**Date:** 01.27.2022

**Topic/Title:** Writing Effective SOPs for Craft Beverages

**Products:** Alcoholic Beverages

**Targeted Course Length:** 4 hours

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

**Objectives**

* Explain the regulatory and business rationale for SOPs
* Discuss how the FDA expects companies to maintain a state of control
* List factors that influence SOP effectiveness
* Describe the process for writing effective SOPs
* Identify how to keep SOPs current
* Describe the pitfalls of SOPs

**Outcomes**

Employees in the beverage industry will gain a clear understanding of documentation expectations of how to create a standard operating procedure that is clear, concise, and effective. They will gain and understanding of why this is important, how it is related to regulation, and how to manage these documents.

**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 technical writing knowledge and previous experience creating SOPs.

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

**Assessment** 5 Question quiz.

**Outline**

1. Writing Effective SOPs introduction
   1. Schedule
   2. Agenda
   3. Objectives
2. Icebreaker: Tell us about yourself
3. Rationale for SOPs
   1. Regulatory considerations
   2. CGMPs
   3. 21 CFR 1.225: Registration with the FDA
   4. 21 CFR 117 Subpart A: Training
   5. 21 CFR 117.95: Animal Food
   6. 21 CFR 117 Subpart F: Record Keeping
   7. Documentation Recommendations by MBAA
4. Activity: Teach back, read the regulations on documentation, and teach your specific section that was assigned to you, to the rest of the class
5. Hierarchical Document System
   1. Regulations
   2. Quality Manual
   3. SOPs
   4. Work Instructions, records, and forms
6. Creating Documents
   1. Style, format, and content
   2. Parts of a document
   3. Effective SOP Review
7. Group Activity: Review and critique hand washing SOP
8. SOP Examples
   1. Biowatzit
   2. Peanut butter and jelly
   3. Trampoline set up
9. Read, Edit Review
   1. Legal implications of documents
10. Group Activity: Look at the Bionetwork’s Quick Reference Cad. How can we make this better? What would you change and why?
11. Know your Audience
12. Creating Documents: Style, format, and Content for Results
    1. Active and Present Tense
    2. Wiggle Phrases
    3. Detail
    4. ABCs
    5. Charts, tables, and graphics
    6. Avoid Pronouns
13. Activity: Draw as directed and compare your drawing to your other classmates’
14. Path to Effective Sops
    1. Plan
    2. Preliminary Outline
    3. Write
    4. Get Feedback
    5. Revise and Finalize
    6. Implement
    7. Approve
    8. Issue
    9. Train or Retrain
15. Keeping SOPs Current
16. Avoiding Pitfalls
17. Group Activity: In your group, write an SOP on how to make popcorn with the provided blank SOP template