

LANCASTER EXCELS IN LABORATORY CONDITIONS

Effective outsourcing of laboratory activities, such as that offered by Lancaster Laboratories, can allow biopharmaceutical companies to achieve improved operational performance.

Meeting the changing demands of development, commercialisation and manufacturing activities as part of a global organisation is a significant challenge and is key to the success of Ireland's biopharmaceutical operations. Outsourcing laboratory activities enables access to extended capabilities and capacity without commitment to additional fixed costs to manage both routine and exceptional demands on GMP operations. Progressive outsourced GMP service providers now present flexible solutions to allow access to resources both within their own GMP operations and those of the client, and are becoming an increasingly strategic component of the pharmaceutical operational modus operandi.

The biopharmaceutical industry in Ireland has changed significantly in recent times. Economic factors have accelerated the actions of global Pharma to rationalise its activities. Implications of patent expiration are forcing the industry to achieve more efficient development and commercial supply chain operations.

Companies no longer rely on pipelines being fed by self-discovered entities and the demands of acquired product candidates, combined with a shift towards large molecule technology, means operations need the ability to accommodate changing requirements, while under the continual pressure to focus their fixed resources on high value activities. More than ever, the realisation that commitment to costs cannot be long term obligations is changing the way global biopharma views what is core and which activities can be delegated to service providers.



Lancaster Laboratories' EU operations base at Dungarvan, County Waterford, Ireland

INCREASING FLEXIBILITY

Procurement is now a key discipline within the operations of Irish facilities. Initially tasked with reduction in cost,



Lancaster Laboratories', Pennsylvania facility.

their responsibilities are evolving to support technical disciplines to create more flexible operations. "They need not only to avoid fixed costs and create a more demand-orientated variable cost base, but also to ensure that operations are not exposed to risk and that delegated or outsourced activities are optimised," explains Mark Glass, Business Development Manager at Lancaster Laboratories. "This means more focus on how service providers are utilised, ensuring interactions are seamless and activities are planned rather than reactionary, so value for money is optimised in both the short and longer term."

Lancaster Laboratories has been in operation, supporting the biopharmaceutical industry for 50 years. In 2007, it established its EU operations base in Dungarvan, County Waterford, through acquisition of Microchem Laboratories, which has been supporting the industry in Ireland for 25 years. The creation of a harmonised global service organisation enables the support of common requirements and demands of operations located in the US, Puerto Rico, Ireland and other industry regions in the UK and mainland Europe. Analytical expertise, methods and support models can be transferred between the US and EU as the demands of their customers dictate, ensuring best practice is accessed and set-up activities are not duplicated.

The pressure from the emergence of new markets and locations in Asia and Eastern Europe accentuated the need to provide flexible service models to enable facilities to meet the demands of their global organisations. GMP service providers have evolved to meet these needs. "This has led to in- and out-sourced service solutions, allowing access to technology and human resources to optimise short, medium and long-term operational needs," notes Glass. "In many cases, adoption of continuous improve-

ment frameworks, such as Lean, are on parity with client organisations. Concerns over financial security and access to capital for investment to meet client requirements no longer exist, as many are part of global diversified corporations, with the ability to respond to industry needs.

“These factors are critical in allowing operating facilities to rely on third parties to support development, manufacturing and supply chain activities. However, successful delivery of facility performance is dependent on the appropriate selection of the right service provider. Investment in that relationship is critical, so that appropriate service models can be utilised, working processes optimised, and waste and cost avoided. The effective supply of therapeutic products into the global supply chain is paramount.”

Biopharma organisations must take a risk-based approach in selecting their service partners. Outsourcing is not a new concept or practice in global industry, but only in recent times has it become part of biopharma strategy. This is due to the emergence of robust and progressive outsourced service providers whose competencies enhance their clients’ operations.

In a manufacturing dominated environment, contract analytical services present a valuable tool set to enhance both the variable demands of production facilities and assurance of quality and compliance. Here are some key factors to consider when evaluating in-and out sourced scenarios.

Service Models:

Several tiers of support exist with activities undertaken either at the service provider location or within client facilities.

