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QUALITY CONTROL AND DSHEA

Dietary **S**upplement **H**ealth and **E**ducation **A**ct of 1994

How Your Vitamin / Natural Product Company Will Benefit from a Quality Control System With a QC Manager As Part of Your Operating Procedures System

Index

Presenter: Ralph Fucetola JD -- during 36 years of practicing law, known as The Vitamin Lawyer

Ten Page Appendix: QCM Job Description & QC SOP

DSHEA is the 1994 Law that allows truthful "normal structure and function" claims about dietary supplements; the Quality Control GMP regulations arise from that Law.

All Slide Information is in the eBook

Organizing for Regulatory Compliance

- FDA tells natural product / vitamin companies:

  "If you own the product label,
  You are the responsible party."

  You must be "in a state of control"
  of the whole process:

  Sourcing Ingredients
  Manufacturing, Labeling, Bottling
  Shipping
  Customer Service

- However, you can contract-out each of these... If...

Standard Operating Procedures Operating Procedures System

Quality Control is Achieved Through Being "In a State of Control" Through the Operating Procedures System (OPS).

The Quality Control Manager (QCM) has an important role in implementing the control systems.

[1] The Standard Operating Procedures (SOPs) document details the operating procedures of the Company, in conformity with FDA and FTC regulations of dietary supplement and similar businesses.

[2] The OPS is the private online repository for the updated official copy of the SOP document, available to the managers of the Company.

[3] The OPS consists of a Google Documents file folder and subfolders with the following items:

The OPS Use Memorandum
The SOP indexed manual consisting, currently, of 24 specific SOPs
The SOP Appendix with standard forms
The Company Branding Profile
The CCDS (Company Core Data Sheet) for each current product.

Quality Control Goals

- Qualifying the Contract Manufacturer as capable of meeting quality, strength, purity and identity standards
- Approving (or rejecting) products manufactured, processed, packed or held under contract by another company
- Approving (or rejecting) procedures and specifications impacting identity, strength, quality and purity
- Approving (or rejecting) packaging, labeling and product containers
- Reviewing and investigating consumer complaints.

Quality Control Manager: QCM

- The QC Manager is primarily responsible for QC.
- The QCM shall review and evaluate with the company managers at least annually

  Complaints,
  Recalls,
  Returns,
  Salvaged products and
  Internal quality investigations

Standards #1

The standards that apply to Quality Control are:

- (1) to assure all claims are

  "truthful and not misleading"

  and

- (2) to prevent :
  adulterated or
  misbranded
  dietary supplement products.

Standards #2

The standards to which the Company's contract manufacturer(s) should adhere must ensure that dietary supplements are manufactured consistently as to:

Identity
Purity
Quality
Strength and
Composition.

Standards #3

- The standards to which claims marketing should adhere must ensure that all claims are:

  1. properly substantiated

  2. correctly recorded in the Structure and Function Claims Notice required to be sent to the FDA within 30 days after first marketing a new claim, and

  3. "truthful and not misleading"

Standards #4

The QCM coordinates these issues with the manufacturer and with company management through

1. enforcing the Quality Control SOP

2. overseeing the implementation of the Contract Manufacturing Agreement as it relates to QC and

3. communicating breaches and potential breaches to the Manufacturer and management.

Standards #5

- QCM Enforces Standards to prevent:

  Superpotent
  Subpotent
  Wrong ingredient
  Drug contaminant
  Other contaminant
  (e.g., bacteria, pesticide, glass, lead)
  Color variation
  Tablet size variation
  Under-filled containers
  Foreign material in a dietary supplement container
  Improper packaging, and mislabeling.

For greater details see the QC SOP in the Appendix

Further QCM Duties

- The QCM shall

  See to the QC requirements of Sec 111.127 (packaging and labeling)

  Oversee all required cGMP records and

  Claims Notice filings.

The QCM needs to keep up with regulatory changes. The Vitamin Consultancy Webinar system can help.

QCM Coordinates

- The Quality Control Manager shall coordinate all QC issues.

