

Contract Manufacturing Roundtable

Now that the GMPs are here, excitement is building at the prospect of a level playing field. But how much of an impact will the new regulations really have on the industry?

BY DANIEL SCHATZMAN, EDITOR

On Friday, August 25, good manufacturing practices (GMPs) went into effect for large manufacturers of dietary supplements. More than a decade in the making, the new rules are intended to ensure that products are accurately labeled and don't contain adulterants and contaminants. Although medium and small manufacturers still have until 2009 and 2010, respectively, to comply with the GMPs, most contract manufacturers don't have that luxury. In fact, many contract manufacturing operations began following the proposed GMPs or even pharmaceutical GMPs well before the final rule was published.

Some experts believe the GMPs will raise the quality bar for manufacturing, making it harder for subpar supplements to end up on store shelves. But others think the new rules won't have much of an effect, since most supplement manufacturers and nearly all contract manufacturers already comply with the GMPs. Additionally, significant questions remain about FDA's ability to enforce the GMPs and what effect the lack of validated analytical methods may have on their testing requirements. *Nutritional Outlook* recently spoke with five leading contract manufacturers about the future of dietary supplement manufacturing in the post-GMP era.

ROUNDTABLE PARTICIPANTS

- Gary Callahan, senior vice president of operations for the drug division of Robinson Pharma Inc. (RPI; Santa Ana, CA)
- Robin Koon, senior vice president of Best Formulations (City of Industry, CA)
- Randy Osmun, marketing manager for global services at Access Business Group (ABG; Ada, MI)
- Michael Schaeffer, president of Pacific Nutritional (Vancouver, WA)
- Suhail Ishaq, president of GMP Laboratories (Anaheim, CA)

How will the GMPs affect the need for contract manufacturers?

Pacific: This is a difficult question to answer, due to the complex, multifaceted environment within our industry. I do anticipate greater demand because very small companies may not be able to cost-effectively meet many of the more stringent requirements.

GMP Labs: Contract manufacturers play a vital role in the worldwide product supply chain and even more so for U.S.-manufactured dietary supplements, since quality control is a paramount issue for consumable goods. The long-awaited GMPs will further support this demand, as they elevate the standard of quality across the board.



The need for experienced contract manufacturers may rise as small companies seek to comply with the GMPs.

Photo courtesy of Access Business Group.

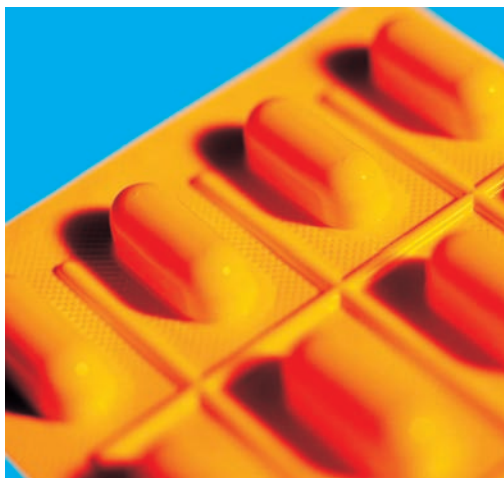
RPI: I don't think the "need" for contract manufacturing will be affected at all. As long as there is a demand for dietary supplements, marketers and distributors will be looking to contract manufacturers to fulfill that demand.

Best: The expanded requirements now required under the new guidelines will most likely increase the need for contract manufacturers. This is because the process of making a product is going to be more difficult, will take longer, and will require a higher level of expertise. More facilities will have significantly more pressure to deliver products on time. They will need to outsource more, in order to continue delivering products in a timely manner.

ABG: Contract manufacturers that are compliant with the new GMPs will be in greater demand. Contract manufacturers will be responsible for meeting the supplement requirements, and at the same time, they will need to be able to meet the requirements of their customers. Those companies that can meet both requirements will have a

distinct advantage in the marketplace.

Has there been an increase in the use of contract manufacturers? Do you foresee even more business as the GMP deadline approaches?



Under the GMPs, contract manufacturers and their customers both may be responsible for ensuring that products conform to label statements.

Photo by Photodisc.

Pacific: We have not seen an increase in the demand for contract manufacturing. However, we have seen an increase in the number of clients looking for contract manufacturers that have third-party GMP certification. So, our business is growing because of customers searching for experienced, certified companies that communicate clearly and know the rules inside-out, despite a general leveling out of the curve in demand. Rather than growth in the industry, or even a flattening, I'd say that the industry is stabilizing and focusing on quality.

GMP Labs: We see this trend gradually increasing as the deadline approaches. Many companies probably will find that it will cost

them less time, money, and frustration to rely on a contract manufacturer like GMP Laboratories that is already GMP

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Best: Contract manufacturing has increased over the last few years. Outsourcing has many advantages for companies that need expanded capacity, can't make products in-house, lack expertise, or want lower overhead. As the new GMP requirements start to take hold, I do see a need for more qualified contract manufacturers.

