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AER Bill Becomes Reality

Having passed both the House and the Senate at the end of the 2006 session of Congress, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (S. 3546) will require manufacturers and certain other distribution chain parties to submit all serious adverse event reports (AERs) to the federal government. Facing implementation of this law, supplement companies, if they haven't already, are honing their AER processes and preparing for compliance.

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Industry Experts Address Contract Manufacturing Issues

To retain a competitive edge, many businesses are choosing to focus on core competencies while contracting external operations for projects requiring supplemental production capacity and/or expertise. For many marketing and manufacturing companies in the dietary supplement industry, contract manufacturers offer advantages over in-house manufacturing including lower costs, flexibility, access to outside proficiencies and reduced capital. However, for expectations to be fully realized, companies must understand what key factors make a contract manufacturing relationship work, as well as what pitfalls to avoid to ensure the intended value is gained from the relationship.

INSIDER: What are the most common reasons your customers choose to work with a contract manufacturer?

Thomas T. Tierney, president and chief executive officer (CEO), VitaTech International Inc., Tustin, Calif.: Contractors are generally steeped in industry experience that rubs off to benefit new market-entry brands. For wise marketers, especially when creativity is their strong suit, letting the contractor do the heavy lifting for equipment capitalization makes sense.

Ron Udell, president, Soft Gel Technologies Inc., Los Angeles: Customers want the benefits of having a manufacturing operation without the headache. By choosing a contract manufacturer to perform the necessary steps to produce a finished product, a customer can focus on other aspects of their business, including the branding, marketing and selling of the finished goods. Contract manufacturers allow companies to conceptualize innovative products, and utilize the skill and expertise of outside vendors to manufacture those products. It's a mutually-beneficial partnership.

Robin C. Koon, senior vice president, Best Formulations, City of Industry, Calif.: There are several reasons why a company would choose to use a contract manufacturer. The customer may not manufacture any products at all, such as a marketing company, or may require a specialty service or specific expertise—such as R&D, softgels or teabags, for example. It is also possible a customer would need help with additional overflow capacity. Finally, using a contract manufacturer allows companies to avoid the financial cost and issues of operating their own plant.

Michael Schaeffer, president, Pacific Nutritional Inc., Vancouver, Wash.: The primary reason for using a contract manufacturer to produce dietary supplements is having a fixed inventory cost and/or price for a wholesale/distribution/marketing company. Contract manufacturers absorb a product's variable costs related to material sampling, formulation overages, production loss and laboratory tests.

Bob Olson, director of national accounts, Century Foods International, Sparta, Wis.: Contract manufacturers specialize in production. They can decrease time to market and lower costs, and the learning curve for training staff is often much faster. Offering full service manufacturing including research and development, engineering expertise, formulating, testing, blending and packaging in one location improves speed and effectiveness of the supply chain. Predictability allows purchasing to contract better pricing on raw materials, which allows production to become more efficient and lowers the risk of obsolete or outdated materials.

INSIDER: What are some of the key considerations in selecting a contract manufacturer and ensuring a successful partnership?

Lucy MacLoughlin, chief operating officer, Rhema Industries Inc., Bellingham, Wash.: The customer and manufacturer need to have a clear understanding and agreement on product specifications. Mutual communication and attention to detail is extremely important

to ensure that objectives (e.g., taste, appearance, appropriate packaging format, price targets, etc.) are met. Often, customers may not be familiar with manufacturing and may expect that a higher dose of actives can be delivered in a single capsule or tablet than can realistically be accommodated. Additionally, they may not allow sufficient time for product development. It takes good communication and a mutual sharing of information between manufacturer and customer to make sure everyone has achievable expectations. As close as possible to the initial contact, the scope and specifications of the project should be determined. Factors such as product development needs, price points, specialized material needs that could impact lead time and many others need to be discussed, agreed upon and formalized by way of raw material and finished product specifications and business agreements.

Kenn Israel, vice president of marketing, Robinson Pharma, Santa Ana, Calif.: Customers should be concerned with the quality of the product they will receive and the integrity of the organization they select to manufacture their product. It is important to not minimize the impact on their reputation that these factors can have. Simply put, the contract manufacturer must be able to get the formula produced correctly and on time. While price is often the first concern, it needs to be balanced with getting the job right. To assure the above, a customer should be very clear and specific about what he wants to manufacture, and direct and upfront in his expectations and needs.

Lucy Ackerman, director of sales, Indigo Labs, Vista, Calif.: A contract manufacturer should be able to assist with formulation and other manufacturing issues. The company should have a host of resources if they know how to use them. We like to talk at length with our clients to first find out what they want to create and when they need it. What is their product? What timelines are already in place? Can we work within those timelines? We also are very clear about our capabilities and create a production schedule based on the product, quantities, required labeling, ingredients, etc.

Richard Kaufman, executive vice president, Paragon Laboratories, Torrance, Calif.: The primary issues include the area of expertise that the contract manufacturer specializes in (i.e. tablets, two-piece capsules, softgels, liquids, powders), level of quality assurance/quality control (QA/QC) applied to the manufacturing process, lead time and pricing. There are often misconceptions about the amount of preparation it takes to manufacture a new product in terms of formulation development, document creation and necessary lead time to source, receive and process the ingredients into the finished product. Having clear expectations established is a function of how experienced the contract manufacturer is and whether the sales person has clearly conveyed to the customer what to expect in all phases of the formulation and manufacturing processes.

Tierney: Business runs on experience, capacity, attitude, talent and cash flow. These are all compromised if the customer is underfunded or the contractor over-promises. Mutual trust—and



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