FDA Regulations for Dietary Supplements Manufacturers (21 CFR Part 111, GMP and QMS)

Date : Apr 19, 2018 - 08:30 AM - Apr 20, 04:30 PM

Event URL : http://www.nyeventslist.com/events/fda-regulations-for-dietary-supplements-manufacturers-21-cfr-part-111-gmp-and

Organizer : MetricStream, Inc.

Venue : To Be Announced

Location : 1, Main St
San Francisco, CA, USA, ZIP: 00000

FDA Regulations for Dietary Supplements Manufacturers (21 CFR Part 111, GMP and QMS)

This course will show the FDA's requirements for dietary supplement manufacturing and teach how to implement the concepts in a plant and manage the compliance requirements using the quality management system approach.

This course will present the following.

1. GMP requirements for dietary supplement manufacturers.
2. The FDA's interpretation of 21 CFR Part 111 GMP requirements.
3. How to develop a Quality Management System for implementing the GMP requirements.
4. How to implement a Quality Management System for compliance to the FDA GMP requirements.
5. How to manage the Quality Management System.
6. The roles and skill sets required for plant personnel to successfully develop, implement and manage a Quality Management System.
7. Personnel interactions required to develop, implement and manage a Quality Management System.

Seminar Fee Includes:

Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
$100 Gift Cert for next seminar
DOWNLOAD BROCHURE

Learning Objectives:

The learning objectives and the areas covered for this seminar are as follows:

1. GMP requirements for dietary supplement manufacturers.
2. Know where to find the GMP requirements
3. Understand the GMP requirements
4. The FDA's interpretation of 21 CFR Part 111 GMP requirements.
5. Understand the purpose of the preamble
6. Learn how to use the preamble
7. Quality Management Systems
8. How to develop a Quality Management System for implementing the GMP requirements.
9. Understand what a Quality Management System is
10. Understand what should be in a Quality Management System
11. How to develop a Quality Management System
12. Learn to implement a Quality Management System for compliance to FDA GMP requirements.
13. Learn to manage the Quality Management System.
14. Learn about the roles and skill sets required for plant personnel to successfully develop, implement and manage a Quality Management System.
15. Learn about the Personnel interactions required to develop, implement and manage a Quality Management System.

Who will Benefit:

Personnel with responsibilities for quality will be benefit from this seminar. The following job descriptions should attend.

1. Quality Managers
2. Production Managers and Plant Managers
3. Quality Technicians
4. Plant Engineers
5. Purchasing Managers
6. R&D scientists

Topic Background:

The FDA gives guidance to dietary supplements manufacturers through 21 CFR Part 111. A thorough understanding of the regulations and their interpretation by the FDA is necessary to apply the requirements in a plant. The application of the regulations requires developing processes and procedures.

The FDA's 21 CFR Part 111 is a list of specific Good Manufacturing Practice (GMP) requirements for how dietary supplements should be manufactured, packaged, labeled and held. The FDA publishes the preamble to 21 CFR Part 111 as a companion to the GMP requirements. The preamble is the FDA's interpretations of its GMP requirements. It is the FDA's responses to questions submitted about the requirements.

The GMP requirements can be applied in a using a Quality Management System (QMS) approach. A QMS is a list of procedures and policies that translates the GMP requirements to a set of executable processes. Understanding the FDA's interpretation of the GMP's is important in helping plants develop their processes and procedures. Processes and procedures and how they are executed by plant personnel are important in determining whether compliance to the FDA's GMP requirements will be achieved. Processes and procedures need to be simple and direct. The roles and responsibilities of plant personnel and their interactions with the QMS are also important and need to be clearly defined.

