BRIDGING THE GAP FROM PROJECT TO OPERATIONS

THE PIVOTAL ROLE OF THE SYSTEM OWNER

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PREMISE

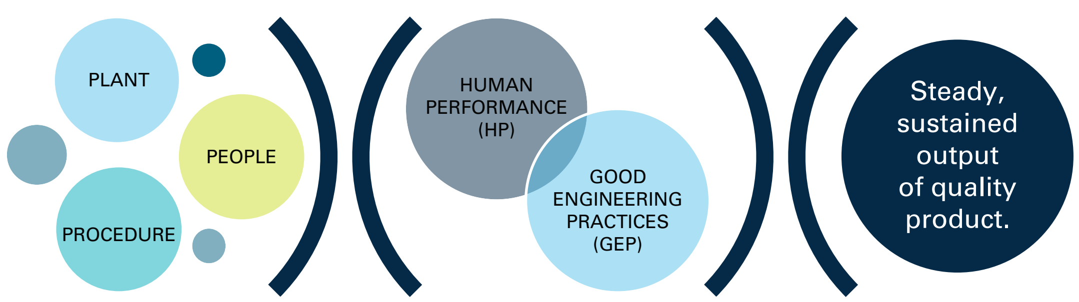
To achieve a state of Operational readiness is to complete all preparation required for the steady, sustained output of quality products. The concept of operational readiness can be best framed as it relates to three interfacing assets including the plant, its people, and their procedures. The synergy among these three "Ps" is the foundation of Good Engineering Practice and Human Performance where:

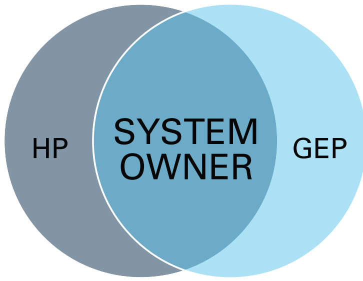
Plant x People = Good Engineering Practice (GEP)

People x Procedure = Human Performance (HP)

It is through the successful engagement of Good Engineering Practice and Human Performance that the desired operational posture is achieved where:

GEP x HP = Steady, Sustained Output of Quality Product





Note that the desired end state includes both the Quality dimension, as characterized by the execution of a Pharmaceutical Quality System (ICH Q10), and the broader business impacts of a sustained manufacturing operation. This paper explores the prospect and rationale for establishing the key role of the System Owner as a bridge and translator at the intersection of Good Engineering Practice (GEP) and Human Performance (HP).

There is an existing definition of the System Owner that has evolved over the last few decades. Most recently, the ISPE Baseline Guide 5 – Commissioning and Qualification, 2nd Ed., defines the System Owner as:

The person ultimately responsible for the availability, support, and maintenance of a system and for the security of the data residing on that system.

It is the opinion of the authors that, in the current state of the industry, this definition is far too limiting with regard to its scope and vision. It requires a radical re-imagining both in definition and in the corresponding practice. Therefore, we offer the following as an alternative:

SYSTEM OWNER: The designated individual within an organization who is accountable for the operational readiness of a given engineered system and is tasked with achieving the maximum production quality and value for that system throughout its lifecycle, from concept through decommissioning.

Under this definition, while the System Owner may not personally execute all daily tasks normally associated with either GEP or HP , they must be well-versed in the principles and requirements surrounding both.

In the following discourse, we first define the "gap" noted in the title of this paper and build the business case for an operational readiness model. We then review the various phases surrounding the gap which progress from GEP-focused to HP-focused, and we illustrate the potential contributions of the System Owner role through each. It becomes evident that the role of System Owner should be neither a collateral assignment nor an afterthought. Individuals should be selected for this role early in a project life cycle and tasked with the primary objective of harmonizing these disciplines. Subsequent to startup, the embedded System Owner should continue to provide important insight and synergy across these disciplines during sustained operations, leading to Operational Excellence.

