**Date:** 01.26.2022

**Topic/Title:** Documentation Management for Craft Beverages

**Products:** Alcoholic Beverages

**Targeted Course Length:** 4 hours. 2.5 hours instruction, 1.5-hour practical application

**Student to Instructor Ratio:** 20:1

**Image** 

**Objectives:**

* Describe documentation management for alcoholic beverage manufacturing
* Understand what documents you may need and why they are important
* Describe what documentation practices are expected from regulators
* Explain how to create traceable documents
* Explain who can access documents, when, and how to access documents
* Describe the importance of document change control

**Outcomes:**

Employees in the beverage industry will gain a clear understanding of documentation expectations of the TTB and FDA. They will practice creating, using, and correcting documents intended for product safety and traceability. Participants should walk away with the knowledge of how these documents and these practices will be useful to them during recalls, audits, and trending analysis.

**Target Industry:**

The course is designed for persons working in alcoholic beverage production, packaging, and contract manufacturing. This may also be useful for those in adjacent businesses such as yeast production, distribution, or suppliers for the industry.

**Primary Audience:**  Production Associates, Supervisors, Quality and Management

**Prerequisites:** Not applicable

**Instructor Baseline SME:** Instruction for this course should be done by an individual with documentation management and beverage safety regulatory knowledge.

**Standards (i.e. reference material):** Regulatory guidance: 21CFR 177 parts A, B, & F. CPG 500.400 and 500.450

**Assessment:** Do’s and don’ts of documentation worksheet

**Outline**

1. Introduction
   1. Examples of documentation mismanagement that lead to recalls
2. Agenda
3. Objectives
4. Get to know one another
5. Exercise and discussion about current documentation system
6. Regulators
   1. FDA
   2. TTB
7. Documentation Regulatory Guidance for food, beverages, and alcoholic products
   1. Importance of FSMA
   2. Documentation Guidance
   3. How documentation expectations differ for the TTB and FDA
   4. How to manage these systems together
   5. The difference between regulatory systems for non-alcoholic vs alcoholic beverages
   6. Audits
   7. Regulatory review
   8. Other food safety-based schemes that may affect your documentation
   9. Exercise & Discussion: How to find resources and guidance from your government agencies, regulatory search of websites and resources
8. Document Creation Concerns
   1. What documents are required, and which are useful?
   2. Structure and format
   3. Traceability
   4. Change control
   5. Access control
   6. Exercise: Practice creating a basic format for your company’s documentation
9. Good Documentation Practices
   1. Dos and Don’ts of filling out documentation
   2. Exercise: Correct mistakes made on the given document
10. Taking Responsibility
    1. Signatures, and what it means to put your name on that paper
    2. Management Buy-in
    3. Supplier, buyer, and distributor document control
    4. Exercise: How would you manage documentation from external parties? What checks would you put in place to ensure you are receiving this documentation.
11. Document Storage and access systems
    1. Data Entry
       1. Commonly used software
       2. Paper based- systems
    2. Structure of filing system
    3. Standards for filing
    4. Protocol for access
    5. Back up
    6. Security
12. Data Analysis
    1. Identifying trends
    2. Continuous improvement
    3. Preventing Recalls
    4. Improving Quality
    5. Exercise: Identify the trend that the given data is pointing to

Change tracking log:

| Version | Preparation Date | Prepared By | Reviewed By | Effective Date | Related Docs Updated? |
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| August 2021 | 08.12.2021 | MMAM | N/A | 08.12.2021 | N |
| Established outline for course. | | | | | |
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