SOURCING THE RIGHT SOLUTION

In today's high pressure pharma and biopharma environment, out-sourced and in-sourced laboratory testing resource solutions, such as those offered by Eurofins Lancaster Laboratories, can enable you with the tools to succeed.

The global biopharmaceutical development and commercial supply chain model is changing. Market forces are causing management to challenge current corporate infrastructure to remove fixed costs and enable greater flexibility and responsiveness. This is impacting the development and commercialisation of new products and also the supply of marketed products to global markets. Mergers and resultant consolidation have only delivered some of the intended cost savings, and global biopharma has been forced to rationalise further in many areas. To further compound these challenges, the generic and biosimilar producers are becoming ever more adept at taking market share quickly.

For the research-based biopharma companies, demands from the regulators for compelling efficacy and safety data from new product candidates have led to numerous failures in clinical development. Clinical functions have increased internal scrutiny on their pipelines and greater selectivity is being practiced to avoid the cost of fruitless development efforts.

Many large organisations have gone from a scatter-gun approach, where multiple development candidates were progressed into late phase to ensure a small number got through, to only developing those with the highest chances of success. Licensing and partnering are high on corporate agendas to address immediate candidate shortages. This has its own effect on development functions, where development candidates are shoe-horned into the CMC development process, and these technologies are often departures from organically developed candidates, exposing both resource and expertise gaps within new leaner organisations.

BLURRING THE LINES

Where product development ends and commercialisation and post-marketing manufacturing operations begin have become blurred. Facilities in western Europe are vying with their low cost, emerging market affiliates and are positioning themselves higher up the value chain, leveraging their experience to support the introduction of late phase clinical and newly approved products to the global supply chain.

Eurofins Lancaster Laboratories has developed models which enable a rapid response to changing demands, while retaining client-specific knowledge of projects and preferred ways of working.

This is a high potential but more unpredictable strategy. Products can fail: market approval does not guarantee immediate success. Scrutiny of individual member states in Europe shows that take-up of new products is slower, with manufacturing campaigns more sporadic.

In the laboratory environment, these factors create opposing objectives. On one hand, biopharma needs rapid access to a wide range of expertise and resources, while on the other, they seek to reduce internal headcount and associated fixed costs.

Through increased out-sourcing of analytical activities, Eurofins Lancaster Laboratories has developed out-sourcing models which enable a rapid response to changing demands, while retaining client-specific knowledge of projects and preferred ways of working.

Full Time Equivalents

The Full Time Equivalent Models (FTE) is based on dedicated testing personnel, who work exclusively for one client. It is most effectively deployed when there is an ongoing need that may increase or decrease in resource demand over time. Typically, analysts are utilised on a monthly basis. A core team operates continuously, with additions accessed when demand spikes. Another significant advantage to this approach is the simplified commercial interaction between the client and laboratory: task specific quotations, purchase orders and invoices are no longer required. Resources are purchased on a 'per headcount, per month' basis, reducing greatly this administration. The client still retains the ability to increase or decrease the resource over time, providing a truly variable cost resource.

A global head of Analytical Development recently discussed this challenge at a business review: "No matter how much we put the effort into defining processes for out-sourcing discreet packages of work to our contract service partners, we always experience inertia at the outset of a new project. Developing project-specific contracts, educating the organisation on our needs and the interaction process to achieve technical transfer always took longer and more resources than we wanted or planned for. Embedding a core team that can service our ongoing needs and the ability to flex the size of the team over relatively short time-frames creates a seamless arrangement between our technical leads and the analytical resources. Once established, the team is familiar with our requirements and can respond quickly, often anticipating our needs."

The FTE approach can be deployed in a number of different scenarios: typically development testing QC or CMC functions utilise it to accommodate gradually fluctuating resource requirements. In the commercial arena, it is often used to provide a cost-effective solution for transitional projects like process development or new product introductions, when the overall scope requires access to specialist expertise over a mid-term horizon. The graphic below shows how FTE ramped up and down over 14 months to support a new solid oral dose product introduction at a manufacturing facility in Ireland.

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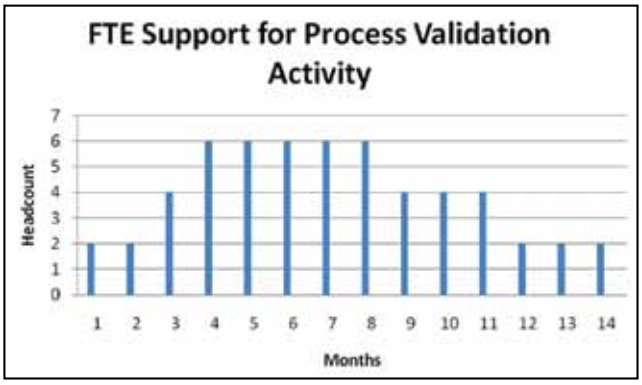


Method Development and Validation	Process Development Support	Stability Set Down

Professional Scientific Staffing

Professional Scientific Staffing (PSS) is an award-winning, in-sourced scientific staffing solution, where Eurofins Lancaster Laboratories utilises its combined scientific and HR best practices to recruit, train and manage testing teams in clients' facilities to undertake specific activities using the clients' quality systems. This model has evolved and extended to meet varying needs of the industry, including discovery, pre-clinical and clinical support, process development, and GMP laboratory services in a variety of scientific disciplines.

