



Quality Agreements with Contract Laboratories

Creating Documents That Meet GMPs *and* Make Good Business Sense

By Roby Blasini

Contract relationships are a well-established business practices, but their use in the pharmaceutical sector is a fairly recent phenomenon. Their implementation is further complicated by their regulatory framework. Quality Agreements (QAGs) are useful documents from a business perspective as well as from a good manufacturing practice (GMP) perspective. QAGs, however, are only helpful when they clearly delineate the GMP responsibilities between the contract giver and the contract acceptor. During the past few years, experience suggests that many conflicts and misunderstandings between companies and contract laboratories are rooted in whole or in part in the lack of a sound QAG. Quite often, relationships crumble as the parties squabble over roles and responsibilities — and productivity is the first casualty.

QAG Content

Because so many of the problems with contract relationships are ultimately traced to misunderstandings, defining responsibilities between the parties is critical to a successful business relationship. QAGs should almost always be incorporated as part of another document — a schedule, appendix, or overall service or supply agreement — although there are times when QAGs can be stand-alone documents. FDA provides little detailed guidance on the subject, but inspectors increasingly look for a QAG with every contractor.

Formatting the QAG. Clearly, the content of a QAG, rather than the format, is critical. Some contract laboratories prefer tabular formats, whereas others favor legal-type formats. General templates can be used to start the draft of a QAG, but each relationship is unique, and no two agreements will be identical. Describing the contents that can or should be included in QAGs would make a good report rather than an editorial. The core sections in a QAG should include, but not be limited to, analytical methodology, required regulatory compliance, sample handling procedures, data handling and reporting, and investigations.

Writing the QAG. Extensive detail in a QAG can be counterproductive, and the QAG should be focused on the objective. It is not a service or supply contract. Semantics are also important because some terminology may be misunderstood by some of the people involved in the agreement. Whereas some personnel understand the QAG as written, others may require clarification. Although some legal documents might have a place for ambiguity, QAGs do not. Clearly defined expectations should be described, understood, and agreed upon by both parties.

The purpose and the scope should be the focus of the agreement throughout the drafting, editing, and negotiating of the QAG. The *scope* delineates whether



Roby Blasini is manager of corporate analytics and laboratory compliance at GS API Biopharma QA, Pharmacia Corporation, 800 North Lindbergh Boulevard, Mail Stop F2EG, St. Louis, MO 63167, 314.694.8376, fax 314.694.5258, robby.blasini@pharmacia.com, www.pharmacia.com.

the QAG is intended for one or for multiple specific products. For instance, a QAG with an analytical laboratory might be for only one assay or one analytical method, or it might be for more than one test or analysis. For a QAG with a stability storage facility, the scope can include the receipt, storage, and shipping of samples, among others.

Legal review. Follow-on review by legal counsel often clarifies imprecisions in the language that might create future difficulties. This review takes place when the business contract, in which the QAG has become a schedule or appendix, is reviewed, or it can be reviewed separately in the case of a stand-alone agreement.

QAG Negotiations

The negotiation phase of these agreements is the most critical step in reaching mutual consensus between the parties. Up-front effort is never as great as later effort to correct mistakes, and much of the work can be done by email and phone calls. Final execution usually demands that both parties meet face to face to finalize the agreement. There may be exceptions, but risk arising from conflict can cost either party tens of thousands (if not hundreds of thousands) of dollars, so adequate planning is a proactive best practice. A face-to-face meeting does not guarantee that conflict never surfaces, but it diminishes the probability of that happening.

QAGs for multiple projects. Large companies might have more than one functional area sending outsourced work to a single laboratory. In such cases, more than one group can be represented in QAG negotiations. It is of paramount importance that in these cases, internal consensus precedes external discussion. Communication with the contractor should be minimized, preferably to one functional unit. Most contract laboratories prefer this approach because it diminishes the confusion that can result from hearing two similar yet potentially confusing messages from the same company.

If more than one group from the same company is represented at face-to-face negotiations, it is good business practice and a powerful negotiating tool for the company to speak with one voice. One of the worst behaviors at a negotiating table is when members of the same company disagree in front of the potential contractor. Not only does such conduct lack professionalism, it tells the other party that the company's people cannot agree among themselves. The contractor will inevitably ask: If they can't agree with each other, how are they going to ever agree with us?

QAGs should be negotiated by trained and qualified quality assurance (QA) personnel only. QA is the authority on GMPs. QA personnel, working closely with their counterparts in procurements and contracts, ensure that all new contracts have QAGs in place before work begins with any new contract laboratory.

Conflict costs money, and often differences could be prevented by putting a sound QAG in place before the start of a business relationship. Formal agreements with contractors not only make sense in ensuring GMP compliance, they also make sense from a business standpoint because such agreements can save money in pharmaceutical and biopharmaceutical operations. Too many easily preventable situations grow into irreconcilable differences that do neither party justice. QAGs are an effective bridge to a successful future. **BP**