

FSP STRATEGIES FOR SUCCESS

AN INTERVIEW WITH IOUSTINI POLLALI,
DIRECTOR, FSP AND COMMERCIAL OPERATIONS

In the dynamic landscape of the pharmaceutical and biotech industries, Functional Service Provider (FSP) models have emerged as a powerful solution for companies seeking to enhance operational efficiency and drive project success.

At Optimapharm, with over 17 years of experience, we have established ourselves as a trusted partner, delivering tailored FSP services that meet the diverse needs of our clients. Our track record speaks for itself: over 170 successful FSP placement were made in the last 3 years and our first contract from 2007 is still thriving.

In this interview, we sit down with Ioustini Pollali, our FSP and Commercial Operations Director, who has a wealth of experience, including firsthand work as an FSP employee. We will explore her insights on the strategies implemented to ensure efficiency and quality of our services, the types of clients that benefit most from our offerings, and our key advice for maximizing the advantages of partnering with an FSP provider like Optimapharm. Additionally, we'll explore a successful partnership case study, current industry trends impacting FSP services, and exciting developments on the horizon.

Join us as we uncover valuable perspectives from our FSP Director, designed to help pharma and biotech companies unlock their full potential through effective collaboration.

Ioustini, can you tell us a bit about your background and how you came to be the FSP and Commercial Operations Director at Optimapharm?

My background is deeply rooted in clinical trials, where I initially started my career. Over the years, I



transitioned through various roles, including Clinical Research Associate, Project Manager, and eventually Head of the Clinical Trials Department. Alongside these positions, I also managed responsibilities in Quality Assurance, Information Security and Compliance.

Furthermore, for many years, I managed our FSP employees, ensuring their alignment with our and our clients standards and objectives.

I worked as an FSP employee for some time, which was very valuable. It gave me firsthand experience with the dynamics and challenges of working at a



client site while being employed by a CRO. This role provided important insights and a unique perspective on the FSP model of working. Although I was outsourced at the time, the term "FSP" had not yet been adopted.

Given my extensive experience and multifaceted expertise, I was offered the opportunity to lead the FSP franchise at Optimapharm. This role allows me to leverage my background to develop and manage our FSP operations with excellence, ensuring we deliver high-quality services to our clients.

What strategies do you implement to ensure efficiency and quality of FSP services provided to clients?

We place a strong emphasis on understanding our clients' culture, business models, objectives, and organizational needs, ensuring that candidates have a solid grasp of the client's specific functional area. We tailor our approaches to meet the specific needs of each client, ensuring flexibility and customization.

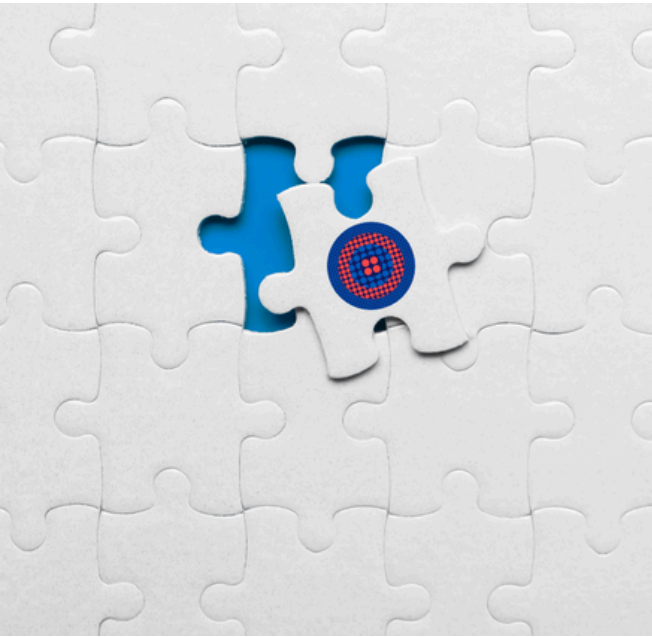
Our resource allocation is optimized to offer competitive pricing without compromising quality. We maintain a pool of highly qualified personnel to quickly scale resources as needed, especially for specialized roles. Our onboarding processes integrate seamlessly with the client's workflows, minimizing delays. By focusing on recruiting and

retaining top talent, we ensure the consistent quality and expertise of our staff, which directly contributes to better project outcomes. We select adaptable and flexible candidates who can smoothly integrate into clients' processes and respond to changing needs. This ensures the right candidate is placed in the right position.

We prioritize aligning our staff with the client's culture to enhance better collaboration and streamline interactions. Effective and consistent communication is a cornerstone of our service, preventing misunderstandings and ensuring smooth coordination. We establish clear communication channels to ensure clients are well-informed and supported throughout their interactions with us. To maintain high-quality service, we gather and analyse client feedback regularly, guiding our service improvements.

We cultivate a supportive work environment to maintain knowledge continuity and ensure stability in our project engagements.

Finally, through these comprehensive strategies, we guarantee the efficiency and quality of FSP services delivered to our clients, promoting successful and enduring partnerships.



The FSP Manager plays a pivotal role in ensuring both client satisfaction and employee performance. It's crucial to communicate to the client the importance and benefits of proper oversight within the FSP program. This dedicated management ensures that both client needs and employee well-being are prioritized.

What measures do you take to ensure FSP employees work efficiently and maintain high-quality standards? Could you describe how FSP employees are managed, supported, and supervised?

