

Manufacturing Perspective:

Contract Development and Manufacturing Organization – The Future

By: Gemini Pharmaceuticals

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With the advent of more rigorous manufacturing and testing standards for industry, the Brand Owner and manufacturer of the product are more intertwined than ever before. This has placed additional burdens on the development process for the Brand Owner, as now ingredient substantiation, sustainable sourcing, and trend analysis are a part of any product launch. It is no coincidence that these factors along with potential liabilities are driving the dietary supplement industry to a more intertwined relationship model for the Brand Owner / Manufacturer.



However, many Brand Owners and many Contract Manufacturing Organizations (CMOs) cannot supply the bandwidth across these disciplines to properly support the product launch and continued supply. Whether it's the slimming of corporate staff, challenges in sourcing or engineering, or ignorance of their responsibilities, the chances for catastrophic failures in a product lifecycle have grown faster than many can react. There is no doubt those odds will multiply as time goes on. Ultimately, the successful launch and support of an item will only happen when these factors are addressed and understood by the Brand Owner from the inception of the product concept.

So how does our dynamic industry deal these concerns while still driving innovation? To create the required successful partnerships in dietary supplements, the industry needs to look at sister industries for guidance. There is the perfect model in the pharmaceutical world – that of a Contract Development and Manufacturing Organization, known as a CDMO. The addition of the “D” is a critical differentiator from the traditional component of the Brand Owner/ Contract Manufacturer’s (CMO) relationship. This service can encompass everything involved with the turn-key development of a product - from sourcing through engineering through manufacturing and everything ancillary to those responsibilities.

While some CMOs currently provide formulation assistance along with engineering options to their brand partners, the Development portion involves a more granular partnership to ensure a successful supplement launch. For instance, a complete understanding of the marketing, sale price, and projected lifecycle as well as related products offered by the Brand Owner helps the CDMO form the development

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of the current item. This way the CDMO can be sure all these issues are considered while creating or engineering an item. This may call for sourcing custom ingredients, deeper dives into the science and related substantiation, packaging considerations, as well as testing method development for the product. Going beyond the traditional design specification, the CDMO can help ensure a turnkey, or partial turn-key, item is launched with all of the considerations covered by a thorough review of this process.

Ultimately, it's easy to see how this relationship is popular in the pharmaceutical industry, where the Brand Owners can identify market opportunities and the CDMO can work with the Brand Owner to bring the idea to reality. This is scalable for the Brand Owner, as the CDMO partnership allows the Brand Owner to stay "out of the weeds" and concentrate on driving the Brand growth. The CDMO can then use their knowledge and experience to source, develop and engineer the items to the required specifications. Ultimately, this division of expertise among responsible parties is a highly efficient model that helps ensure quality and repeatability through the entire sourcing and manufacturing process for the life of the product.

There is no doubt that some in our industry will be resistant to this model, since letting a manufacturing partner "into the room" is something which has been discouraged for a variety of reasons. However, much like the concept of transparency was also once unheard of, the growth of the supplement industry will ultimately be led by Brand Owners that recognize the inherent value of a relationship with a CDMO and the ability of quality-driven CDMO's to deliver the required innovation to their Brand Partner. The inevitable pull of the supplement industry into this model of product development is becoming stronger, and the Brand Owners who can adjust to this evolution by finding the right CDMO partner will be far ahead of the competition.

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