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The Fractional Staffing Model

Maximizing efficiency with the fractional staffing model for staff integration.

In the fast-evolving industries of life sciences and biotech, the demand for highly specialized talent is ever-present. To meet the intricate demands of projects ranging from clinical trials to regulatory compliance, companies are increasingly turning to the fractional staffing model. This approach allows organizations to access expert skills on a flexible, part-time or project-specific basis, optimizing cost efficiency and scalability. While the benefits are clear, seamless integration of fractional staff into existing teams presents unique challenges that demand innovative solutions, meticulous planning and strategic execution.

INTEGRATING FRACTIONAL STAFF

Careful planning and attention to four separate areas are essential for successful integration. These activities include conducting a skills assessment, determining cultural fit, performing knowledge transfer, and setting expectations.

Conducting a skills assessment. A pivotal step in the fractional staffing process is conducting comprehensive skills assessments. This entails evaluating not only the technical proficiencies of potential candidates but also assessing their soft skills and

cultural alignment with the client organization. By conducting in-depth needs assessments, companies can pinpoint the essential qualifications for each role, such as specific technical expertise, educational background, work experience, and geographic considerations. For example, a biotech firm embarking on a new therapeutic development might require a regulatory expert well-versed in pre-IND product filings. A rigorous skills assessment ensures that the selected candidate not only meets these technical requirements but also integrates seamlessly into the project team.

Determining cultural fit. Often overlooked yet critical for successful staff integration is cultural fit. Understanding the nuances of an organization's corporate culture and work environment is essential. This involves detailed interviews and assessments designed to gauge how well a candidate aligns with the company's values, work pace, and team dynamics. For instance, the dynamic culture of a startup may prioritize agility and innovation, whereas a larger pharmaceutical corporation might place greater emphasis on adherence to established protocols and regulatory standards. Ensuring alignment between the candidate's cultural orientation and the company's expecta-

tions enhances integration and overall performance.

Performing knowledge transfer. Effective knowledge transfer is crucial for maintaining operational continuity and safeguarding critical information. Establishing bidirectional knowledge transfer protocols ensures that both the client and fractional staff are well-informed and aligned from the outset. This includes developing robust onboarding and training programs designed to facilitate seamless integration and knowledge retention.

For example, when integrating a quality assurance expert into a pharmaceutical company undergoing a quality uplift initiative, thorough onboarding ensures the new team member is well-versed in existing processes, procedures, and regulatory requirements. This proactive approach minimizes disruptions and supports consistent performance throughout the project lifecycle.

Setting expectations. Clarity in expectations is foundational to successful fractional staffing arrangements. Establishing mutual agreement on deliverables, timelines, and performance metrics from the outset is essential. Regular monitoring and evaluation enables proactive identification of any gaps and prompts corrective action, ensuring continuous alignment with project objectives. For instance, a biopharmaceutical firm engaging supply chain experts to implement new processes for clinical trial materials benefits from clearly defined expectations and ongoing performance evaluations. This approach not only optimizes project outcomes but also reinforces accountability and transparency in the staffing arrangement.

REAL-WORLD APPLICATIONS

Fractional staffing has proven impactful across diverse sectors within the life sciences and biotech industries. For example, large biopharmaceutical corporations, niche biotechs, Contract Development and Manufacturing Organizations (CDMOs), Contract Research Organizations (CROs), research hospitals, and non-profit entities have all benefited from tailored staffing solutions.

Examples of fractional staffing support include:

Regulatory expertise for a 505(b) company: Comprehensive support was provided across multiple product filings, including Phase 1 through Phase 3 clinical trials. This involved meticulous document preparation, communication facilitation, and compliance with stringent regulatory standards.

FDA compliance audits for a pharmaceutical distributor: Conducting mock audits for a pharmaceutical distributor, the team evaluated Quality Management Systems, Design and Development processes, Laboratory Systems, Facilities, Production/Packaging Systems, and Warehouse and Storage Systems. This ensured adherence to FDA regulations and enhanced operational compliance.

Senior quality assurance support for a large pharmaceutical firm: During a Quality Uplift initiative, senior Quality

Assurance expertise was supplied. This included approval of validations, Standard Operating Procedures (SOPs), and other critical QA documents essential for maintaining high product quality and regulatory compliance standards.

Quality support for a biotech company: Assistance was provided to a biotech company with Quality Support expertise. Activities included reviewing and approving Qualification and Validation documents, addressing validation discrepancies and investigations, and supporting procedural enhancements to streamline operations and reinforce compliance adherence.

These examples underscore the versatility and efficacy of fractional staffing in addressing specific industry needs across various operational domains. By leveraging fractional staffing solutions, companies mitigate the need for long-term commitments associated with full-time hires while optimizing operational efficiency and cost-effectiveness.

CONCLUSION

The life sciences and biotech industries are undergoing profound transformations marked by heightened regulatory scrutiny, technological advancements, and evolving market dynamics. Fractional staffing has emerged as a strategic imperative, aligning seamlessly with these trends by offering a flexible, scalable solution for talent acquisition.

By addressing integration challenges through rigorous skills assessments, cultural alignment, robust knowledge transfer protocols, and clear performance expectations, companies can maximize the benefits of fractional staffing. As the industry continues to evolve, embracing innovative staffing strategies will be essential for maintaining agility, driving innovation, and achieving sustainable growth. **CP**



LISA COZZA, Principal at Tunnell Consulting, is a seasoned executive with over 35 years' experience in biomanufacturing and cGMP operations, quality, and supply chain for bulk drug and final drug product in all stages of clinical and commercial production.

She also has extensive knowledge of operations leadership, lean process improvements, external supplier management, CDMO contract negotiations, business development, sales and marketing and alliance leadership. Before rejoining Tunnell Consulting, Lisa was COO at Ridgeback Biotherapeutics, VP at Catalent, Executive Principal at BDO, Executive Director at AstraZeneca, and spent nine years with Human Genome Sciences and nine years with Lonza Portsmouth, all in roles that directly worked with CDMOs.



VALERIE MYERS, Business Director at Turesol Staffing Solutions, has more than 25 years of leadership in talent acquisition and client relations. Her expertise encompasses managing all aspects of the business unit, from candidate sourcing and recruitment to placement and account management.