PEER REVIEWED

Operational Readiness – The Precursor to Operational Excellence

Following any tech transfer project, the subsequent startup of the manufacturing line is almost always full of challenges. The goal is to startup as soon as possible once the project is completed but also to achieve steady state throughput as quickly as possible after the startup begins. This type of startup is what is called a "Vertical Startup." In practice, vertical startups are rare because management teams typically focus their attention on having the facility and the equipment qualified in time to meet the process qualification milestone. The consequences of this thinking is that a broad range of workstreams are often neglected or receive inadequate attention although they are critical to startup. Workstreams like staffing, training, procedure development, supply chain, analytical methods, etc. must all be 'ready to go' by this important milestone. The result can be like having perfectly tuned race cars lined up on the starting line of a Formula 1 race, but with untrained drivers, little gas, unpracticed pit crews, and no spare parts.

Vertical Startups do not happen by accident. The first step requires management teams to transition their focus from a process qualification milestone to an Operational Readiness milestone. Once this happens, operations departments can achieve a Vertical Startup by applying the principles of Operational Readiness, a proven methodology used across the spectrum of manufacturing industries. Not only is it a proven methodology, it is central to the practice of technology transfer. Despite its importance, Operational Readiness is often not fully understood, not correctly applied, or is confused with the principles of Operational Excellence.

The primary objective of this article is to inform the reader (particularly those who are a part of management teams) about Vertical Startups and how Operational Readiness is the organisational state that needs to be reached in order for vertical startups to exist. The secondary objective is to help the reader build an understanding of Operational Excellence in addition to Operational Readiness. The series will also highlight the need to: (1) design systems which are comprised of production-friendly equipment that is easy and safe to maintain and operate; (2) implement organisational systems to allow for the swift and smooth startup of new equipment recognising safety, product quality, and cost; and (3) decrease the Life Cycle Cost (LCC) of equipment and facilities.

Why a Focus on Readiness?

Getting off to a good start is the essence of Operational Readiness (OR). OR is a management approach widely used in the chemical production and energy sectors which has direct applicability to drug makers. These industries use formal Operational Readiness and Assessment (OR&A) programs as a risk management paradigm to guide management practices for performing pre-startup reviews of (1) new processes regardless of scale, from big plants to small plant startups, (2) processes that have been shut down for modification, and (3) processes that have been administratively shut down for other reasons. However, being "ready" needs to go beyond just performing pre-startup reviews – particularly for the life sciences industry. It needs to include an analysis of the product input and output variances and the control strategy deployed – not to mention evaluating the actual startup afterwards, which is one of the best performance indicators of OR. For all engineering project startups, anything less than getting up to speed swiftly and smoothly should be considered a lack of preparedness. Considering these points and the definition used in other industries, we define OR as:

Operational Readiness is the state of preparedness attained by an organization when they can safely and efficiently startup, achieve design throughput within the design timeframe, and operate that process in control,[1] in a sustainable and environmentally friendly manner.

Whereas the idea of Operational Excellence is broader by nature and involves a focus on the value stream:

Operational Excellence is when each employee is commited to mastering their role, can see the flow of value to the customer, and works to continuously improve that flow.

This definition of Operational Excellence is insightful when considering the concept of the Pharma 4.0™ "holistic control strategy," which is enabled by digitisation and targets all stakeholders along the value chain. "All the necessary data are managed in real time, fully transparent, and available for sound real-time decision-making, improving quality, manufacturing process efficiency, and accuracy. In sum, the holistic control strategy ties regulators, industry members, and patients together in an overall holistic value network structure driven by the Pharma 4.0™ operating model."[1] Given the different domains of both definitions, it is easy to see why it is necessary to separate the terms from one another.

