ARE YOU READY?

WHITEPAPER

ROLE-BASED TALENT PLANNING FOR OPERATIONAL READINESS

PART III IN A SERIES OF PAPERS ON OPERATIONAL EXCELLENCE IN THE LIFE SCIENCES

BY HARRY BENSON

ROLE-BASED TALENT PLANNING FOR OPERATIONAL READINESS

As capital projects and technology transfers wrap up and facilities grow nearer to startup, site leaders and team members may be filled with a sense of excitement or dread depending on their confidence in the site's operational readiness. Among the many workstreams of focused effort required to achieve readiness, the acquisition, placement, performance support, and retention of experts, supervisors, and staff for each operational department can be particularly vexing. There is a certain "chicken-and-egg" element to staffing for operations because of budgeting factors and uncertainty about timing. An experienced team is needed first to translate the process to operations at the plant and system level, to map the production process to a set of job roles, and develop procedures and qualifications to control the variability risks of those roles and achieve sustained targeted output and release before the real hiring and training can begin. It is essential that site leadership builds a talent plan and begins the staffing process, including appropriate budgeting, early enough to hit the vertical startup objectives described in Part I of our Operational Readiness series.

This paper intends to provide guidance on talent planning, with specific emphasis on role clarity. Given the flurry of activity being conducted during capital projects and transitions to operations, developing a talent plan may appear to be somewhat administrative or insufficiently urgent. This often leads site leaders to forego a focused and thoughtful talent planning process, treating the "people" workstream of Operational Readiness as a purely tactical staffing effort assigned to recruiting and HR and possibly with insufficient ownership from operational workstream leaders.

The unfortunate results are too common in the life sciences industry: recruiting scrambles; urgent cross-training due to a shortage of qualified and/or proficient staff; startup and production delays due to insufficient expertise in transferring or scaling to the existing production facility; and unsustainable costs during engineering and early production runs as supervisors and staff perform heroic efforts to produce each batch; each product release becomes mired in deviations from "human error". The causes of these and other outcomes are rooted in an insufficient emphasis on the site's talent plan. Just as thoroughly constructed and well-executed tech transfers and master validation plans are effective in controlling risks to process/procedure and plant variability, a well-designed and executed talent plan provides the best risk control for the variability the "people" aspect of sustained full-scale operations (Figure A).

FIGURE A: PRODUCTION VARIABILITY & CONTROL

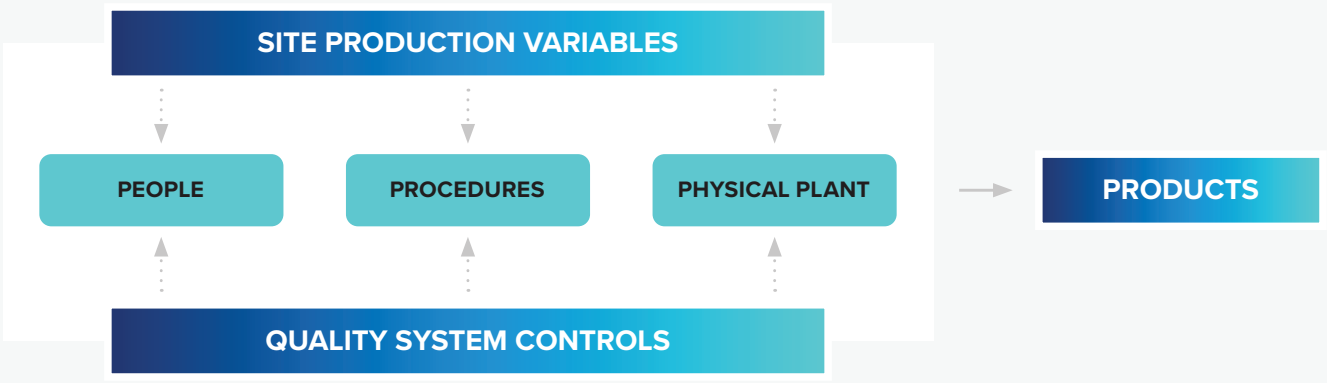
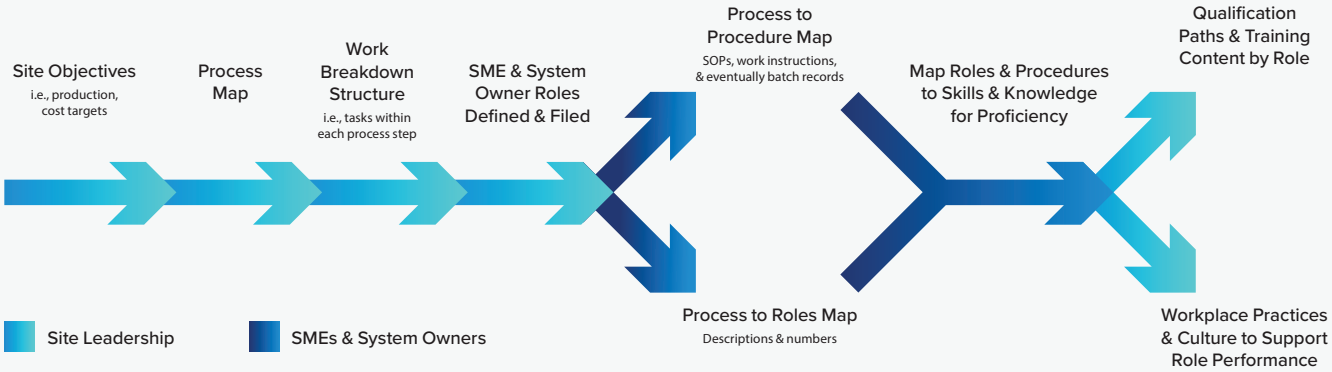


