



Dietary Supplement Good Manufacturing Practices: Preparing for Compliance

William J. Mead

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Dietary Supplement GMP is a one-stop "how-to" road map to the final dietary supplement GMP regulations recently issued by the FDA covering the manufacture, packaging, and holding of dietary supplement products.

The recent regulations, outlining broad goals, intentionally avoid specifics to allow for future technological advances—leaving implementation to the discretion of each firm. Given this latitude and flexibility, this new resource is an essential source of workable and practical suggestions on ways the industry can best meet the goals. Based on broad experience with GMP compliance techniques worked out over the years in the food, drug, and medical device industries, it is a must-have guide for all DS companies, especially the many smaller firms for whom this is new territory.

Dietary Supplement GMP provides:

- a practical guide in easy to understand language to help navigate through the requirements for systems covering process and quality control
- suggestions and practical recommendations on "how-to" achieve full compliance
- explanation of the FDA's role regarding inspection, enforcement, recall/seizure of products and prosecution

Dietary Supplement Good Manufacturing Practices (GMP) covers:

- Personnel
- Plants and Grounds
- Equipment and Utensils
- Sanitation of Buildings and Equipment
- Quality Assurance and Laboratory Operations
- The Quality Control Unit

- Production and Process Controls

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