To become operationally ready, leaders must begin working toward that objective early in the project – ideally at the beginning stages of the project during the preliminary design review (but no later than the Design Qualification). This early involvement may surprise most operations managers, but this effort is essential. The traditional approach at these design review stages is to evaluate design concepts for feasibility, technical adequacy, risks, and general compliance to requirements. However, with the ever more complicated equipment being introduced to the market, along with the complex processes being designed, organisations need to start evaluating how friendly the equipment and processes are to operate and maintain, and procuring resilient equipment which eliminates unplanned downtime. Traditionally, these earliest design activities frequently overlook the operators and maintainers, which becomes evident during plant startup. Instead, the inputs received to the design in the early stages come from scientists who usually don't have production-scale manufacturing experience. This is a typical miss and projects lose the opportunity to have people experienced in manufacturing provide early input into the process design. Consider the following tale of two startups in two different imaginary companies:

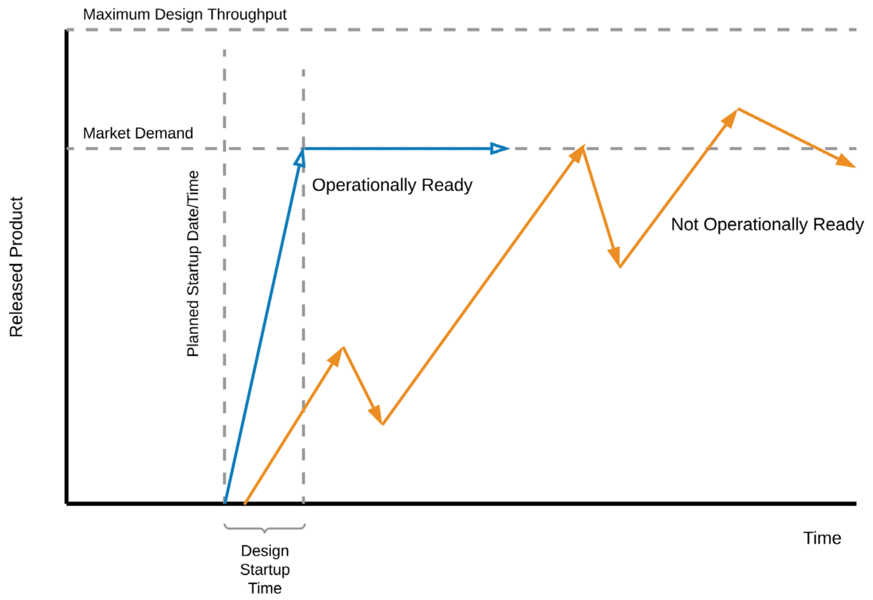

Figure 1 – Startup Profiles for Two Different Companies

In Figure 1 above, the blue graph represents a company who has invested the time and energy early in the design and prepares its operators and supervisors to startup and operate the equipment. Their startup is on time and it is "vertical." One could conclude that this company is "Operationally Ready" and they achieved that preparedness level prior to startup. Whereas, the orange graph represents an average company's attempt at readiness. They have a "flat" startup, which is costly to patients and investors, and exhausting to their staff. Demand goes unmet or competitors launch competing products. Startup costs rise. And despite their best efforts to reach capacity, their startup period grows longer by the day. Everyone's been there, but it doesn't have to be that way. There are three main areas for consideration by leaders that could ease the challenge of any startup regardless of the end purpose. These are: (1) problem prevention, (2) production friendly equipment and systems, and (3) an organisational approach that formalises operational readininess into an human organisational assessment system.

Systems Thinking for Problem Prevention

First, the industry must change when problem identification occurs. Evidence shows that the earlier problems are identified in any engineering project , the better the project performs both in the short term and throughout the entire life cycle of the project. In most engineering projects, designers, project teams, and customers still more or less react and address problems when they arise during the post-construction testing and startup stage as they rush to project completion. Instead, entering the project with a prevention mindset will tend to drive problem identification early "on paper." This is not an easy activity since there is no physical equipment to look and the best you often have is preliminary drawings. This approach succeeds when using multi-functional teams guided by a rigorous process that requires a "systems thinking" mindset before construction begins. "Systems thinking" can mean different things to different people but for this paper it simply means that one should always think in terms of the whole system rather than the parts of the system. As an extreme example, thinking strictly about building a greenfield facility without thinking about getting ready to operate the new facility could reasonably result in a project that delivers ahead of schedule and under budget but without anyone who is ready to turn it on. Or more commonly, not thinking about how easy or difficult the plant is to operate when the design is on paper (and changes are less costly to make) and waiting on a "debugging" period to identify problems before, during, and after plant startup does not follow a "systems thinking" mindset.

Refer to Figure 2. In this figure, the number of problems identified are now included as a bar graph depicting a simple count of problems versus time. When comparing the timing to the startup, operationally ready companies eliminate problems through redesign, procedure development, and training prior to startup. The net effect is improved operability and maintainability.

