

## OPERATIONS MANUAL

### *Overview*

*The Operations Manual provides computer control personnel and computer operators with a detailed operational description of the information system and its associated environments, such as machine room operations and procedures.*

## **1 GENERAL**

### **1.1 Introduction and Purpose**

Describe the introduction and purpose of the Operations Manual, the name of the system to which it applies, and the type of computer operation.

### **1.2 Project References**

List, at a minimum, the User Manual, Maintenance Manual, and other pertinent documentation.

### **1.3 Glossary**

List any definitions or terms unique to this document or computer operation and subject to interpretation by the user of this document.

## **2 SYSTEM OVERVIEW**

### **2.1 System Application**

Provide a brief description of the system, including its purpose and uses.

### **2.2 System Organization**

Describe the operation of the system by the use of a chart depicting operations and Inter-relationships.

### **2.3 Software Inventory**

List the software units, to include name, identification, and security considerations. Identify software necessary to resume operation of the system in case of emergency.

### **2.4 Information Inventory**

Provide information about data files and databases that are produced or referenced by the system.

#### **2.4.1 Resource Inventory**

List all permanent files and databases that are referenced, created, or updated by the system.

# Manual Documentation Template

**Joseph Philip, Frank David Todd**



## Manual Documentation Template:

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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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