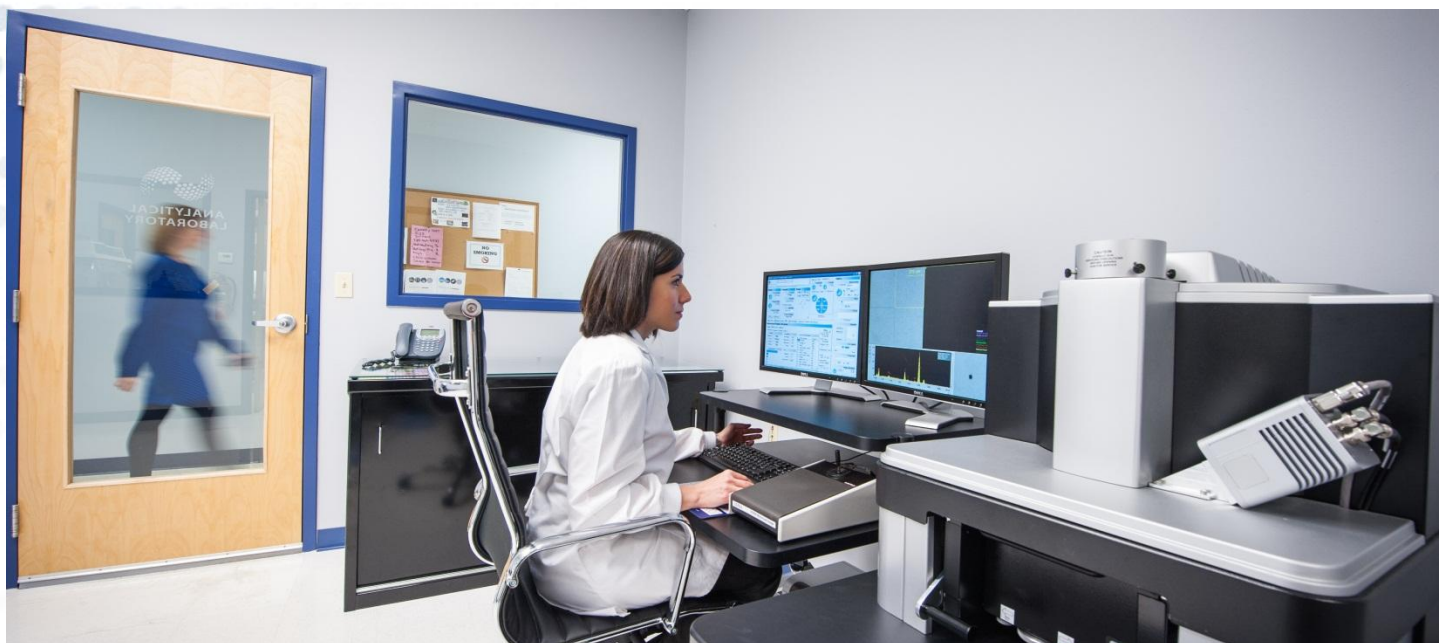




Recommendations for Evaluating Equipment Purchase vs. Outsourcing of Analytical Testing Services

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Introduction

Companies in need to improve their product development and/or process control are in the market to find either the right analytical equipment or contract a testing partner to conduct the analytical testing activities. Depending on the situation, the lack of the right technical expertise in-house or funds for a CapEx purchase might steer these efforts towards finding the right contract testing facility. Outsourcing is a value proposition where companies delegate to the right partner the important task of collecting information necessary to make timely decisions regarding product development and process control.

For instance, let's say that a manufacturer of parenteral products is required to conduct analytical testing to demonstrate that the final product is essentially free of visible foreign particles. During the process of finding the right solution to meet the testing requirements, the manufacturer realizes that for parenterals, the USP General Chapter <788> specifies light obscuration and microscopy as the methods for the counting and sizing of particles in the $\geq 10\mu\text{m}$ and $\geq 25\mu\text{m}$ size range. However, particle analysis can be also conducted using a wide variety of techniques including infrared spectroscopy, raman microprobe, laser diffraction, optical microscopy, and automated scanning electron microscopy. All of these particle testing techniques have advantages and limitations, and the final decision for the most appropriate technique lies on the manufacturer and the type of information needed to control the process and ultimately deliver the best product to the market. If the manufacturer doesn't have the right expertise in-house, the decision-making process regarding buying the right technology vs. outsourcing might be overwhelming, time-consuming, and ultimately expensive.



For companies that decide to outsource, the best choice might be to partner with an equipment manufacturer that has the testing capabilities and a quality system in place for contract analytical services. For example, ASPEX is a manufacturer of scanning electron microscopes and a cGMP compliant services provider where the same SEM-EDX technology that is available for sale is used to conduct analytical testing services. With today's increasing demand for outsourcing of testing services, many equipment manufacturers like ASPEX have taken the necessary steps to become full-fledged contract analytical laboratories.

This article discusses the use of equipment manufacturers as providers of contract analytical testing services. The article also highlights the advantages of developing a long-term relationship with a given equipment manufacturer before purchasing an instrument.

When Should Outsourcing be Considered?

A company with one or more of the following issues is an ideal candidate to consider contracting with an established equipment manufacturing company:

- *Short-term testing required to investigate a process failure;*
- *Long Cap Ex purchase approval processes, but an immediate solution is needed;*
- *Unsure of which analytical instrument should be used to find the right solution;*
- *A need to understand and test the instrument before committing to purchase; and*
- *Currently own instruments that have not been able to satisfy their needs.*



Finding Analytical Services Providers

The most common approach to finding a contract services provider is to search the Web for contact information and technical content – data sheets, case studies, application notes, vendor-sponsored webinars, etc. –that can be used to compile a list of service providers. Attending trade shows, reviewing print advertisements in trade magazines, and looking through buyer's guides are also traditional sources used during a company's preliminary screening process.