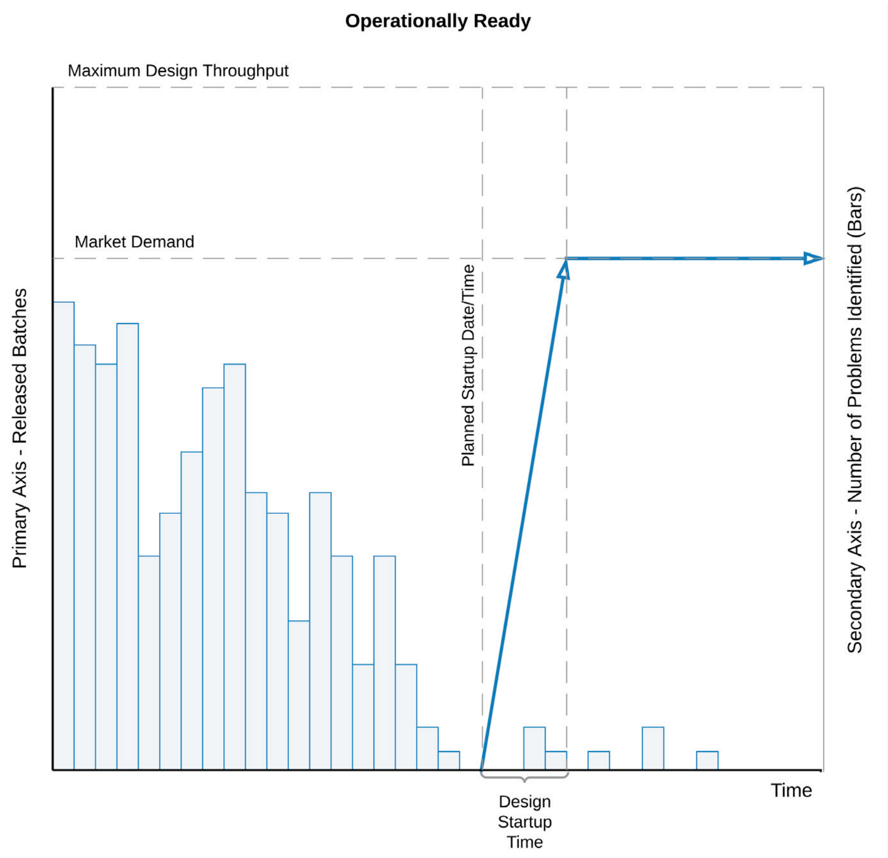

Figure 2 – Operationally Ready Company – Problem Identification Timeline

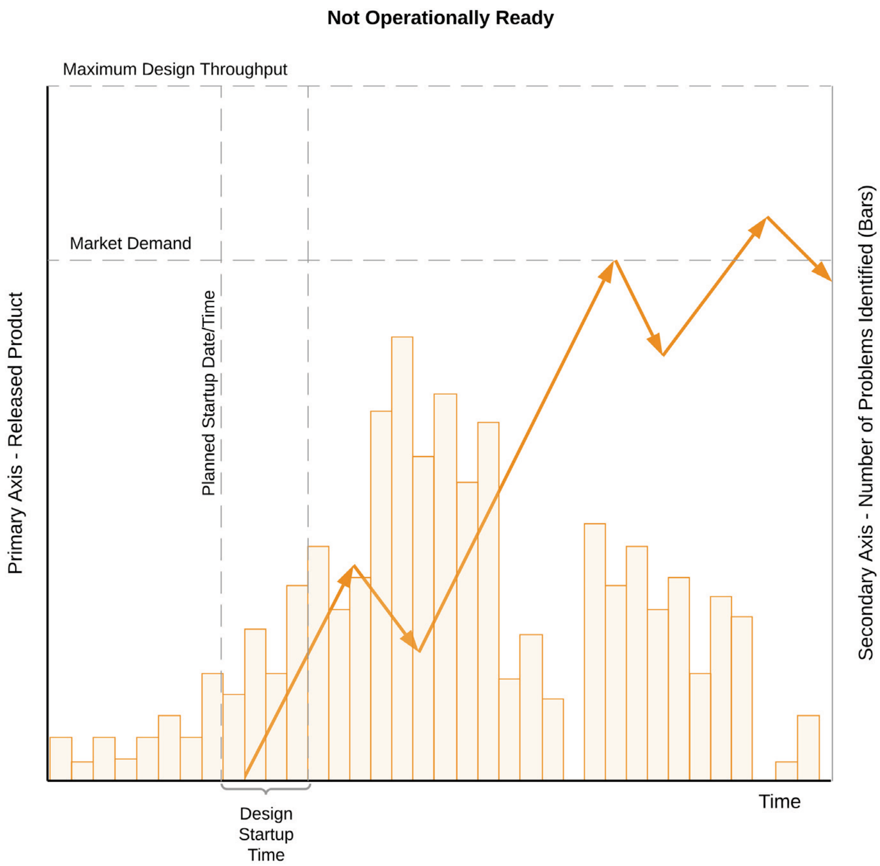

Figure 3 – Not Operationally Ready Company – Problem Identification Timeline

Whereas in Figure 3, problems with maintainability, operability, safety, and supportability are identified during testing and after startup. This delays the facility achieving full-scale operational output. Moreover, overall life cycle costs increase as design changes become cost-prohibitive or are intentionally delayed.

The inevitable time pressures from this company's poor startup will lead to "heroic," uniquely designed fixes that are unsustainable operationally or financially, creating further waves of problems to solve long after startup.

Operational Readiness and User Friendly Plants

Second, designers must begin adding a new function to the design team, someone skilled in the ways of operability – similar to the function of a user interface designer on a software engineering team – to maintain "production friendly" status throughout the project. Human-machine interface best practices can be used to greatly improve equipment operability. A properly designed interface solution not only enhances productivity of the operator, but also provides system insight to control and maintain the machine.

Much of the pioneering done in this area relied on carefully documenting lessons learned and constructing varying levels of mockups in advance of building the final product. Lessons learned would have the greatest impact when designs were repeated in "a cookie cutter" approach which is not as prevalent today. Similarly, mocking up designs were used when the technology tended to be more static and were not expected to undergo substantial changes throught the life cycle of the equipment.

The fast pace of change in the industry precludes much of this from being as effective as it was in the past. Nevertheless, the end goal of a vertical startup must incorporate human-machine interface development in order to improve plant operability, maintainability, and throughput. User friendly equipment makes the condition of being operationally ready that much easier to achieve.

Formal Operational Readiness and Assesment Program

