

The Brand Owner/Own Label Distributor and the Contract Manufacturer

A quality partnership built on a strong relationship

by Michael Finamore

What does the phrase “quality partnership” really mean, and how integrated does the relationship need to become? Metaphorically, are the two parties interested in casually dating, going steady or are they on the road to marriage? Fortunately for the brand owner/own label distributor, their desires and actions are still the primary drivers for the direction of the relationship with a contract manufacturing organization (CMO). However, the brand owner/own label distributor that wishes to enjoy the “single life” without engaging and investing into a deeper relationship with its chosen CMO partner is ignoring the significant additional responsibilities imposed by FDA and cGMPs (current good manufacturing practices).

Most of the brand owners/own label distributors and CMOs, along with key personnel, have been active in this industry long before the implementation of cGMP requirements a few years ago. For them, both then and now, the old buyer/seller paradigm works just as well. Many brand owners/own label distributors still see themselves as only the marketer/seller of their unique dietary supplements and intentionally distance themselves from the manufacturing of their products. By creating a gap between themselves and their CMO, they have not taken ownership of the process by which the product is sourced, engineered, manufactured, packaged and tested in the way FDA expects them to. This is obvious from the numerous warning letters that have now been issued to the brand owner/own label distributor, penalizing them for cGMP violations concerning their brand. Not one of those warning letters mentioned or cited the CMO.

In the pre-cGMP paradigm, price and possibly service were the overriding concerns of the brand owner/own label distributor. In a sense, because there is no commitment by either party beyond a purchase order, every transaction is at arm’s length. In some cases, the brand owner/own label distributor has taken a small positive step forward by asking the CMO to complete a manufacturing questionnaire or a paper audit. This is equivalent to looking up a potential date on Facebook—nice pictures without insight into the true character of the potential partner.

Believing this is a sufficient foundation to begin or on which to continue a relationship with a CMO is a major liability for the brand owner/own label distributor. At this “casual dating” phase, a thorough background check on their potential CMO partner should be done through every means available. A detailed questionnaire, a strong quality agreement, a plant visit and online research using industry and open sources should be done to get a detailed picture of the CMO. Most CMOs are not going to volunteer to provide information if not asked—the legal obligation is with the brand owner/own label distributor to take the lead and determine the course of the relationship. While many brand owners/own label distributors aren’t staffed or willing to make necessary investments in non-revenue generating departments, it’s clear a competent quality department is just as critical to the growth and health of a company as its sales team. A thorough investigation by the quality team during this casual dating phase helps ensure the company will not knowingly enter a bad relationship, no matter how strong the initial attraction.

Assuming the CMO and brand owner/own label distributor make it through the dating phase and are thinking of getting serious, it’s time for the couple to do a deeper analysis of their relationship before moving forward. Because no one knows their partner like their family and close friends, it is prudent to “go home” to meet these people, which in this case, means a detailed audit of the CMO after a few lots of product have been produced. This will allow the brand owner/own label distributor to take a close look under the hood, see through all of the “alphabet soup” of registrations and memberships of the CMO, and see if their partner is legitimate or just smoke and mirrors hiding poor character.

To do a thorough audit, the brand owner/own label distributor must closely examine all aspects of the facility, the CMO’s standard operating procedures (SOPs), and the records pertaining to their products. If not yet staffed with qualified personnel, any number of highly qualified independent auditing companies are available to give the brand owners/own label distributors a complete picture of what’s going on at the CMO. This

expensive and lengthy process is a place where the true value of the CMO becomes apparent, as the time spent by the auditor is directly correlated to the quality systems in place at the CMO. If the information is freely available and the documentation complete and orderly, the audit should be accomplished quickly. If the CMO is evasive or uncooperative, then what secrets or problems is the CMO afraid to reveal? It’s great to trust the CMO is following cGMPs, but this behavior needs to be verified. Remember, FDA clearly is holding the brand owner/own label distributor accountable for cGMP compliance related to their products throughout the supply chain.

The real key at any stage in this relationship-building process is openness, which is in direct conflict with the pre-cGMP paradigm thinking of this industry. However, as in any relationship, there needs to be a free and open exchange of important information between both parties. FDA is mandating that to the industry, as shown by its enforcement of cGMPs and issuance of warning letters and other public statements. The brand owner/own label distributor is being forced into a more serious relationship with its CMO by FDA. The brand owner/own label distributor has to ensure the tools for a strong relationship are available from the right CMO partner. Access to batch records, a signed quality agreement and regular audits are critical, but to ensure a strong marriage, other additional steps need to be taken.

While even the strongest relationships sometimes fail or go through rocky times, without a solid foundation, the potential for failure is almost guaranteed (and is shown by FDA’s warning letters). The cost of that failure is ultimately borne alone through irreparable harm to the brand owner/own label distributor. ■



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