NATURAL PRODUCTS INSIDER®

A Certificate of Analysis Does Not Equal Transparency

by Michael Finamore

All too often, a certificate of analysis (CoA) is the only document some brand owners see from their contract manufacturer; and for a long time, that represented the apex of a quality relationship. However, one should not confuse a CoA with transparency.

A finished product CoA for each lot of product manufactured is necessary and should reveal analytical results demonstrating the ingredients claimed on the label are present at designated levels, contaminants are identified and accounted for, and other release specifications for the dosage unit are met. Thus, while a CoA does provide confirmation of product composition, it offers no insight into either the process or the procedures by which the product was made.

FDA and cGMPs (current good manufacturing practices; 21 CFR Part 111) have made it clear the brand owner—and not the manufacturer or raw material supplier—is responsible for the quality of its dietary supplement. Therefore, all CoAs in the supply chain—including all raw materials and the final finished product—must be accurate for both the product contents and required manufacturing specifications. These must dovetail into design specifications and be confirmed throughout the manufacturing and product life cycles.

In addition, leaving the obligation for raw materials specifications to the contract manufacturer to ensure the material's quality is a thing of the past. The brand owner should use qualified testing facilities to establish a baseline confirmation of key components of the material before considering the material for its product. Only with this knowledge should the brand owner assume the ownership and liability of introducing it into the product, as ultimately the brand owner's discretion is key when reviewing quality responsibilities between the parties.

For materials both specified and not specified, careful attention needs to be paid to the ingredient CoAs and the testing done by the contract manufacturer to confirm identity and ingredient potency during the design and production phases. Ultimately, this information needs to be harmonized among the raw material suppliers, contract manufacturers and brand owners to demonstrate quality and ensure transparency throughout the supply chain.

FDA and cGMPs (current good manufacturing practices) have made it clear the brand owner—and not the manufacturer or raw material supplier—is responsible for the quality of its dietary supplement.

The responsibility of digging deeper into the product supply chain needs to be an integral part of a brand owner's relationship with contract manufacturers. An important first step in this process is a thorough audit of the contract manufacturer's operations done against cGMP standards, ensuring the "c" in cGMP is embedded in the culture of both companies. A prime example would be the new ANSI 455 audit standard offered by the Global Retailers and Manufacturers Association (GRMA), which was developed in conjunction with NSF International. An audit to a national standard that demonstrates compliance to 21 CFR Part 111 will provide insight and confirmation of a contract manufacturer's quality systems beyond what a traditional audit can offer. This allows the brand owner to have confidence in the veracity of the systems and transparency offered by its contract manufacturing organization (CMO).

Of the two components in a quality system relationship—the "macro" of quality agreements and audits, and the "micro" of batch records—the contract manufacturer's production batch records (BPRs) is the most important to transparency. The brand owner needs to have access to and carefully review the batch record for each lot of product. This needs to be closely reviewed against the CoA for the same lot to ensure there are no incongruities or discrepancies. This part of the brand owner's quality system, which compares these findings to its release specifications, needs to occur before the item is released to commerce. It can neither be delegated to the contract manufacturer nor be built solely on the contract manufacturer's paperwork.

A finished product CoA alone is insufficient to ensure the quality of a product, but it does represent a very strong indicator of the viability and specific elements of the product lot, especially when read in conjunction with a batch record. Without a CoA, a product cannot and should not be released to commerce. Additionally, a CoA with incomplete or contradictory information may indicate a larger problem with the supplier and its quality systems. Such due diligence by both the brand owner and contract manufacturer will help keep quality strong throughout the manufacturing process and, coupled with a solid supply and quality agreement, will provide the platform for a confident, transparent partnership.

Michael Finamore is CEO of Gemini Pharmaceuticals Inc. (geminipharm.com), a contract manufacturer of both dietary supplements and over-the-counter (OTC) pharmaceuticals for more than 30 years. All Gemini production is carried out in a pharmaceutical cGMP (current good manufacturing practice) environment.