

## ANALYTICAL OUTSOURCING

### The Raw Materials Testing

#### WHY SHOULD YOU OUTSOURCE?

The choice to outsource is a somewhat difficult decision, but it is one that can be both analytically and financially rewarding. By carefully considering all the services and choosing an appropriate outsourcing company, a laboratory can gain a great deal of freedom.

The reasons laboratories outsource are as varied as the analytical processes currently being outsourced. There are **many financial and analytical benefits** to employing an outsourcing lab. One of the most prominent reasons companies outsource is to access expertise, experience and limited use analytical equipment not available in-house.

Outsourcing analyses that require a high degree of technical expertise or limited use instrumentation can save money by eliminating the need of experts or capital-intensive instrumentation.

Using a contract laboratory will facilitate the management of new projects shifting toward outside the focus on these special, extremely large, and often low priority analytical activities in the very first stages.

#### WHICH ADVANTAGES DOES OUTSOURCING PROMISE?

Outsourcing customers can be confident in the data quality and services provided:

- Faster Analytical Response
- Lower cost
- Reliability
- Focus to Data Safety
- Partnership Development





## TACTICAL VS. STRATEGICAL OUTSOURCING

The analytical service can be as simple as drug identification or as complex as method development with detailed consultation on FDA or GMP regulations. Outsourcing basically breaks down into two categories:

- 1) TACTICAL
- 2) STRATEGICALS

The first step in the decision to outsource is determining in which category your needs fall.

**TACTICAL OUTSOURCING** is a short-term solution. The need for this type of outsourcing can result from a fluctuation in demand for products or services due to seasonal variation, one-time large orders or other factors. Tactical outsourcing can also give temporary relief of bottleneck situations when a lab is overwhelmed by large volume or slow output.

**STRATEGICAL OUTSOURCING**, on the other hand, involves a long-term partnership. By utilizing this type of outsourcing, a laboratory can reap many long-term benefits, including decreased overhead costs and the ability to advance projects of lower priority. When choosing an out-sourcing lab it is important to know what types of testing or consultation you require.

*Due to the great diversity in analyses and testing available, identifying what services will best suit your needs is a critical step in the decision to outsource.*



**Outsourcing is a scientifically viable and financially valuable tool for pharmaceutical and biopharmaceutical companies.** By determining what type of outsourcing is required and choosing the most appropriate laboratory, companies can reap a great deal of benefits, which far outweigh the drawbacks. Whether your need to outsource is temporary or you're looking for a long-term option, there are an **abundance of testing options**, so choose wisely. Make sure the laboratory you choose not only meets your scientific needs but your financial, information management and customer service needs as well.

## CTP SYSTEM IS THE RIGHT CHOICE

### WHAT KEY BENEFITS DOES OUTSOURCING PROMISE?

With the following five pillars in place, outsourcing customers can be confident in the data quality and services provided:

- Ongoing assessment, accreditation and monitoring of the network of labs
- Development and careful implementation of protocols and methodologies to ensure consistent production of accurate data
- Best-in-class project management processes, implemented by a team with demonstrated experience within the target industries
- Best-in-class data and information management processes and systems (LIMS)
- Best-in-class data reporting and interpretation capabilities





## GMP analytical testing

### CTP SYSTEM ANALYTICAL SOLUTIONS

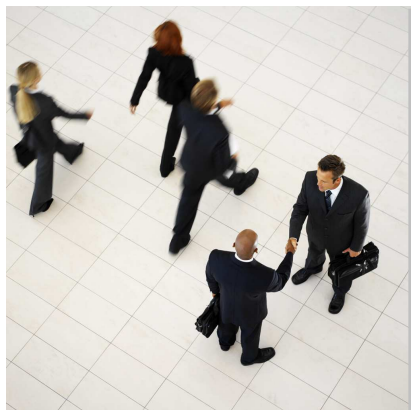
#### Chemical and Physico-Chemical Testing

- Assays and chemical tests (e.g. HPLC, GC, AA, IR, UV/Vis)
- Identification of active ingredients and impurities.
- Physical and physico-chemical determinations (e.g. pH, viscosity, melting point, flash point, loss on drying).
- Limit tests (e.g. heavy metals, ash, anions)
- Residual solvents (volatile organic compounds, organic volatile impurities).
- Pharmaceutical technical procedures (e.g. disintegration, dissolution)
- Sampling and analyses of water for pharmaceutical purpose and controller process environments (e.g. TOC)

#### Microbiological testing

- Lal test
- Mycoplasma testing
- Preservatives testing and microbial challenges
- Microbial contaminant identification
- CBT, Growth promotion test
- Supply and analysis of the bioindicator for validation purpose
- Holding time calculation.
- D-Value





## PLANNING FOR THE FUTURE

Outsourcing analytical testing is **a trend on the rapid rise**. Complete with proven success and plentiful benefits, it offers companies a viable solution to their **cost concerns, time constraints and data quality requirements**. According to a statistical studies analytical spending in the life sciences 80 percent and healthcare 68 percent over the last five years. These statistics show that analytical spending continues to rise, necessitating quality analytical outsourcing solutions that embrace the entire spectrum of our economy.

Outsourcing is "one of the greatest organizational and industry structure shifts of the century."

## CTP SYSTEM IS THE RIGHT SOLUTION



**Chemical Laboratory GMP certificate n. aM-186/2008**

**GLP certificate n. 19/25/2006**



**Microbiological Laboratory GMP certificate n. aM-176/2008**



[www.ctpsystem.com](http://www.ctpsystem.com)  
[info@ctpsystem.com](mailto:info@ctpsystem.com)

Località Salceto, 91/93  
53036 Poggibonsi (Siena)  
Tel. +39 0577 98481  
Fax +39 0577 980762

Via G. Stephenson, 94  
20157 Milano  
Tel. +39 02 2520181  
Fax +39 02 25201844

Via dei Castelli Romani, 41  
00040 Pomezia (Roma)  
Tel. +39 06 9122873  
Fax +39 06 9120289