



Document Control Procedures

Denise Robitaille



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How to Establish a Document Control System for Compliance with ISO 9001:2015, ISO 13485:2016, and FDA Requirements

Stephanie L. Skipper, 2015-10-14 This book explains the requirements for compliance with FDA regulations and ISO standards 9001 13485 for documented information controls and presents a methodology for compliance The document control system DCS or documented information control system DICS is the foundation of a quality management system It is the first quality system element that must be implemented because the establishment and control of documented processes and information in a quality controlled environment is dependent on the ability to proactively manage access to documents and the movement of documents through the document life cycle A well developed document control system benefits business by Improving knowledge retention and knowledge transfer within and across business units Improving access to knowledge based information Improving employee performance by providing standardized processes and communicating clear expectations Improving customer communication and satisfaction by providing documented information from which common understanding can be achieved Providing traceability of activities and documentation throughout the organization Improving organization of and access to documents and data Sample documents are included in the appendixes of this book to help clarify explanations and a full set of formatted procedures and document templates are available for download to get you off to an even faster start This book provides a process based approach that can be used for controlling all forms of documented information that are required to be managed under the quality management system

Hazard Analysis and Risk Based Preventive Controls Patricia A. Wester, 2017-12-06 Hazard Analysis and Risk Based Preventive Controls Building a Better Food Safety Plan is directed to those food safety professionals charged with ensuring or assisting with FSMA s preventative controls PC implementation and compliance in their routine job duties The target audience includes those currently involved in the development management and execution of HACCP and or other advanced food safety management systems as well as those interested in advancing their knowledge base to gain a more thorough comprehension of HARPC requirements FSMA topics covered include identifying the food safety team and PCQI creating the HARPC implementation strategy starting the food safety plan conducting a thorough hazard analysis identifying adequate preventive control measures determining appropriate PC management components recognizing applicable verification and validation activities supply chain management program recall plans Other operational topics include document control systems internal audit programs third party audit management regulatory visit preparation and maintaining compliance Provides a step by step guide to achieving FSMA compliance for food safety professionals who develop and manage food safety management systems Written by industry experts with direct experience in the formulation of the HARPC regulations Presents insights into the underlying approach of FSMA s preventative controls Transitions readers from HACCP to HARPC using GAP assessment to adapt existing food safety programs to the FSMA preventative controls requirements

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Quality Safety Management and Auditing Michael B. Weinstein, 1997-08-11 Total Quality Management TQM is a business philosophy that yields customer satisfaction and continuous process improvement This new reference and workbook embraces the TQM revolution and explains to readers how TQM principles are applied to safety and health programs The text also focuses on the ISO 9000 Quality Program Voluntary Protection Program and Process Safety Management For each of these topics the key principles are identified and described and the quality principles are adapted to safety **Document Control** Denise Robitaille, 2011-09 They re supposed to be useful tools but whether they re printouts computer files flowcharts or forms documents can often give more headaches than help And yet without them most organizations couldn t function ISO 9001 and other quality management systems place great emphasis on documents and for good reason Documents aren t individual stand alone elements of the management process They re interrelated formatted in different media and controlled by various and distinct functions Keeping critical information current and in the right hands requires more than just signing off on procedures Document control is essential but where should you begin Inside you ll find clear explanations about the document control process as well as practical solutions for creating organizing and maintaining documents including A discussion of different kinds of documents including electronic media and QMS requirements Identifying and defining responsibility Understanding the relationship between documents and records Tips for document writers Managing and maintaining documents Issues of accessibility Handling revisions and deviations Writing document control procedures **Environmental and Quality Systems Integration** William C. Culley, 2019-09-17 Global competition corporate downsizing and corporate restructuring have forced many firms to reevaluate their operating methods Today corporations must do more with less while still watching the bottom line and improving profitability ISO 14000 and ISO 9000 because of their similar management system requirements and auditing procedures are g Green Profits Nicholas P Chermisinoff, Avrom Bendavid-Val, 2001-05-17 Green Profits covers two tightly connected topics environmental management systems EMS and pollution prevention P2 in a single volume Authored by an environmental engineer and an economist planner Green Profits shows how to implement an EMS especially ISO 14001 so that it leads to profitable pollution prevention innovations and how to identify and implement pollution prevention measures in a sound strategic business framework Green Profits provides the knowledge and tools for enterprise managers to achieve the benefits of both EMS and P2 and to do so in ways that fit in with existing management systems in their enterprises Environmental management systems are planned and organized ways for an enterprise to manage its interactions with the environment in particular those interactions that consume resources degrade the environment and create human health risk Part I of Green Profits provides a thorough and practical understanding of the elements of EMSs in general and ISO 14001 in particular tools and techniques for implementing an EMS and achieving ISO 14001 certification and help with getting the implementation process started Pollution prevention involves replacing process technologies that generate pollution with those that do not or

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