in the organizational mindset, or even a change in formal processes or procedures.

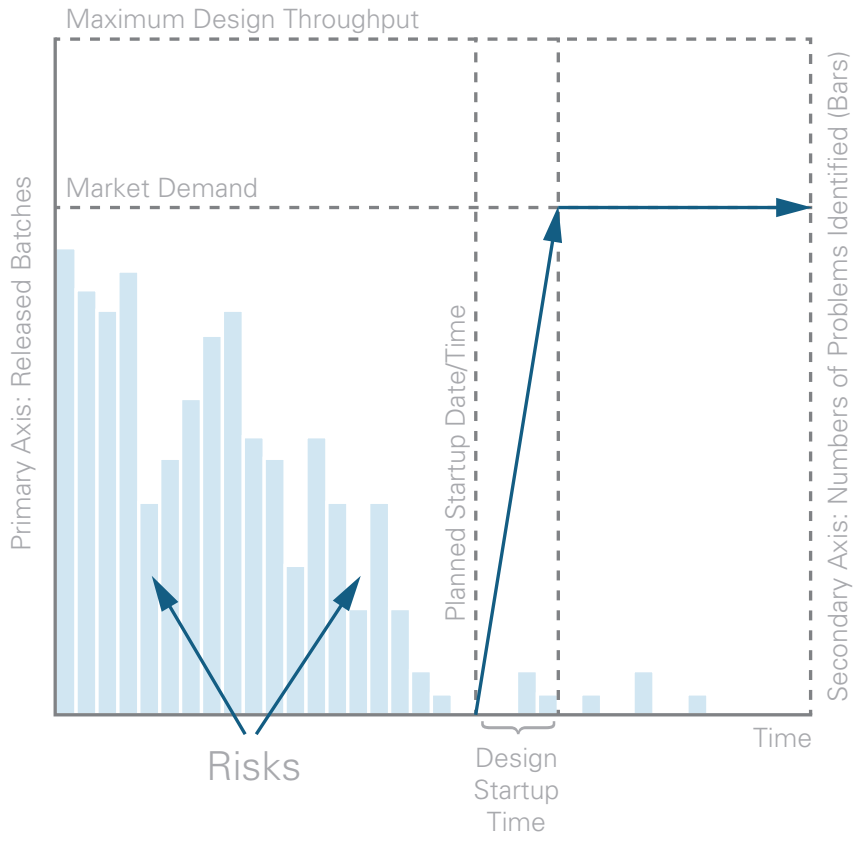
It is not enough to "finish" the project on schedule and within budget. The facility/asset must perform to targeted capacity with sustainable and predictable costs immediately upon start-up. The real goal is to achieve full scale operations within the targeted timeframe. THAT is the definition of success!

