A Compliance Guide for "The *IMCJ* Supplement Quality Audit Form"

Rick Liva, ND, RPh

This guide was prepared to assist clinicians in performing a review of their vendors' quality practices after these vendors have filled out "The *IMCJ* Supplement Quality Audit Form." The audit form asks a series of questions to discern compliance in regard to the good manufacturing practices (GMPs) and quality control (QC)/quality assurance (QA) processes of a chosen company. Answers to these questions should be reviewed using a graded approach—which these guidelines help to do—to assess a given vendor's ability to produce quality products. The main benefit of the form is that it requests documentation to prove that vendors are, in fact, following quality parameters.

In this version of the audit form (20 questions total), the following questions and their related answers would be considered critical or major to an appropriate quality system.

Critical questions: 3, 8, 10, 11 or 12, 13A, 13B, 17, 18, 20

Issues: Missing answers to these critical questions should ring warning bells as they highlight potential problems with product authenticity, strength verification, purity (ie, there is a danger of adulteration and/or contamination), and label claims as well as lack of suitable employee training in quality issues. These questions deal with the company's GMPs and QC specifications, including essential testing of raw materials and final products, as well as appropriate monitoring/verification of any subcontractors who perform such actions for them.

Actions: Any issues surrounding the testing of raw materials and/or finished products should be carefully scrutinized. If it appears the company is not performing adequate testing/examination to provide proof of a material's quality, 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 find out how they validate the source of that information.

Typically, it only takes 1 critical question to derail use of a vendor since the questions concern crucial QC testing measures.

Major questions: 1, 2, 6, 14, 15, 16, 19

Issues: Missing answers to these major questions shows serious gaps in the company's quality program. These gaps include a lack of designated quality control personnel, necessary quality procedures, suitable use of expiration dates, appropriate retained samples, and compliance with current labeling regulations for potential allergens.

Actions: If the company's answers indicate possible quality gaps, 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 that they be treated in the same manner as critical issues and the vendor should be rejected until the issues are cleared.

Points to Remember

1. Typically, it takes only 1 critical issue question to derail use of a vendor since the questions concern material/product authenticity, strength verification, contamination and/or adulteration issues, and label claims.
2. The vendors who supply you with independent proof are testing, and those who give you doublespeak and supply nothing are not testing. If a company has the means to answer the questions, it will—there is no need to bluster.
3. In each situation, after the initial review is completed, the vendor should be notified of results from the review. Vendors should be given the opportunity to correct deficiencies and provide proof of the corrections before you start or resume doing business with them.

A Matter of Conscience

These products go into people's bodies, and to sell a supplement to a patient without ascertaining how sound it is is a risky business (just look at all the problems explained in various articles on the *IMCJ* website, www.imjournal.com—click on "Quality Assurance" under "Resources & Content"). Clinicians are the gatekeepers of quality. If we won't buy from companies that have demonstrated poor quality, then they will have to improve their quality parameters. And this way, we support the "good guys." Thus, we can help to make a better world.

If you are unfamiliar with product quality issues or need further clarification, please contact me at rickliva@center4health.com.