

## **THE OPTION TO OUTSOURCE: WHY DO IT AND WHAT TO CONSIDER**

by Mel Weiss and Ed Murphy

**The contract laboratory industry** has grown exponentially over the past five to ten years, to the point that it is now regarded as a key player in the development, testing and release of products in a wide range of industries. Laboratories now offer functions ranging from quality control and assurance through research programs for new product development. Increasingly, companies with tighter budgets and deadlines have found the contract laboratory to be a vital partner to the growth and stability of their operations.

The question therefore arises: Who are these laboratories, and how can they be of assistance to my company? To answer this, you should look at your company with a clear, unjaundiced view. What can you do inside? At what cost? What problems do you now have in getting your work done by your inside laboratory, and will the use of an outside lab help in resolving these problems?

When looking at contract laboratories, the client company should ask certain key questions:

### **Why Should I Use an Outside Laboratory?**

The most common reasons for not using a laboratory are ones of control and cost. Analyze the potential of working with a contract laboratory versus doing the work in-house in terms of which saves you more money, time, regulatory headaches or any combination thereof. Are you set up to do the work inside, or do you have to outfit a whole new laboratory? Does it make good business sense to send the work elsewhere while you turn to the next project on your ever-increasing list of things to do?

As you assess your workflow, and the manpower/equipment requirements created by it, you may meet a problem prevalent in the industry: Too much work and not enough resources. A good contract laboratory will be able to provide technically qualified personnel with experience in the type of testing required to handle the overflow of work.

Turnaround time may also be a critical requirement. Everyone knows that inventory sitting in the warehouse costs money, and a backup at the in-house lab, or a general inability to have that lab get the work out in a reasonable time frame, may lead you to an outside service.

Another answer to the question of why you should use an outside lab is the need for a third-party opinion as to the quality of your product. Having a third party perform the testing releases the nagging question of whether performing the testing in-house is a potential conflict of interest. While they do not like to give bad news, contract labs should do so freely, and attempt to help you find the reasons for any less than acceptable results.

Finally, there is the question of expertise. Nobody is all-knowing, especially when it comes to questions of quality and regulatory compliance. Also, with the changing environment in regulatory issues and the new claims coming into the marketplace on almost a daily basis, it is important to have a source to rely on to assure that you are not left in the dust as your competitors rush for new label claims. A contract laboratory and its personnel can be a font of information in these areas.

A testing lab should be eclectic enough to provide a good overview of the marketplace at large, experienced enough to develop testing plans with you to substantiate your claims, and flexible enough to provide both of these services in a reasonable time at a reasonable cost.

### **What Should I Look for in a Contract Laboratory?**

The contract laboratory you choose should be specifically qualified to meet your requirements. Different industries use labs in different ways. The cosmetic industry has traditionally sent a majority of work to outside labs, where the myriad of claims, many of them unique and not found in compendial works, can be addressed. Pharmaceutical manufacturers, on the other hand, have most of their work governed by very specific guidelines, and the choice is often based upon what is logistically and financially feasible to the individual company.

Contract laboratories should not be mysterious places where magic is somehow performed and all your wishes

come true. They are an independent source of information about technical and regulatory issues that may affect your product. You should look upon them as an extension of your own company, and utilize them much the same as you would a consultant. They should be ready to work with you, and to provide you service.

Too many times, testing laboratories do not or will not perform studies because the study does not fit their profile. At this point, you, the client, are being told to take it or leave it. This is not how a lab should be working for you. Your lab should be flexible enough to design programs and protocols specific to your needs, not theirs.

However, this does not mean that a laboratory should bow down immediately to the client's claims, especially when the claim is unprovable. The laboratory that guarantees that your new product will reverse the aging process or make other spurious claims may only be looking to take you for a ride. A laboratory must build itself on a foundation of honest and scientifically viable work, even if it does, at times, disappoint the hopes of the client. Several critical traits should be inherent to your laboratory.

\* **Technical Expertise** The laboratory you choose should have the space, equipment, systems and personnel required to perform the types of work you need. It is critical that you visit your outside laboratory periodically to check up on its facilities and personnel. You should know if it is GMP/GLP/GCP- compliant, and whether it has the proper calibration done on the equipment used to test your product. You should be able to see the curriculum vitae and training charts of those personnel involved, and review the protocols used to assure the quality of the work performed. These are your rights as a client, and your responsibilities under regulatory compliance.