FIGURE B: THE WORKSTREAMS OF OPERATIONAL READINESS

Perhaps the clearest way to illustrate how a talent plan serves to control such risks is to work backward from the desired state of full-scale operations: the production and release of targeted product output with costs sustainably within budget. This state of operations requires staff and supervisors proficient in performing their roles consistently and able to respond effectively to non-standard conditions as they occur with minimal deviations, waste, or loss. To achieve this level of staff proficiency and responsiveness, the site requires a training and qualification program to drive consistent performance under standard conditions while building the knowledge and process understanding necessary to address abnormal situations. To support this path to proficiency, the site must have clean workflows and procedures (both SOPs and Batch Records) to support these workflows. To translate a process from a tech transfer to efficiently streamlined workflows with associated procedures, role designations, and staff qualifications, you need at least one experienced staff member for each functional area – referred to as "workstreams" in Part II of our series, shown in Figure B above. Such experienced people may be designated as System Owners, or maybe Subject Matter Experts (SMEs). Here is where a site's staffing plan begins as part of the talent planning process, as shown in Figure C.

FIGURE C: TALENT PLANNING FLOW DIAGRAM



So how far in advance should site leaders begin their talent planning? As a benchmark, production sites of all sizes and purposes take as much as 2 to 3 years to gain staff proficiency for consistent full capacity production and release within the targeted costs if consistency is reached at all. This is to be expected given that procedures and training are frequently assigned for development somewhat randomly to various team members as collateral duties among all the other project, startup, and production activities. However, if the site builds a talent plan that designates SME and System Owner roles in all the workstreams required for Operational Readiness, this staff proficiency timeline can be greatly accelerated by granting the SMEs / System Owners singular focus, authority, and organizational support to construct all the elements needed for workstream performance excellence.

This practice of granting singular focus, authority, and organizational support can be referred to as **role clarity** and is one of the top two critical factors affecting staff performance – the other being **organizational purpose**. These two factors are closely linked in providing a sense of meaning to inspire consistently effective performance and retention. Workplace psychology has defined role clarity as the degree to which individuals feel they have clear guidance about expected roles and behaviors associated with their job. (Kahn, Wolfe, Quinn, Snoek, and Rosenthal - 1964). There is a strong link between role clarity and performance because individuals who understand what is expected from their roles can tolerate higher levels of job demands (Lang, Thomas, Bliese, Adler – 2007). Conversely, role ambiguity correlates to a higher degree of work stress and the resulting negative mood (Stewart and Barling – 1996), which will adversely impact performance and retention.

For role clarity to be effectively linked to organizational purpose in the mind of a given performer, the individual must perceive a supportive work environment. This demonstrates that the organization values that individual's specific role in achieving the organization's purpose. **A truly supportive work environment requires an intentional focus on the performance health, development, career progression, and retention of this person in the form of:**

- Well-articulated organizational purpose, vision, and measures of success
- Clearly communicated priorities and performance expectations consistent with job descriptions and metrics of success
- Deliberate avoidance of conflicting or shifting priorities from all sources of authority (policies, procedures, site leaders and supervisors)
- Stated levels and limits of authority for the role with escalating procedures
- Sufficient job security and fair compensation for the level of work and associated stresses
- Reliable support resources such as systems, people, policies & procedures. This includes judgment-free outlets for expressing uncertainty or concerns
- Programs, procedures, or channels for improvements and innovations

