Contract Manufacturing Advocacy: How to Avoid the Common Pitfalls of Dietary Supplement Contract Manufacturing

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A trusted advocate is a must when using dietary supplement contract manufacturing services...and here's why!

Whether you are a newcomer or an experienced marketer in the nutraceutical industry, choosing and utilizing a contract manufacturer can be a confusing, frustrating, and daunting experience. There are over 400 nutraceutical contract manufacturers in North America alone. Finding a reputable manufacturer is not as easy as it may seem. And trusting one can be a very precarious proposition!

In 2013, 65% of dietary supplement companies inspected by the FDA received a Form 483 for alleged violations of Good Manufacturing Practices (GMPs). An FDA Form 483 is the official document issued to a manufacturer following an investigation in which the inspector observes conditions that are in violation of dietary supplement GMPs. The most common violations of GMPs, outside of administrative issues, were related to inadequate or *absent* ingredient and finished product testing.

Who is watching over the product development and manufacturing process *on your behalf*? Do you know if your contract manufacturer is working in your best interest?

Here are 10 things to consider in avoiding the potential pitfalls of contract manufacturing:

1. Do you have a clear understanding of and facility with each step in the product development process?

Dietary supplement product development—from ideation through manufacturing—is a highly complex process. There are many steps and procedures that must be followed, and *stewarded*, to insure successful forward progress and to prevent the myriad breakdowns that can occur. Consider that those who are not experts in product development are *completely unrelated* to the complexities of the process! Factor in working within a stringent regulatory framework and you have an undertaking that is no less challenging and daunting than climbing a mountain.

2. Do you have a viable, feasible formula that you are getting the most of?

Formulating dietary supplements is much more like creating a master recipe for a great tasting and nourishing dish than combining chemicals in a lab! Great formulation is an art *and* a science. To get the most out of your products—including generating revenues—requires a great formula from the start. There are several aspects of feasibility: ingredient

choice, delivery mode, dosage determination, costing (including factoring in testing requirements), packaging, etc. Knowing what is feasible in the short and long term takes experience, and making sure your formula is feasible from the start could save you a lot of time, money and headaches!

3. What are your stage gates as you bring a product to market?

Setting up and following stage gate procedures can be a make-or-break step in the overall product development process. Stage gates can insure that you don't waste time and resources bringing a product to market and ultimately fail, potentially costing you money—or even hurting your brand. Depending on your product development model, stage gate screens include such things as product concept, science and technical review, costing and formulation, marketing and positioning, and product piloting.

4. Do you know how to choose and ultimately vet quality ingredients? If not, *who will*?

Ingredient quality is, overall, *the most important aspect* of product development. Without quality ingredients you will not have a quality product. It's that simple. And violations in the area of quality are the most common infractions committed by dietary supplement manufacturers. Unfortunately, incompetence and even defiance are relatively common with supplement manufacturers. ***Utilizing expertise in choosing and vetting quality ingredients is the single most important step in the product development process!***

5. Are the ingredients in your formula safe? How would you know? What is the proof?

A baseline safety analysis of each ingredient is the first step in insuring product safety. And product safety is paramount inside a commitment to consumer wellbeing. After all, *what is the purpose of a dietary supplement but consumer health and wellbeing?* There are very specific elements involved in a comprehensive safety analysis, such as a determining NDI and GRAS status, ingredient technical review, toxicity summary, adverse event and drug interaction report, and adulteration risk review. Making sure each ingredient in your formula is safe is not only the proper foundation for a product in development—from a compliance and marketing perspective—but provides confidence and peace of mind that your product will do what it's designed to do: support the health and wellbeing of the consumer.

6. Does your contract manufacturer have a proper, well-developed and managed Supplier Qualification program? Who is ultimately accountable for follow through?

Supplier qualification is a requirement of GMPs. But, surprisingly, not all contract manufacturers have a well-developed and managed program. And even those with well-designed programs in place don't have the staff or expertise to implement and/or follow through on raw material qualification. Quality control is, necessarily, a detail-oriented realm and it is commonplace for some of those important details to fall through the

cracks if not properly managed. Having a trusted advisor who knows those details and can insure raw material qualification is properly carried out can be a huge asset in the realm of GMP compliance.

7. How will you avoid potential ingredient breakdowns—such as shortages, supplier issues, patent infringement, and analytical testing failures?

Supply chain issues can be one of the most frustrating, obstructive, and potentially *destructive* aspects of the product manufacturing process. Responsible contract manufacturers have savvy, experienced purchasing staff who make sure to qualify secondary suppliers of ingredients whenever possible. However, not all manufacturers develop or follow procedures that safeguard ingredient availability. You can be sure—ingredient breakdowns *will* happen, and when they do, will your manufacturer be prepared so you aren't in the unenviable position of being out of stock? And is your manufacturer even *conscious* of potential IP issues? Advocacy in these areas can make a huge difference to your bottom line and, depending on your marketing channel, literally save your business!

8. How will you avoid production delays?

Just like ingredient breakdowns, production delays are a reality of the supplement manufacturing world. While some delays are unavoidable, many are due to breakdowns in schedule management, poor communication, and/or economic motivation. There is an old adage "forewarned is forearmed." Advocacy can be your armor in the world of contract manufacturing.

9. Does your contract manufacturer have skilled, properly trained staff (scientific, quality, regulatory and legal) to develop clean labels?

Once ingredients are properly qualified and vetted to meet the very basic standards set out by GMPs, clean labels are the next priority. After all, if your ingredients are authentic and safe, but your label is incorrectly or improperly developed, you are falling short in the area of product integrity and do your product a tremendous disservice. In addition, a clean and properly developed label can directly impact your marketing and sales success. However, as surprising as this may seem, **contract manufacturers often do not employ staff with expertise in clean label development.** There are several dimensions of label development (other than marketing), including scientific, technical, quality, regulatory, and legal. Input and review from all of these areas is a must for proper label creation. Guidance in this area is critical not only for compliance but for powerful marketing of an authentic product.

10. Do you know which packaging options will best protect and maximize the shelf life of your products?

While proper packaging can be crucial in the marketing dimension of product development, it is equally as crucial in the area of product stability and compliance.

Packaging effects ingredients, and thus label claim. The right packaging will protect product integrity; the wrong packaging can lead to a dead product. It's that simple. And often packaging choices are an afterthought! Consulting with a contract manufacturing advocate around appropriate and wise packaging choices can be the determining factor between success and failure in the marketplace, from a quality, compliance and sales perspective.

*For more information on our **Contract Manufacturing Advocacy** programs, contact Virtuosity Formulations: http://virtuosityformulations.com/contact-us/ or call (561) 886-7302.*