ABG: There may be more business for contract manufacturers that have the ability to comply with the dietary supplement regulations. Smaller businesses that have a difficult time complying with the new GMPs may need to rely on contract manufacturers. Large companies will use the new GMPs as a credibility check and a way to reduce their risk.

Would your company be likely to petition FDA for an exemption from 100% identity testing? If so, under what conditions?

RPI: I believe that many companies will pursue an exemption. It depends on how well they are equipped to meet the new testing regulations. We are fortunate to have ample equipment and manpower to meet the testing requirements.

Some experts believe the GMPs will raise the quality bar for manufacturers.

Best: That's a very good question. The primary issue or problem we see with the GMP regulations is with the testing requirements. There really are no industry testing guidelines, methods, or standards (e.g., USP, AOAC, etc.) on so many of the raw materials being used today. ID and assay testing standards need to be determined and established before any enforcement can be done. We are reviewing this option.

ABG: Yes, there is potential to petition FDA for an exemption due to unavailable methods and standards, especially for botanical items. We work with many botanical items, so there may be a need to petition for an exemption in these cases. Any petition needs to be backed up with substantiated evidence. Currently, we are looking into different technologies to help identify nonstandardized raw materials, such as near infrared (NIR). However, NIR method development may take time due to the collection of the 20 data points before implementation of an identity test.

Is FDA ready to enforce the GMPs? What will happen if it isn't?

Pacific: Today, we don't believe FDA has the resources to enforce the GMPs throughout the industry. However, we don't know what the legislature will provide FDA to increase their enforcement capabilities in the future. We do



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know FDA will be performing inspections and may contract with state authorities for assistance.

RPI: I was informed early last year that FDA had budgeted for the enforcement of the new regulations. I think the question should be "Are they going to enforce it, and if so, when?" Currently FDA rarely visits manufacturers of drugs or dietary supplements. I believe that more-frequent visits will help companies avoid moving in the wrong direction. A company may believe that they are or have been doing a good job for years. Then suddenly, FDA may show up and tell them differently. It's important to follow FDA's Guidance to the Industry documents to help avoid traveling down the wrong path.



The GMPs are intended to ensure that what is in the bottle matches what is on the label. Therefore, testing is a key component of the new regulations. Photo courtesy of Access Business Group.

Best: No, we do not believe FDA is ready to enforce—entirely—the new GMPs. It does not have the staffing or infrastructure to entirely handle current pharmaceutical companies, much less the addition of nutritional companies. However, we believe that, over time, FDA will eventually get up to speed. Most likely, it will start by focusing on larger companies first.

ABG: We believe that FDA will be in a position to enforce the GMPs. FDA has given due dates to affected manufacturers to comply with the new regulations. What will happen if it isn't? The industry momentum to comply may stall. Because we are a large, compliant company, we will continue to meet GMP requirements, regardless of FDA's ability to enforce them.

Some marketers appear to be confused about labeling under the GMPs. Is the marketer or the contractor responsible for assuring that the product conforms to label statements?

Pacific: One rule to remember is that the company name listed on the label will be the first to be contacted by FDA or FTC regarding claims on the label. We work with our clients in reviewing labels for compliance due to the fact that, as the manufacturer and the entity that applies the label to the bottle, we are also responsible for ensuring the product is not misbranded as an unapproved new drug. In addition, as a manufacturer of dietary supplements, we are required to ensure that each batch meets the specifications for identity, purity, strength, composition, and contamination limits. This is perhaps the most revolutionary aspect of the GMPs—every link in the chain of production, from raw materials to finished product on the store shelves, must be ready to meet specifications of some kind and will need to work with others who are also meeting all requirements.

RPI: We, as contract manufacturers, are responsible for

what label we put on the product. In many cases, we are the consultants to our customers. They may not be aware of all the regulations regarding labeling, but we should be. FDA looks at who did the branding of the product, i.e., who actually put the label on the box or bottle. Contract manufacturers should have a system for approving customer labels before the customer spends the money for printing. Beyond that, the contract manufacturer must keep an approved copy of the label for comparison to labels received. This is also a requirement of the GMPs. All labels must be examined and compared to an approved label prior to the release of the labels to packaging. Although I've seen it done in the past, contract manufacturers should not accept an approval letter from their customer stating that they have approved the label or that they will accept responsibility. Applying an incorrect label is in violation of the GMPs.

About the Roundtable

Robinson Pharma (RPI) has provided contract manufacturing services to the dietary supplement industry since 1989. The company operates a manufacturing facility that includes eight softgel lines, powder- and liquid-filling equipment, and 10 continuous-drying softgel machines. RPI is registered as a drug establishment by FDA and holds a drug manufacturing license from the state of California. For more information, visit www.robinsonpharma.com.