DEFINING THE GAP

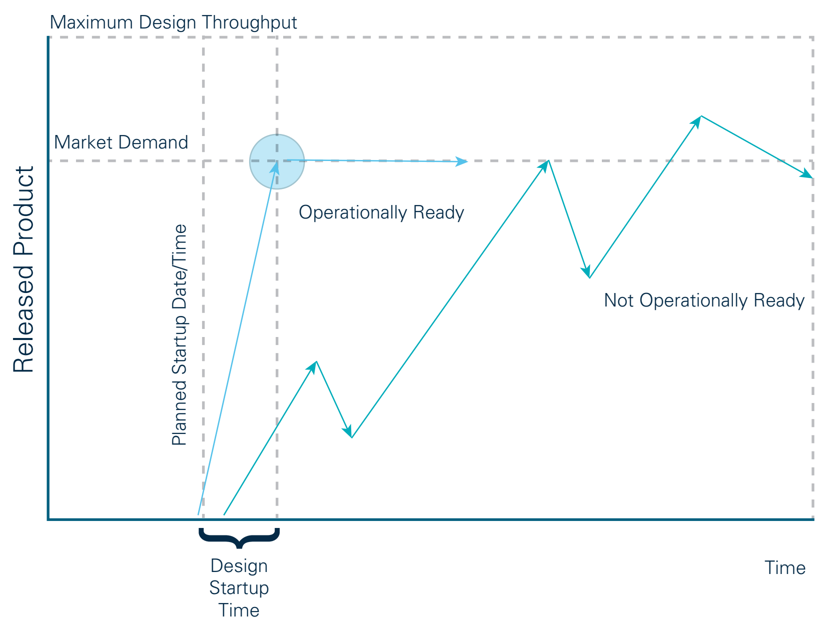
Many organizations struggle with the transition between projects meant to design build and deliver a facility or upgrade, and its subsequent operation. This struggle is both predictable and understandable. The activities and skill sets involved in delivering a project are very different from the activities and skill sets involved in the ongoing, year-over-year operation of a production facility. Consequently, these activities are usually performed by entirely different teams. In addition, the project and operation teams are present for entirely different timeframes and in practice, may scarcely interface, if at all. Thus, few natural opportunities exist to embed human continuity in the transition. When the operations team onboards, they must go through their own cycle of forming, storming, norming, and performing (FSNP)– the four classic stages of a team during project execution. However, little consideration is given to the fact that such teams must also weather the storming with the facility itself which, of course, takes time.

Some companies understand the need to onboard operations staff earlier in the build, but the who, what and when aspects of this hire are complicated. How early should such an individual be hired, and which budget does their hire impact? What can we do with those individuals during the early project phase? They are frequently air-dropped somewhere in the middle of the gap to wander around for a while attempting to get their bearings, eventually climbing their way to an operational state. Wouldn't it be better to give them a bridge?

Perhaps less obvious is the fact that the dipole of project versus operations does not appoint itself a natural owner for the shift from one to the other. In best-case scenarios, the transition is owned by a site head, and possibly a handful of department heads, who integrate with the project team and are ostensibly responsible for ensuring adequate coordination between the project team and the operations team during the transition. Unfortunately, this is often poorly executed, and these high-level managers are not directly to blame. In current common practice, there is a lack of critical focus. The solution, then, is that ownership of the transition should reside at a more granular level, such that the storming period with the facility is more broadly distributed across the design, build and early operation.

OPERATIONAL READINESS AND THE VERTICAL STARTUP

If we assume the objective of a GxP site is to consistently produce and release quality products to market with sustainable costs, we can show the progression of a given project toward that objective, and compare a typical project lifecycle to the ideal state to determine solutions for closing the observed gap.



The diagram above contrasts these two results by plotting the amount of product released to market over time. The plant result in blue meets the designed timing for startup (nearly vertical) then immediately begins to produce and release product to design capacity. It then continually improves, or at least consistently sustains, that performance. This result represents the full achievement of operational readiness.

The orange line shows a more typical startup sequence plagued by repeated delays and requiring additional engineering and qualification runs. This results in inconsistent operational outputs which rarely and only temporarily achieve the targeted production and release capacities.

The business case for making investments that bring you closer to a true state of operational readiness lies in the area between the blue and orange curves. This area, representing post-startup operations, illustrates the difference in optimal versus suboptimal operational readiness as measured in product released to market . Translating reduced product released to market into actual loss of revenue clearly establishes the business justification for the hiring of experienced system owners early in the project phase. The associated cost justification based upon batch production ROI is illustrated below

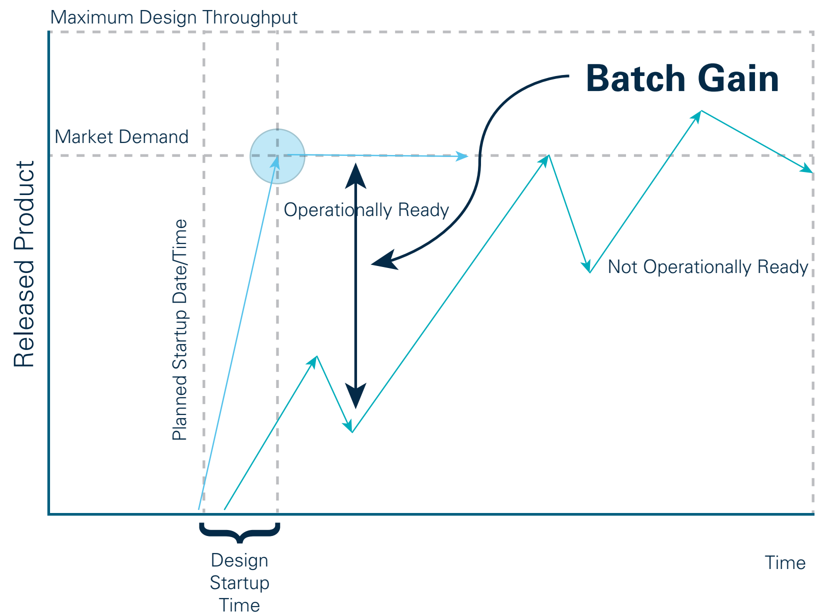
$$\frac{\text{Cost of System Owners}}{\text{Value per Batch}} = \text{\# of Gained Batches to Break Even}$$