A BETTER WAY TO OPERATIONAL READINESS

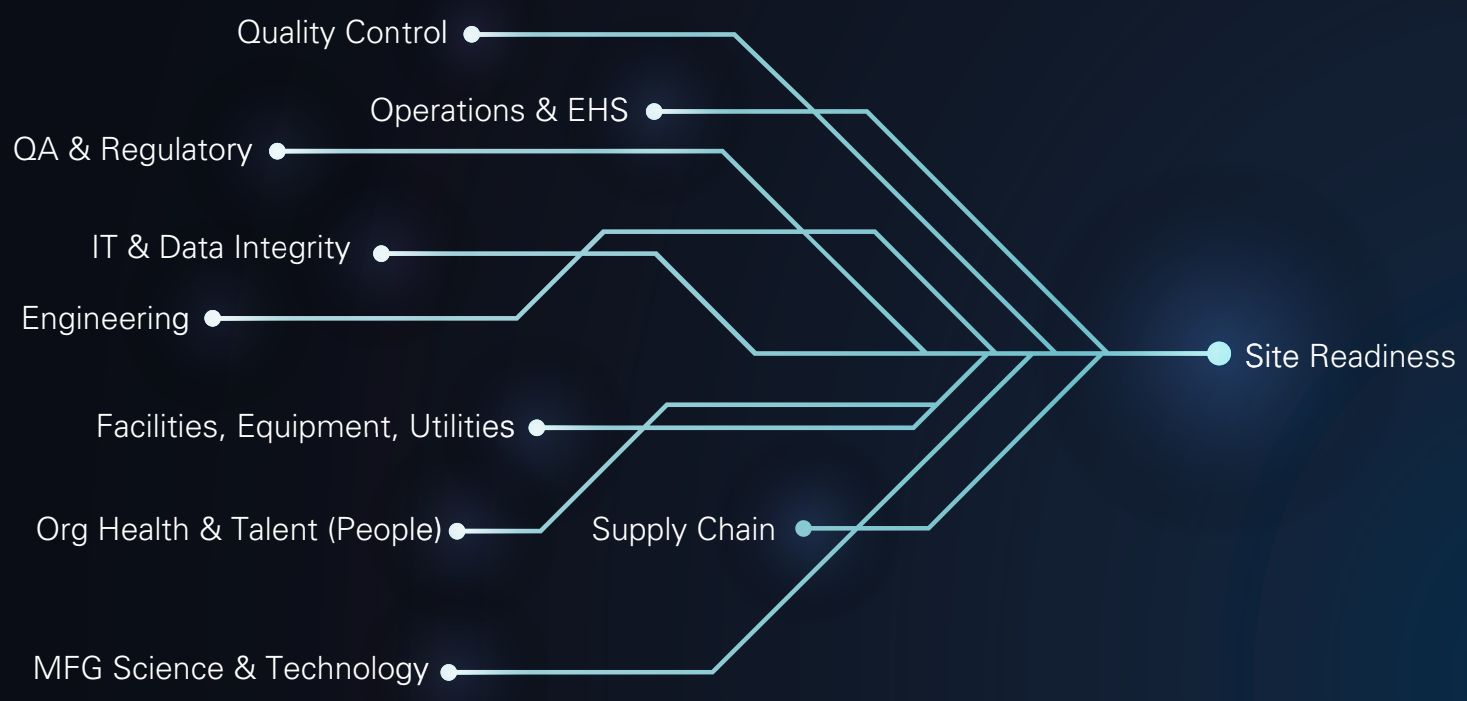
The most common (and often flawed) approach to Operational Readiness is to segregate a multitude of activities from the Capital Project: such as hiring smart and competent people, procuring systems and equipment, bootstrapping materials acquisition, writing batch records and SOP's simultaneously, and then racing through change controls and staff training to achieve PPQ, inspection, etc. This is all attempted through the heroic efforts of smart, and driven problem-solvers.

There is a better way.

Focusing on Operational Readiness as a "traditional" Project Manager is not an intuitive behavior. As mentioned, historically, PM's working on capital projects focus solely on the delivery of the facility and equipment. *So, what does a PM do to achieve Operational Readiness?* From a high level, the Project Manager must work with the team to identify the various Workstreams which will lead to the identification of critical OR activities, resources needed to complete the activities, and most importantly, determine what gaps need to be filled in order to be Operationally Ready when the project is complete. The objective of Operational Readiness is to identify and mitigate risks to a fully operational facility BEFORE the startup. Using the "traditional" approach to Project Management typically results in issues in operations being addressed following startup – causing delays in achieving Market Demand. The graphic on the right shows the desired result utilized Operational Readiness in the approach to Project Management.



Operational Readiness Workstreams in the Pharmaceutical Industry



Above is an example of the various Workstreams that would need to be addressed to achieve Operational Readiness for a new project in the Pharmaceutical Industry. Within each Workstream lies a multitude of functions or activities that contribute to the readiness of each Workstream.

Once the team has gone through the process of identifying the applicable Workstreams for the project, it is imperative to develop a Work Breakdown Structure (WBS) for each Workstream. Identifying all of the various activities, their duration, dependencies, as well as the resources required will translate into invaluable input in the development of an Integrated Project Schedule which will "wrap around" the overall construction schedule. All of these activities should be addressed in the Initiation and Planning phases of the overall Project. In a high performing project, the Project Manager takes charge of this initiative and organizes the team into a collective dynamic, working together, to ensure all of the details of activities are well thought out, organized, and time bound.

There are many methods where this initial planning stage may be achieved. The most productive and efficient method is to conduct a series of workshops with the relevant stakeholders to build out the activities. Early involvement of Subject Matter Experts is imperative to ensure all activities are identified, duration estimates are accurate, and dependencies are clearly identified. As one can imagine, this can become a rather complex spider web of connecting and dependent activities that need to be structured and organized. Collaboration across the team is essential. However, the "first pass" is rarely (if ever) completely accurate. Iterations are absolutely essential, and the Project Manager should ensure a routine cadence of team engagement is established with a functional communications plan.

