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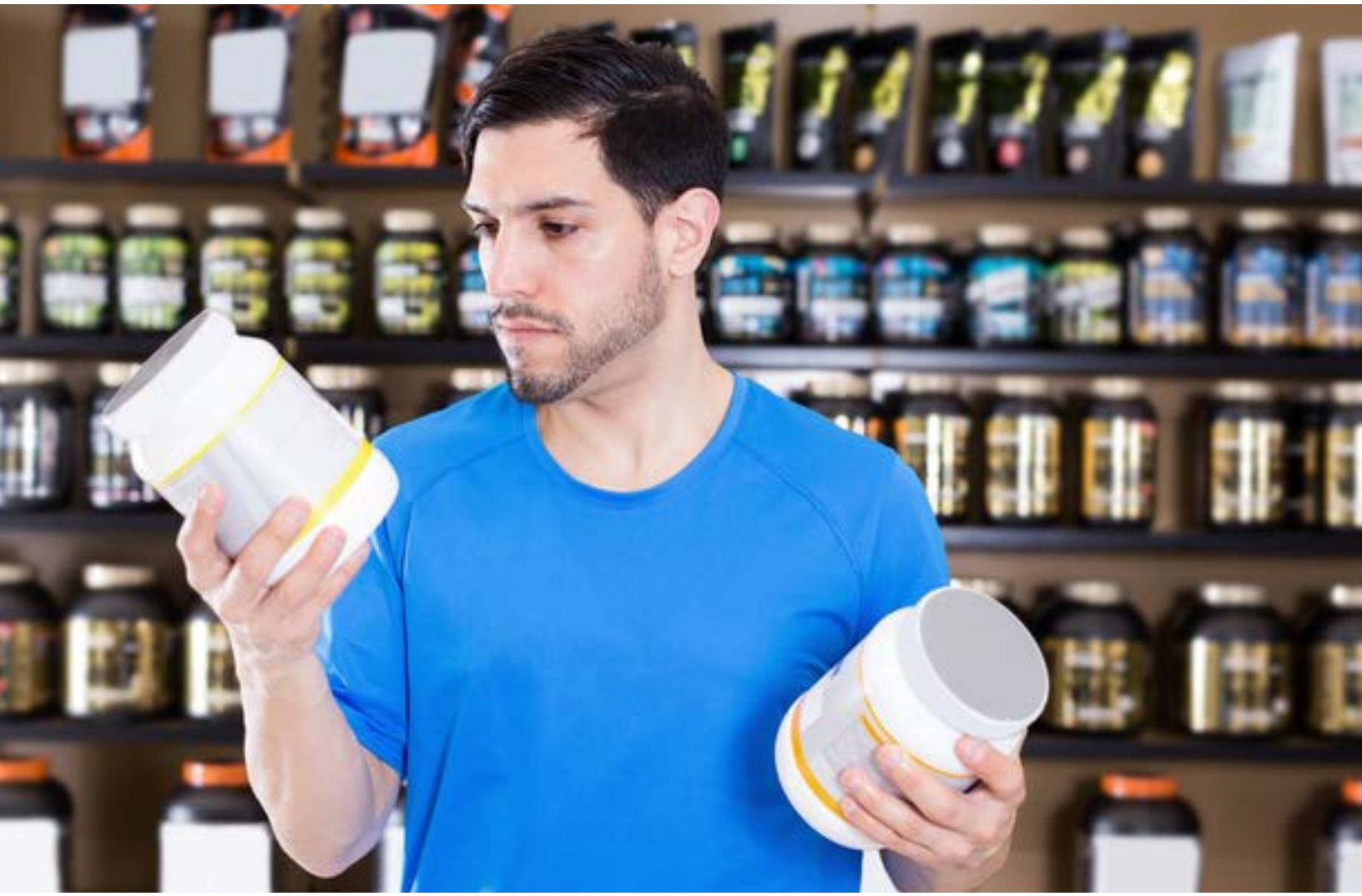

Manufacturing Perspective:

