EAS Consulting Group

Good Manufacturing Practices for the Cannabis Industry

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Senior Director of Dietary Supplement and Tobacco Services

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Presenter

- **Tara Lin Couch, Ph.D.**, EAS Senior Director of Dietary Supplement and Tobacco Services
  - Ph.D. Analytical / Organic Chemist with exceptional analytical abilities and over 25 years of diverse laboratory and regulatory experience in academic, field, contract, and manufacturing.
  - Expert on Quality Systems in pharmaceutical, dietary supplement, and tobacco facilities.
  - Technical background to establish scientifically sound material and product specifications and ensure development of product formulations that will meet set specifications.
  - Laboratory expertise to develop well-organized, sophisticated laboratories.

The Farm Bill

- Agriculture Improvement Act of 2018 (The Farm Bill) was signed into law on December 20, 2018.
- Game Changing for the US Hemp Industry
  - Removes growing and cultivation of "Industrial Hemp" in all States.
  - Removes all parts of the Hemp Plant, including CBD and other extracts from the Controlled Substances Act.
  - Not more than 0.3% Tetrahydrocannabinol (THC) on a dry weight basis.
  - States can monitor and control the growing and cultivation within their state by submitting a plan to the Secretary of Agriculture.
    - Trade should be interested in plan uniformity
  - DEA completely taken out of the equation

FDA Authority

- (Outgoing) FDA Commissioner, Dr. Scott Gottlieb, immediately issued a statement after the 2018 Farm Bill passed, reiterating the FDA stance on cannabis products and cannabidiol (CBD) in products for human and animal consumption:
  - *"Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act"*.

FDA Categories

- Every product for sale in the U.S. which is either ingested or applied to a human or animal body has a regulatory category in the FDA.
  - Hemp derived CBD products will have to fit into one of those categories or it will NOT be legal.

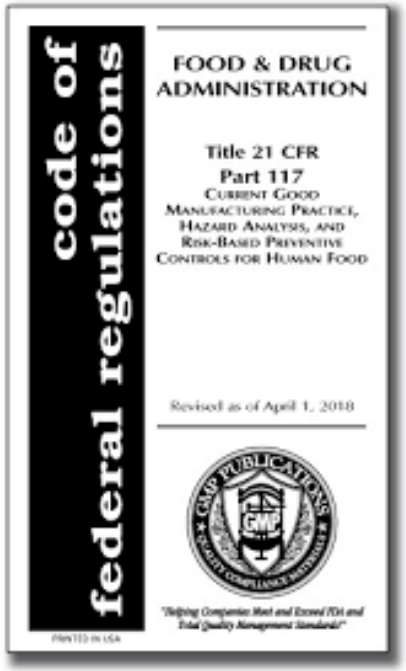
Food Safety Modernization Act of 2011 (FSMA)

- 7 Rules of Food Safety Modernization Act (FSMA)
  - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human and Animal Food (HARPC)
    - 21 CFR 117: for Human Food
    - 21 CFR 507: for Food for Animals.
  - Foreign Supplier Verification Program (FSVP) Rule
  - Intentional Adulteration Rule
  - Product Safety Rule (Fruits and Vegetables)
  - Sanitary Transportation Rule
  - Standard for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
  - Voluntary Accredited Third-Party Certification Program

21 CFR 117

- 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Rick-Based Preventative Controls for Human Food*

- Subparts:
  - A – General Provisions (Applicability, Definitions, and Exemptions)
  - B – Current Good Manufacturing Practices
  - C – Hazard Analysis and Risk-Based Preventative Controls
  - D – Modified Requirements
  - E – Withdrawal of a Qualified Facility Exemption
  - F – Requirements Applying to Records That Must be Established and Maintained
  - G – Supply Chain Program



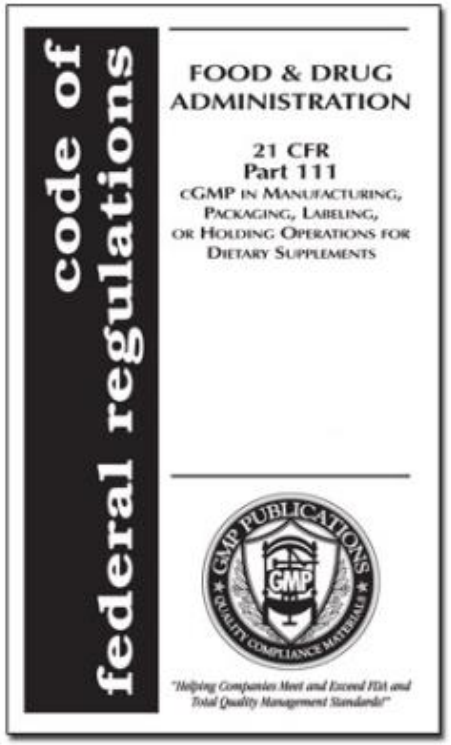
The Dietary Supplement and Health Education Act of 1994 (DSHEA)

