

FDA GMP's for the dietary supplement industry

In March 2003, the U.S. Food and Drug Administration (FDA) published a proposed regulation that would establish "current good manufacturing practices" (cGMPs) for dietary ingredients and dietary supplements.

Similar regulations already exist for foods (food cGMPs) and drugs (pharmaceutical cGMPs). The dietary supplement industry has been required to only meet food cGMPs that address food safety concerns such as equipment cleaning, worker hygiene, and plant sanitation. Pharmaceutical cGMPs incorporate food cGMPs *and* require proof of product identity, strength, quality, and purity—data achieved through testing, controlled manufacturing, and detailed documentation.

Many consumers of Shaklee dietary supplements and food products are familiar with the more stringent of these regulations, pharmaceutical cGMPs, because many aspects of these manufacturing practices have been part of Shaklee for years. Both raw materials and finished products are tested to ensure their purity, freshness, and safety. Raw materials are assayed for potency and stability to assure that the finished product contains 100% of the bioactive nutrients stated on the label throughout its shelf life. Extensive documentation is maintained to satisfy regulatory requirements, such as in the case that a product has to be recalled. Our documentation meets the highest standards, ensuring that our products contain exactly what the label claims (not misbranded) and do not contain potentially harmful substances (not adulterated).

The manufacturing plant in Norman, Oklahoma, where Shaklee manufactures dietary supplements, is already operating at or above the proposed dietary supplement/ingredient cGMP level. Part of this control is in the form of documented Standard Operating Procedures (SOPs) that address the main components of the proposed cGMPs:

Personnel

- Training
- Personal hygiene

Physical Plant

- Construction
- Sanitation & ease of cleaning
- Cleanliness of production & storage

Equipment & Utensils

- Proper design and selection
- Process controls (temperature, calibration)

Production & Process Controls

- QA unit (laboratory assays, inspections, raw materials and finished products testing).
- In-process controls to monitor adherence to specifications and SOP's.
- Maintaining production records to ensure batch-to-batch consistency.

Holding & Distribution

- Warehousing
- Storage conditions to prevent contamination and ensure product stability

Consumer Complaints

- Adverse event monitoring

Records and Record Keeping

- Maintenance of records open to FDA inspection

Consider that the proposed cGMPs do not mandate the use of written SOPs, yet it is doubtful that any company could consistently achieve our high level of product quality without them. Also, Shaklee's dietary ingredient vendor qualification program far exceeds what is proposed, and only the very best suppliers are able to meet our high standards.

Shaklee Corporation has set the benchmark for many years in compliance with these common-sense requirements—long before the FDA felt it necessary to turn them into law in response to abuses by segments of the dietary supplement industry. Adhering to these requirements takes time, commitment, and money. The new requirements spell out what it takes to make high-quality, high-value dietary supplements. Shaklee not only has a head start on this process, but continues to improve its practices to bring our consumers safe, efficacious dietary supplements that, in our view, are the best of their kind on the market today.