AGENDA

DAY 01(8:30 AM - 4:30 PM)

- 08.30 AM - 09.00 AM: Registration and Meet & Greet.
- 09.00 AM - 09.30 AM: Seminar objectives review, expectations and scope
- 09.30 AM - 10.30 AM: Review GMP Requirements and FDA Interpretations (Subpart A-C)
    - General Provisions - Who is regulated under these regulatory requirements.
    - Personnel requirements - Preventing microbial contamination from personnel, supervisory requirements, records and written procedures requirements.
    - Physical Plant and Grounds - Sanitation and design and construction requirements.
- 10.30 AM - 10.45 AM: Break
- 10.45 AM - 12.00 PM: Review of GMP Requirements and FDA Interpretations (Subpart D-F)
    - Equipment and Utensils – Requirements for equipment and utensils
    - Production & Process Controls – Quality control operations specifications, process sampling, reserve samples, process deviations.
    - Quality Control Requirements – Laboratory operations, material review and disposition, packaging and label material operations, manufacturing and batch records, returns and product complaints.

- 12.00 PM - 01.00 PM: Lunch
- 01.00 PM - 02.30 PM: Continue Review GMP Requirements and FDA Interpretations (Subpart G-I)
    - Requirements for Components, Packaging and Labels – Those received for use in the production of dietary supplements and finished dietary supplements received for packaging and labeling, rejected packaging, labels and components.
    - Requirements for Master Manufacturing Records
    - Requirements for Batch Production Records
- 02.30 PM - 02.45 PM: Break
- 02.45 PM - 04.30 PM: Continue Review GMP Requirements and FDA Interpretations (Subpart J-L)
    - Requirements for Laboratory Operations – Methods for testing and examinations
    - Requirements for Manufacturing Operations – Sanitation, contamination prevention, rejected dietary supplements.
    - Requirements for Packaging and Labeling Operations

DAY 02(8:30 AM - 4:30 PM)

- 08.30 AM - 09.00 AM: Registration and Meet & Greet.
- 09.00 AM - 09.30 AM: Continue Review GMP Requirements and FDA Interpretations (Subpart M-N)
    - Holding and Distribution Requirements – Components, dietary supplements, packaging and labels, in process materials, reserve samples of dietary samples, distributing dietary samples.
    - Returned Dietary Samples – Destruction/disposal of returned product, reprocessing requirements, investigation requirements.
- 09.30 AM - 10.30 AM: Continue Review GMP Requirements and FDA Interpretations (Subpart O-P)
    - Product Complaints – Review and investigation requirements.
    - Records and Recordkeeping Requirements
- 10.30 AM - 10.45 AM: Break
- 10.45 AM - 12.00 PM: Introduction to Quality Management Systems (QMS)
    - What is Quality Management System?
    - What is contained in a Quality Management System
    - Types of Quality Management Systems
- 12.00 PM - 01.00 PM: Lunch
- 01.00 PM - 02.30 PM: Development, Implementation & Management of QMS
    - Specific Clauses in Quality Systems
    - Roles of clauses in Quality Systems
    - How a Quality Systems provide order and compliance to FDA 21 CFR 111
    - Interactions of plant and production personnel with Quality Systems
- 02.30 PM - 02.45 PM: Break
- 02.45 PM - 04.30 PM: Examples and Exercise Developing QMS
    - Working with plant personnel to implement system

- Feedback systems in QMS (Internal Audits)

SPEAKER

Chris Stefanadis
Quality Assurance, Quality Systems, Regulatory Affairs Professional

Chris Stefanadis has over 20 years of Quality Management systems and process improvement experience and is Six Sigma Black Belt certified.

His Quality Management Systems experience includes the development, implementation and management in manufacturing plants and service organizations of ISO 9001, ISO 13485, TS 16949, ISO 14001, GMP, FDA 21 CFR Part 111 and Part 820.

A strong manufacturing background with Nutraceuticals, Medical Devices, Plastic Extrusion & Compression Molding, Acrylic Latex and Chemical Manufacturing has also given him experience with Lean Manufacturing and Process Improvements.

Please contact the event manager Marilyn (marilyn.b.turner(at)nyeventslist.com) below for:
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