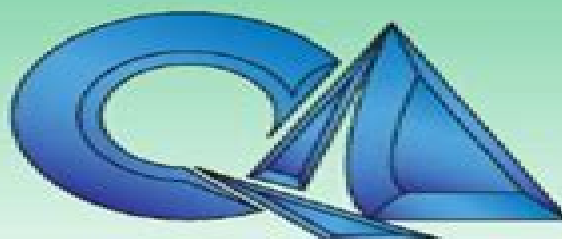


LABORATORY QUALITY MANUAL

Third Edition

Implemented and Effective: October 2009



Note:

The CFSAN Laboratory Quality Manual contains basic quality requirements. The Quality Management System is in the process of being implemented; therefore, some procedures are in draft form.

As implementation takes place, more supporting documents may be added.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
College Park, Maryland 20740

Quality Manual Lab

Ying Liu



Quality Manual Lab:

The Laboratory Quality Assurance System Thomas A. Ratliff, 2005-02-25 Both the 17025 1999 standard and especially ANSI ISO ASQ 9001 2000 standard require that a laboratory document its procedures for obtaining reliable results The Laboratory Quality Assurance Manual details to the user how to prepare a new laboratory quality assurance manual which will be appropriate to use as a procedures manual for a particular laboratory a sales tool to attract potential customers a document that can be to answer regulatory questions and ultimately a tool to become a registered ISO 9001 2000 Lab and gain related certifications based on the standard The Laboratory Quality Assurance Manual Incorporates changes to ANSI ISO ASQ 9001 2000 pertaining to laboratories Provides blank forms used in preparing a quality manual Provides information on the interrelationship of ANSI ISO 17025 1999 and ANSI ISO ASQ 9001 2000 *A Laboratory Quality Handbook of Best Practices* Donald C. Singer, 2001-09-25 Based on the work of a collection of experts from the laboratory science and quality assurance fields A Laboratory Quality Handbook of Best Practices and Relevant Regulations provides all of the information needed to run a successful laboratory that is in compliance with all regulations From sample tracking to accurate documentation training to methods validation maintenance to calibration and out of spec responses to preparation for audits a combination of people instrumentation and documentation must work in sync for high quality results This handbook provides information that will help a laboratory achieve high quality results and compliance Contents Quality Assurance in the Laboratory History of Regulation Training in the Laboratory Laboratory Documentation and Data Sample Control and LIM Systems Methods Validation Guidelines for Laboratory Quality Managers Saverio Mannino, 2022-11-22 This useful and extensive set of guidelines is designed to assist food control laboratories in gaining accreditation from an internationally recognized external body providing all of the necessary information and practices in an easy to read step by step fashion Authored by an experienced consultant for laboratory accreditation in many different countries with this text food control lab owners now have all of the up to date information they need to gain accreditation in a single source Guidelines for Laboratory Quality Managers covers the essentials for quality management in the food control laboratory from testing processes to current quality management systems The ISO standards for accreditation are extensively explored including managerial requirements organizational aspects complaint handling procedures internal audits and sampling An entire section is dedicated to the implementation of managerial and technical requirements from quality control to program monitoring and evaluation Analysis selection preparation and validation is covered extensively and an entire section is dedicated to basic statistics from data presentation to distribution Each section comes with helpful tips for lab managers plus definitions and terms Comprehensive easy to use and up to date Guidelines for Laboratory Quality Managers is the guide for accreditation for food control laboratories National Voluntary Laboratory Accreditation Program NVLAP (Program : U.S.), Jon M. Crickenberger, 1994 **Good Clinical, Laboratory and Manufacturing Practices** Phillip A. Carson, Nigel J.

Dent,2007 Provides practical advice for the quality assurance professional responsible for monitoring compliance with legal requirements and accepted standards of preclinical safety studies clinical trials and manufacture of drugs This book also offers a framework for integrating these standards with other quality management systems **NIST Handbook** ,1989

Guidelines for Quality Management in Soil and Plant Laboratories Food and Agriculture Organization of the United Nations,1998-01-01 Quality Labs for Small Brewers Merritt Waldron,2020-08-03 Quality assurance and quality control QA QC is both a system and a state of mind In Quality Labs for Small Brewers author Merritt Waldron walks you step by step through the process of establishing and writing a quality program for your brewery Your quality policy should align with your company values and inculcate a quality first culture throughout your brewery Building an effective quality program will empower staff to directly influence the consistent production of safe quality beer from grain to glass A good quality program has many moving parts but it is underpinned by good manufacturing practice GMP and food safety requirements GMP covers every aspect of a brewery s operation not just how personnel comport themselves but how goods in are handled and stored how beer is held in the warehouse and how equipment plant and the grounds are maintained Learn how to set standards and critical control points and how to effectively monitor your process so that any deviation is quickly addressed Discover how policies procedures and specifications can help ensure quality throughout every process Involve your staff in establishing standard operating procedures corrective actions and improvements Learn how to effectively delegate responsibility and also ensure that management is armed with the information they need to ultimately make what may be some tough decisions If the worst happens understand that being able to make a tough call and having a robust recall procedure in place means you can move quickly to rectify matters which helps your brewery retain the confidence of your customers and distributors Brewers will see results through the application of GMP and food safety prerequisite programs Your quality manual laying out standard operating procedures product specifications and corrective action plans will give your staff the confidence to implement your quality program With these programs in place the author then takes you through each area of your brewery operation and breaks down how key parameters are measured and analyzed at critical control points Sampling plans are outlined for monitoring density temperature pH yeast viability and growth alcohol carbonation dissolved oxygen titratable acidity fill height and packaging integrity Explore setting up an effective sensory panel even a small one that will help ensure each beer remains true to brand Waldron outlines building your brewery laboratory and looks at how to implement an in house microbiology program Throughout this the focus is on scaling your efforts to the size of your operation and always being ready to expand your quality program as your brewery grows The author makes it clear that no brewery is too small to implement QA QC and discusses pragmatic solutions to building out your capabilities Beyond taking meaningful accurate measurements the author also explores how to analyze data Learn some basics of statistics and data organization and how to apply these techniques to continuously monitor processes and spot when corrective action is needed These routines will help

pinpoint any risks or areas of improvement and ensure that only quality beer reaches the customer time after time NBS
Handbook ,1996 **Manuals of Food Quality Control** P. G. Martin, Food and Agriculture Organization of the United
Nations, 1986

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