



MEETING THE "FINAL RULE" for DIETARY SUPPLEMENT MANUFACTURING

**Dietary Supplement Manufacturing is at the threshold of a new day.
FDA's issued final rule, 21 CFR Parts 111 and 112 went into effect on June 25, 2007.**

This set of rules establishes the minimum cGMPs necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. The Final Rule is designed to promote and protect public health.

Compliance with cGMPs is critical for companies to take advantage of opportunities in the global marketplace. Several dietary supplement manufacturers are already in compliance — *and using it to differentiate themselves in a marketplace*. Other manufacturers have a need to develop a strategic business plan to meet the aggressive timetable required by the new CFRs.

Strategic Thinking, Advances in Quality Systems, Capital Facility Investments, Engineering Upgrades, and Process Optimization are Key.

IPS' strategic business planning is the starting point in assessing each client's individual needs, potential shortfalls in areas of compliance and path:

- Overall Compliance
- Business, Quality, Manufacturing, Warehousing and Distribution Processes
- Cost effective and simplistic approaches to design requirements, including energy efficient scenarios and master planning.

Knowledge and Support

Meeting the challenge successfully requires a strategic plan that achieves compliance and provides an acceptable level of risk management within time and capital constraints. IPS has worked with numerous dietary supplement manufacturers to help prepare for and elevate manufacturing compliance standards. In addition, we have created a series of services designed to determine how client facilities and manufacturing operations compare against 21 CFR Parts 111 and 112.

IPS VALUE

- **IDENTIFY**
Gap and Risk Areas
- **PROMOTE**
Compliance and Cost Awareness
- **DEVELOP**
Procedural Solutions
- **MANAGE**
Document and Materials Control Systems
- **RECOMMEND/IMPLEMENT**
Corrective Actions
- **COMPLETE**
Projects on Time and within Budget

DIETARY SUPPLEMENT SERVICES

- Gap Analysis / Risk Assessment
- Facility / Environmental Impact Audit
- Product Development
- Compliance / Documentation Review
- Manufacturing Capacity Modeling
- Quality Control Laboratory Optimization
- Materials Management Consultation
- Validation Master Planning
- SOP Preparation
- Computer / Cleaning Validation
- Critical Systems Assessment