  QC Policy shall be coordinated with –

  (A) Refund, Delivery & Returns Policies,
  (B) Standard Disclaimers,
  (C) Standard Testimonial Waiver,
  (D) Email Privacy Policy,
  (E) Document Retention Policy
  (F) Order Record Keeping
  (G) Adverse Event Reporting
  (H) QC Policy.

Conclusion

Thank you for participating in this P.E.L. webinar. The Appendix includes further detailed job description of the QCM (3 pages) and the QC SOP (9 pages) which covers:

Introduction
Purpose and Standards
Manufacturing Standards
Review and Distribution Standards
Claims
Substantiation
Notices
Complaints
AERs and Product Recalls
Maintenance and Contamination Control
QC Policy Coordination

Ralph Fucetola JD

Practical, **E**thical and **L**egal Webinars

APPENDIX - 1
QCM Job Description - 1

My thanks to www.AlwaysQuality.biz for this job description.

GENERAL DUTIES

Assume responsibility for the Quality Control management of all food and supplement products .

Direct the holding and releasing of incoming products in the warehouse and manage 3rd party testing to ensure conformation with specifications prior to release.

Manage internal and external audits and questionnaires.

QCM Job Description - 2

- Manage and document the holding and release of incoming food and supplement products to the warehouse.
- Direct incoming product testing to ensure finished product specifications are met.
- Establish a stability testing program and work with Product Development for planning, testing, and record all necessary testing information and substantiation documents.
- Compose, author, edit and modify Master Validation Plan.
- Educate and train employees as to their impact on the quality management system, and oversee CGMP Quality training initiatives.
- Compile, organize, and maintain records for quality related documentation on all products either digitally or on-site hard copies.

QCM Job Description - 3

- Serve as the primary quality resource for problem identification, resolution and continuous improvement.
- Perform root-cause analysis and other problem solving activities to identify corrective actions and process improvements.
- Author, actualize, and maintain records for CAPA process.
- Report quality issues, trends and losses to management.
- Implement and manage an annual-internal self-auditing program.
- Direct self-audit questionnaires to current and potential contract manufacturers and maintain records.
- Interface with contract manufacturers concerning problems with quality and assure that effective corrective action is implemented regarding deviations and non-conforming material reports (NCMR).
- Provide input and direction for strategic Quality initiative as company.
- Inspect and document the disposition of returned food and supplement products.
- Compile and report quarterly total Quality expenditures and expected future budget to upper management or accounting.

Appendix – 2 – QC SOP

Operations Manual SOP #7
Quality Control Procedures
Claims Controls

Index:

- Introduction
- Purpose and Standards
- Manufacturing Standards
- Review and Distribution Standards; Claims; Substantiation; Notices
- Complaints, AERs and Product Recalls
- Maintenance and Contamination Control
- Policy Coordination

QC SOP

1. Goals and Annual Review

[a] Quality Control – QC – is a major responsibility of the Company to its customers.

The CEO shall appoint a Quality Control Manager (QCM) (or shall hold that position if none other is appointed).

See also: Change Controls / New SOPs – p 18.

The Company has adopted this QC Procedure Statement to establish Current Good Manufacturing - Marketing Practices (cGMPs) as they apply to the Company's products, under 21 USC 342(g), and subject to the final regulations issued by the FDA June 22, 2007 - http://www.cfsan.fda.gov/~dms/dscgmps6.html - http://edocket.access.gpo.gov/2007/07-3039.htm .

The QCM is primarily responsible for QC.

[b] The QC Manager shall review and evaluate with the company managers at least annually:

Complaints,
Recalls,
Returns,
Salvaged products and
Internal investigations

QC SOP

[c] QC Goals include:

- Qualifying the Contract Manufacturer as capable of meeting quality, strength, purity and identity standards

Approving (or rejecting) products manufactured, processed, packed or held under contract by another company

- Approving (or rejecting) procedures and specifications impacting identity, strength, quality and purity
- Approving (or rejecting) packaging, labeling and product containers
- Reviewing and investigating consumer complaints.