An FSP Manager is assigned to each FSP employee. This role is essential for maintaining high standards and effective oversight of the FSP program. The FSP Manager plays a pivotal role in ensuring both client satisfaction and employee performance. It's crucial to communicate to the client the importance and benefits of proper oversight within the FSP program. This dedicated management ensures that both client needs and employee well-being are prioritized. The main tasks of the FSP Manager are the following:

- **Main Point of Contact to the Client:** The FSP Manager serves as the primary liaison between the client and our team. They hold regular cadence meetings with the client's counterpart to ensure alignment and address any issues promptly.
- **Addressing Client Concerns and Questions:** The FSP Manager addresses any performance-related concerns and implements corrective actions,

handles the exchange of personnel when necessary to meet client needs, ensures that overtime is managed effectively to prevent burnout and ensure productivity, coordinates vacation schedules to maintain adequate coverage and meet client expectations and works closely with the client to prepare and conduct performance evaluations for FSP personnel.

- **Proactive Resource Planning:** The FSP Manager is engaged in proactive planning with the client to anticipate and address resource needs, such as adding more personnel to the team when required.
- **Line Management of FSP Personnel:** The FSP Manager do periodic calls with the employees to monitor employee progress, provide support, and address any issues, oversees and approves leave requests, ensuring that operations run smoothly without disruptions, is responsible for maintaining high levels of employee satisfaction by addressing concerns, fostering a positive work environment, and supporting career growth, conducts regular performance evaluations to provide feedback, set goals, and support employee development.

In your experience, what types of pharma and biotech companies or specific project scenarios would benefit the most from utilizing FSP services?

All types of pharma and biotech companies, particularly those with fluctuating workloads, can benefit from utilizing FSP services. As these services offer flexibility, allowing companies to scale resources according to project demands, and provide access to specialized expertise for complex or niche projects like gene therapy or oncology. By outsourcing certain clinical trial services, companies can concentrate on their primary activities, minimizing the expenditure of time, money and resources.

FSP services are also beneficial for companies aiming to expedite time-to-market by streamlining drug development processes and ensuring regulatory compliance. Additionally, growing companies and those seeking to reduce overhead costs find FSP services advantageous for maintaining efficiency and focus on core competencies without the burden of extensive in-house resources.

What key advice would you give to pharma and biotech companies looking to maximize the benefits of partnering with an FSP provider like Optimapharm?

- **Clearly Define Objectives and Expectations:**

Establish clear objectives and expectations from the outset. This includes aligning on timelines, quality standards, and project milestones to

ensure everyone is on the same page and working towards the same goals.

- **Ensure Strategic Alignment:** Align FSP provider capabilities with the company's goals. Regularly monitor performance and provide constructive feedback to maintain high standards and achieve desired outcomes.
- **Maintain Open and Continuous Communication:** Establish and maintain open communication channels. Continuous and transparent communication is vital for promptly addressing any issues that arise and ensuring the smooth progression of projects. Open, and continuous communication channels are vital for addressing issues promptly and ensuring smooth progress.
- **Leverage Specialized Expertise:** Take full advantage of the specialized expertise that the FSP provider brings. This can significantly enhance the efficiency and effectiveness of the company's operations, leading to better project outcomes.
- **Cultivate a Long-term Relationship:** Focus on building a long-term relationship with the FSP provider. This fosters mutual trust and deeper integration, which can lead to more fluid collaboration and better overall results.

FSP services provide flexibility to scale resources and access specialized expertise, ideal for expediting time-to-market and reducing costs.



Can you share an example of a successful FSP partnership with a pharma or biotech client and the outcomes achieved?

Over the past 17 years, we have successfully partnered with many big pharma companies, as well as mid-size pharma and biotech companies, using our FSP model. With over 170 FSP placements in the last 3 years in key functions such as Clinical Operations teams (CRA, Lead CRA, Clinical trial Assistant), Regulatory (Regulatory Officer, Site Contract Specialist), Data management (Data Manager, Coder), Biostatistics (Statistical Programmer, Biostatistician), Medical Writing (Medical Writers, Safety Officer), TMF (TMF Specialist), and Quality (Auditor), our experience and expertise have consistently delivered outstanding results.

One of our most notable partnerships began in 2007 and is still ongoing, demonstrating our dedication and the sustained value we provide. This enduring collaboration has enabled our client to achieve significant milestones, ensuring timely and efficient project execution.

Our proven track record in delivering high-quality FSP services highlights our capability to adapt and meet the evolving needs of our clients, driving their success in the competitive landscape.

What future trends or developments in FSP services are you excited about, and how are you preparing to address them?

The pharma and biotech industries are encountering significant trends that influence FSP services, including increased outsourcing, the adoption of advanced technologies like AI and big data, evolving regulatory requirements, patient-centric approaches, and a focus on rare diseases and personalized medicine.

Future trends include the expansion of real-world evidence, decentralized clinical trials, enhanced data security, AI integration, and sustainability initiatives.

To adapt to these changes, we invest in cutting-edge technologies, continuous workforce training, strategic partnerships, regulatory compliance, and sustainable practices, ensuring we deliver innovative, efficient, and compliant solutions. Additionally, we maintain a comprehensive database of suitable candidates to stay current and identify the right talent.

With more than 170 FSP placement in the last 3 years and proven record of over 17 years of supplying FSP services, demonstrates our ability to deliver outstanding results and sustain long-term, successful partnerships.

