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Creating Contracts for Partnership and Transparency

by Michael Finamore

The new focus on contracts within the dietary supplement industry has sometimes created more confusion than clarity. While companies now distribute supply agreements like Halloween candy, most parties do not appreciate the terms, conditions, liabilities and obligations imposed by these documents. In many cases, these contracts may assign responsibilities that are unassignable, or attempt to get around GMP (good manufacturing practice) requirements by overly wordy stipulations that do more harm than good. These business contracts should be more than just legal documents; they should be a means to create or foster a partnership between the brand owner and the contract manufacturing organization.

A contract is a binding, enforceable agreement between two or more persons or parties. The impersonal and defensive nature of contracts sometimes creates an adversarial situation with everyone looking to protect their interests. This runs counter to the spirit of business and our industry, where close collaboration and shared liabilities between groups are the basis of success. However, despite these challenges, it's clear that much like any relationship, the sooner the difficult details are hashed out, the sooner the documents get filed away, and the partnership outlined in these documents becomes part of the shared DNA between companies.

Despite some confusion, a manufacturing or supply agreement/contract is not required by regulations or FDA. However, best practices would encourage this agreement. A strong document confers tremendous value to a company and the other signee for a multitude of reasons. Thus, while FDA will likely not ask to see such an agreement during an audit, often the presence and acknowledgement of this agreement will demonstrate control over the entire manufacturing process and provide substance for answers given to regulators. While the manufacturing/supply agreement usually deals with the "commercial terms" of the relationship, with increased liabilities imposed upon brand owners, it's imperative these areas are addressed and resolved.

Critical items to include in a manufacturing or supply agreement/contract are:

- Names and addresses of the legal entities entering into the contract
- Nature of the agreement—exclusive or nonexclusive
- Confidentiality
- The products covered by the agreement
- Product pricing
- Terms for submitting and accepting purchase orders
- Change order procedures
- Provision for supplying a forecast of needs and deliveries
- How changes to specifications are addressed by both parties
- Payment terms
- Who is liable for which taxes
- Product manufacturing issues, such as raw material specifications, formulation and meeting label claims
- In-process and/or finished product testing
- How to communicate and handle delivery delays
- Shipping requirements
- Acceptance or rejection criteria by the brand owner, as well as timing
- How defective product and/or product returns are handled
- Regulatory issues and notices
- Quality assurance (QA) requirements to ensure compliance with 21 CFR part 111
- Quality documentation, including batch records
- Audit rights of brand owner
- Standard clauses on warranties, product liability and indemnification
- Term and termination
- Governing jurisdiction for the contract

The brand owner and contract manufacturer can work together without a contract. Many of the items contained in the contract are standard business practices, or part of the terms and conditions considered when submitting and accepting a purchase order. However, a supply agreement covers issues not present in conventional purchase orders and addresses them in a controlling document.

Best practices mandate a family of these contracts and documents be executed and followed as a framework for every business relationship. While a manufacturing or supply agreement/contract is expected to be present, it's only after this document is harmonized with other necessary items that the essential partnership can be created.

A quality agreement is more critical to the relationship than a manufacturing or supply agreement/contract. It outlines the aspects of quality that are required to be met in order to comply with regulations and the specific quality responsibilities of each party. A quality agreement should be kept separate from the manufacturing or supply agreement/contract. During an FDA audit, the auditor can ask to see the quality agreement.

However, without harmonization with the manufacturing or supply agreement, the quality agreement stands alone. Both documents outline essential liabilities and parameters needed to release the product to market. For the contract manufacturer, the certainty of a business partner offers a greater incentive to support that partnership, and the tie-in between companies allows for the free flow of ideas and information to stimulate growth.

Meeting requirements set forth in these documents create a strong foundation and a necessary partnership between the brand owner and the contract manufacturer. Working in concert with one another, the parties can achieve the business terms and quality standards necessary for regulatory compliance. The two companies must interact at all levels to ensure the desired finished product and product quality is achieved. It is, at that point, where the partnership and transparency created by these documents show their value, and why the most successful companies have made these agreements a requirement for their business relationships.

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