- Created a legal class of foods, called “Dietary Supplements”
- Broadened the historical definition of Dietary Supplements
- Provided for structure/function and health claims
- Authorized FDA to promulgate Good Manufacturing Practices (GMPs)
- Carved out other unique regulatory requirements and exemptions.

Dietary Supplement Regulations

- Dietary Supplement Health and Education Act of 1994 (DSHEA)
- Current Good Manufacturing Practices (cGMPs) dictated in 21 CFR 111, *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,*
- Labeling requirements provided in 21 CFR 101, *Food Labeling*,
- Electronic system requirements in 21 CFR 11, *Electronic Records*, *Electronic Signatures*
- Requirements for reporting Serious Adverse Events per the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006
- New dietary ingredient notification (NDIN) requirements provided per 21 CFR 190, *New Dietary Ingredient Notifications.*
- Food Safety Modernization Act of 2011 (FSMA)
  - Dietary supplements are classified as Foods by the FDA

21 CFR 111 Subparts



- A - General Provisions
- B - Personnel
- C - Physical Plant and Grounds
- D - Equipment and Utensils
- E - Specifications and Testing
- F - Quality Unit Responsibilities
- G - Components, Packaging, and Labels
- H - Master Manufacturing Record
- I - Batch Production Record
- J - Laboratory Operations
- K - Manufacturing Operations
- L - Packaging and Labeling Operations
- M - Holding and Distributing
- N - Returned Products
- O - Product Complaints
- P - Records and Recordkeeping

GMPs

- All manufacturing operations, regardless of category, must comply with Good Manufacturing Practices (GMPS).
  - Good Manufacturing Practices (GMPs) - The regulations that are issued and enforced by the Food and Drug Administration (FDA) to control and supervise companies that manufacture, package, hold, and distribute foods, drugs, and cosmetics to the public.
  - GMPs are a system of procedures and documentation for the proper design, monitoring, and control of manufacturing processes and facilities to ensure product has the identity, strength, quality, and purity which it is represented to possess
- Adhering to GMP regulations requires a Quality Management System approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors. This in turn, protects the consumer from purchasing a product that is not effective or even dangerous.

Quality Management System

- A Quality Management System (QMS) - A formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.
  - Sets Company Policies
  - Defines and Improves Processes
  - Facilitates Training
  - Reduces Waste
  - Lowers Costs
  - Engages Personnel

FDA's Perspective

- A robust Quality Management System addresses the FDA's goal of protecting the public health to ensure the manufacturers provide consistent high-quality products to consumers and reduce the number of recalls, returned or re-worked products, and defective products entering the marketplace.

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Thank you

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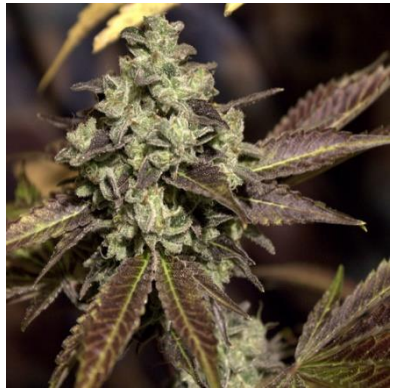
ASTM International and Cannabis

- **Technical Committee D37 on Cannabis**
  - Established in 2017
  - 900+ members from 30 countries
  - 10 subcommittees and 15+ standards for quality and safety
  - Covering: cultivation, quality assurance, laboratory considerations, industrial hemp, devices, packaging, security, and more.

- **Subcommittees D37.02 on Cannabis Quality Management and D37.04 on Cannabis Processing and Handling**
  - CAPA, HACCP, Recall & Withdrawal
  - Sanitation and Waste Disposal
  - cGMP and Environmental and Public Health and Safety best practices



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