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Contaminant-Free Contract Manufacturing

by Joe Archer

The supplement industry is increasingly being challenged to deliver contaminant-free products. In December 2010—after all manufacturers should have been fully compliant with federal cGMPs (current good manufacturing practices)—FDA Commissioner Margaret Hamburg sent a letter to the industry stating: “FDA laboratory tests have revealed an alarming variety of undeclared active ingredients ... chemical ingredients of unknown safety ... active pharmaceutical ingredients removed from the market for safety reasons ... and controlled substances ... in products marketed as dietary supplements.”

This type of contamination is not only extremely dangerous to consumers, but casts a pall over the industry. Unfortunately, as consumers lose confidence in the supplement products they buy, it damages the entire industry, not just the bad actors. So how can marketers select a contract manufacturing partner and ensure the finished products are pure, safe and contaminant-free?

Here are some basics to help in making an informed decision:

Asking Questions, and Getting Answers in Writing

While asking questions might seem a little rudimentary and hardly worth mentioning, it's asking the right questions that makes all the difference. For instance, don't be shy about asking whether a potential contract manufacturer has steroids or other banned substances in their facility. If the answer is no, ask for the documentation. If yes, request to review the procedures in place to ensure traces of those substances can't cross contaminate any supplement production lines.

Another area of interest is raw material procurement. Where are the ingredients sourced, and how are they tested for purity? Raw materials can be innately contaminated from growing conditions due to environmental pollutants or through the manufacturing and packaging process—an unclean facility, intentional spiking, poor process controls, etc.

Obviously, quality control systems and GMPs are based upon written protocols. And a large portion of those protocols

is recordkeeping. Ask to review a company's quality protocols and records. This will offer insight into the overall mindset and meticulousness of the organization.

Take a Look

There's no better way to judge a facility than to take a metaphorical "look under the hood." Check out the processing, packaging and storage areas; they should be separate. Observe the employees. Do they look content and mindful of quality practices? Because if they're not fully engaged when a visitor is there, they certainly won't be when they're on their own.

If an in-person tour and audit is impractical, consider engaging a third-party organization to conduct an on-site audit. This process will ensure proper quality procedures and testing mechanisms are in place so contaminants will be detected.

Testing 1, 2, 3

Raw materials can be a source of contamination. Check to see whether the manufacturer is checking every container in every lot for contamination. Also, be sure materials are tested for heavy metal contamination, ideally to Prop 65 levels. Contamination can occur during processing too, so be sure the finished products are tested for both purity and product strength.

Pennies Well Spent

Quality manufacturing, raw materials and repeated product testing come at a cost. But it is less expensive to pay for quality upfront than to have a recall or to endanger consumers with contaminated products. Informed consumers will buy a product they know has been tested thoroughly for purity. □

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