Improving Batch Production Records for cGMP Manufacturing

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A dietary supplement company called Milk Specialties Global got an FDA warning letter after an inspection of its plant in Wautoma, Wis. According to the FDA, the company kept incomplete records of its batches of supplements and failed to record how it makes decisions when changes are made during the production process. Prismic Light International was cited for failing to produce a batch record each time they produced a batch. NatureMost of New England was cited because their batch production records did not include complete information such as:

- The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs.
- Documentation that the finished dietary supplement meets specifications.
- Documentation, at the time of performance, of packaging and labeling operations.
- Documentation at the time of performance of any required material review and disposition position.

Why Batch Records are Important:
Dietary product manufactures and packagers have to maintain production records to be certain that they are documenting when product was produced, what lots of raw materials and dietary ingredients were used, that the product was made in compliance with the master manufacturing formula and that any deviations were investigated and resolved. Following these requirements will allow the manufacturer to produce uniform batches that meet established quality requirements and specifications. Should a problem occur or a customer complaint received after the batch is shipped, there will be adequate records that can be reviewed. When a good, compliant batch record system keeps track of the raw materials and ingredients that go into a batch, it will be easy to find a root cause and prevent the problem from recurring.

How to improve compliance:
According to GMP requirements, your BPR must include the following information:

- Identity of the equipment and processing lines used in producing the batch
- The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs
- The identity and weight or measure of each component used
- A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing
- Documentation that the finished dietary supplement meets specifications
- Documentation, at the time of performance including the initials of the person responsible for weighing or measuring each component used in the batch, the initials of

the person responsible for verifying the weight or measure of each component used in the batch, the initials of the person responsible for adding the component to the batch, and the initials of the person responsible for verifying the addition of components to the batch

- Documentation of packaging and labeling operations including the unique identifier that you assigned to packaging and labels used, the quantity of the packaging and labels used
- Documentation that quality control personnel reviewed the BPR; approved or rejected any reprocessing or repackaging; approved and released, or rejected, the batch for distribution
- Documentation of any required material review and disposition decision
- The physical location of the product label

If capsules or tablets are being produced, BPRs should include the actual results which were obtained during the monitoring of the operation (i.e., encapsulating, tableting) associated with their in-process inspection. Capsules should be collected in to determine if any were dented or broken or tablets were defective in any way. Manufacturing processes for tablets should include the use of filters or strainers, traps, magnets, electronic metal detectors, or any other comparable means to protect against the possibility that metal or other foreign materials from equipment might get into the product.

InstantGMP-Lite™ is an electronic batch record software system that makes it easy to keep track of each batch and each material used in the batch. Its batch records can document the use of each raw material and dietary ingredient as they go into the batch in real time. The software runs over the internet and the data is stored in the cloud so it is easy for collaborators to work together from different locations to view materials and ingredients that were used in each batch or to review the operating steps that were used to make each batch. InstantGMP-Lite™ makes cGMP manufacturing easy.