



Good Manufacturing Practices for Craft Breweries

Background

The United States (U.S.) Department of Health and Human Services, Food and Drug Administration (FDA) now has jurisdiction in breweries under the Federal Food Safety Modernization Act (FSMA). This Act was signed into law by President Obama in 2011. All breweries are now subject to FDA regulation based upon the statutory requirements of the FSMA. The foundation for this major shift in jurisdiction from the federal government regulating breweries solely under the former Bureau of Alcohol Tobacco and Firearms (and now the Tax and Trade Bureau of the Department of Treasury, or TTB) was the Bioterrorism Act of 2002. FDA and TTB now share joint authority over all breweries in the U.S. that either acquire raw materials or any process equipment from across state lines or that sell finished goods across state lines. So if you can grow all your raw materials in your home state, and have all your tanks and kegs fabricated in your home state, then you don't have to worry about the additional burden of regulation derived from the FSMA.

If you are interested in learning more about the role of the FDA and the FSMA as they relate to breweries, you can reference a presentation from the 2013 Craft Brewers Conference in the members-only content from the Brewers Association website under "Resources: Presentations: FDA Regulation of the Brewing Industry." Additionally, the Master Brewers Association of the Americas (MBAA) has some helpful content on its website that is available to all viewers, not just MBAA members, at mbaa.com/brewresources/foodsafety/Pages/default.aspx.

Disclaimer

This document has been created as a resource of the Brewers Association (BA) by the Quality Subcommittee of the BA Technical Committee and is intended to serve as a guide for craft breweries in implementing good manufacturing practices and to assist with FDA compliance. This guide is merely a tool that can aid a craft brewery in this regard, but it is not intended as a guarantee of complete compliance nor is it an FDA-sanctioned document. Any additional compliance requirements that are beyond the scope of this guide are the responsibility of brewery management.

FAQ	Answer
What is this document?	In keeping with the pattern of FDA form 2966, these checklists go through each item on FDA form 2966 and expand upon the checklist items, as well as provide a number of best practice recommendations to increase the value in this document intended for a craft brewer audience.
Why is this document needed?	When a brewery is visited by an FDA officer for a site inspection, the officer will be using FDA form 2966 as their guide in conducting the inspection. Using the same pattern as FDA form 2966 to proactively prepare for an inspection as well as taking initiative to maintain FDA compliance will demonstrate to any interested party that the brewery is serious about compliance and aims to do so in as efficient a manner as possible.

How do I use this document?	These checklists can be as useful as a brewery desires. The starting point for compliance is not this document, but rather the brewery's intention. This document is best viewed as one of several tools that can be helpful in carrying out the intent to comply. Working through each item on the checklists will illuminate where specific improvement is needed in brewery's operations. Each checklist covers a separate heading of FDA form 2966 and each item in the checklists is numbered to match the item numbers contained in FDA form 2966
What are GMPs?	GMPs is a plural abbreviation for "Good Manufacturing Practices." In certain industries, the abbreviation is alternately expressed as cGMP or CGMPs to reference Current Good Manufacturing Practice regulations enforced by the FDA.
Why am I required to comply?	The FDA has the responsibility to ensure brewery compliance with GMPs and has authority to levy actions and fines for non-compliance.
What is this document based on?	The checklists are based on Form FDA 2966 (3/13) and the Code of Federal Regulations (21CFR110). The most recent version of FDA form 2966 can be found at: www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071343.pdf

References

www.fda.gov/Food/GuidanceRegulation/FSMA/

www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071343.pdf

www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-part110.pdf

www.mbaa.com/brewresources/foodsafety/Pages/default.aspx

Title 21 of United States Code, Chapter 9, Subchapter 2, Section 321, paragraph f: "The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." In other words, beer actually is food.

