

# ISO 13485:2016 Gap Analysis Checklist

## 4 QUALITY MANAGEMENT SYSTEM

ISO 13485:2016 Gap Analysis Checklist New 2016 Requirements are Shaded in Yellow		
REQUIREMENTS		OBSERVATIONS
<b>4.1</b>	<b>General Requirements</b>	
4.1.1	Is there a Quality Management System in place that has been established and documented to meet the requirements of the ISO 13485:2016 Standard and the applicable regulatory requirements?	
	When the standard specifies that a requirement, a procedure, an activity or arrangement be "documented", is it implemented and maintained?	
	Are the role(s) undertaken by your company under the regulatory requirements (as a manufacturer, a distributor, an authorized representative, or an importer) documented?	
4.1.2	Determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization	
	Is a risk-based approach to the control of processes applied?	
	Are the sequence and interaction of the processes determined?	
4.1.3	Determine criteria and methods needed to ensure that both the operation and control of these processes are effective	
	ensure the availability of resources and information necessary to support the operation and monitoring of these processes	

# Iso 13485 Audit Checklist

**Wolfgang Guggemos**



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## **Table of Contents Iso 13485 Audit Checklist**

1. Understanding the eBook Iso 13485 Audit Checklist
  - The Rise of Digital Reading Iso 13485 Audit Checklist
  - Advantages of eBooks Over Traditional Books
2. Identifying Iso 13485 Audit Checklist
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Iso 13485 Audit Checklist
  - User-Friendly Interface
4. Exploring eBook Recommendations from Iso 13485 Audit Checklist
  - Personalized Recommendations
  - Iso 13485 Audit Checklist User Reviews and Ratings
  - Iso 13485 Audit Checklist and Bestseller Lists
5. Accessing Iso 13485 Audit Checklist Free and Paid eBooks
  - Iso 13485 Audit Checklist Public Domain eBooks
  - Iso 13485 Audit Checklist eBook Subscription Services
  - Iso 13485 Audit Checklist Budget-Friendly Options
6. Navigating Iso 13485 Audit Checklist eBook Formats

- ePub, PDF, MOBI, and More
  - Iso 13485 Audit Checklist Compatibility with Devices
  - Iso 13485 Audit Checklist Enhanced eBook Features
7. Enhancing Your Reading Experience
- Adjustable Fonts and Text Sizes of Iso 13485 Audit Checklist
  - Highlighting and Note-Taking Iso 13485 Audit Checklist
  - Interactive Elements Iso 13485 Audit Checklist
8. Staying Engaged with Iso 13485 Audit Checklist
- Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Iso 13485 Audit Checklist
9. Balancing eBooks and Physical Books Iso 13485 Audit Checklist
- Benefits of a Digital Library
  - Creating a Diverse Reading Collection Iso 13485 Audit Checklist
10. Overcoming Reading Challenges
- Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
11. Cultivating a Reading Routine Iso 13485 Audit Checklist
- Setting Reading Goals Iso 13485 Audit Checklist
  - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Iso 13485 Audit Checklist
- Fact-Checking eBook Content of Iso 13485 Audit Checklist
  - Distinguishing Credible Sources
13. Promoting Lifelong Learning
- Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
14. Embracing eBook Trends
- Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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