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# Flexible Outsourcing Solutions

## Leveraging Strategic Laboratory Services Partnerships

**Ensuring the efficient development of a safe, differentiated, high-quality drug and supplying it to patients in need is at the heart of the strategy and decision-making in any pharmaceutical company. Making this a reality though comes with many challenges.**

Outsourcing is an established strategy in the Pharmaceutical industry and there is a growing trend in larger organizations adopting a more streamlined approach to working with partner service providers. Outsourcing of CMC-supporting laboratory services offers developers and manufacturers **solutions to remain competitive and flexible** in a world with a challenging economic environment where there is a continual need for **innovation, strengthened pipelines,** and **performance improvement.**

There are multiple modes of working within the sphere of outsourcing laboratory services. These include arrangements where partner staff become embedded within the sponsor organization, transactional relationships where a defined set of testing is performed on a case-by-case basis and also contracts based on Full-Time Equivalent (FTE) agreements.

**Strategic partnerships can bring benefits across your business, from finance to technical. These close relationships are critical to success.**

- **Procurement Director** – Benefits: Tighter vendor management enables close control over costs and reduction in costs.
- **Outsourcing Manager / Third Party Overview Team** – Benefits: A better understanding of what the vendor does, including capacity, capabilities and flexibility. A close work relationship facilitates the fertility of this growing relationship, for example, enabling open discussion about future technical requirements which may involve significant investment in kit and people in the partner organization.
- **Technical Team - Management** – Benefits: Closer working relationship with the technical teams in the partner organization, enables effective and efficient assessment of methods prior to work commencing and supports the need for a full understanding of the capabilities of each vendor and the expectations and perceptions on both sides.
- **Technical Team - Technical Expert** – Benefits: More efficient and interpersonal interaction technical staff on equal footing, like mind and using the same language and background.

## Strategic Partnerships Examples

### 01 FTE Agreements

Within an FTE contract agreement, the partner provides a dedicated project team that is suitably aligned to the sponsor's project for a specified period with a pricing model based on a fixed rate per FTE unit. This arrangement is typically more appropriate for a long-term relationship or project and its suitability depends on the nature and scope of the work, timelines, and study duration, as well as the level of commitment that sponsor and partner can invest. Examples of projects that are typically suitable for an FTE arrangement are included below.

| Typical Projects Suitable for an FTE Agreement |
|---|
| Raw materials quality control testing |
| Stability programs for multiple compounds or multiple dosage strengths/forms and package configurations |
| Commercial release and stability testing for a new drug product |
| Formulation and stability programs for multiple dosage strengths/forms and package configurations |
| Analytical method development and validation for new chemical entities in the sponsor |
| Process and cleaning validation studies for a finished product |

**Critical Considerations for Success**

**Joint Oversight** – Positioning joint management teams internally and externally can work to facilitate communication and define "escalation paths" to joint steering committees.

**Joint Training** – Enables a better-aligned understanding of how work will be done (training on SOPs, on roles and responsibilities, etc.) as well as a common vocabulary regarding the project in mind.

**Transparency** – When CROs has greater insight into the goals/plans of their sponsors, they can anticipate resources better.

### 02 Contingency Outsourcing

Where an organisation finds itself in a position where they need to prioritise one program over another due to unforeseen pressures on internal resources, contingency outsourcing comes into its own. Across 2020, organizations experienced unprecedented challenges related to the available resources due to the need for social distancing or the need to refocus team members to vital development projects.
Contingency outsourcing can also help to de-risk large complex parts of development programs such as stability studies which demand considerable financial investment, time and scientific expertise. Disruption to these programs could directly affect a product's development activities, potentially impacting the product's market launch.

Transferring a program, or a part of a program, to a partner such as Intertek would minimize the need to slow down any activity whilst helping to overcome potential pressure points such as the smooth transfer of analytical methods.

For organizations who perform ICH stability programmes in-house the need to reduce risks associated with stability storage can be reduced by working with a specialist outsourcing partner with large capacity stability storage, who can offer responsive relief storage in the event of disasters (e.g. extreme weather, flooding, fire, electrical failures, power outages, software failure or even human error).

### 03 Mitigating Risks in Batch Release

To ensure business continuity in relation to quality control programs and release of pharmaceutical products, an analytical supply chain risk mitigation program supporting sourcing of reagents, columns and other analytical consumables can help the agility of your organisation to respond to supply based challenges, for example, such as those associated with COVID-19 or Brexit.

### Case Study: Success is in the detail

**The use of an alternate ELISA kit for quantitation of a marker protein in a cell-based potency assay was investigated. On reviewing specification, the products appeared identical and as such considered an ideal alternate. On testing, however, no protein was quantifiable in the sample using the alternate product, although operability was confirmed from standards.**

**On investigation, the same anomaly was observed with the validated product. The root cause of the issue was identified due to a change in the well plate. The plate used was in accordance with the specification in the original method, however, not enough detail was documented. An equivalent plate was sourced and it was demonstrated that the assay had an equivalent performance with both the original and alternate kit.**

**This scenario is the perfect example in when performing equivalence or alternate evaluations the validated method needs to be fully understood and that the first point in experimentation is establishing the operability of the validated approach without any change.**

## Our Method Transfer Solution

**Method transfer is a key part of any analytical development partnership. It is important that this is performed efficiently and accurately with foresight ready to respond to any unforeseen challenges that may arise.**

- Our teams reviewed what drove success in a method transfer, and we believe the following considerations are key to the process;
- Ensuring as close as possible an **equipment match**, down to make and even model of liquid chromatography system, and naturally ensure all equipment/system(s) are qualified, monitored and in compliance with any specifications.
- We have our **experts fully review all methods and previous validation reports** pertaining to the method prior to initiation, to highlight any points of ambiguity before we start.
- We only apply resources where **staff are highly trained in technique and application.** For complex methods, we welcome sending out a team to your site or having your experts supervise training within one of our facilities.
- **Communication is key**, we ensure that we are aligned on critical aspects we will be evaluating to show **method suitability prior to initiation** and encourage technical to technical contact, with full access to all our team from the analyst performing the work to our technical experts.
- **Regular contact meetings** are encouraged where we can discuss any issue and work together to resolve it. **Partnerships** always produce the **best results.**

## Intertek, your Total Quality Assurance Partner

As a quality and science-led **Total Quality Assurance** company, our scientists can add value to your processes and products through high-quality partnerships focused on getting exactly the right laboratory services resources you need to meet your milestones.

Our team support you across your development and production lifecycle including **cGMP and GLP/GCP compliant** characterization, stability, release testing and bioanalysis. You will need a **strategic partner** who invests in scientific and technical excellence to help you to develop and launch a pipeline of new products that meet the needs of patients, buyers and consumers.

At Intertek, our purpose is to **bring quality and safety to life** and as a strategic partner, we share your concerns and will support the speed and efficiency of your innovative pipeline development with a focus on delivering consistently with **precision, pace and passion**, enabling you, our customer, to power ahead safely.

- **30+ years' experience in regulatory-led analytical services**
- **Over the last decade, our scientists have developed several major vaccines**
- **Experience delivering a variety of outsourcing models, from FTE basis to entire laboratory outsourcing**
- **Europe's largest facilities: ICH Stability & GMP for OINDP development support, and a 60,000sqft Centre of Excellence for Biologics**

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**Please contact our support team to see which solution would work for you.**

**TOTAL QUALITY. ASSURED.**