WORKPLACE FACTORS IMPACTING PERFORMANCE

WORKPLACE FACTOR	DESCRIPTION	IMPACT
ALIGNMENT OF PURPOSE & PRIORITY	• Meaningful mission & goals • Alignment on priorities • Accepted definition of success	+ Inspire staff + Productivity – Silos, dysfunction
ROLE CLARITY	• Clear expectations • Clear authority and escalation procedures • Clear workflows to achieve goal	+ Steady production – Confusion, waste – Exhaustion, apahty
CO-WORKER CONNECTIONS	• Communication regularity, transparency & clarity • Respectful, collaborative, supportive climate • Accountability at all levels	+ Team collaboration + Inter-dept. trust – Internal politics, rumors
COMMITMENT TO IMPROVE	• Staff involved in regular process & workflow review • Process, systems & SOP adequacy & usability • Leadership attitudes / support toward change	+ Quality & efficiency + Staff pride – Disengagement, silence
STAFF DEVELOPMENT, QUALIFICATION & TRAINING	• Strucured paths to qualify for roles / advancement • Opportunity for skill & career developement	+ Quality & Productivity + Goal-driven staff – Skill gaps, apathy
PAY & INCENTIVES	• Fair market value, consistent & dependable • Clear expectations for advancement	+ Valued staff, loyality – Bitterness, turnover
HIRING & ADVANCEMENT STANDARDS	• Standards for recruiting & selection • Fair role assignment & advancement process	+ High standards + Peer respect – Resentment or burden

The above provides a summary of the workplace factors with the most impact upon job performance, including the positive or negative impact of each effective or ineffective workplace factor, respectively. Note that boundaries for decision-making in the form of clarity on limits of authority and procedures for escalation of non-standard situations are important elements of role clarity since understanding one's degree of decision-making latitude can offset the negative effects of increasing job demands *(Karasek, 1979)*.

The effectiveness of a site's communications, within departments and cross-functionally, also has a major effect on performance. A structured approach to site communication routines will enhance clarity on factors that may impact one's ability to perform. Sites should consider the use of a RACI (Responsible, Accountable, Consulted, Informed) model that delineates which roles are to be engaged in any given site effort – whether operational or project-based.

Additionally, using the practice of a cascading cadence of updates on st atus against metrics, near-term priorities, and other site-wide messaging, the site can ensure all individuals maintain clarity of current state vs. desired state, empowering each person to adjust their work efforts accordingly to best impact organizational goals.

Biotech and pharmaceutical production sites should make the elements of role clarity a cultural norm throughout the organization, avoiding the tendency to distract role performance with the "urgent" issues of the moment. **Yet real issues arise on a regular basis:** unexpected QC lab results, failed integrity tests, utility or network outages, supply shortfalls, equipment failures, human mistakes, personnel turnover, safety incidents.

One effective practice to avoid distracting focused performers from their real priorities is the use of "Tiger Teams". A Tiger Team is a set of versatile and creative troubleshooters and problem solvers who can provide an "off ramp" to take ownership of such urgent issues from triage to full resolution as required to maintain controlled focus on the site's larger objectives. This approach is not uncommon in controlling workflows associated with deviations and should be considered for all areas of non-standard workflows.

From the preceding material, along with other lessons of past and future articles in our series, we can list the critical elements of a role-based talent plan as follows:

1. Organizational Purpose and Vision
2. Organizational Structure: identifying roles within workstreams and/or departments, showing the alignment of resources toward achievement of purpose
3. Job Descriptions by Role: with prioritized expectations and task areas, metrics of success, and levels and limits of authority
4. Procedures and Practices for Communications: types with purpose, structure, frequency, affected roles (may be illustrated with a RACI diagram and/or a Communication Planning Table)
5. Staffing Plan: beginning with workstream SMEs and System Owners, continuing with supervisory and staff roles and number per role as mapped from the processes
6. Compensation Plan: categorized and bracketed for fairness and consistency
7. Onboarding and Orientation Program: for a consistent level of initial clarity for all employees of all backgrounds and levels of experience
8. Role-based Training and Qualification Program: setting a consistent structure for establishing role-based curricula and content
9. Succession and Knowledge Management Plan
10. Organizational Support Program: comprehensive explanation of resources focused on maximizing the success of each employee in their role while inspiring their improvement and innovation contributions and their professional and career development

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Serving as the Director Human Performance Services at CAI, Harry Benson leads a team of experienced professionals in developing and executing programs, processes, and tools with our clients to standardize and improve the performance of their people. A former nuclear-trained submarine officer and Master Training Specialist, he is an expert in learning solutions design and delivery with over 20 years of experience in applying current methods for organizational effectiveness and learning within highly technical environments. His methods have led to major skill improvement, driving results-based performance for the U.S. Nuclear Navy and companies ranging from small to Fortune 500.Mr. Benson has a Bachelor's degree from the U.S. Naval Academy, and a Master'sin International Business Administration from Wright State University. He is a specialistin organizational culture and structure, human performance, adult learning, trainingprogram development, and data center infrastructure design and operations.

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