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**Brand Owners and Own Label Distributors:
Do You Really Know the Quality of Your Dietary Supplements?**

By

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Like before the implementation of cGMP regulations by the FDA, the Brand Owner or Own Label Distributor has just received a new shipment of product from their Contract Manufacturing Organization (CMO). The packing list is there, nothing is damaged, and the Certificate of Analysis (C of A) is attached – so just like before, the product is ready for you to send to your customers and satisfy orders. All should be Good To Go – Right?

Wrong! Without a complete understanding of the manufacturing process based on a strong quality relationship, the key paperwork, i.e. C of A, received by the Brand Owner/ Own Label Distributor mentioned above only addresses the few tablets or capsules that were sampled during the analytical testing of the finished product. It explains absolutely nothing about the overall quality of the product or whether it met specifications throughout the manufacturing process. This, according to the FDA and cGMP regulations, does not provide the Brand Owner/ Own Label Distributor with enough information to release the product to market with confidence.

One only needs to look at the string of FDA Warning Letters issued to Brand Owners/ Own Label Distributors to realize that more information will be required to be reviewed and approved before the product gets released to market. As a Brand Owner/ Own Label Distributor, if the information is not provided by the CMO, you have little confidence in your ability to interpret it if made available to you, and/ or you have not set a system up to review it prior to shipping product to clients, you are placing your company at great risk.

As shown in the Warning Letters and in published literature from the FDA, during an audit the FDA will be asking the Brand Owner questions about how the product was produced and details about certain lots. This responsibility, formerly able to be pushed to the CMO by the Brand Owner, is now shared – and since it is the Brand Owner's name on the product, it is imperative the Brand Owner is familiar with both the regulations and CMO's processes. This done by having a written Quality Program, regular audits of the CMO, and a working knowledge of the batch record and quality documentation the CMO creates for every lot of product.

The Brand Owner or Own Label Distributor has chosen to work with and trust a CMO to correctly and to effectively manufacture their product. In exchange for this trust and the competitive prices paid, it is no longer reasonable for a CMO to not provide this documentation to the Brand Owner on a regular basis or for the



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CMO to use the excuse that “what we do is secret or proprietary” when it comes to not disclosing or sharing production and quality information with their customers.

Why have the CMOs historically not provided information to their Brand Owner customers? The common response is a fair concern that the customer will take their manufacturing procedure to a competitor, resulting in a competitive disadvantage. This is certainly a possibility (and has happened before), but that also indicates there is not a strong Quality or Manufacturing Agreement between the parties, and also that the CMO has failed to either provide a quality product at a competitive price, or has not built a solid relationship with the client.

However, batch records and other quality paperwork are becoming increasingly company-specific and tailored for individual CMO machinery and practices. While the batch record may give the second CMO some insight as how to process the materials, their cost of creating paperwork and implementing those practices will still need to be done. So, more than ever, both Brand Owners and CMO’s are learning the days of “hopping around” to save a few pennies is foolish, as the cost of compliance, testing, qualifications etc. mandated by cGMPs is forcing them to find more ways to work together, rather than finding a motivation for the client to look elsewhere.

Another reason commonly given by CMOs for not sharing information is their “batch records are too complex” for the client to understand. While it is certainly true that a 20+ page batch records and other quality documents contain a lot of information, it is not “rocket science” to interpret them as they are designed to be working documents at all levels of production. Incorporating a training program into the Quality and Manufacturing Agreements between the CMO and Brand Owner/ Own Label Distributor on how to read and review the quality information is an essential step to ensure compliance. An uncooperative CMO is truly the wrong partner for future growth.

Do not rely on the other commonly used tactic by CMO’s, “we will provide you batch records in the event of an FDA audit”. As the company whose name is on the product, the FDA auditor will be asking your quality team the questions about how the product was made not the CMO. Getting a 20+ page quality document from a CMO that you have not seen before the FDA audit is placing your business at risk. The Brand Owner’s/ Own Label Distributor’s quality team need



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to review the quality documentation before each lot product is shipped to your clients not just during an FDA audit.

The Brand Owner/ Own Label Distributor can no longer relinquish the responsibility for the quality of their products to the CMO, where the evolution of GMPs and FDA enforcement requires Brand Owners/ Own Label Distributors to invest their own quality systems. From onsite audits through batch quality paperwork review, Brand Owners and Own Label Distributors have to take responsibility for the quality of the product that bears their name since it is their company and reputation at risk if everyone is not cGMP compliant. Bottom line – Brand Owners must select a transparent CMO who understands quality trends, who wants to be their partner, and who freely shares needed documentation and information. Unfortunately, this is not always available from the CMO with the lowest price, but the risks today of noncompliance mandate the Brand Owner/ Own Label Distributor see the overall value proposition in working with a reliable, forward-looking CMO to ensure sustainability and profitability for their company.