

ISO 13485 Audit Checklist Sample Report

ISO 13485 Audit Checklist		1. Issues, 10/1/2023
Management Controls		
Quality Manual defines scope of QMS, procedures (or reference to) within QMS, and description of the interaction of processes within QMS? (ISO 13485:2016: 4.1, 4.2.2)	Yes	
Criteria and methods are in place to monitor and control processes for effectiveness? (ISO 13485:2016: 4.1.3(a), 4.2.1(d), 8.4)	Yes	
Firm has established and conducts Management Reviews, at least annually? (ISO 13485:2016: 5.1(d), 5.6)	Yes	
Management reviews examine suitability and effectiveness of quality systems, improvements needed because of customer requirements, and resource needs? (ISO 13485:2016: 4.1.3(c), 5.6.1, 5.6.3, 6.1, 8.4)	Yes	
Management review addresses audit results, customer feedback, process performance, Corrective and Preventive Actions (CAPAs), previous management reviews, changes to QMS, recommendations for improvement, and new or revised regulatory requirements? (ISO 13485:2016: 5.6.2)	Yes	
I think we can improve on this moving forward not that we have utilized our digital audit tool. We previously depended on paper checklists for audits and we just found we missed audits in the past.		
Firm has established a Quality Manual and Quality System Procedures and Instructions that are appropriate? (ISO 13485:2016: 4.1.2(a), 4.2.1(b), (c))	Yes	
Firm has established Quality Plan? (ISO 13485:2016: 4.2.1(d), 5.4)	Yes	
Quality Planning addresses QMS needs and Quality Objectives? (ISO 13485:2016: 5.4.2)	Yes	
Firm has implemented Quality Policy and Quality Objectives? (ISO 13485:2016: 4.2.1(a), 5.1(b), (c), 5.3, 5.4.1)	Yes	
Firm has established Quality Audit procedures and conducts audits? (ISO 13485:2016: 4.2, 8.2.4)	Yes	
Will meet with head auditor to check on the new tool we have.		
To Do Assignee: SafetyCulture Staff Priority: Low Due: 18.05.2023 18:15 PST Created by: SafetyCulture Staff		
Update on digital audits		
Quality audits examine compliance and effectiveness? (ISO	Yes	

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Stephen F. Amato, Robert M. Ezzell Jr

A red circular graphic with a gradient, appearing as a partial circle or a stylized arrow pointing to the right, located to the right of the authors' names.

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ISO 13485 Itay Abuhav, 2011-10-20 Although complex and lengthy the process of certification for the ISO 13485 can be easily mastered using the simple method outlined in ISO 13485 A Complete Guide to Quality Management in the Medical Device Industry Written by an experienced industry professional this practical book provides a complete guide to the ISO 13485 Standard certification for medical device manufacturing Filled with examples drawn from the author's experience and spanning different sectors and fields of the medical device industry the book translates the extra ordinary requirements and objectives of the standard into feasible activities and tasks The book provides a full analysis of each clause and sub clause through quality perspectives the implications on an organization its processes management human resources infrastructures work environment control and effectiveness documentations and records The book is organized like the standard itself the table of contents is identical to the ISO 13485 Standard's table of contents making it user friendly familiar and unimimidating You can use the book as a consulting session read it explore it extract ideas and draw on the information and knowledge that suits you and your organization and then apply it effectively to your quality management system and processes

ISO 13485:2016 Itay Abuhav, 2018-05-11 Summary This book provides valuable effective guidance for understanding interpreting and implementing ISO 13485 2016 standard requirements Despite its more than 800 page length the author has specifically designed its contents to maximize usability for the reader with a table of contents identical to that of the ISO standard itself which enables easy navigation and orientation Pragmatic in style and down to earth in tone this book draws real life examples and case studies from the author's many years of experience in consulting to illustrate even the most complex of ISO 13485 2016 standard requirements and their implementation Identifying relevant requirements and how they harmonize with quality management systems developing processes for design and development as well as product realization and validation are just a few of the issues covered in depth by this publication In addition the author constantly reviews the distinctive characteristics and aspects of the medical device manufacturing industry so that the reader can also appreciate the subject of this book in an everyday context Features A pragmatic and down to earth approach towards the reader's understanding of ISO 13485 2016 standard requirements implementation Uses examples and cases from real life based on the author's many years of experience in quality management A table of contents structured identically to that of ISO 13485 2016 itself allowing easier navigation and orientation for the reader Emphasises guidance for ISO 13495 2016 standard requirements which are difficult to interpret and implement Constantly reviews the aspect of medical device industry characteristics and distinctive so the reader can reflect the content with its daily work

