

# Supplier Qualification Programs: Establishment and Implementation

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This article serves as a comprehensive resource in establishing and implementing an effective supplier qualification program. This article reviews the myriad of issues involved in three major subject matter content areas, including an in-depth review of Good Manufacturing Practice (GMP) Parts 210 and 211 requirements related to supplier qualification. Secondly, this article provides information on establishing an effective supplier qualification program, as well as how an evolving supplier qualification program can continually meet Quality requirements.

## ARTICLE EXCERPT BEGINS

### Interactions between Quality Assurance, Purchasing, Quality Control and Production

One of the key activities in the successful implementation of a supplier qualification program is the establishment of an effective internal organization for evaluating suppliers within your company. Key members of this group would include personnel from the purchasing department, quality department, quality control, engineering, operations and manufacturing. Personnel from research and development and technical services operations can also provide input into the supplier qualification program if the material that will undergo supplier qualification is related to a new product introduction.

After the internal team is formed, often a supplier qualification working group is formed and directed toward seeking concurrence on objectives, definitions and approach that would be communicated to suppliers. Normally, after completion of this phase, the design, development and implementation of a formalized program is provided to the supplier. The team will incorporate the benefits of a supplier qualification program, including sourcing specific production material design requirements, to develop selection criteria in selecting a supplier.

The actual measurement of a company's capability to initiate a supplier qualification program is in identifying the ability of its own manufacturing supply operations to conform to established criteria the company has defined for itself. The experience of a customer qualifying their own internal process will provide an indication of some of the difficulties that will be encountered in working with external suppliers.

## **Utilizing Quality Agreements**

The concept of the quality agreement can serve a useful role in the supplier qualification program. The quality agreement can serve to define roles and responsibilities for quality between the supplier and customer for meeting contractually agreed upon component, container or closure specifications and requirements. The quality agreement is a mutually agreed upon “contract” that both the supplier and customer quality departments sign. Often, it becomes an extension of the business agreement. The quality agreement will include cGMP requirements, responsibilities for testing materials, investigations, dispute resolution and communication of significant change. In addition, using the quality agreement as an assessment tool during an audit can be a useful exercise.

## **Managing Change**

A formal change control system should be established at both the supplier and customer operational systems to evaluate all changes that may affect the production and control of the supplied components, containers or closures. Written procedures should provide for the identification, documentation, appropriate review and approval of changes in raw materials, specifications, analytical methods, facilities, support systems, equipment, processing steps, labeling, packaging materials and computer systems.

Any proposals for GMP relevant changes should be drafted, reviewed, and approved by the appropriate organizational units, and reviewed and approved by the quality unit. The supplier should establish and maintain written procedures for the identification, documentation, appropriate review and approval of changes within production processes. The quality assurance department is required to have the responsibility and authority for the management and final approval of changes. Significant operational changes should be validated on excipient performance. The effect of the changes should be communicated to both internal and external customers.

## **Impact of Change**

Areas that should be closely monitored for the impact of change on the quality characteristics and functionality of the component, container, or closure include changes to the site of manufacture, equipment or equipment configuration and change in the scale or “batch size” of the material. Other areas to review the impact of the change include a change in raw material ingredients, or method, or sequence of manufacture.

Change control is a key aspect of the supplier-customer quality agreement. During the quality assessment, the supplier’s change control procedures should be verified that it includes notification of change to its customer base.

**ARTICLE EXCERPT ENDS**



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