

# Contract Manufacturing in the Time of CGMPs

With new CGMPs taking effect this month, contractors must work harder than ever.

BY GREG WILLIFORD, VICE PRESIDENT OF SALES AND CUSTOMER SERVICE, VITA-TECH INTERNATIONAL INC.

As nutritional supplement manufacturers, it's our job to educate our clients about the fact that FDA (Rockville, MD) has adopted new standards for Current Good Manufacturing Practices (CGMPs). These CGMPs will go into effect June 25 for manufacturers with more than 20 employees. (Those manufacturers with fewer than 20 employees have until June 25, 2010, to comply with the new CGMPs.)

The new CGMPs deal with testing, documentation, standard operating procedures, and formal training. The new standards are significantly different from the old ones—particularly with respect to the greatly increased testing and documentation that's now required. And all of these things need more people and more time to accomplish.

For example, there are now increased testing requirements for raw materials, both incoming and outgoing, in finished products. Also, documenting of all aspects of manufacturing, such as cleaning procedures, equipment settings, sampling procedures, and event recording, must now be done in much more detail. As a result, contract manufacturers must update their standard operating procedures, put new processes into place, and either rewrite existing documents or create new ones.

Clients count on their manufacturers to maintain an environment that is completely CGMP compliant. Good contract manufacturers have always based their standards



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on the highest requirements. For example, we have specific procedures in place for handling and testing all raw material that enters our facility. These procedures remain constant, regardless of which product and client the material will be used for.

If FDA or any other entity comes to the plant to check on compliance, we must always be prepared to show that our practices meet the highest standards for safety and quality. The consequences of not complying with the new rules are great. Under current laws, if FDA or another licensing agency

inspects a manufacturing facility and determines that the facility is not compliant, all of the products made in that facility may be considered adulterated—regardless of whether or not some products passed all of the relevant tests. An adulterated product can be recalled from the marketplace—a potential nightmare that everyone in our industry wants to avoid.

## CGMPs Are Top of Mind

With so much press and awareness about the new CGMPs, more people are asking about

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## THE CGMP EFFECT

BY JAMES WAGNER, PUBLISHER

**SAY WHAT YOU WILL** about CGMPs, but they have forced companies to analyze their strengths and weaknesses and focus on improvements, according to Katie Harrell, marketing specialist, National Enzyme Co. (Forsyth, MO).

Harrell sees new customers seeking CGMP compliance as part of their search criteria for a contract manufacturer. Distributors also depend on their contract manufacturers to understand the CGMPs and to be forthcoming in offering information and advice to clients on their products.

As expected, documentation and ingredient requests are experiencing steady growth. "The consistency and depth of questions being asked are indicative of an increased

level of ingredient knowledge in the industry," says Harrell. "Over the past couple of years, I've seen a steady growth in the number of requests for information related to macronutrients, allergens, source organisms, country of origin, BSE [bovine spongiform encephalopathy] statements, and detailed ingredient declarations for formulas."

Not every query is about CGMPs. "I can't really attribute this entire increase [in information requests] to the GMP requirements," says Harrell. "FALCPA [the Food Allergen Labeling and Consumer Protection Act], BSE regulations, changing international regulations, and a general change in attitude within the industry have all been contributing to this increase in questions."

them in general. First and foremost, they want to know whether a contract manufacturer is CGMP certified. More specifically, we've seen a big increase in requests for additional testing and documentation regarding raw ingredients. And these requests aren't just coming from our existing clients. Potential clients also want to know that we can be CGMP compliant.

Clients want to know as much as possible about their raw ingredients. Vendor audits have become very important. Manufacturers need to go back not just to an ingredient's distributor, but also to the importer, and ultimately the ingredient's manufacturer. Who made the material? What is its country of origin? Has the importer visited the plant? Is the manufacturer CGMP certified? All these questions are very common these days.

Clients also want to be sure that raw materials are fully tested, and that all tests are properly documented. We have especially seen an increase in requests for testing of heavy metals, pesticides, insecticides, melamine, and



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other contaminants.

Many clients are also requesting that we add considerably more detail to the Certificate of Analysis, such as a product's country of origin, the analytical methods used to test the ingredients, the results of specific tests, and more. Although we have always tracked this information, what's new is that people

are asking to see the data. For manufacturers, additional time and effort is needed to transfer data from their original state to the Certificate of Analysis.

### Wide Range of Knowledge

While there has been a big increase in requests for testing of raw materials, each manufac-

turer's clients still have unique needs, requirements, and resources. Some clients are quite sophisticated and know to ask for specific tests and testing methods. Others assume, and rightfully so, that contract manufacturers are doing everything properly. Therefore, they may not ask for any specific testing or even to see the Certificate of Analysis.

Many of the larger companies that we work with have internal product development and marketing departments and are really just looking to us for our contract manufacturing services. Our more-sophisticated clients are very aware of the ingredient sourcing requirements of the CGMPs and frequently ask us to fill out detailed forms in order to monitor and document our compliance. They have very formal specifications regarding the raw ingredients used in their products. And they want to know whether we tested for active ingredients and contaminants.

However, other companies need a great deal of assistance in developing their products. In those cases, can help them through the process—including understanding CGMPs.

### Expectations and Education

Contract manufacturers need to educate clients about how the new standards may affect them. We also need to let clients know how the new CGMPs may make it difficult, if not impossible, to comply with some of the requests for rush orders that may not have been an issue in the past. We must explain to clients that the numerous tests that must be performed and documented take time.

If a client has concerns about any aspect of CGMP compliance, contract manufacturers should be able to truthfully assure them that everything is in place. Ultimately, the changes that are being put into place will make for a more healthy and dynamic industry and result in safer products in the marketplace. Although it may seem like a headache right now, it will be a win-win situation for everyone. ■

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