Fee for Service:

This is the traditional, transactional outsourcing method, which is still optimal for many sporadic or short term capacity or technology needs. Client organisations request a defined test or service which is delivered and invoiced. Raw material testing is often managed under this arrangement because of the inconsistent stream of samples which client facilities are increasingly reluctant to support themselves, so avoiding maintenance of costly laboratory infrastructure for this ‘non-core’ testing activity.

Full Time Equivalent (FTEs):

When projects are longer term and analysts can be dedicated to a single assignment, utilisation of FTEs can be a more cost effective way to sub-contract laboratory projects. Clear deliverables and project milestones must be defined and regular interactions between supplier and client to ensure performance metrics are delivered and the project is on track. Longer term project based work such as process development, method remediation, stability programs and cleaning validation studies often lend themselves to the FTE service model.

Professional Scientific Staffing (PSS) Models:

Many pharmaceutical operations have the facilities

and systems established to support activities but have a constraint on headcount. Often, temporary contracts are deployed to fill this interim or contingent need. This approach can create challenges for the incumbent management team, supporting training and induction needs and backfilling the often higher attrition rate of temporary staff. PSS enables more effective access to trained staff with on-site management and remote oversight, ensuring that more effective training, deployment and performance management of in-sourced teams is achieved. Lancaster has deployed PSS teams into biopharmaceutical operations in Ireland and the UK. This is often implemented to allow allocation of permanent staff onto high value or core activities.

PSS Teams are a proven solution to more efficient environmental monitoring operations where key process learning from the contract environment has been successfully applied to enhance in-facility testing operations.

PSS can also be utilised to augment functional units which need to flex as business needs change. This can be achieved by the provision of a pool of trained staff that can join development or QC testing teams as required to accommodate work loads. An on-site supervisor analyst coordinates the allocation of resources to the various client functions being supported.



GLOBAL PRESENCE WITH THE ABILITY TO INVEST

It is important that service organisations have comparable financial stability and global footprint to their clients. Many pharmaceutical companies have operations in the US, Europe and increasingly in Asia. “As part of Thermo Fisher Scientific’s Biopharma Services Division, Lancaster has established operations in both the US and Europe and can invest to meet the needs of the evolving industry,” explains Mark Glass. “Large Molecule product testing, UPLC, Genotypic Microbial Identification and a global LIMs platform are examples of capability investment to meet the needs of a changing landscape. This infrastructure and capability allows Lancaster to provide parallel services to their clients’ global locations, enabling alignment of best working practices.”

This diversity of locations, service models and client base allows varied technical and ancillary career development. Contract Analytical Services combines the need for

COVER STORY

excellent scientific expertise with those of client services and project management, quality assurance, IT and business development. Lancaster's employees have the opportunity to combine their technical training with important client facing skills, working within their own facilities and those of their clients.

COMMUNICATION AND CONTINUAL IMPROVEMENT

How organisations work together to ensure objectives are met and processes are improved is core to successful outsourced relationships. The service providers must be experienced in managing the communication task with dedicated client services and project management functions.

The use of performance metrics to allow objective assessment of how well activities are being expected is essential to implement continual improvement initiatives and drive efficiencies throughout laboratory service operations.

QUALITY AND COMPLIANCE

Only by having an in-depth, experienced-based understanding of GMPs in the major regulatory zones can service providers meet the expectations of global biopharma. Many of Ireland's operations supply global markets, so a strong inspection history with the Irish Medicines Board and the Food and Drug Administration is essential.

IN CONCLUSION

Outsourcing of GMP analytical services and the access to contingent technical staff is becoming an important part of the GMP facility tool set. World class outsourced service providers have emerged to meet these needs and now form a growing part of the industry, both in Ireland and globally. To support the biopharmaceutical client base, outsourcing partners need to have the corporate stability and access to resources to ensure capital investment and staff development continue to meet the ever increasing demands of the industry. Experience with the industry regulators and a track record of continual improvement will ensure effective relationships with operational and quality counterparts across client and service provider organisations.

"Whether the challenge is to manage the variable demands of globally compliant raw materials testing, drive efficiency in environmental monitoring operations or to access analytical expertise to support in process or finished product testing," concludes Glass, "the GMP service industry has the capacity and capability to enable you to achieve operational success."

For more information on outsourced solutions and Lancaster Laboratories, visit www.lancasterlabs.com or contact Mark Glass on +353 58 48300.