Lastly, companies should develop and implement an OR&A program that anticipates problems and either eliminates them or puts management systems in place to mitigate them. OR&A programs have historically recognised that an operational system is comprised of multiple elements: (1) People, (2) Procedures, and (3) Equipment. Consequently, an organisation's preparedness efforts need to address these three areas individually as well as in an integrated fashion. Logic trees are frequently used for this effort as a visual diagnosis that lays out a problem and all its possible solutions, allowing you to choose the best course of action.

Figure 4 lays out the three key elements to achieving Operational Readiness through an "AND" relationship, which means all three are required. These three elements provide only half of the analytical picture, however. Consideration must be given to the interfaces among these elements.

- Do the people match the equipment? Is the equipment properly operable for the people who have been selected and trained to operate it; e.g., have we selected people with proper color discrimination to deal with color-coded equipment elements?

- Do the procedures match the equipment? E.g., have we avoided situations in which the operators have been given Version 1 procedures manuals to operate Version 2 equipment?

- Do the procedures match the people who are to use them? Do we have selection procedures which assure a proper degree of functional literacy for people who must read and understand complex work procedures; e.g. have we written procedures that focus a person's attention on the step-by-step task amid the distracting surroundings?

Conclusion

The confusion that surrounds Operational Readiness is understandable. The ideal behaviors needed on the Operational Excellence journey are the same behaviors needed to achieve Operational Readiness. Accepting that both have different contexts is critical to eliminating the mix-up. Operational Readiness requires a mindset of problem identification, anticipation, and elimination in advance of starting up. Operational Excellence is an obsessive focus on the value chain throughout the life of the product, which still requires the same identification, anticipation, and elimination of problems in addition to the other behaviors that drive continuous improvement.

