Better Compliance through Master Manufacturing Records

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The FDA inspections of dietary supplement manufacturers have resulted in 1 in 4 producers getting a Warning Letter that could shut down their business. We have analyzed the inspection notices from these manufacturers in the hope that we can give you some perspective on your own state of compliance.

A review of warning letter trends revealed that many are issued because firms not keeping proper Master Manufacturing Records (MMR). An example is in the Warning Letter issued to United Nutrition Labs, Inc in July, 2012. The FDA cited them for numerous violations including failing to provide any documentation of changes to their Master Manufacturing Records. In other cases, companies failed to keep proper documents of the steps used for their manufacturing processes nor documented the outcomes of their manufacturing steps.

Why Master Manufacturing Records are important:
The FDA says you need to prepare and to follow a written master manufacturing record (MMR) for each unique formulation of a dietary supplement that you manufacture and you must have one for each batch size. This ensures uniformity in the finished product from batch to batch. It also ensures that the proper ingredients are added and that each processing step is completed according to an established procedure. For example, the blending processes for each dietary supplement product may be different depending on the time or the agitation speed needed to get the best possible blend.

The Master Manufacturing Record can identify the specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. When Master Manufacturing Records were not used, the FDA found that operators making the batch left out important ingredients. They also identified where critical steps were not controlled which could lead to compromised quality. Every firm wants to make sure their customers get their highest quality product. Using a well-defined Master Manufacturing Record is an essential step in this process.

How to improve Master Manufacturing Record compliance:
Each MMR needs to include the measure of each dietary ingredient that will go into the product. This will keep employees from adjusting the amounts of ingredients from memory or based upon ratios learned from other employees. MMRs should specify the equipment to be used to ensure the equipment is of an appropriate design and should require that equipment cleaning is checked to make sure its use will not result in the contamination of the dietary supplement. Each MMR should include:

- A complete list of components to be used
- An accurate statement of the weight or measure of each component to be used
- The identity and weight or measure of each dietary ingredient

- A statement of theoretical yield at each step of the manufacturing process where control is needed to ensure the quality of the dietary supplement
- The expected yield when you finished manufacturing the dietary supplement
- Written instructions, including specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement
- Procedures for sampling
- Written instructions for manual operations, for example, one person to add and another person to verify the addition of the components

InstantGMP-Lite™ makes generating Master Manufacturing Records easy. This electronic batch record software system automatically keeps track of each MMR and each version of the MMR as updates are needed. Individual steps can be defined in detail so operators will know exactly what actions to take, what controls are necessary at each step and what range of action is acceptable. This cloud application runs through any internet browse. It allows authors and quality assurance to work together on-line from different locations to generate and to approve each MMR. The software meets GMP and 21 CFR Part 11 compliance requirements and quality checks are built into the software so it's easy to do cGMP manufacturing.