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Published on *IVT Network* (http://www.ivtnetwork.com)

Supplier Quality Audit Questionnaire and Checklist

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There continues to be considerable interest in the pharmaceutical industry today on the subject of supplier or vendor certification. Supplier qualification programs are intended to be applied to inactive and active components, drug product container and closures, and other packaging materials. There is a critical list of elements that make up a successful vendor certification program. However, certifying or qualifying a vendor or supplier requires different types and levels of effort from various suppliers. It must be recognized, therefore, that circumstances may vary depending on the type of operation, nature of the process involved, and product standard requirements in order that a certain amount of latitude and judgment be used when establishing a supplier qualification program.

Supplier qualification is often based on a total quality management system that assures that a supplier's product is produced, packaged, and shipped under a controlled process that results in consistent conformance to customer requirements. The supplier qualification program is based on the principle of defect prevention, as opposed to defect detection and selection. It supports the concept of quality at the source by ensuring adequate controls and systems are in place the first time around. It substantially reduces or eliminates the need for final quality inspections by the supplier or the customer. Finally, if successfully implemented, sup- plier qualification should be de- signed to achieve the desired objectives of product quality improvement, delivery performance improvement, increase in productivity, and cost reduction.

The primary objective of supplier qualification is to assure consistent high quality as demonstrated by predictable conformance to customer requirements. The basic premise of supplier qualification is that when the customer and supplier work together to establish the proper design characteristics, specifications, test criteria, and process controls, the result will be a product that is consistently fit for use and free of defects. While the customer is responsible for assuring the suitability of the item for its particular use or application, it is the supplier's sole responsibility to meet customer requirements. A supplier quality audit questionnaire, checklist, and informative article is provided.

Download the Supplier Quality Audit Questionnaire

Download the Supplier Quality Audit Checklist

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