Another option is to look right in your own backyard. In other words, consider using your equipment manufacturer as a contract analytical services provider. By partnering with a manufacturer that has the capability to provide quality analytical testing services, companies gain the opportunity to reduce overheads on specialized equipment.

A partnership with an equipment manufacturer can begin as a short-term strategic option in response to an increased demand for testing, a need to reduce sample backlogs or to quickly conduct a product quality investigation requiring an immediate answer.

Evaluation of Service Providers

When evaluating an equipment manufacturer as a potential contract services provider, it is important to remember that not every contractor has the right facilities, necessary standard procedures and quality assurance systems in place to perform the type of testing required. Often, vendors conduct demonstration testing services to support equipment sales, but these services are not necessarily regulated or documented, nor are their methods validated. Reports submitted by non-regulated testing facilities frequently come with disclaimers indicating that the data collected is not indicative of the properties from the material tested.

During the first phone call or meeting with a prospective analytical services contractor, the contracting company should make sure that quality policies and standard operating procedures are in place. An audit should be performed before signing any contracts, especially for a long-term project. Also, quality manuals and certifications should be available upon request.

Seven Benefits of Successful Contract Services

Outsourcing is a growing trend among companies looking to incorporate specialized analytical services into product development and production. Here are some advantages of working with an equipment manufacturer for analytical testing services:

#1: Technology experts: work with a team of experts who know the instrumentation

#2: Cost analysis: accurately define the projected costs of the applicable technology

#3: Immediate results: data collected during the contract can be used immediately

#4: Build the case for purchase: results obtained during the analytical testing period may form the basis of a proposal to purchase the equipment

#5: Rationalize capital expenditures: capital equipment purchase approvals can take months, but the process can be easier if proof-of-concept data are presented to decision makers

#6: Lab design for in-house testing: costs can be reduced by using the contracted service provider's lab design and layout when ready to bring the analytical testing in-house.

#7: Long-term relationship with contractor: contracting company can build a strong relationship with its service provider and future equipment vendor

Short-term and Strategic Outsourcing

New analytical instrumentation can be evaluated during a short-term outsourcing project. Short-term outsourcing is a flexible solution used as a response to a sudden demand for analytical testing. This can be the case when one sample needs to be tested as part of a quality investigation or if a small batch of samples needs to be processed to evaluate an ongoing manufacturing process.

For service providers, short-term outsourcing can lead to an increased number of smaller value projects, and, if successful, it might result in a long-term project. Short-term contract work should be highly straightforward because there is neither enough time nor money to develop and implement a more customized solution.

Strategic outsourcing leads to a long-term relationship between the contracting company and the contracted equipment vendor providing services. Therefore, the relationship must be based on a mutual understanding: the service provider must understand the problem that needs to be resolved and the contracting company must understand the instrumentation and services available, as well as how this technology will be used to solve their problem. These questions can be answered during the initial phase of problem definition and evaluation.

When a project is in its first stages, the contracting company's product development team is responsible for identifying the proper technology and instrumentation needed to perform all necessary tests before a product can be released commercially. Ease of use, analysis throughput, data interpretation, amount of statistical information, equipment size, laboratory space, and implementation costs are some of the factors considered during the decision making process.

Without the appropriate personnel who possess the necessary technical expertise and training, a contracting company must rely mostly on the salesperson's pitch and knowledge about the technology. Typical sales presentations include a long list of specifications, features, and benefits, but unless the end-user has the opportunity to "test drive" the equipment with their own samples over a period time, there are no guarantees that the selected equipment is the best choice for the project.

Selecting inadequate methods or buying the wrong equipment might lead to unsatisfactory results, longer-than-expected analysis times, unanswered questions, and a significant waste of time and money. Problems associated with selecting the wrong instrumentation can be prevented by using an equipment manufacturer with a trusted track record as a contract services provider.

Extended Contracts

In the event that the instrumentation in question is the right fit to solve a company's problem, extending the outsourcing period can minimize the need to invest in specialized capital equipment immediately. These savings are compounded by not having to pay for maintenance and/or calibration services and not sacrificing the floor space necessary to house the equipment and supplies.

During the extended contract phase, the contracted lab will use their trained personnel to develop and validate the necessary testing procedures. Sample preparation, analysis parameters, data interpretation, and reporting will be optimized and converted into a turnkey solution that can be easily transferred to the contracting firm when appropriate.

What about quality?

Regardless of the type of contract sought, every contracting company is responsible for diligence in evaluation of all possible analytical services providers, especially with regards to quality policies. Contracting companies must verify that their selected analytical services provider has a Quality Management System in place that adheres to the latest regulatory guidelines of the industry. Competent service providers will be able to generate quality scientific data using certified equipment and demonstrate that they are following standard operating procedures and validated methods.



Conclusion

An equipment manufacturer that has laboratory facilities and testing capabilities available for contract analytical services is the simple and logical choice for outsourcing analytical services. Whether the reason is time, money, or expertise, contracting these services gives companies an invaluable resource for completing analyses correctly and on time, as well as granting them an inside peak at instrumentation available for future purchase. An added benefit of outsourcing to an equipment manufacturer is the relationship that can be developed between the parties over time, which can turn into a lasting support system.