

STRATEGIC OUTSOURCING – A BIOASSAY CASE STUDY

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Increasingly, pharma and biotech firms are searching for new drivers of revenue and profit growth. There are a number of trends and forces within the pharmaceutical industry that are causing companies to rethink their approaches to growth and cost management. These include:

- Shrinking pipelines of new drug candidates
- Soaring Pharma R&D costs
- Expiring patents for existing drugs, allowing generic drugs to erode sales of billion-dollar “blockbuster” drugs
- Increasing price pressures in the US and many European countries, cutting into margins

Outsourcing is one of the commonly used approaches that pharma companies use to achieve the above goals. It has brought a number of advantages that appeal to those companies:

- Cost savings
- Ready access to expertise
- Speed and flexibility
- Conversion from a fixed cost structure to a variable one
- Avoidance of big capital outlays, allowing to use capital more efficiently
- Opportunity to focus on core competencies

Pharma companies vary widely in their outsourcing policies. For the sake of the discussion here, we are limiting ourselves to analytical outsourcing. In that laboratory context, each outsourcing activity typically fits in one of the two following models:

Tactical outsourcing - relates to short-term projects that cannot be handled internally by the pharma company for reasons such as lack of lab capacity or resources. Peak work loads can be handled by tactical outsourcing, and decisions are made on a project by project basis.

Strategic outsourcing - based on the receiving partner's core strengths and long-term goals. More than in the case of tactical outsourcing, capital expenditure in expensive lab infrastructure and equipment can be limited, and the pharma company can focus on core competencies.

While SGS performs a high volume of analytical services that are outsourced by its pharma clients in a tactical context, there is a trend to more strategic relationships. This means that more and more preferred providerships are put in place, which are materialized by global master agreements that contain quality requirements, volumes of tests, pricing and sometimes other aspects such as turnaround time. In this model, synergies between pharma company and the contract laboratory can be maximized, as such partnership allows for effective communication, and even transfer of work practices to the receiving laboratory.

CASE STUDY – A LAB FOR THE OPSONOPHAGOCYTOSIS BIOASSAY FOR A SINGLE CUSTOMER

Picture the following scientific context. An effective way of preventing pneumococcal infections is to vaccinate the population. A conjugate pneumococcal vaccine elicits antibodies to pneumococcal capsular polysaccharide, and these antibodies protect the host by opsonizing pneumococci and thus facilitating phagocytosis. The ability of a serum sample to opsonize bacteria can be measured by various in vitro opsonophagocytosis assays (OPAs), and OPAs have been shown to be the

best functional correlate of protection in various studies (Romero-Steiner et al., 2006).

SGS Life Science Services was approached by a biopharmaceutical company that was looking for a partner to execute its version of the OPA bioassay in the context of such pneumococcal vaccine development. The selection of SGS as partner was based on the expertise of the staff, the infrastructure of the dedicated biotechnology laboratory

at SGS's Wavre (Belgium) facility and geographic proximity. Sufficient space of the correct biological safety level (BL2) was available at the Wavre facility – which is the competence center for biological assays and all other “biotech”-type of analytical requirements. However, in the context of this OPA assay, more than a dozen bacterial strains would have to be cultivated, as well as the phagocyte cell line. To minimize all contamination risk with other ongoing bacterial and cellular work at the facility, it was concluded that

an exclusive single-client OPA lab would have to be established. These client requirements were counterbalanced by a long-term master service agreement.

Outsourcing can never mean: leaving it all to the receiving lab. A project manager at the pharma company (client) carefully organized the knowledge transfer to SGS. This included applying the client's specifications in setting up the lab and purchasing and qualifying equipment, as well as extensive hands-on training of all SGS personnel directly involved in this intricate assay at the client premises. Setting up the dedicated OPA lab, and organizing the assay at SGS, was truly a joint effort, with the client providing a custom-made robot, and a key consumable. Results are delivered directly into the client's electronic data system. The client's QA department audited SGS's

lab, and a representative number of bridging samples were assayed.

All OPA technicians, and the infrastructure, with the operations as a whole, successfully completed the qualification process. SGS and the pharma client, with its particular bioassay needs, are now launching the routine stage of the operation. Both parties are celebrating the win-win situation that advanced strategic outsourcing can bring.

CONCLUSION

A cell-based functional assay was transferred to SGS in a carefully managed process of qualification and knowledge transfer. The long-term contractual agreement was based upon the client assuring capacity and quality levels at an interesting price, while SGS, as the

outsourcing partner, invests without hesitation in infrastructure and dedicated staff. Such advanced strategic outsourcing will allow the pharma company to focus on its core competencies, and to have its drug product on the market faster, at reduced cost.

REFERENCE:

Romero-Steiner S., Frasch C., Carlone G., Fleck R.A., Goldblatt D. and Nahm M.H. (2006). Use of Opsonophagocytosis for Serological Evaluation of Pneumococcal Vaccines. CLINICAL AND VACCINE IMMUNOLOGY, p. 165–169

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