Improving Documentation of GMP Procedures

Recent FDA inspections of dietary supplement manufacturers have resulted in 1 in 4 producers receiving a Warning Letter that could shut down their business. We have analyzed these inspection notices and published this series of articles in the hope that we can give you some tools for improving your own state of compliance.

One of the most common failures cited by FDA inspectors in Warning Letters is lack of adequate documentation. As an example, a dietary supplement manufacturer in Ohio was issued a warning letter that described in detail how they failed to make and keep written procedures for Specifications, Quality Control operations, Master Manufacturing Records, and for returned goods and equipment. The FDA wanted to see written documentation that specifications were set and testing was completed prior to a component or ingredient being used in manufacturing. They expected documentation to show that quality control personnel performed review and disposition of product batch records at the time of performance. They also wanted to see written master manufacturing records (MMRs) for each unique formulation of a dietary supplement. When the firm failed to follow through on their promise to create written procedures the FDA issued a warning that failure to provide adequate documentation may result in seizures and injunctions.

Why good documentation is important:

There are many GMP requirements for producing and distributing good quality dietary supplement products. It would be hard to stay in compliance if there were no written procedures describing how to assure that each of the requirements are met. The production and quality staff can be easily trained and can stay in compliance if there are written procedures for them to read when they first learn a procedure and that they can refer back to when they need a refresher. Without written procedures, the staff may not remember the correct way to do things or they may slowly drift from protocol over time. Written procedures enforce uniformity and quality which is what consumers deserve and the FDA mandates. Records are an indispensable component of CGMP. The records required by the FDA provide the foundation for the planning, control, and improvement processes that constitute a quality control system. Implementation of these processes in a manufacturing operation serves as the backbone of cGMP.

How to improve compliance:

The first rule of GMP compliance is “Document what you do, and do what you document.” The FDA guidance document on GMP regulations has very thorough instructions on what is required for compliance. You can interpret their guidance and write up your own processes for how you will comply with each of the major functions of

GMP manufacturing. Once you have the documented your processes as Standard Operating Procedures, the SOPs must be followed each time a task is performed.

FDA hot buttons:

All of the FDA's requirements are listed in their GMP for Dietary Supplements, however, there are some issues that are more commonly cited. You can avoid these citations if you:

- Establish written procedures for manufacturing operations
- Make and keep records of the written procedures for cleaning the physical plant and equipment
- Make sure quality control personnel approve or reject all processes, written procedures, controls, tests and examinations, and deviations
- Have a control process for issuing and using the product labels.
- Set up procedures for sampling and provide a cross-references to procedures for corresponding tests or examinations.
- Document corrective action plans for use when a specification is not met.
- Demonstrate that quality control personnel reviewed the results of tests or examinations of any work-in-process or finished product at the time of performance
- Keep written records as required for one year past the shelf life date, if the shelf-life dating is used, or two years beyond the date of distribution of the last batch of the dietary supplements associated with the records

To make it easy for you to get into or to stay in compliance, InstantGMP has a complete set of manufacturing Standard Operating Procedures (SOPs) and Policies available for GMP manufacturing. You can choose individual SOPs to supplement your legacy system or you can use the entire set as a foundation for a complete quality system.