\* **Integrity** One thing you need more than anything else from your laboratory is the knowledge that the test information given to you is true and unbiased. You must be prepared for a forthright analysis of the work performed, and possibly the bad news that the product did not pass muster. Every contract laboratory has tales of "shooting the messenger," where the lab is blamed for less than satisfactory results. The laboratory is aware of how important your test results are. But if it lacks the integrity of giving accurate results based on its perception of your reaction to those results, then it's time to find a new lab.

\* **Quality** A testing laboratory should be an extension of the client company in the level of quality it provides. It should be prepared to meet and exceed, if necessary, those reasonable procedures set up by the client for its product testing. The laboratory should have a separate quality assurance and control function, not responsible to production management. Further, it should be aware of GMP, GCP and GLP standards, where necessary, and have appropriate SOPs for quality operations and out-of-specification results. It should have available to you any results of regulatory audits in the areas affecting your work, and be prepared to assist you in developing quality programs for your product testing.

\* **Communication** A testing laboratory should be like a scientific wing to your company. You should be able to retrieve information as easily as if you walked down the hall to the lab in your building. Communication should extend to having technical personnel available to discuss issues, track samples, and provide timely response in a user-friendly format for the client. A microbiological test result need not have a detailed description, history and examination of every microbial strain used, especially if it does the client no good and only serves to confuse the issue.

\* **Timeliness** A contract laboratory must be responsive to the needs of the client and provide the service agreed upon. The laboratory should have a sense of when your work should be done, and advise you of this upon receipt of the sample. Just as in other areas of your business, a laboratory should be judged upon its ability to meet their commitments in this and other areas.

In the contract laboratory business, there is a principle called EWEY, or Everyone Wants Everything Yesterday. Contract labs work on time schedules and manpower and materials availability. A lab may be able, on occasion, to react to a rush assignment for you. However, refrain from crying wolf for every sample, as it will only serve to create undue stress. Talk to your contract laboratory and set up reasonable criteria for turnaround time and a plan when special rush projects arise. The staff should be flexible to your needs, just as you should be flexible to theirs.

### **How Do I Choose a Contract Laboratory?**

First, define what you need. Are you having an overflow problem? Do you need an analytical method validated or a stability study performed? Do you want an SPF claim on your product? Having a clear definition of what you need is important and may save time and money.

It is possible that you may not have a good grasp on what is required of you. Contract laboratories get these types

of calls every day, and a good laboratory will take the time to help you develop your testing plan. Second, determine how much of what you need to have done you wish to take outside. Using some of the criteria we have just discussed, make a good business decision, just as you would in buying a new piece of equipment. Third, find some labs, not just one lab. Find the one that's right for you. "Where do I find labs?" you ask. A good source is to ask your colleagues in the business, or technical organizations you may belong to or be aware of. You can even call the regulatory agencies, which won't recommend a lab, but will tell you ones that are qualified to perform the testing.

After finding the labs, contact them with specific questions. Do they do the type of work you want done? What is their average turnaround time? What is the cost? Are they open for a visit or audit? Are they GLP/GMP/GCP compliant? Have they had a regulatory audit recently, and what were the results of the audit? The laboratories should be open with this information, and their responses will give you an initial opinion as to how they deal with customers.

Once you have spoken with the laboratories, and received their literature and quotations, choose one or two to visit. Audit their facilities not only on their technical capabilities, but with an eye to their regulatory expertise, flexibility and how easy they are to deal with. Remember, cost isn't everything. These people will be integral in your operation, and their work and communication skills will reflect on your bottom line and your relationship with regulatory agencies governing your products.

You should audit a laboratory at least once a year in order to comply with GMPs. The labs know this and should be open to it. If they are not, or if they set up roadblocks to your seeing them, such as charging a fee, then you should review your relationship with them.

If it has been determined that you will be sending a large amount of material out for testing within a given time, then you should be able to negotiate a contracted price for this service, thereby saving your company money and probably ensuring a quicker turnaround time than normal.

### **Be prepared**

The reasons for using contract labs are based firmly in good business practice. If you are familiar with these reasons, then you can address them when your management asks you why you want to throw the company's money out the window at these people. You may surprise them and save your company a lot of problems and money at the same time.

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