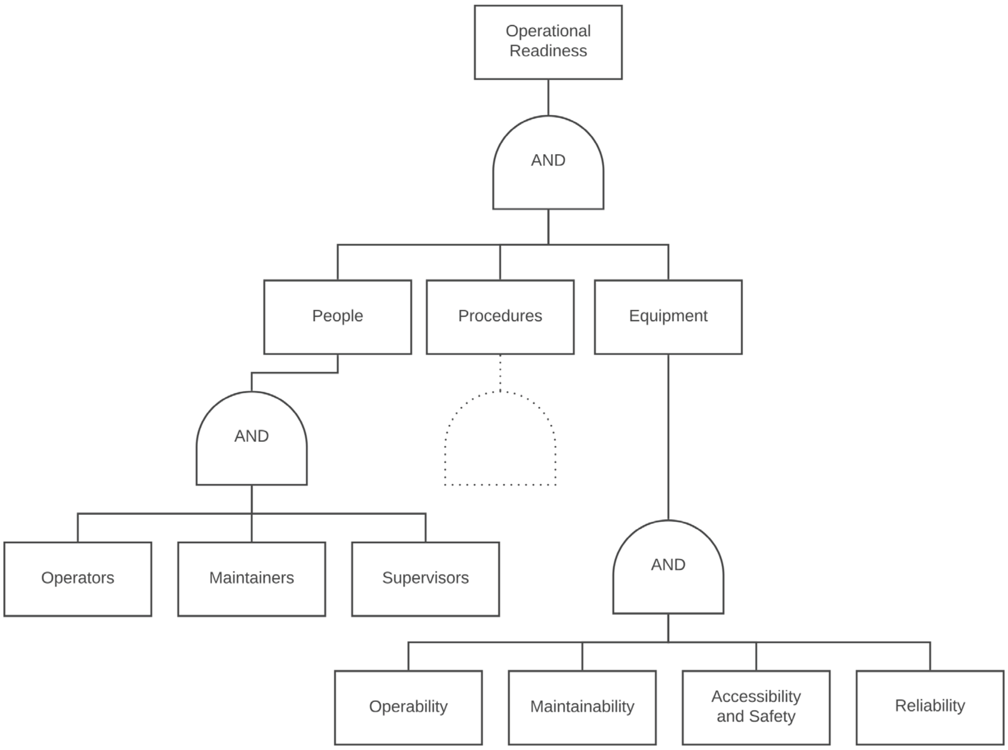

Figure 4 – Logic Diagram for Operational Readiness

Generally speaking, when it comes to OR&A programs companies have two choices: They may invest time and money to perform the extra early work to prepare as in the case of our imaginary company with the vertical startup, or they may accept the uncertainties and/or lack of system control that may result by waiting until the last minute. The evidence clearly favors the former (compare Toyota and GM's approach and performance in the 1970's and 1980's); therefore, all parties involved in engineering projects and the subsequent startup need to be clear that the objective is to achieve Operational Readiness, as opposed to merely completing the project.

REFERENCES

1. The phrase "in control" is important because it brings together the guidance of ICH Q8(R2) through ICH Q12 which address the development of a control strategy to ensure that a product of required quality will be produced consistently. ICH Q10 defines control strategy as: "... a planned set of controls, derived from current product and process understanding, that assures process performance and product quality."
2. Heesakkers, H., C. Woelbeling, T Zimmer, N. Al-Hafez, L. Binggeli, M. Canzoneri, L. Hartmann. "Applying Holistic Control Strategy in Pharma 4.0™" Pharmaceutical Engineering 40, no 1. (January — February 2020). https://ispe.org/pharmaceutical-engineering/january-february-2020/applying-holistic-control-strategy-pharma-40

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As COO, Rich is responsible for CAI's global operations. He is a hands-on senior leader with extensive experience leading operational excellence efforts in diverse types of businesses. He is dedicated to helping companies achieve readiness and resiliency in their operations through high-performance teams. As a lean operations expert and leader, he is personally credited with the lean transformation of 9 manufacturing sites and coaching over 34 manufacturing sites in advanced lean and six-sigma techniques. Rich's professional career began in the US Navy where he served over twenty-two years on active duty supervising nuclear power operations on four submarines. He has since served in multiple leadership roles from Engineering Director to COO in three manufacturing companies prior to joining CAI. He is currently working on his dissertation for a Doctor of Engineering from George Washington University where his research focuses on multi-criteria decision analysis. He holds an MBA from Southern Methodist University and a Bachelor of Science degree from Columbia College.