Developing an ISO 13485-Certified Quality Management System Ilkka Juuso, 2022-03-20 Developing an ISO 13485 Certified Quality Management System An Implementation Guide for the Medical Device Industry details the lessons learned from a real world project focusing on building an ISO 13485 2016 Quality Management System QMS from scratch and then having it officially

certified It is a practical guide to building or improving your existing QMS with tried and tested solutions The book takes a hands on approach first teaching the top 25 lessons to know before starting to develop a QMS and then walking you through the process of writing the quality manual and the standard operating procedures training the staff on the QMS organizing an internal audit executing a management review and finally passing the necessary external audits and obtaining certification It helps you to progress from one task to the next and provides all the essential information to accomplish each task as quickly and efficiently as possible It does not attempt to replicate the standard but instead drills into the standard to expose the core of each section of the standard and reorganize its contents into a practical workflow for developing maintaining and improving a Lean QMS The book includes a wealth of real world experience both from the author s personal dive into quality management and from the experiences of other companies in the field and provides handy checklists for ensuring key documents and processes are fit for use the emphasis here is to help ensure you have considered all relevant aspects In addition the book is not intended as a cheat sheet for the standard or as a review of the standard that only adds lengthy commentary on each of the clauses Instead the book fixes easy misunderstandings regarding QMS provides insight into why the various clauses are written the way they are and provides a great base to both understanding ISO 13485 QMS and developing your own QMS The book is intended to serve both experts and novices audiences it provides special insight on the most crucial and effective aspects of QMS

Executive's Guide to COSO Internal Controls Robert R. Moeller, 2013-12-11

Essential guidance on the revised COSO internal controls framework Need the latest on the new revised COSO internal controls framework Executive s Guide to COSO Internal Controls provides a step by step plan for installing and implementing effective internal controls with an emphasis on building improved IT as well as other internal controls and integrating better risk management processes The COSO internal controls framework forms the basis for establishing Sarbanes Oxley compliance and internal controls specialist Robert Moeller looks at topics including the importance of effective systems on internal controls in today s enterprises the new COSO framework for effective enterprise internal controls and what has changed since the 1990s internal controls framework Written by Robert Moeller an authority in internal controls and IT governance Practical no nonsense coverage of all three dimensions of the new COSO framework Helps you change systems and processes when implementing the new COSO internal controls framework Includes information on how ISO internal control and risk management standards as well as COBIT can be used with COSO internal controls Other titles by Robert Moeller IT Audit Control and Security Executives Guide to IT Governance Under the Sarbanes Oxley Act every corporation has to assert that their internal controls are adequate and public accounting firms certifying those internal controls are attesting to the adequacy of those same internal controls based on the COSO internal controls framework Executive s Guide to COSO Internal Controls thoroughly considers improved risk management processes as part of the new COSO framework the importance of IT systems and processes and risk management techniques

The Internal Auditing Pocket Guide,

Second Edition J. P. Russell, 2007-01-01 This best seller pocket guide prepares auditors to conduct internal audits against quality environmental safety and other audit criteria This handy pocket guide covers all the steps necessary to complete an internal audit from assignment to follow up New and updated chapters reflect new techniques to address vogue requirements more illustrations and examples ISO 19011 thinking and verification of auditee follow up actions This condensed easy to read book is a valuable resource and great tool for training others on how to perform an internal audit It is appropriate for those who have no prior knowledge of audit principles or techniques **Brink's Modern Internal**