Examples:

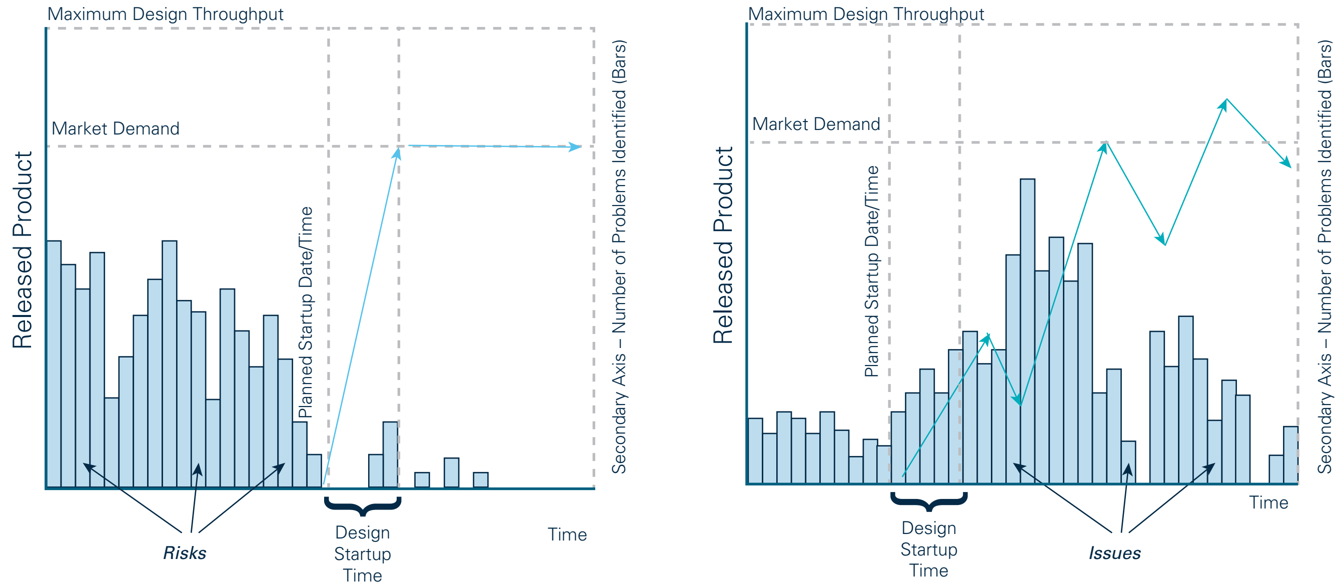
$625K* / 400K + 1.6 Batches

$1.9M / $800K + 2.4 Batches

*Assumes system owners hired 1 year in advance of startup.



There are many risk factors that contribute to the erratic operational reality that is represented by the orange line. Often, site leadership is expected to own the Risk Factor Analysis and Prevention Plan and to translate that plan into ongoing GMP-ready production. However, in modern, high-capacity production systems, this is an unrealistic expectation which is riddled with pitfalls including competing priorities coupled with limited bandwidth for individuals who cannot be expected to have comprehensively mastered the breadth of experience and expertise necessary to "own" all of the identified risk factors at the root cause of the orange line. As a more viable alternative, site leadership should assign this risk identification to designated System Owners with the experience and defined mandate to forecast, evaluate and manage the potential risks. By identifying the likely issues, which are generally well-known to experienced System Owners, and planning for risk mitigation during the pre-startup phase, the site can implement the necessary pre-startup controls to achieve a consistent, sustained output and release of product, on time and meeting quality standards. In the diagram below the bar graphs represent potential system issues, illustrating the benefit of early investment in this approach with experienced, focused System Ownership.



We will now explore the various dimensions of the System Owner role, and how it can translate to what is known as a vertical startup (the blue line) and the desired operational posture.

