Ten Questions to Ask Your Prospective Contract Laboratory

1. What is their relevant experience?

The most important reason to select a laboratory is because they are the experts on products such as yours. When talking to prospective service providers, you should determine how much relevant experience they have working on similar on products. One of the best ways to determine this is to ask them to describe, from their experience, the unique problems that are associated with working on your type of product and how they resolved these problems.

2. What is their FDA inspection history?

A laboratory that has a history of supporting product filings will also have a history of FDA inspections. If any compliance issues were found during the inspection a form 483 will have been issued listing them. You should ask your prospective laboratory for a list of the FDA inspections it has undergone, copies of any 483's that were issued and copies of the written responses that the laboratory issued. Check to confirm that they followed through on their commitments. Remember, even good facilities will be issued 483's from time to time – it is their positive response to these 483's that differentiates them from their lesser competitors.

3. Who will be the primary point of contact?

Some organizations use project managers as the primary point of contact and some use a technical person who, at some level, is involved with the actual work. It is always preferable to have a technical person as the point of contact given two conditions: they are reasonably easy to reach and they are not too involved with many other projects. You want a person who is highly experienced working on your project, but that is not necessarily the best point of contact if they are so distracted by their obligations that they can't return your calls and answer your questions in a timely manner.

4. How is training performed for individual analysts?

In general, the more highly trained the person working with the samples, the fewer problems will occur. But how a person is trained is very important. The laboratory should have a systematic training procedure in place that is uniformly implemented. The best programs include reading and discussing relevant SOP's; team or "buddy" training; and requiring the analyst to perform some type of practice sample. This training should be documented in individual training files.

5. How are samples logged-in, tracked, and reported?

Requirements such as chain-of-custody, fast turnaround time, and specific testing instructions require a laboratory to have a thorough system for logging in new samples (or samples pulled from stability chambers), assigning tests, and reporting results. All of this is easily done with a laboratory information management system (LIMS). Additionally, LIMS can be used to expedite data collection and review and automate reporting. Some facilities even give the customer limited access to LIMS to check on the status of their samples in "real time."

6. How do they segregate GLP/GMP compliant work from non-compliant (research) work?
Some laboratories perform work to support research activities, besides providing GLP- and GMP-compliant testing. By its nature, research is very flexible and is not performed under the strict requirements of GLP or GMP. Regardless of the type of activities you intend the prospective facility to support, research or compliant, the laboratory should have clearly defined procedures for differentiating compliant vs. non-compliant samples and the requirements for each.

7. What is their policy towards the validation of methods?
Methods that are being used to support research activities do not require the same type of validation as methods that will be used to support the final product filing. This requires a well-established system of escalated validation at laboratories that support activities throughout the discovery and development spectrum. The laboratory should have SOP's that clearly spell out to what degree any particular type of method will be validated and what the validation will consist of at any stage of the development program.

8. What is their retest policy?
Regardless of whether the testing is supporting GMP or GLP activities, the laboratory should have a clear retest policy that conforms to industry standards. It should be clear from their SOP under what circumstances they escalate a problem. Regardless of the procedure that they follow for the retesting, their SOP should require them to contact the client and disclose the reason for the retest. Any sample retests should be clearly noted in reports.

9. How do they review test results?
Many clients accept the reported test results that they receive without any additional checking. This approach requires the client to have confidence in the reported results. This requires the client to understand just how thoroughly, and independently, results are checked by the laboratory prior to reporting them. The best systems rely not only upon peer and supervisor review, but also upon trained, technically competent reviewers who did not work directly on the project. The review procedure should be established in an SOP and the review itself should be documented. Reports that are generated directly from results in a database are the least susceptible to transcription errors.

10. What is their system for handling customer complaints?
It is important to gain an understanding of the prospective laboratory's customer complaint system. Even at the best facilities things go wrong occasionally. As a customer you want to work with a service provider who understands this and has a system set up to receive questions and complaints from the customer, especially if they involve sample results, to ensure that the appropriate corrective action occurs. A good system documents all questions and complaints and feeds the legitimate ones into the QA system to be dealt with in a similar manner as problems found within their own testing organization.