Vitature® FAQ: Compliance and Standardization

Vitature® is the cloud-based compliance solution for the dietary supplement industry that digitizes, centralizes, and standardizes data and documentation and automates workflows, approvals, and expirations.

Here, we'll address how Vitature facilitates compliance with federal requirements pertaining to manufacturing dietary supplements and qualifying raw material suppliers.

What This Brief Covers:

- FSMA Compliance
- Part 11 Compliance
- DSHEA Compliance

What Is FSMA?

The FDA Food Safety Modernization Act (FSMA) was signed into law in 2011 by President Obama and aims to ensure the safety of the US food supply chain by proactively preventing contamination, rather than just retroactively responding to it. According to the FDA, FSMA is the most sweeping reform of our food safety laws in over 70 years. FSMA requires raw material suppliers to have documented protocols in place to manage risk and ensure supply chain accountability.

How Does Vitature Facilitate FSMA Compliance?

Vitature tracks important FSMA requirements and stores related documentation for every supplier and raw material in your database. This includes documentation for Hazard Analysis and Risk-Based Preventive Controls (21 CFR 117—Subpart C), Supply-Chain Program (21 CFR 117—Subpart G), Sanitary Transportation of Human and Animal Food (21 CFR 1—Subpart O), and Foreign Supplier Verification Programs for Food Importers (21 CFR 1—Subpart L). In addition, Vitature stores FSMA-related documentation for each supplier, such as a supplier's Food Safety Plan (21 CFR 117—Subpart C) and Food Defense Plan (21 CFR 121—Subpart C).

What Is Part 11?

21 CFR Part 11 (Part 11 for short) refers to the FDA's regulations and procedures put in place to ensure accuracy, reliability, authenticity, availability, and integrity of electronic records and electronic signatures for persons (and companies) using closed systems to create, modify, maintain, archive, retrieve, or transmit electronic records.

To ensure Part 11 compliance, companies that manage records electronically are required to have controls in place to validate the consistency and accuracy of the intended functionality of the system, to safeguard against alterations or falsifications of records or electronic signatures.

What does all this mean? It means companies need to plan for assessing and managing risk when it comes to managing and maintaining electronic records.

How Does Vitature Facilitate Part 11 Compliance?

There are five major components to Part 11 that companies managing records electronically need to account for: Validation, Audit Trails, Copies of Records, Record Retention, and Electronic Signatures.

1. **Validation**: Part 11 requires validation of systems to ensure accuracy, reliability, integrity, availability, and authenticity of required records and signatures.
    a. Vitature runs methodical testing with both human QA staff and automated scripts to ensure the accuracy, reliability, integrity, availability, and authenticity of its features, functionality, and data.
2. **Audit Trails**: Part 11 requires the use of secure, computer-generated, timestamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Further, record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for FDA review and copying.
    a. Vitature logs and saves all actions and activities with user, time, and date stamps. This audit trail is accessible through standard reports and administrator requests.
3. **Copies of Records**: Part 11 requires the ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the FDA. Persons should contact the FDA if there are any questions regarding the ability of the FDA to perform such review and copying of the electronic records.
    a. All Vitature data is available for export both in raw form and as structured, human readable documents. All exports are available through controlled user access based on a permissions system.
4. **Record Retention**: Part 11 requires protection of records to enable their accurate and ready retrieval throughout the records retention period.

a. Vitature follows best practices to securely store all data and satisfies current good manufacturing practice (CGMP) records retention requirements.

5. **Electronic Signatures**: Part 11 requires signed electronic records contain information associated with the signing that clearly indicates all of the following: 1) The printed name of the signer; 2) The date and time when the signature was executed; and 3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.
   a. For all activity assigned, Vitature provides digital signature information, including authenticated user name, printed name of the signer, date and timestamp, reason/meaning (i.e., status change, document approval, etc.).
   b. All signature activity in Vitature is accessible via a digital audit trail on the associated activity/document, as well as through overall digital audit trail reports.
      i. Data and documentation exported from Vitature includes digital stamps of signature activity.
   c. Vitature ties electronic signatures to authenticated user profiles, ensuring the user is both a) authenticated by Vitature upon logging in; and b) authorized at the time of signing through additional password entry and user permissions.
   d. Additionally, Vitature provides test kits to reduce the cost and complexity of the validation process. These test kits can include documentation, test cases, and reports.

What Is DSHEA?

The Dietary Supplement Health and Education Act of 1994 (DSHEA) was passed in response to a push by individual citizens and the dietary supplement industry to regulate dietary supplements and provide consumer education. DSHEA created a new regulatory framework for dietary supplements, in part by distinguishing them from drugs and food additives.

Under DSHEA, dietary supplement manufacturers have the essential responsibility to substantiate the safety of the dietary ingredients used in manufacturing a product. Manufacturers are also responsible for determining that any representations or claims made about their products are substantiated by adequate evidence to show they are not false or misleading. As part of DSHEA, Congress gave the Secretary of Health and Human Services and the FDA the express authority to issue regulations establishing CGMPs for dietary supplements.[1]

How Does Vitature Facilitate DSHEA Compliance?

Vitature ensures that companies can efficiently comply with dietary supplement CGMPs as required by DSHEA. Specifically, Vitature implements standardized processes and tools to assist supplement manufacturers in qualifying suppliers and their raw materials, in part by building upon the Standardized Information on Dietary Ingredients (SIDI™) Work Group's recommendations.

The SIDI Work Group is a coalition of three industry trade associations—the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), and the United Natural Products Alliance (UNPA)—and a number of their member representatives.[2] The SIDI Work Group has published a set of material datasheet templates, for both botanic and non-botanic ingredients, which are included in Vitature and expanded on—making it easy to build and compare raw material specifications and streamline the qualification process. The primary goal is to standardize the process of qualifying and managing suppliers and their raw materials to increase efficiency (for both manufacturers and suppliers) and ensure compliance with federal regulations.

[1]https://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm110863.htm

[2]http://www.sidiworkgroup.com/