Best Formulations, founded in 1984, produces tablets, capsules, softgels, powders, tea bags, and liquids in a state-of-the-art, 120,000-sq-ft facility that is NPA certified and TGA approved. The company's team of formulators, chemists, and PhD staff possess more than 100 years of combined experience in nutritional, biological, and pharmaceutical sciences. For more information, visit www.bestformulations.com.

GMP Laboratories was founded 12 years ago as a contract manufacturer of vitamins and nutritional supplements. The company's NPA-certified GMP facility was designed for drug manufacturing and can produce at least 500 million tablets and 400 million hard-shell capsules per month. The company also offers coating, powder blending, milling, and granulating services. For more information, visit www.gmplabs.com.

Pacific Nutritional has provided custom contract manufacturing services to the dietary supplement industry since 1980. The company offers formulation, sourcing, blending, processing, tableting, encapsulation, bottling, and labeling services in a kosher- and NPA-certified GMP facility. For more information, visit www.pacnut.com.

Access Business Group, a division of Alticor, manufactures more than 500 different products, including personal-care items, cosmetics, and nutritional supplements, powders, and liquids. Access has more than 3000 employees, including more than 400 scientists and engineers, who work at 65 R&D and QA labs around the world. For more information, visit www.accessbusinessgroup.com.

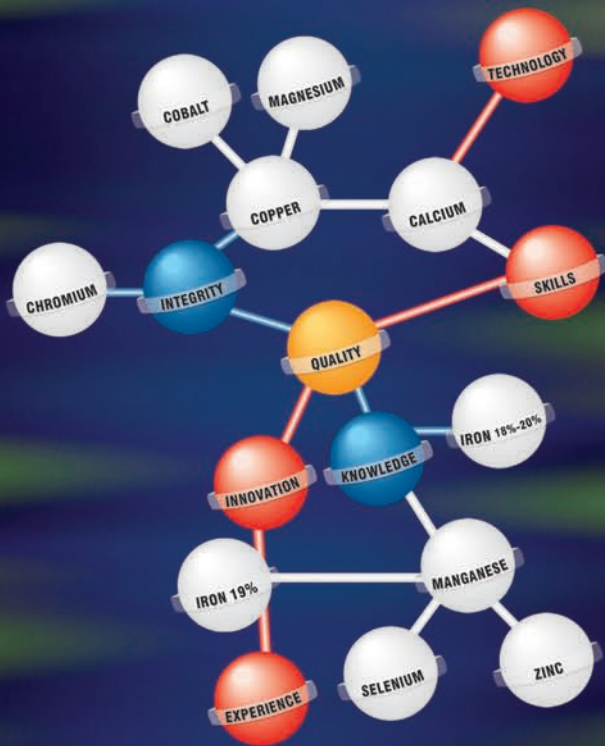


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Best: Both. The company that performs the packaging is responsible for ensuring accuracy of the label on the product. In our company, when we apply a label or package a product, we must have in-house approval prior to labeling any product. Some sellers—and some manufacturers—do not have the ability or expertise to check this in-house and rely on the manufacturer to do so. It is either (or both) the company selling the product in the marketplace and the manufacturer that packaged it that FDA will seek if the labeled product is incorrect or makes unapproved claims.

ABG: The ultimate responsibility for label statements is with the customer. It is the customer that makes the claim on the product and not the contract manufacturer.

Overall, were your impressions of the GMPs favorable or unfavorable?

Pacific: My impression is that the GMPs are a part of our industry's growing experience and will provide global opportunities. I am in favor of strategic continual improvement. Remember, the GMPs will provide reassurance to the public, and this will benefit all of us.

GMP Labs: By comparing the initial proposed GMPs and what was finally issued, it is clear that FDA has made concessions to the industry's sentiments. Overall, we think that they are fair and favorable to the industry while providing confidence to the public.

RPI: Personally, I welcome the GMPs. I started in the drug manufacturing industry, where we also manufactured dietary supplements. I was trained to follow the same policies and procedures for both. When I started my own company in 1992 (InterTech Pharmaceuticals Inc.), I found it difficult to compete against many of my competitors. I can only guess that a few companies may have been giving their customers the price they wanted, while possibly sacrificing quality or potency. The GMPs will put all companies on the straight and narrow, and help to level the playing field.

Best: Definitely favorable. The nutritional industry has been plagued for years with unethical manufacturers and sellers. This "Wild West" environment hurts all of us. All consumers deserve to get a product that meets with the label claims. After all, they are swallowing the product into their body—shouldn't we care, too?

ABG: The regulations ensure that manufacturers establish and abide by the GMPs, that manufacturers are responsible for the safety of the products and label claims, and that controls are in place to meet quality and customer standards. According to FDA, the GMPs promise to enhance safety and quality in drug manufacturing while increasing efficiencies. These goals are aligned with our goals of safety, quality, and efficiency. The regulations give companies more control and also make them more accountable for their activities. ❖

*For more discussion from the Contract Manufacturing Roundtable, please visit our Web site, www.nutritionaloutlook.com.
The Contract Services Grid follows on page 35.*