PROJECT DELIVERY

Good Engineering Practices (GEPs) have long served the pharmaceutical industry as a crucial pillar of project delivery but their scope and emphasis have evolved over time. For decades, engineering departments have generally operated as a service to other departments. Their principal clients were often manufacturing and capex groups with a need to build or improve manufacturing capacity. Following the traditional phase gate model for project delivery, engineering teams would then pivot to serve validation and quality groups, whose independent verification activities would often uncover key gaps and necessary improvements. Enter, then, the process manufacturing group with the revelation of new requirements and the cycle would begin anew. More recently, engineering groups have been under pressure to abandon the phase-gate model and iterative field efforts. The goal, now, is to proactively coordinate and resolve the issues of many different stakeholders in parallel, to achieve quality-by-design and right-first-time delivery, leading to a vertical startup. In addition to competitive market pressures, regulators have repeatedly emphasized their focus on quality risk management, which demands a more holistic approach to project delivery.

These types of integrated approaches have been codified in industry guidance documents, including ASTM E2500 (2010), ISPE Baseline Guide 5 2nd Edition (2019), and most recently, ISPE's accompanying revision to the Good Practice Guide for Good Engineering Practice (2021). All emphasize the importance of Good Engineering Practice as a disciplined approach to project delivery and asset management, proactively engaging with stakeholders, instead of reacting to "unforeseen" needs. Most issues requiring re-work in the field are preventable, in that they represent satisfaction of a "new" requirement that was not at all "new" to the person who suggested it—that person simply wasn't involved early enough to identify it.

Nevertheless, many companies have struggled to implement these principles. In addition to the normal obstacles to organizational change, the industry has seen a gradual shift to outsourced project delivery, including “turn-key” projects in which owner-involvement is minimized. Contract engineering and construction management firms are increasingly expected to deliver projects holistically but without the benefit of understanding who the various stakeholders are and without the authority to demand their input and involvement. This includes not only owners but also vendors and subcontractors with whom the contractual relationship may be thin or non-existent. In many cases, owner firms share the engineering role with a design and build firm and take it upon themselves to purchase critical manufacturing equipment, expecting the contract firm to mold the facility around it, without the benefit or recourse of any contractual relationship with key vendors. Owners may even maintain master services contracts with automation and integration providers and mandate coordination between this firm and the GC, while again, neither is contractually bound to the other.

In the turn-key landscape, Commissioning & Qualification (C&Q) service providers are brought in early and often find themselves serving as interim System Owners, facilitating the cross-communication between stakeholders to assure all requirements are properly defined, met by design, and appropriately tested. While a good C&Q provider can certainly accomplish this job, the model has its shortcomings. First and foremost, on a turn-key project, the C&Q provider is often subcontracted to the GC, which represents a conflict of interest. Secondly, the C&Q provider, as a contractor is a temporary resource. At the conclusion of the contract, an organization is left with no institutional memory related to the systems they owned. Newly appointed site personnel are subsequently relegated to dissecting and re-piecing the systems to achieve system-specific expertise. While owner firms generally attempt to assign staffing in what they believe to be a reasonable time to assume ownership of the facility, early staffing often focuses on the traditional operations and facilities support staff. As a result, their focus is typically on downstream activities rather than in-process performance. Consequently, project teams are often forced to retain high-cost C&Q providers as engineering support staff for months following handover to bridge this gap.

Contrast such situations with one in which the owner implements a program and assigns System Owners at an early stage in the project. The System Owner may or may not be an engineer but is engaged in system design by virtue of defining and owning the various requirements that are relevant to the system. Because these individuals are full-time employees who are naturally looking ahead to the operational posture in which the system will need to function, they are strongly motivated to ensure all relevant stakeholders are consulted and better able to understand the relative importance of requirements in the context of an operating facility. For example, to a project engineer, a requirement that an instrument can be calibrated without removing it from the system may be a “nice to have” thereby representing a cost/benefit line item on a spreadsheet. To an operator, however, this requirement is critical as it represents avoidance of lost production time. Likewise, while a requirement for ergonomic access to an HMI may be a top priority for an EHS representative who may be loosely assigned to the project and merely looking at a requirements checklist, an operator may understand that this particular

HMI will be used only four times per year and that proper machine guarding represents a much higher priority.

In the realm of quality by design, early assignment of System Owners can have a profound impact. The philosophy of QRM establishes risk as a spectrum and posits that the level of effort should be commensurate with the level of risk. Consider, for example, a dilution step in which the system is designed to achieve a target concentration using component fluids of a known concentration. The System Owner owns the requirement: “System shall be capable of reliably achieving target concentration” throughout the evolution of the system. Contrast this with a traditional phase-gate model in which no System Owner is assigned until the end of the commissioning process:

<table>
<tr><th>Early Empowered System Owner</th><th>Little/No System Owner Involvement</th></tr>
<tr><td colspan="2">Design Firm recommends In-Line Blending based on the hazardous nature of component fluids. Target concentration is to be achieved by a feedback loop. While not commonly used in such processes, specialized vendors are known to be capable of delivering this technology.</td></tr>
<tr><td>BoD issued and System Owner assigned to in-line blending (ILB) systems. System owner defines the intended use by establishing user requirements and is involved from the beginning of the system life cycle, including vendor selection and coordination.</td><td>BoD is issued and GC takes lead on vendor selection and coordination.</td></tr>
<tr><td>System owner recognizes criticality of the target concentration process parameter and immediately adds performance of in-line blenders to the project risk register. System owner also engages early with vendors on the intended feedback loop mechanisms.</td><td>GC issues design spec to vendor. GC may appreciate criticality or novelty of the ILB technology but trusts vendor to meet specs.</td></tr>
<tr><td colspan="2">Vendor proposes a break tank and flow control of individual influents as the mechanism to achieve proper concentration.</td></tr>
<tr><td>System owner facilitates formal design review against user requirements in the context of their associated risks and, further,challenges vendor on why this approach was taken when process calls for in-line measurement of output concentration. Vendor reveals that no suitable in-line sensor exists to measure the concentration of interest and, therefore, influent flows are the only viable option. System owner recognizes this as compounding an already high risk by not directly measuring/controlling the parameter of interest. Project team pushes process development to conduct benchtop studies and expand the allowed concentration tolerance.</td><td>GC receives submittal and identifies the P&ID does not fully align with BoD. GC updates field-routing of piping and I&C components to accommodate vendor drawings. Design phase is completed.</td></tr>
<tr><td colspan="2">Vendor fabricates skid and executes FAT</td></tr>
</table>

System owner insists on challenging flow control in all applicable scenarios and plans for surrogate fluids to be used at the factory. System owner identifies instability in output concentration at low end concentrations that is not visible in flow controller data. As a result, they push harder on PD to expand tolerance and suggest they focus on low-end concentration studies to issue interim report if possible.	With C&Q team oversight, skid performs per design. FAT passes without issue.
Vendor installs and starts up skid, executes SAT	
System owner brings operators to floor during SAT for training and ensures training effectiveness. Sample batch records and SOPs are included to annotate based on observations.	With C&Q team oversight, skid performs per design. SAT passes without issue. Vendor is contracted to provide training during SAT. Facilities representative receives brief overview.
System is qualified and released for use. Process Engineering runs are executed.	
Engineering runs are based on expanded concentration tolerance from recent benchtop studies. Engineering runs prove the new tolerance at scale. Process performance meets expectations. Proceed to PPQ and commercial production.	Engineering runs do not start on time. Operators are not yet trained. Once able to start, engineering runs identify inability to control low end concentration. Significant investigation is required to correct skid performance. Recalibration of flow controllers has no effect. Additional engineering runs are executed to identify viability of expanding allowed concentration tolerance. This sequence results in PPQ and commercial production being 6 months behind schedule.

In the example depicted above, one can imagine many other variations on the sequence of events but in general, the system owner who carries both the perspective of the greater production operation and the authority to guide and focus on GEP is more likely to: 1) identify and correct issues sooner; 2) anticipate operational gaps during planning; 3) achieve the intended startup schedule; and 4) transition smoothly into an operational posture.

TRANSITION PERIOD

While the accepted industry approach to the role of GEPs during the project phase is well defined and documented, there is less clarity around the transition period. Likewise, regulatory framework and industry guidance provide a clear picture of how to define and close the "project" with the qualification of the facility, systems, and equipment. They also provide a clear picture of operational posture, in that basic programs should be in place, such as SOPs, training, change control, and others. However, very little guidance is given around the transition between the two. Although ISPE recently revised its Good Practice Guide on Good Engineering Practice in an attempt to close this gap, the transition defined therein is a process by which the engineering department transfers ownership to the department that will use the system. While such processes can be effective when completed rigorously, in practice, this is rarely the case, in large part due to the same issues discussed in "Defining the Gap."

Most companies struggle with the transition period, not only in execution but also in defining its mechanical nuances. What level of control should be placed over equipment configuration after the equipment is released, but before the process engineering runs have been executed? When should we require that SOPs be approved, versus in a draft state? Does the material we use for engineering runs need to meet all quality metrics or just some of them? Does it invalidate the run if not stored at the right temperature? Does the warehouse staff need to be trained and qualified at this point? These are just some of the many questions that companies grapple with when preparing to make the transition to operations.

The application of GEPs during the transition period is of critical importance to the success of that transition as it relates to efficiency and efficacy. Who is better suited to ensure the success of such an application than the dedicated system owner? Embedded in the team long before the transition begins, the system owner is asking these questions before the answers are needed. Moreover, the answers to such questions may inform their decisions in the review of design documentation. Is this parameter hard-coded or configured? Is it a system-level parameter or is it defined by the recipe? Understanding the different phases of control from design through operation, in the context of the intended operational posture and the likely progression of activities required to achieve it, can meaningfully inform the answers to such questions.

