

## Five Good Reasons to Consider Outsourcing Analytical Testing

Defining what you do best as a company, where you add most value, and conversely, areas of lower efficiency can be a productive route to greater profitability. For manufacturers, analytical testing is essential, from R&D to QC, but it is not a primary output and often not a core competency. This raises the question of how much in-house analysis is optimal. The answer is unique to each organization but the factors in favor of contract testing are universally applicable. In this short whitepaper we look at five of the most compelling.

### 1. To access the analytical expertise required for robust, precise measurement and reliable data interpretation.

Certain analyses are extremely simple, but many others, particle size analysis being a prime example, remain more challenging than is often appreciated. External analytical experts bring an experienced and objective perspective to analytical problem-solving. They can accelerate the development of a robust method - for a new instrument, material or application - and ensure effective data interpretation, maximizing the value of an analysis.

Accessing the right expertise is crucial. Better, more effective analysis may require a different technique or instrument, a revised method that works for a wider range of materials, or smarter data analysis. Look for experts that can demonstrate a thorough knowledge of relevant technology, an in-depth understanding of the factors that impact measurement, and the scientific fluency to present data in a valuable and relevant way. Industry-specific experience and proven skills handling the sample type of interest is highly valuable. Using a contract service offered by an analytical instrumentation company may be a good route to world-class analytical expertise, with the best having the independence to draw on solutions from multiple vendors to enhance their offering.

Outsourcing buys analytical expertise to support complex tasks such as method development and data interpretation, ensuring optimal data quality and usage.

'I've changed suppliers and was assured the raw materials were the same. Now I'm having problems with quality'

'These pharmaceutical tablets dissolve at different rates even though the formulation was the same'

Sometimes it is easy to recognize that an analytical strategy is no longer fit for its intended purpose. A failure to detect difference, which only becomes apparent during processing or to the customer, is a potentially expensive problem and a frequent prompt to seek expert help.

### 2. To ensure that analyses are carried out with the best instrumentation for the application.

Contract testing laboratories compete by having optimized analytical solutions for a range of applications. Innovative techniques and up-to-date instrumentation are therefore business critical for the best providers. Companies that don't specialize in analysis, in contrast, tend to hold only essential instrumentation. When it comes to accessing the information needed, for example, to reach an R&D goal or solve a processing problem, this instrumentation may simply be unable to provide the necessary information.

Purchasing a new instrument is a high-risk solution. Which is the best instrument to buy? Will a single, new instrument be able to provide all the answers? And how much will it be used over the long term? Accessing the necessary information by outsourcing analysis is lower risk and more cost-efficient. Analysts in a good contract testing lab have access to a wide range of state-of-the-art instrumentation that optimizes the utility of a technique. Furthermore, samples are easily analyzed on multiple instruments to gather the complementary and relevant data required to unlock progress.

Outsourcing buys an optimal analytical solution at modest cost, avoiding the risk and investment associated with new instrumentation.

### 3. To reduce analytical expenditure, most especially capital investment.

A major benefit of contract testing is that it eliminates the requirement to justify capital investment in analytical instrumentation. The flexibility to 'pay-as-you-go', without committing CAPEX is especially valuable in the earliest stages of a project when the long-term need may be unknown. However, contract testing is more generally competitive with in-house analysis when fully built up cost per sample is accurately assessed.

The costs of contract testing are of course, transparent. They are based on a defined analytical specification and response time – with higher costs for faster analysis. In-house costs may be less immediately obvious but include:

- The expense of recruiting, hiring, employing, training and re-training personnel to maintain an effective analytical capability
- Ongoing spending on maintenance and repair to minimize downtime and safeguard instrument availability
- The purchase of consumables – hardware and chemicals (dispersants, solvents, liquid nitrogen etc.)
- The disposal of any hazardous waste produced during analysis.

Outsourcing is extremely cost-effective because it minimizes CAPEX and the costs associated with maintenance, consumables and analytical personnel.

### 4. To alleviate the effort and costs associated with compliance.

Compliance with relevant standards is an essential aspect of industrial life, especially in the highly regulated industries such as pharmaceuticals. However, it is an arduous and exacting task. With outsourcing compliance becomes largely the responsibility of the contract laboratory saving time and effort. Such savings extend to the requirement to routinely – weekly or monthly – measure reference/calibration standards for validation purposes, with standards that may be surprisingly expensive.

Accreditations provide external confirmation of the technical competence in the operation of a contract laboratory and reassurance that work is going to be carried out to the required standards. Compliance is with recognized bodies that have established standardized test methods and

practices. Key bodies include the International Organization of Standardization (relevant standards: ISO 9001 and 17025), the American Society for Testing and Materials (ASTM), and the United States Pharmacopeia (USP). Registration and licensing with regulatory agencies such as the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) are a must when working with the substances that these organizations regulate using specific controls and procedures. For FDA registration these controls include the regulations associated with Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP).

Outsourcing transfers much of the arduous burden of compliance to the contract lab, saving time and money

### 5. To effectively manage in-house workload, particularly when analytical requirements are minimal and/or increasing rapidly.

In many organizations, particularly in the developed economies, labor accounts for the majority of variable costs. Optimizing the skills, area of focus and workflows of the in-house team is therefore essential. Outsourcing analysis frees up time for in-house teams to develop core competencies and focus on higher value tasks and can be especially valuable when resourcing requirements are in flux.

In the early stages of a project, for example, the analytical requirement may be light. There may be too little work to justify a recruit, but too much to easily pick up. Later in development, the data requirement may rise rapidly, swamping an existing analytical facility and making the purchase of an additional resource the easiest answer. Contract testing valuably accommodates rapid and significant changes in analytical demand with no requirement for the company to change structure, organization or to invest in re-training.

Outsourcing analysis allows the in-house team to concentrate on higher value activity and allows a flexible, rapid response to fluctuating analytical requirements.

“We need to understand how this catalyst behaves at high pressure and temperature – what kind of performance can we expect?”

“How well does our new milling process control the particle size of our active pharmaceutical ingredient?”

Outsourcing analysis effectively hires a team of experts to answer the questions you need to address. There's no need to have a technique or method already in place – an optimal solution can be developed based on the information required and sample type.

## The bottom line...

Outsourcing analytical testing isn't always the answer. At-line analyses to drive process control, for instance, are often an integral part of company operations. However, outsourcing is a commercially compelling, low risk, flexible strategy for much analysis and can be particularly attractive for accessing the very best support in R&D. Choosing the right contract testing service is key. Look for one with the depth and breadth to successfully tackle your analytical issues, with the efficiency to deliver at a cost and price that meets your requirements and with the accreditation that provides you with the necessary reassurance of quality. The right service will improve analytical effectiveness, while at the same time reducing costs.

“Characterizing this formulation in as much detail as possible is going to help me optimize efficacy, effectively scope a design space for the process and provide a more secure basis for regulatory submissions.”

In some industries, pharmaceuticals being a prime example, the prize of being first to market makes the very best analytical information extremely valuable. Outsourcing analysis can be a cost-effective way to access the latest and most relevant techniques.