Meeting the Retail Dietary Supplement Requirements

By: Mike Finamore - CEO

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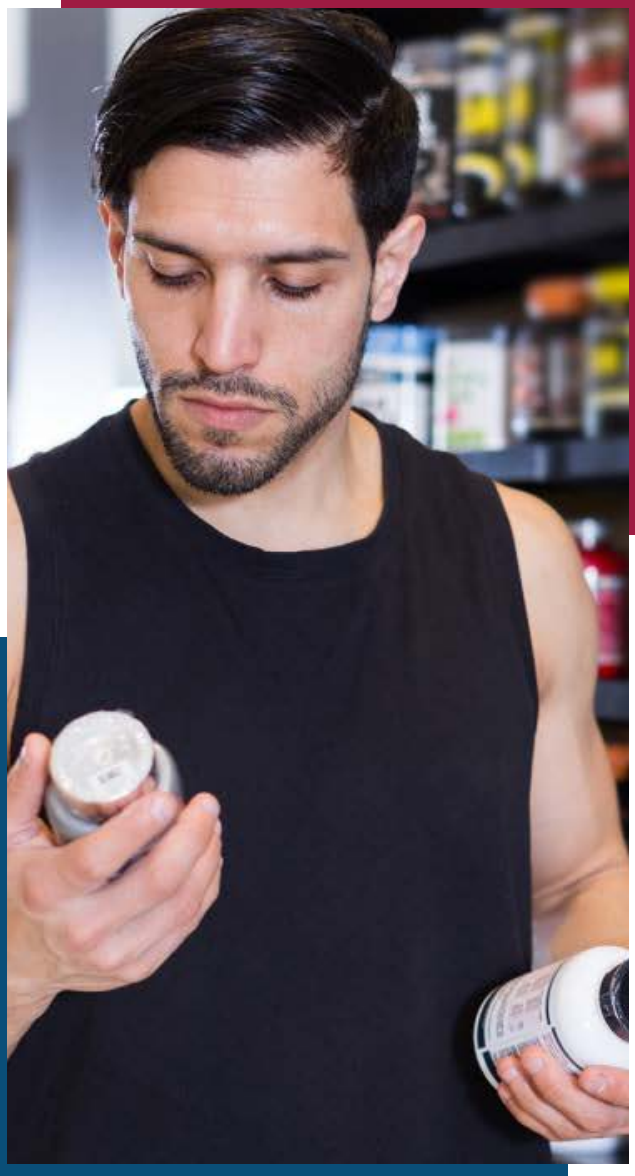
Most Brand Owners understand the requirements of meeting dietary supplement cGMPs set forth in 21CFR Part 111. However, now many Online Retailers and Retail Brick & Mortar Stores have added a new set of requirements for the Brand Owners to be able to market dietary supplements through these outlets. Finding the right manufacturing partner who understands these requirements will significantly impact the Brand Owners success through these sales channels.

Retailers have taken a unique approach to create their own quality programs that set the bar for any items to be sold on their digital marketplace or physically on a shelf. The goal is to ensure Brand Owners have put in place the correct policies and procedures to guarantee the dietary supplements being sold have been manufactured properly, tested accordingly, and demonstrate they meet specifications. Ultimately these programs are consumer focused to ensure the end customer is receiving a safe and non-adulterated product.



However, Brand Owners may face unique challenges when trying to satisfy these quality programs now required by the retailers. They can be technically demanding and require additional expense to make sure all the boxes are checked. Leveraging the expertise of a competent Contract Manufacturing and Development Organization (CDMO) who has successfully navigated these compliance programs is a great start.

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One of the requirements of the Brand Owners is to have the supplements produced by a CDMO who has demonstrated cGMP compliance. This is best accomplished through an audit to a recognized standard. The GRMA (Global Retailer Manufacturer Alliance) working with NSF International has created the most comprehensive dietary supplement cGMP audit standard available. This standard uses a grading scale rather than a pass/fail approach used by other cGMP audits. It provides greater insight to the quality of the manufacturing organization and their level of cGMP compliance. A successful audit against this standard (NSF/ANSI 455-2) with a high grade will provide the Brand Owners and the Retailers with the highest level of confidence that the dietary supplements are made in complete compliance with the cGMPs.

CDMOs, who are members of GRMA or have been audited to NSF/ANSI 455-2, will have in place all of the documentation required of the Brand Owner by the various Retail organizations. The key is for the CDMO and Brand Owner to start working together from the start, i.e. the design of the formula, ingredient selection, labeling, and testing, to ensure a smooth transition to an online listing or on-the-shelf presence.

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Having the proper in-process and finished product testing in place is another critical step to ensure cGMP compliance. Retailers will often require the test results come from an ISO 17025 accredited laboratory. The ISO accreditation proves the testing laboratory has in place a quality management system and the technical competence to provide accurate and reliable testing withing the scope of their accreditation. Brand holders should look to work with CDMOs whose inhouse laboratory is ISO 17025 accredited. This can help fast track their product acceptance by Retailers and provide a greater level of confidence in the results that are published on their product's Certificate of Analysis.

This latest round of requirements by Retailers is all part of the evolution of the transparency the industry has been experiencing since the implementation of the cGMPs. This puts reputable CDMOs and Brand Owners at the forefront of this rapidly growing industry by giving consumers greater confidence in the quality of the products they buy.

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