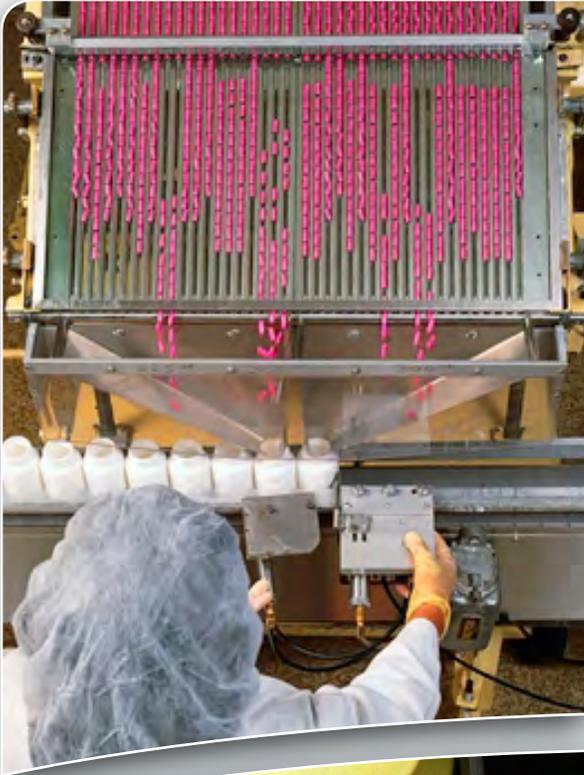




# CONTRACT MANUFACTURING



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The following are excerpts from Engredea's Contract Manufacturing Mini Guide, published May, 2015

## *How Contract Manufacturers can Help a Marketer Ensure Quality*

**G**ood contract manufacturers (CMs) can bolster a company's quality-control chain and help brand owners ensure the quality of their product. They can be the key element in keeping intact a brand's hard-won industry and public respect. But sub-par CMs can be the deadly weak link that corrupts a company's quality efforts. For all that you might save by shaving a few pennies per kilo on an ingredient order from a CM, nothing hurts more than a product recall— let alone one accompanied by a class-action lawsuit or two. What's more, brand owners can no longer hide behind contract manufacturers in court, let alone in the public eye. Total responsibility falls on the brand, and the FDA accepts no substitutes that it's not you, it's the CM. So, how do you make sure your CM is a partner in your success and not an unsuccessful scapegoat in your failure?

### **The changing role of contract manufacturers**

Have a brilliant formula but lack things like a Bosch Manesty TPR 500 automated press that can generate 400,000 tablets an hour?



That's where contract manufacturers come in. They've been around since the dawn of the supplement industry, but in recent years their role, and the brand owner's role in relation to them, is changing. In 2011, the FDA issued a Warning Letter to New York-based Confidence, Inc., the first issued to a supplement brand owner spelling out that they— not only the contract manufacturer— were responsible for the quality of the product. (<http://newhope360.com/supply-news-amp-analysis/dietary-supplementsunapproved-drugs-seized-new-york>)

"The FDA's made it really, really clear that if your [the brand owner's] name is on it, you're responsible for releasing the product to commerce, and you need to know how it's made ... quality is now the responsibility of both parties," says Mark Jost, Sr. Vice President, Business Development at Gemini Pharmaceuticals, based in Commack, New York. "It's a partnership, a marriage," says Jost, who, previously worked as the Vice President of Operations at Chromadex, where he was responsible for their contract manufacturer relationships. "Both parties have to contribute time and effort or it's not going to work."

### **How to find a CM that will help, not become a liability**

How to make sure your supplement manufacturing marriage doesn't end in divorce, or worse, a recall? Be sure you choose a quality company that will be a valuable asset, not a liability.