Typically a number of drivers lead clients to this solution:

- They have permanent headcount restrictions;
- Traditional temporary contract workers are not delivering the expertise, productivity and consistency in tenure for the needs of the operation;

- Temporary employment legislation is creating commercial and compliance issues for the client operations;
- They require the activities to be conducted within their facilities, IT and quality systems.

"PSS was partly invented by our customers," explains Beth DiPaolo, Global VP of PSS. "Our relationships began with traditional out-sourced services, but discussions began to take us to a more in-sourced solution to meet their needs. They had specific technical leadership expertise. They needed a flexible resource but were looking at rapid expansion of their development and QC GMP lab operations. PSS evolved to provide staffing solutions and has expended across the industry. Now we have more than 500 staff deployed across approximately 30 client locations in the US and Europe."

Taking Over Routine Operational Functions

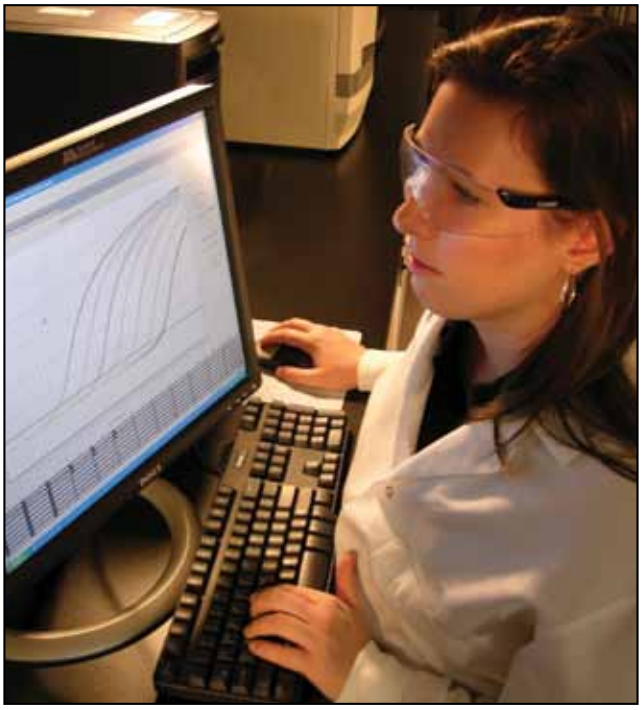
Organisations often use PSS to take over routine ring-fenced operational functions, such as EM and QC testing. As a high throughput GMP testing operation, Eurofins Lancaster Laboratories' PSS has a decade of experience in optimising sample throughput through establishing continual improvement initiatives with the client's lab, achieving improved productivity and ultimately cost reduction.

PSS can also be used to augment functional testing teams within the overall laboratory structure, when demands move from area to area over time. Cross-training enables staff to move within functions easily, giving greater inherent flexibility to support headcount demands as they arise across the wider organisation.

All PSS Teams have an on-site leader, who is responsible for providing technical contributions, team oversight, client satisfaction, and ensuring all quality and productivity metrics are met. This provides effective point of communication with on-site client management for planning purposes and ensures performance of the group is effectively managed. It also ensure compliance with the Temporary Workers Directive, in that the management of resources is orchestrated by Eurofins Lancaster Laboratories, so clients are freed up to focus on their priorities. All PSS staff are full-time Eurofins Lancaster Laboratories personnel, outside of the client's reporting framework. Employees receive all the benefits of Eurofins Lancaster Laboratories full-time positions.

A PSS Case Study

"We recently met with a major UK-based pharmaceutical client," notes Beth DiPaolo. "The discussion followed an increasingly familiar path. Their needs were diverse: focusing fixed internal headcount on high value technical projects, while achieving high efficiency in the more routine microbiology QC laboratory, with the ability to flex to variable demand. Sometimes, activities are not able to be remotely out-sourced, as capital equipment and facilities are in place. The implications of working outside the organisational LIMs and quality systems can be too significant, with quality and compliance at the top of the client's agenda. For this client, PSS proved the perfect solution."



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Success was dependent on delivering the elements of the project:

- Appropriate recruitment and skill sets;
- Cleary defined scope of work and operating procedures;
- Effective and fast induction and training;
- Ongoing management within a continual improvement framework.

Both FTE and PSS models provide solutions to manage laboratory testing activities effectively. Both scenarios allow access to Lancaster Labs' technical expertise and experience through variable cost frameworks. The right solution depends on the client scenario and their operational and risk assessment approach. Increasingly, organisations use these models in combination, thereby achieving maximum flexibility.

For either in-sourced or out-sourced resource solutions, contact Mark Glass, Business Development Director at Eurofins Lancaster Laboratories by email: mglass@Lancasterlabs.com.