SUSTAINED OPERATIONS

Once an engineering project has been completed, the sustainability of operations requires the continuous application of GEP. The mechanisms for controlling change and making other decisions evolve once those decisions have the potential to impact the commercial products. There are countless additional activities to be managed to maintain the engineered system in good operating condition over its life cycle. Because it is common for system owners to be assigned when the transition from project to operations takes place, at which point those individuals are highly focused on the operational posture, they are less likely to be involved in the engineering process, and instead expect the system to simply "work." Nevertheless, they become a gatekeeper in the sense that they are responsible for approval of all activities that affect their systems. This approach is normal and necessary in the sense that, if the maintenance group intends to halt use of a piece of equipment for regular service and calibration, they should rightfully coordinate that event with the operations team. However, when the system owner's core responsibility is to maintain the production schedule, there is risk of a passive approach to system ownership, characterized by: 1) delayed maintenance and calibration dates; 2) deferred replacement of components that are near failure; and 3) hasty execution of the associated work. This is a recipe for a reactive planning process which can snowball into major problems and, ultimately, compliance issues.

One may argue that the expectations noted above are reasonable. Engineers should turn over systems that "just work," shouldn't they? Current industry experience suggests that often enough, they do not. When a system owner is empowered under our model, they do not simply expect it. They demand it and plan and manage the obstacles to achieving this more perfect state.

Consider how the mindset of a system owner changes when they are assigned during the early engineering phases of a project. They spend a considerable amount of time, often more than a year, identifying the various user requirements from all stakeholders while closely monitoring the design, fabrication, and commissioning of the system to understand how those requirements are met and adjudicate changes. They will have also worked closely with maintenance to ensure calibration and service requirements are well understood, spare parts are on hand, special tools available, and any number of other considerations are managed. When a system owner is heavily invested in the good engineering practice that surrounds a given system, that system owner's core responsibility shifts in focus and perspective. It is no longer from the production schedule onward. Rather it is from the perspective of gaining maximum value for the cost of ownership of the asset. This comes from their initial investment in time and energy being centered around the asset itself and subsequent time and energy around the use of that asset for manufacturing purposes. **A system owner with this perspective is more willing and able to add value in many ways such as:**

1. Proactive and opportunistic scheduling of maintenance and calibration activities
2. Application of thorough technical and practical understanding of the various impacts of decisions which are critical in the documentation and management of changes
3. Generation of creative suggestions on how to better employ the asset; and 4) engagement in the industry of the technology and assessment of valuable upgrades and improvements with an understanding of relative engineering costs versus efficiency gains.

One may argue these are all "Operational Support Practices" within the realm of GEP and, as such, are the responsibility of engineering. Thus, innovation and continual improvement should derive from engineering's responsibility to support the intended use of systems. In practice, however, engineers often have little incentive and less understanding of how to achieve these ends.

In addition, it is noteworthy that the landscape of processing equipment available on the market today is such that many systems purchased for a single purpose are, in fact, capable of much more. The system owner who is involved early will gain an intimate understanding of what a given asset is capable of, regardless of whether that functionality is part of the intended operational posture. There are hidden gains in this knowledge. For example, they will be better equipped to write SOPs with the flexibility to maximize the efficient use of the asset. A procedure need not be explicit on many points when the operators are well trained by a competent system owner.

- Words like "as appropriate" can be used with greater latitude in an SOP.
- OEM manuals can be leveraged more heavily without regurgitation of their content.
- Frequent referencing of OEM literature can expand the team's understanding of a system and the best use of its capabilities.

STAFFING PLANS AND RESOURCE OPTIMIZATION

Meanwhile in the realm of human performance, certain specific operational readiness activities are necessary but are frequently dismissed until the latter phases of project delivery. Having observed quite a number of teams across a range of departments working to support operational objectives, we have often seen these teams falling short of timing and/or production expectations while also experiencing staff burnout and attrition.

With few exceptions, the identified root causes are listed below, all of which can be addressed through the focused attention of System Owners:

- Failure to map the process to job tasks, resulting in ambiguous roles with inadequate qualification and training for the roles and tasks.
- Insufficient staffing plans from a failure to link the role-based staffing plans to a legitimate production schedule that forecasts production capacity during the pre-startup phases.
- Lack of schedule harmonization and communication between manufacturing and other departments who support operations.
- Supervisors (across all departments) mired in the performance of too much operational work, themselves, and losing focus on communication, coordination, scheduling, staff training & qualification, and continuous improvement efforts.
- Inefficient utilization of skills (i.e., experienced staff losing valuable productivity time as they perform other necessary activities). The practice of skill matching is critical here: more junior roles can focus their energy on such activities and can actually be more efficient than senior staff as they are repeatedly performing these activities across the whole department. This approach is an efficient use of skill, and helps mitigate the tendency to hire more highly experienced specialists to perform the full breadth of tasks.