2. Purpose and Standards

The primary purposes of this policy are (1) to prevent claims that are not "truthful and not misleading" and (2) to prevent adulterated or misbranded dietary supplement products. The standards to which the Company's contract manufacturer(s) should adhere must ensure that dietary supplements are manufactured consistently as to identity, purity, quality, strength, and composition. The standards to which claims marketing should adhere must ensure that all claims are properly substantiated and are "truthful and not misleading"

The QCM coordinates these issues with the manufacturer and with company management through (1) enforcing the QC SOP, (2) overseeing the implementation of the Contract Manufacturing Agreement as it relates to QC and (3). communicating breaches and potential breaches to the Manufacturer and management.

QC SOP

3. Manufacturing Standards

Subject to the SOP on Contract Manufacturing Agreements: (A) The minimum standards that apply to the manufacturers include requirements that the design and construction of physical plants facilitate maintenance, cleaning, and proper manufacturing operations, for quality control procedures, for testing final product or incoming and in-process materials, for handling manufacturer aspects of consumer complaints, and for maintaining records.

(B) Problems the Company expects that correct manufacturer cGMPs will help prevent are: superpotent, subpotent, wrong ingredient, drug contaminant, other contaminant (e.g., bacteria, pesticide, glass, lead), color variation, tablet size or size variation, under-filled containers, foreign material in a dietary supplement container, improper packaging, and mislabeling.

(C) This policy requires the use of industry-wide standards in the manufacturing, packing, and holding of dietary supplements, thus reducing risks associated with dietary supplements that are contaminated with harmful or undesirable substances such as pesticides, heavy metals, or other impurities or are not properly labeled to accurately describe what they contain. The QCM shall inspect received runs of product to assure QC compliance.

(D) Manufacturers are required to follow the cGMPs and to maintain three types of records:
(1) batch records, with unique batch Lot Numbers on each label, to limit the scope of any potential recalls,
(2) Calibration Records [but not process and equipment validation] and
(3) standard hygienic requirements for facilities and employees, all modeled after current good manufacturing practice regulations for food, as provided by Law.

Records also need to be kept in accordance with -

Subpart C: Sec. 111.6 (written cleaning and pest control procedures),
Sec. 111.20 (physical plant design) and Sec. 111.15(e)(2) (water used in processing);
Subpart D: Sec. 115.25 (instruments, equipment, utensils and preparation surfaces);
Subpart E: 111.75(c)(3) (compliance with product specifications) and
Sec. 111.95 (records regarding the Company "qualifying" its suppliers and manufacturers).

QC SOP

4. Review & Distribution Standards; Claims Standards; Substantiation Note Book

(a) With regard to the distribution of the products, the policy is intended to ensure that the identity, purity, quality, strength, and composition of dietary supplements are accurately reflected on the product label, to assure consumers they are purchasing the type and amount of ingredients declared. All product labels and product information copy shall be reviewed for scientific accuracy and legal requirements before release to the public.

(b) As required by FDA regulation, for the Company's own labeled products, the active ingredients should normally be independently tested at least once to assure the "identity, purity, quality, strength, and composition" of the product, and thereafter at reasonable intervals.

(c) All claims shall be stated as Support of Normal Structure and Function Claims. All claims shall be substantiated by reliable and competent scientific evidence. All required Notices of Structure and Function Claims shall be filed with the FDA within 30 days of making any claim. Any new Structure and Function Claims Notice shall be filed in the Substantiation Note Book.

(c-1) Staff having contact with any person giving a Testimonial (or as a Model or Experimental Subject) should be aware that Testimonials or other communications are not substantiation for claims, but are claims in and of themselves. Since Nov. 2009 it has not been lawful to rely upon the old "safe-harbor" of using the "results not typical." Instead, all Testimonials must be "typical" of the results the average user may expect while following directions. What is "typical" can, in the view of the Federal Trade Commission only be determined by proper, third party clinical studies (or, in the case of subjective results, post market surveys of users). The Standard Testimonial or other Waiver, from this Manual, must be signed for each Testimonial, Model or Experimental Protocol Subject.

QC SOP

This is the standard Testimonial Disclaimer: "Testimonials represent a cross section of the range of results that appear to be typical with these products. Results may vary depending upon use and commitment."

