cGMP Certification—What does it mean?

cGMP stands for Current Good Manufacturing Practice. cGMP's are established and enforced by the FDA. Since FDA inspections do not take place regularly, PLS utilized a third-party certification body (ASI) to audit our facility to confirm we are adhering to the cGMP's outlined in 21 CFR Part 111.

As a certified cGMP company, we have proven that we understand and comply with the FDA's extensive rules and regulations. We certify that we are distributing unadulterated and accurately labeled dietary supplements.

By passing this rigorous audit, we have demonstrated that:

1. Our facility is of the proper design to store, package and label dietary supplements.

2. We have proper monitoring and verification procedures in place for all processes.

3. Our Quality Management System is thorough and covers all facets of qualifying, receiving, storing, packaging, testing and shipping dietary supplements.

4. The products we are distributing are safe and reputable.

We have detailed SOPs and correlating records for our:

- ***Quality Systems***
  - Vendor Qualification
  - Employee Training/Personnel Hygiene
  - Internal Audits
  - Bulk, In-Process and Finished Product Inspections
  - Complaint Management
  - Corrective and Preventative Action Programs
  - Label audits
- ***Pest Control***
  - Licensed Pest Control Operator treats our facility and manages pest control program
  - Internal weekly bait station inspections
- ***Operational Methods***
  - Incoming and Outgoing Trailer Inspections
  - Chemical Control Program
  - Product Hold and Release Policy
  - Calibration Programs

- ***Production Processes***
  - We have established specifications for each point in the process.
  - Master Packaging Records: Instructions for each order
    - Customer information
    - Order information (count size, units ordered)
    - Bulk product information (weight, color, part number)
    - All custom packaging information
    - Copy of approved label
    - Equipment settings
    - Sample Collection procedures
    - Monitoring Procedures
  - *Batch Records: Results from each run*

- Lot number information for every component used
- Copy of label—QC reviews and signs off on label, lot number and best by date
- Results from monitoring procedures and sample collection
- Production totals & label reconciliation
- Quality Review

- ***Equipment and Facility Maintenance***
  - Preventative Maintenance
  - Temporary Repairs Policy
  - Contractor Guidelines
- ***Cleaning Programs***
  - Individual Equipment SOPs and cleaning logs
  - Third-Party Sanitation used for entire facility
- ***Packaging***
  - Packaging Vendor Qualification
- ***Allergens***
  - Color coded tags and utensils used to identify and segregate allergens
  - Designated allergen storage area
  - ATP testing completed after running allergens
- ***QA Labs***
  - We use ISO/IEC 17025:2005 Certified; A2LA Accredited third-party labs
- ***Food Defense***
  - We comply with the Public Health Security and Bioterrorism Preparedness and Response act of 2002
- ***Traceability and Recalls***
  - Recall Program and traceability procedures tested on a quarterly basis
  - We performed a mock recall during our cGMP audit and quickly traced 100% of the product forward and backward.