As the project transitions into the execution stages, the team must continually identify and deconflict resources throughout the organization to support the execution of the activities in the various workstreams. This is typically one of the biggest challenges every organization faces in preparing for Operational Readiness. Depending on the size of the organization, the majority of the Workstreams identified above have many cross functional teams supporting in the delivery. Which leads to individuals supporting multiple Workstreams, and becoming overloaded. Going through the WBS process, along with the development of an accurate AND agreed upon RACI, will do wonders for expectations of productivity across the team.

The most effective method to utilize as a starting point is the end. At the onset of planning, ask the team the following questions:

- What is our final milestone (e.g. GMP Ready, Product out the Door, Full Scale Production, Regulatory Filing, etc)?
- By what date do we need to achieve our final milestone?

Most often, these answers are readily available through the business case, Capital Action Request, or other similar guiding documentation or process. However, in some cases, these answers are not easily determined. This may require significant engagement with organizational leaders to determine the path forward. Once the answers to these questions are met, the team will need to develop the WBS and align the activities necessary to achieve OR with the end date and milestone. This will inevitably result in the determination of resourcing needs to meet those requirements.

GETTING STARTED IS THE HARD PART

The question that gets asked most is the "how". How is Operational Readiness actually achieved, successfully?

CAI has developed a comprehensive approach to OR. Through many years of experience across all of the workstreams relevant to the pharmaceutical industry, a model was developed. This model includes a baseline Level 3 schedule which is implemented as a starting point and addresses each workstream. For example, a client of CAI is building a manufacturing facility to scale up from "benchtop" based production. Following completion of the facility, they plan to build an additional larger scale plant.

CAI was engaged at the very early stages of planning, and worked with the team to implement CAI's OR model. The first steps were to determine the objectives of the manufacturing facility, including production goals now and in the future. As these objectives had not been fully vetted, CAI challenged the head of operations to determine the production goals. Subsequently, the team developed a vision to achieve the execution of 26 simultaneous production runs. Our team immediately recognized that the current design, with respect to flow of materials, product, people, and waste, would be insufficient to meet the goals of Operational Readiness for the facility. Through the methods previously described, our team conducted a series of workshops to flush out all of the activities required from design through operations to ultimately achieve the Owner's objectives.

Although this is a specific scenario, the challenges this Owner faced are typical throughout the industry. The Project Manager should be ready to identify the challenges to achieving Operational Readiness, bring the team together, and develop a singular, and focused, solution. Ultimately, this will mitigate conflict throughout cross functional teams who are all moving in different directions, while striving to achieve the same result – a fully functional and operationally ready facility.

CONCLUSION

Delivering Capital Projects is a massive accomplishment, particularly when the project is executed on time, and on budget. As a Project Manager, broadening the scope of activities to achieve Operational Readiness will take the project to the next level of success. Maintaining a consistent focus on all of the Workstreams necessary to achieve OR will promote collaboration, improve efficiency, and gain valuable insight into the needs of the facility beyond the delivery of the facility, equipment, and support systems.

CAI's Program & Project Management (PPM) Team has substantial experience in achieving Operational Readiness. The breadth and depth of experience at CAI cover all of the aspects needed to achieve OR, across all stages of the Lifecycle of Project Delivery. If you are interested in seeing more of CAI's OR processes, or you have a project and need a consistent, and proven approach to achieve Operational Readiness, contact one of our PPM experts and see what we can do to achieve your goal of product to patient.

ADDITIONAL RESOURCES/REFERENCES

1. CAI's definition of Operational Readiness is the culmination of nearly 30 years of experience in the delivery of operational facilities around the globe, driven by experienced experts throughout the industry.

Josh Hoops

Global Director, Program & Project Management

Josh Hoops leads teams to achieve excellence in the delivery of mission critical facilities around the globe. As an expert in operations management and an inspirational leader, his experience across multiple industries has proven success in improving a wide array of fundamental and complex aspects of organizational efficiency and effectiveness. As CAI's Global Director of Program & Project Management, his vast experience in the execution of major projects (from ~$2M to over $100M) across multiple industries around the globe provides the foundation and a detailed level of oversight and practicality necessary to ensure the CAI team is efficient and effective in every aspect of Program & Project Management delivery.