Significant contributing factors include:

- Insufficient "bench strength" for each role due to a lack of focus on progressing the structured, on-the-job training (OJT) qualification of new or cross-training staff.
- Insufficient tracking "dashboard" systems wasting valuable staff time answering questions and sitting in long status meetings.

This resulting staffing situation often leads to unplanned staff overtime, last-minute shift changes and "call-ins", and heroic efforts to complete production runs and product releases. This, in turn, results in exhausted or apathetic staff and, eventually, attrition.

A more efficient, sustainable, and productive approach is to have each System Owner develop a staffing plan during the early phases of a capital project that is based on valid operational schedules. The primary objective is to avoid the state of being unsustainably behind from the start by giving site teams a strong starting point. These may require additional pivots based upon unforeseen changes in site operational goals and workflows. Since System Owners are the most knowledgeable of the processes, procedures, and tasks within their area of ownership, they are best suited to build the associated staffing plans, procedures, and corresponding role-based qualification paths.

THE ROLE OF THE SYSTEM OWNER

The System Owner role is ideally positioned to straddle the two intersecting disciplines of HP and GEP as the project progresses through the roadmap of operational readiness.

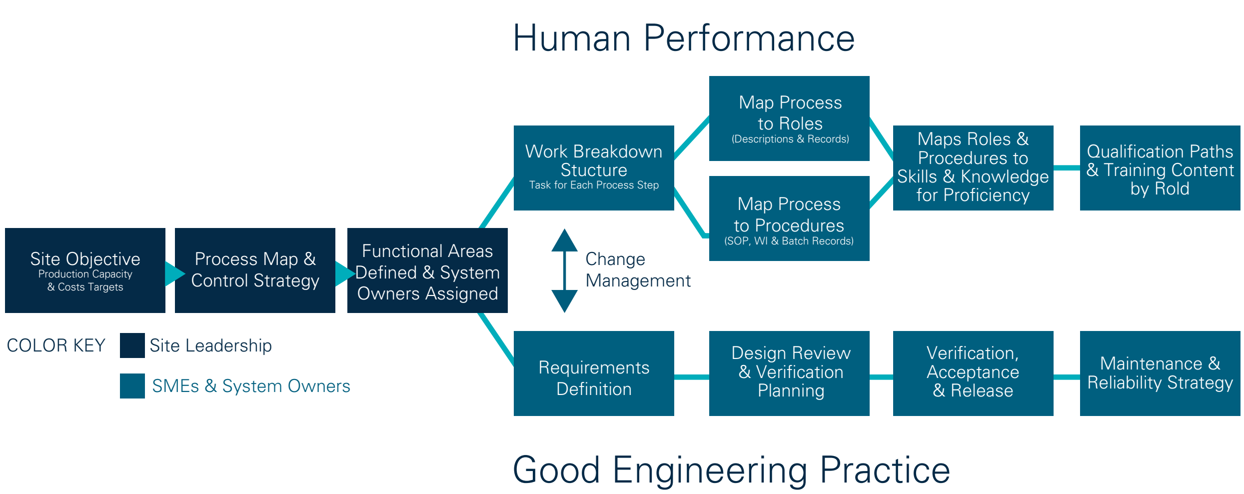


Figure 1 - Operational Readiness Roadmap (Partial)

A useful exercise is to contrast the road map above with an example of what typically happens in our industry:

Each site has a few skilled, experienced people to execute the site vision together. They hire a few more mid-to-senior action-oriented people to pull together the project plan for site readiness.

In the GEP arena, this team remains in a driven, often exhausting, state of catch-up throughout the entire project, relying on contracted resources to keep the project moving forward.

On the HP track, SOPs are assigned for authoring and the "qualification" for each role is simply a list of SOPs to read, as tracked in an LMS or document management system. OJTs or performance checks may be required for a small subset of tasks, but these are often chosen in a haphazard manner designed more to "check a box" than to ensure strong operational readiness. Other than GMP/GDP training, there is virtually no knowledge-centric training, whether in a classroom, via e-learning, video, or otherwise.

The results of this haphazard approach are predictably undesirable and are often responsible for everything from inspection shortfalls and broken workflows to poor productivity, lost product, and release delays due to preventable, human-related deviations.

Thus, one should consider the System Owner approach as a form of risk control. It is a financially sound investment to accelerate the site's productivity by reducing post-start-up issues through the identification and mitigation of risks during the project phase.

Most sites don't assign this type of focused ownership to their systems within the controlled space. While sites in our industry may use a System Owner approach for utilities, these resources often lack the integrated connections to the other departments that have no assigned System Owners. This is curious and certainly warrants consideration of this model for all areas of operations.

From an organizational performance viewpoint, the effective System Owner will leverage their expertise and past experiences to assess the staff performance risks and gaps in their system or process area, then focus fully on developing and instituting technical, procedural, and behavioral controls.

