



## Quality Agreements: Regulatory Considerations for Development and Implementation

by enKap

This article discusses a number of critical issues related to executing Quality Agreements. Subject matter content includes a discussion of the regulatory basis for Quality Agreements (GMP regulations; specifically CFR 211.22). It also reviews the elements of a Quality Agreement, including an outline for content (chart) of a Quality Agreement between a contracting company and a contractor. Finally, the article discusses the use of a Quality Agreement during audits and inspections, as well as negotiating and legal review.

### ARTICLE EXCERPT BEGINS

#### Vendor Assessment

“...Conducting a quality audit of a vendor or supplier is the first step the contracting company will initiate before establishing a Quality Agreement. Understanding the vendor’s quality systems through a well-designed quality audit allows an in-depth view of the vendor’s capabilities, and allows the Quality Agreement to be designed for the specific roles and responsibilities required between the contracting company and the contractor. The audit allows an evaluation of the contractor’s quality systems for effectiveness and efficiency, and minimizes the inclination to impose a secondary set of requirements, specific to the contracting company’s quality system, that may already exist under an equivalent quality system at the contractor. Quality system design characteristics, such as change control management, deviation/CAPA management and the process for release of product are important areas to be evaluated during the contracting company’s quality audit.

#### Designing the Quality Agreement

The “scope” of a Quality Agreement should be one of the first considerations in designing the Quality Agreement. The Quality Agreement should specify the product(s) or service(s) for which it is intended. For example, a Quality Agreement with an Active Pharmaceutical Ingredient (API) manufacturer might include all aspects (synthesis and purification) of the production of an API, as well as its release and stability testing. A Quality Agreement with a supplier may apply to only one item or service or to multiple items or services. Therefore, a Quality Agreement with a stability storage facility may include only the receipt, storage, and shipping of samples, but not any testing, which may be performed by the contracting company itself or another contractor.

#### Relationship of the Quality Agreement to the Business Contract

The Quality Agreement is often written as part of the actual business contract with the contract or service provider, usually as an addendum. However, sometimes the Quality Agreement is issued as a “stand-alone” separate document, but usually has greater enforcement when incorporated as part of the business contract.

Following the selection and qualification processes (including a quality audit, which we will discuss later in this article) involved in choosing a supply/service provider, a company that decides to enter into a business contract with a provider should ideally include a Quality Agreement as part of the supply/service agreement.

A Quality Agreement can often be prepared and negotiated, while the more encompassing supply/service business (contract) agreement is also being prepared and negotiated. The resulting Quality Agreement can



then be incorporated into the final contract agreement as an appendix or schedule. In this way, the Quality Agreement will receive ample legal review when the entire document is evaluated. When the agreements are concurrently reviewed, conflicting information can be identified and resolved more easily and quickly than if the two are reviewed separately.

There are, however, various reasons why a company might implement a Quality Agreement as a standalone document. These include the lack of a finalized supply/service agreement, delays in the revision of a supply/service agreement, and inheriting a supply/service agreement without an existing Quality Agreement when licensing a new drug from another company that was previously using third-party contractors. Irrespective of the reason, if a Quality Agreement is to be implemented as a standalone document, there should be additional clauses or components (some that will be of a legal nature) in the Quality Agreement that are not necessarily included when it is part of a supply/service agreement..."

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