

SLNO.	<u>System Audit Questionnaire</u>	
	<u>Background</u>	
1	What is the information technology environment?	
2	Give a brief description of the equipment.	
3	Has a map of the installation been prepared? Otherwise, obtain one.	
4	What are the operating systems in use?	
5	What are the communications systems in use?	
6	What are the various applications which have been computerized?	
	<u>organisation</u>	
1	Prepare or obtain an organizational chart of information technology department.	
2	Determine job title, job descriptions and names of the persons in IT department.	
3	Is there a segregation of duties such as:	
	a. Functions and duties of systems design, programming and data administration are separate from computer operations;	
	b. Programmers do not operate the computer or regulate processing runs;	
	c. Operators have access only to such data and programs as is necessary for performing their assigned tasks;	
	d. Personnel in data processing department are not performing any duties relating to organizing transactions or making changes to master files.	
4	Are the duties of computer operators periodically related?	
5	Are there well-documented operating procedures?	
6	Are the operating functions being properly supervised according to programmed operating procedures?	
	<u>Control Functions</u>	
1	Are there persons specifically given the responsibility for performing the control function in the information technology department?	
2	Do these duties include control over receipt of input data and recording of control information?	
3	Is there control over distribution of output?	

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Ilkka Juuso



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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 ISO 9001:2015 Internal Audits Made Easy Ann W.

Phillips,2015-09-21 Implementing the requirements of ISO 9001 can be a daunting task for many organizations In an attempt to develop a system that will pass the registration audit we are tempted to establish processes with the primary purpose of conforming to the requirements of ISO 9001 In doing so however it is easy to lose sight of the primary intent of the standard to continually improve the effectiveness of the quality management system QMS implemented at our organization This book is intended to help managers quality professionals internal audit coordinators and internal auditors implement a practical internal audit process that meets the requirements of ISO 9001 2015 while adding significant measurable value to the organization The tools techniques and step by step guidelines provided in this book can also be used by those organizations that have a well established internal audit process but are looking for easy ways to make that process more effective

GMP Audits in Pharmaceutical and Biotechnology Industries Mustafa Edik,2024-06-28 The fact that good manufacturing practice GMP audits in the pharmaceutical and biotechnology industries have to be evaluated and with very limited resources has created a gap in this field The lack of trained and qualified GMP auditors is on the rise in all organizations that are

required to implement FDA EMA MHRA WHO TGA and PIC S regulations This volume is an essential reference source for those organizations operating in the field of health and presents the basic knowledge needed to perform audits The author also provides useful tips and a selection of samples about GMP audits that are indispensable for professionals and health inspectors working in industry and health authorities Features An essential reference source for those organizations operating in the field of health and presents the basic knowledge needed to perform audits Anyone working in the manufacturing sector needs to be aware of GMP be able to identify operational flaws as well as legal violations and have a clear understanding of how to meet GMP standards Assists readers in understanding the importance of GMP and how they can apply each aspect in their working environment Covers a global regulatory landscape Suitable for relevant degree courses including industrial pharmaceuticals and pharmaceutical biotechnology Total Quality Management R. S. Naagarazan,2005 This Book Explores The Topics Included In The Syllabus Of Anna University Extensively A Reference Table On The Factors For Quality Control Charts Numerical Examples For Each Control Chart The Questions For Short Answers And A Few Web Site Addresses Have Been Included To Obtain And Sustain The Interest Of The Student Community And The Teaching Fraternity In This Second Edition A Chapter Was Added With Details On Topics Such As Quality Circle Zero Defects Just In Time Kanban And Poka Yoke To Cater For The Expectations Of The Students As Well As Teachers The Details On 5S Yy Analysis Five W S And Two H S Analysis And Brainstorming Methodology Have Been Enlarged With Examples Twenty Three Case Studies Have Been Added In This Edition To Extend The Scope And Knowledge Of The Student Community In Addition To This Twelve Numerical Problems On Different Aspects Of Spc And Six Sigma As Illustrative Examples And The Enriched Question Bank Have Been Added For Clarity In Teaching And Learning This Book Can Be Used As A Textbook By All The Final Year B E B Tech Students Of Anna University EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP Orlando Lopez,2015-04-06 Good Manufacturing Practice GMP ensures medicinal products are produced consistently and controlled to the quality standards appropriate for their intended use and as required by product specifications or marketing authorization Annex 11 details the European Medicines Agency EMA GMP requirements for computer systems The purpose of Annex 11 is **Is Quality Just a Word We Use?** Tom Taormina,2024-12-03 Quality management systems are essential for businesses to meet customer needs ranging from product control to enterprise wide process management Effective management can elevate organizations to brand domination while poor management can ruin an enterprise This book equips quality experts with skills to champion business excellence and risk avoidance Is Quality Just a Word We Use The Evolution from Managing Quality to Championing Organizational Excellence explores the history and flaws of quality management offering a career opportunity for professionals that can lead to professions as expert witnesses in products liability and organizational negligence litigation It introduces a novel quality auditing method focusing on forensic level investigations and case studies to illustrate the

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