(d) Before using a label, the responsible person at the Company shall (in accordance with Subpart D, Sect. 111.75: (f)(2): "at a minimum, conduct a visual examination of the label and review the supplier's invoice, guarantee, or certification to determine whether label specifications are met" -- (g): "You must, at a minimum, conduct a visual examination of the packaging and labeling of the finished packaged and labeled dietary supplements to determine whether you used the specified packaging and applied the specified label" -- and (h)(1) "You must ensure that the tests and examinations that you use to determine whether the specifications are met are appropriate, scientifically valid methods."

(e) Subpart D 111.80: The Company shall contract with the Manufacturer to maintain "(e) Representative samples of each lot of packaged and labeled dietary supplements to determine whether the packaging and labeling of the finished packaged and labeled dietary supplements meet specifications established in accordance with Sec. 111.70(g), and as applicable, Sec. 111.70(a)."

(f) The company shall develop over time and maintain a Product Substantiation Notebook (PSN) or files, as part of these SOPs that shall include, for each product:

(1) A copy of the product label and the CCDS
(Company Core Data Sheet) with Spec Sheet.
(2) Copy of the Notice(s) of Structure and Function Claims
(1) Abstract pages of relevant scientific journal articles
(2) Clinical study reports, if any, about the ingredients and combinations of them
(3) Ethnographic reports on traditional uses
(4) Expert opinion articles or letters, if any

(g) The QCM shall see to the QC requirements of Sec 111.127 (packaging and labeling), oversee all required cGMP records and any Claims Notice filings.

QC SOP

5. Complaints, Adverse Reactions & Product Recalls - See SOP #11 for "Serious Adverse Event" standards and Medwatch reporting form.

(A) With regard to (1) consumer complaints and (2) serious adverse reaction reports that come to the attention of the Company, the following policy shall apply: the Company shall establish and maintain a dated record of each such complaint or Report received by the Company and shall report any serious adverse events to the FDA as required by the Dietary Supplement and Non-Prescription Drug Consumer Protection Act -- http://www.fda.gov/cder/regulatory/public_law_109462.pdf The Report shall include:

a. Date and time of receipt of initial report and subsequent information.

b. Name of person (i) providing the information (unless anonymous) and (ii) name of person recording the information.

c. Type of Report: (i) Complaint; (ii) Adverse Reaction (all reported adverse reactions shall be recorded, including reactions that would not be considered "serious" and therefore might not be required to be reported to the FDA; any final determination as to the "serious" character of a reaction shall be made in conformity with FDA regulations and professional advise).

d. Narrative of the complaint or reaction (including whether any reaction may potentially be associated with, (i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (v) a congenital anomaly or birth defect).

e. List of any documents included with the Report.

(B) The persons in the Company responsible for the maintenance of the Reports shall present written summary information about same to the chief officers of the company on a regular basis.

(C) In the event of a Product Recall, Management shall assure immediate and complete compliance with the requirements of such recall. See SOP #16 for added details.

QC SOP

6. Maintenance and Contamination QC Requirements

The Company requires that its suppliers, manufacturers and warehouses adhere to appropriate Maintenance Standards.

Contamination control must be adequate during every production shift in these six areas:

1. Personnel — Personnel to follow all written production and process controls, from sampling to aseptic technique.
2. Environmental Systems — Requires: cleaning-in-place or when necessary, sterilization-in-place.
3. Maintenance — Program to catch potential contamination spots before they happen?
4. Facility and Equipment Design — Thorough engineering consideration must be given to facility design as that impacts environmental control.
5. Monitoring — Requires: routine monitoring processes and validation techniques.
6. Cleanup — Requires: standards to assure elimination of all contamination that may affect the identity, purity, quality, strength, and composition of the products.

7. Policy Coordination

The Quality Control Manager shall coordinate all QC issues. QC Policy shall be coordinated with (A) Refund, Delivery & Returns Policies, (B) Standard Disclaimers, (C) Standard Testimonial Waiver, (D) Email Privacy Policy, (E) Document Retention Policy and Order Record Keeping / AER Reporting Policy.

Thank You!

Further Information:

www.VitaminConsultancy.com