Auditing Robert R. Moeller, 2016-01-05 The complete guide to internal auditing for the modern world Brink's Modern Internal Auditing A Common Body of Knowledge Eighth Edition covers the fundamental information that you need to make your role as internal auditor effective efficient and accurate Originally written by one of the founders of internal auditing Vic Brink and now fully updated and revised by internal controls and IT specialist Robert Moeller this new edition reflects the latest industry changes and legal revisions This comprehensive resource has long been and will continue to be a critical reference for both new and seasoned internal auditors alike Through the information provided in this inclusive text you explore how to maximize your impact on your company by creating higher standards of professional conduct and greater protection against inefficiency misconduct illegal activity and fraud A key feature of this book is a detailed description of an internal audit Common Body of Knowledge CBOK key governance risk and compliance topics that all internal auditors need to know and understand There are informative discussions on how to plan and perform internal audits including the information technology IT security and control issues that impact all enterprises today Modern internal auditing is presented as a standard setting branch of business that elevates professional conduct and protects entities against fraud misconduct illegal activity inefficiency and other issues that could detract from success Contribute to your company's productivity and responsible resource allocation through targeted auditing practices Ensure that internal control procedures are in place are working and are leveraged as needed to support your company's performance Access fully updated information regarding the latest changes in the internal audit industry Rely upon a trusted reference for insight into key topics regarding the internal audit field Brink's Modern Internal Auditing A Common Body of Knowledge Eighth Edition presents the comprehensive collection of information that internal auditors rely on to remain effective in their role **The ASQ Certified Supplier**

Quality Professional Handbook Mark Allen Durivage, Stephanie L. Parker, 2023-11-15 This handbook explains in detail each section of the Certified Supplier Quality Professional Body of Knowledge updated 2023 It is a handy reference for those already working in the field and is an essential text for those working toward a CSQP certification [Regulatory Affairs for Biomaterials and Medical Devices](#) Stephen F. Amato, Robert M. Ezzell Jr, 2014-10-27 All biomaterials and medical devices are subject to a long list of regulatory practises and policies which must be adhered to in order to receive clearance This book provides readers with information on the systems in place in the USA and the rest of the world Chapters focus on a series of

procedures and policies including topics such as commercialization clinical development general good practise manufacturing and post market surveillance Addresses global regulations and regulatory issues surrounding biomaterials and medical devices Especially useful for smaller companies who may not employ a full time vigilance professional Focuses on procedures and policies including risk management intellectual protection marketing authorisation university patent licenses and general good practise manufacturing

Mastering and Managing the FDA Maze, Second Edition Gordon Harnack, 2014-04-14 The number of FDA regulations and the agency's increased expectations is staggering and their content tedious creating a regulated industry need for compliance insight and appropriate detail This book is the reference needed to successfully navigate through the FDA maze The target audiences for this desk reference include Regulatory professionals who know their responsibility to keep their firm's employees trained and competent on FDA device regulations and who need a preliminary desk reference that can be used throughout their enterprise to help train and ensure compliance Neophytes who know nothing about FDA but need a resource that provides both broad and specific information in sufficient detail to be useful Beginners who know a little about FDA need to know more and need a reference tool to help them be more effective and productive on the job Intermediates who know enough about FDA to know they need to know more and who need a reference tool that provides them with both more basics and executable detail Busy managers who need to know regulatory requirements and FDA expectations in order to manage compliance in their specific activity Busy executives CEOs COOs and operations managers whom FDA holds responsible for all regulatory compliance who also need a desk reference with specific information to quickly assess regulatory compliance identify potential noncompliance and review corrective preventive and compliance actions

Medical Device Regulatory Practices Val Theisz, 2015-08-03 This book is intended to serve as a reference for professionals in the medical device industry particularly those seeking to learn from practical examples and case studies Medical devices like pharmaceuticals are highly regulated and the bar is raised constantly as patients and consumers expect the best quality healthcare and safe and effective

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