

# 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
4.1	General Requirements	
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

**JR Anderson**



## **Iso 13485 Audit Checklist:**

## Unveiling the Energy of Verbal Art: An Emotional Sojourn through **Iso 13485 Audit Checklist**

In a world inundated with screens and the cacophony of immediate interaction, the profound power and mental resonance of verbal art often fade into obscurity, eclipsed by the continuous assault of noise and distractions. However, located within the musical pages of **Iso 13485 Audit Checklist**, a charming perform of literary beauty that impulses with organic emotions, lies an unforgettable journey waiting to be embarked upon. Published with a virtuoso wordsmith, this mesmerizing opus guides visitors on an emotional odyssey, gently exposing the latent possible and profound affect embedded within the complicated internet of language. Within the heart-wrenching expanse of the evocative examination, we will embark upon an introspective exploration of the book is central styles, dissect their charming publishing model, and immerse ourselves in the indelible impact it leaves upon the depths of readers souls.

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