While System Owners certainly must have support from other department staff, they must be the architects and champions of all aspects related to the readiness and continuous improvement of the plant, procedures, and people within their area of ownership. In short, they must own operational readiness and operational excellence.

Consider the following detailed role description for the typical System Owner, and the various skills and talents one should seek in identifying these critical resources.

SYSTEM OWNER – ROLE DEFINITION

Engineering Discipline	Human Performance Discipline
WHAT SHOULD THEY BE EXPECTED TO DO?	
• To fully understand, compile and, if necessary, define user requirements from all stakeholders to form the basis of acceptance for the system in question. • To own the traceability matrix – the information map that illustrates the way the system meets those requirements, throughout its lifecycle from design through release for use and beyond. • To own and curate the library of engineering documentation associated with the system and maintain a working knowledge thereof. • To own the maintenance and calibration schedule for the system, and to assist in the definition and continuous improvement of the maintenance and calibration activities themselves.	• To define work breakdown structure as it relates to systems and equipment utilization. • To define the roles needed to perform the work and establish staffing plan based on production targets. • To develop and maintain standard operating procedures and other instruction-focused resources necessary to perform the work. • Train and qualify personnel in their roles. • Identify and train subject matter experts who represent the next-generation of System Owners.
WHAT SKILLS AND/OR TALENTS SHOULD THIS PERSON START WITH?	
• Basic engineering aptitude (NOT a specific background—this criterion is talent-based, not skills-based.) • Non-zero field experience – Not afraid to push buttons and turn valves.	• Workstream Expertise – Detailed understanding of individual tasks to be performed and the skills required to perform them. Typically a served shift lead or equivalent in a similar or related process.

- Demonstrated sense of ownership and accountability.
- Willingness to work across organizational boundaries.
- Collaborative nature.

Engineering Discipline	Human Performance Discipline

WHAT SKILLS SHOULD THEY BE EXPECTED TO DEVELOP QUICKLY?

Engineering Discipline	Human Performance Discipline
• Interdisciplinary engineering background, as applicable to their system. (i.e. How does it work, and why?) • Integrated C&Q process understanding. • Engineering change management and change control principles. • Applied risk management principles.	• Technical writing skills applicable to SOPs, etc. (Organization-specific.) • Scheduling tools and theory. • Management and reporting techniques. • Familiarity with operational excellence tools and best practices.

WHAT SKILLS SHOULD BE PRIORITIZED?

- Workstream expertise – this should be emphasized as an entering argument for minimum effectiveness. The rest can be learned.
- Willingness to learn – top candidates will demonstrate an eagerness to learn and work across reference frames.
- Anti-silo – individuals should be selected based on an appetite for working across organizational boundaries.

WHAT DEPARTMENT SHOULD THEY BE IN?

- Whichever department is most directly concerned with the system's operational use.
- May or may not be engineering.

Note: All System Owners on the site should work together in a community of practice.

AN EFFECTIVE SYSTEM OWNER PROGRAM

A structured System Owner Program starts with setting clear expectations for the role which, as with any role, should include a method to qualify individuals for the role of System Owner. Focus skill areas to consider might include:

- Basic Engineering Knowledge
- cGMP Knowledge
- System Design and Operational Knowledge
- Defect & Troubleshooting Capability

Site leadership should grant them the responsibility, authority, focus, and full site support to own their section of the operational process. Being a technical SME on a system or process, they must recognize that their equipment is subject to failure and that humans are still necessary to make their systems and processes work as designed. This means they are accountable for the system & equipment design & verification, performance, failure prediction and control, procedures, staffing requirements, role qualifications, and training content. They can't do it all alone and will require support. This support will come, in part, from a broader team of System Owner peers who meet regularly as a support. This group would work collaboratively, supporting and holding each other accountable to effectual output and consistent practices.

CONCLUSION

We have explored the role of the System Owner, starting from the perspective of the ingredients necessary to achieve Operational Readiness, as combined to form the two key disciplines of Good Engineering Practice and Human Performance. When viewed from this perspective, the System Owner role forms a natural bridge between these two disciplines and can be leveraged, from a project and site management perspective, to achieve faster speed to market, better production results, and a more integrated and diverse organizational culture with an emphasis on ownership and accountability, as opposed to the more typical, siloed departmental metrics. We have also established a straightforward business case to justify the early investment in identifying and designating these individuals. We have expanded on the various elements of each discipline that are necessary to the role as we define it and illustrated the ways in which value can be added by this approach throughout the project and operational life cycle. It should go without saying that the role of the system owner does not stop with the successful startup. Continuous improvement is not only good for business but it is a regulatory requirement as well. The system owner should be expected to seek operational improvements and strive for operational excellence through the optimization of their combined assets, namely the plant, people, and procedures.

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