

Supplier Certification Questionnaire Guidance

Supplier Certification Questionnaire Compliance Guide

This guidance was prepared to assist practitioners in their review of suppliers. To effectively use the supplier certification and quality assurance questionnaires, some background information was needed. The questionnaire asks a series of questions regarding the quality practices and GMP compliance of the supplier. These questions should be reviewed using a graded approach to determine the level of quality practices the supplier has.

In this version of the questionnaire (22 total questions), the following questions and their related answers would be considered critical, major or minor points to an appropriate quality system.

Critical questions: 8, 12, 14A, 15, 18, 19, 20, and 22.

Missing answers to the critical questions show potential adulteration and/or contamination problems with materials/products supplied. These questions deal with information about the supplier's quality control personnel, specifications and related testing of raw materials / finished products, possible contamination of materials/products due to inadequate sanitation practices, inability to substantiate label information, and non-compliance with current food labeling regulations for potential allergens. If the supplier's answers indicate possible contamination/adulteration issues with materials/products, the use of the supplier should be rejected.

Major questions: 6, 7, 11, 14B, 16, 17, and 21.

Missing answers to the major questions show serious gaps in the supplier's quality program. These gaps include lack of the following: designated quality control personnel, necessary quality procedures, suitable employee training program, adequate internal GMP audit program, suitable review of raw material suppliers, appropriate monitoring of contract labs, required testing of raw materials, adequate re-testing of released raw materials, suitable use of expiration dates, appropriate retained samples, and appropriate monitoring/verification of sub-contracted production. If the supplier's answers indicate possible gaps in the quality program, the number of gaps must be reviewed to determine how much of the quality system is missing or compromised. If the majority of these questions are not answered appropriately, it is recommended these be treated in the same manner as critical issues.

Minor questions: 1, 2, 3, 4, 5, 9, 10, and 13.

Information required by the minor questions should be readily available since it deals with the supplier name and address, manufacturer's name and address and contact personnel. The remaining minor questions deal with items that are not mandatory for food producers such as: GMP audit of the supplier by a 3rd party, written employee training program, frequency of internal GMP audits and how reports are handled, auditing of raw material suppliers, and basis for re-testing of released raw materials.

Any issues surrounding testing of raw materials and/or finished products should be carefully scrutinized. If it appears the supplier is not performing adequate

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testing/examination to provide proof of a material's identity, purity, strength or composition, the material should be considered suspect and not eligible for use.

If they are relying on outside sources for analytical data, it is necessary to ask how they validate the source of that information.

Typically, it only takes one critical issue question to derail use of a supplier since the questions concern material/product contamination and/or adulteration issues. In each situation, after the initial review is completed, the supplier should be notified of the results of the review. Suppliers should be given the opportunity to correct deficiencies and provide proof of the corrections.