

ISO 9001:2015 Quality Management System Audit Checklist

4.3 Determining the scope of our quality management system

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Has our organization determined the boundaries and applicability of our quality management system to establish its scope? (Scope Statement available?)		
2	When determining this scope, did our organization consider: a) the external and internal issues referred to in 4.1? b) the requirements of relevant interested parties referred to in 4.2? c) the products and services of our organization.		
3	Did our organization apply all the requirements of the ISO 9001:2015 standard if they were applicable within the determined scope of our QMS?		
4	Is the scope of our organization's quality management system visually available and maintained as documented information somewhere ?		
5	Does the scope state the types of our products and services covered, and provide justification for any requirement of the ISO 9001:2015 standard that our organization determines as not applicable to the scope of our quality management system?		
6	Are we aware that conformity to the ISO 9001:2015 standard may only be claimed if the requirements determined as not applicable do not affect our organization's ability or responsibility to ensure the conformity of our products and services and the enhancement of customer satisfaction?		

Iso Audit Questions For Production Department

Oliver Schmidt



Iso Audit Questions For Production Department:

The Process Approach Audit Checklist for Manufacturing Karen Welch, 2004-12-31 Finally a comprehensive process audit checklist has been developed to be used with ISO 9001 2000 This manual was developed to assist anyone involved with conducting or planning quality system audits including quality auditors quality managers quality system coordinators management representatives and quality engineers In addition potential auditees in any function or position should find the questions useful in preparing for an audit Although the checklist could be amended to work for a service company the manual was created with a focus on the manufacturing sector to cover common processes such as production management customer related design and development training purchasing etc The manual includes a brief overview of the process approach discussion of problem areas often found by third party auditors the process audit checklist and forms to be used in conjunction with the process audit checklist to increase audit effectiveness Pharmaceutical Technology: Concepts and applications S. Bharath, 2013 *Pharmaceutical Technology Concepts and Applications* articulates on the various pharmacological concepts associated with industrial pharmacy The book not only focuses on providing comprehensive information on formulation development and affiliated areas but also emphasizes on their industrial applications With a plethora of examples that illustrate important concepts the book equips students of pharmacy to rise to the requirements of the industry ISO 9000 Quality System Jack Kanholm, 1994 *THE ISO 9000 QUALITY SYSTEM DEPARTMENT BY DEPARTMENT IMPLEMENTATION FOR THE CERTIFICATION AUDIT* Practical implementation guide with examples audit situations illustrating what auditors will be looking for how they will react in specific situations Written by an IQA certified NACCB RvC auditor international consultant it is the complete body of knowledge experience needed to prepare for receive the certification audit 168 p 98 00 *ISO 9000 DOCUMENTATION A 20 SECTION QUALITY MANUAL 26 OPERATING PROCEDURES* An excellent sample of fully developed ISO 9001 documentation Can be used as an illustration to better understand the standards as a model for designing a quality system or as ready made documentation The book is also available on computer disk with a copyright permission license 142 p 88 00 *ISO 9000 EXPLAINED AN INTERPRETATION GUIDE* Section by section explanation of the ISO 9000 standards Empowers to confidently interpret adapt the standards to any company 73p 57 00 *ISO 9000 IN YOUR COMPANY A SELF STUDY COURSE FOR PERSONNEL* Intended for distribution to all employees eliminates the need for costly disruptive classroom training Explains what are the requirements of ISO 9000 how a quality system works how employees should prepare for certification audit 38 p 28 00 Order from AQA Co Phone 213 222 3600 FAX 213 222 5239 *The Colonial Office List, Comprising Historical and Statistical Information Respecting the Colonial Empire, List of Officers Serving in the Colonies, Etc* Great Britain. Colonial Office, 1948 *ISO 9001 for Engineers and Designers* Stephen J. Schoonmaker, 1997 This step by step guide shows engineering professionals how to successfully take advantage of the ISO 9001 standard It covers such critical processes as documentation design output design verification

and design validation **Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for Fiscal Year 2008** United States. Congress. Senate. Committee on Appropriations. Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies,2007 **Parliamentary Papers** Great Britain. Parliament. House of Commons,1913 Pharmaceutical Quality Systems Oliver Schmidt,2000-04-30 When a pharmaceutical company decides to build a Quality System it has to face the fact that there aren t any guideline that define exactly how such a system has to be built With terms such as quality system quality assurance and quality management used interchangeably even defining the system s objectives is a problem This book provides a pr *Quality Manager's Complete Guide to ISO 9000* Richard B. Clements,1999 **Poultry Meat Processing** Casey M. Owens,Christine Alvarado,Alan R. Sams,2000-12-26 When the first edition of Poultry Meat Processing was published it provided a complete presentation of the theoretical and practical aspects of poultry meat processing exploring the complex mix of biology chemistry engineering marketing and economics involved Upholding its reputation as the most comprehensive text available Poultry Meat Pro

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