

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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Jay J. Schlickman



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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

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