Visit the facility. Don't just ask prospective CMs if you can visit. See how prospects handle the unexpected. It's fine to have a prospective CM fill out a questionnaire, but "CM's can lie through their teeth. Go there and make sure they actually do what they say they do in the questionnaire," says Jost, who has visited CMs of all sizes, found discrepancies from what they reported, and rejected them

Marketers can hire third-party auditors to investigate for them. This can cost a couple thousand dollars, but is absolutely worthwhile.

### Transparency and education

CMs should be completely transparent and willing to share their quality documents—and not just after you get a call that an auditor’s coming. The days when manufacturers could claim “proprietary” and “secret” methods are gone. “It’s the brand owner’s responsibility to push back and say, ‘Here’s the deal, if you don’t help with the quality documents, I’m going somewhere else,’” says Jost. “Walk away.” Jost estimates that only about 50 percent of CMs are willing to agree to the level of transparency marketers should demand. And not all those unwilling to share are little manufacturers, he says. Where a good CM can truly help marketers ensure quality is making sure that when they do share documents, marketers



understand what’s in front of them. “It’s a batch report,” says Jost, “it’s not rocket science.” Gemini’s cGMP Partnership program conducts multiday trainings for brand owners to make sure they understand the documents and the processes they include. The education not only benefits the marketer, it strengthens the CM’s position, too. “If the FDA walks in to audit a client, these people become an advocate for Gemini,” says Jost. “If our paper isn’t understandable to them, we both look bad.” “As a brand owner, the last thing you want is the FDA out there saying you don’t know the quality of what’s in your product. That could sink your whole business. It’s a business based on trust,” he says. A true partnership between CM and brand owner, and integration of the brand owner into the quality processes, helps assure quality. “You want a relationship that goes beyond just a supplier-buyer relationship, you want one where the client is truly integrated into the quality process,” says Jost.



### Helping keep brand owners ahead of the curve

CM’s can help their clients by being proactive when it comes to new analytical technology and processes.

(<http://newhope360.com/new-products/validating-quality-your-contractmanufacturer>)

“It’s really a matter of making sure that test is the appropriate test for the product and what you’re looking for.” “[For botanicals]) no one test method is best,” Roy Upton, executive director of the American Herbal Pharmacopoeia, which has produced dozens of monographs demonstrating appropriate testing methodologies to use for a range of botanicals, told newhope360.com in a post about adulteration among (<http://newhope360.com/ingredients-general/ botanical-industry-faces-music-its-adulterationproblem>)

botanicals. Being a savvy brand owner means knowing what adulterants are being used to circumvent tests. CMs and brand owners can keep up with the industry's Most Wanted Lists, like information through the Botanical Adulterants program and the American Botanical Council bulletins.

Experts also agree manufacturers can help make sure their clients are current with upcoming changes in implications of regulations and any new requirements.

A good manufacturer can not only assure quality sourcing and processing, they might even be able to improve your formula.

### **You get what you pay for**

With more stringent GMPs, and California Proposition 65 (with some standards even more stringent than federal regulations), testing is more comprehensive and time-consuming than ever. "Think about it as a risk management strategy for the brand owner," says Jost. A quality contract manufacturer can help brand owners reduce that risk by not only producing a high-quality product as a true partner, but also by making sure brand owners understand what they're doing and why.



To view the original article in its entirety, please go to:

[http://newhope360.com/contract-manufacturing-mini-guide-0?utm\\_rid=CNHNM000001043137&utm\\_campaign=12218&utm\\_medium=email&elq=a998ac9c50f74fb481cd39b5112659f2&elqCampaignId=4940&elqaid=12218&elqat=1&elqTrackId=9e6669206fed4f6594963d3a5ff04efd](http://newhope360.com/contract-manufacturing-mini-guide-0?utm_rid=CNHNM000001043137&utm_campaign=12218&utm_medium=email&elq=a998ac9c50f74fb481cd39b5112659f2&elqCampaignId=4940&elqaid=12218&elqat=1&elqTrackId=9e6669206fed4f6594963d3a5ff04efd)