

# QMS Audit Observation

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# Introduction

The purpose of a QMS audit is **to ensure your company has established the appropriate processes and procedures within your quality management system (QMS), and that those processes and procedures are being followed**. I know a lot of people dread audits, but they're simply a fact of life in the medical device industry.

Tab

Tab

# QMS Audit Observation

The screenshot shows a web browser window with the title 'QMS Audit Observation: QMS/...'. The browser's address bar shows 'Home (70634)'. The page title is 'QMS Audit Observation'. The form contains the following fields and values:

Client	XYZ Foundation	Organization	MainHQ
Document No	QMS/1000015		
Document Type	QMS Audit Observation		
Description		QMS Audit Schedule	QMS/1000010_Jun-21
User/Contact	Selva	QMS Audit Plan	QMS/1000009
Document Date	30/06/2021	QMS Audit Master	Internal Audit Department 2021
Account Date	30/06/2021	Audit Type	InternalAudit
Period	Jun-21	Date Start Schedule	01/06/2021
ISO Clause			
Reason			
Document Status	In Progress	<input type="checkbox"/> Approved	<input type="checkbox"/> Processed
	<input type="button" value="Document Action"/>	<input type="checkbox"/> Approved Level 1	<input type="checkbox"/> Approved Level 2

## Critical Fields :

1. Document No : Individual Identity of the record, It is an unique value
2. QMS Audit Schedule : This is used to select the QMS Audit Schedule data from the QMS Audit Schedule
3. Account Date : Used to mention the Accounting date
4. User/contact : Used to select the user name
5. Period : Used to mention Plan Period
6. Date Start Schedule : Used to mention the plan start date

7. Extension Period : Used to give the period for extension
8. Extension Date : Used to give the Extension Date
9. Reason : Used to mention the Reason

## **Critical & onetime setup fields :**

1. Organization : This Field is used to select the organization
2. Target Document Type : This Field is used to select the type of the document that you are going to process

## **Non-Critical Fields :**

1. Description : Used to give any note about the document.

## **Zoom condition's :**

Tab

# QMS Observation Line

Home (70634) QMS Audit Observation: QMS/... x

QMS Audit Observation > QMS Observation Line 1/3

Data requested

Client	XYZ Foundation	Organization	MainHQ
QMS Audit Observation	QMS/1000015_Jun-21	QMS Line	QMS/1000010_Jun-21_10
Line	10	QMS Plan line	QMS/1000009_10
Description	Document Control	QMS Check List	Document Control
Product		Node	
Department	Marketing		
	<input checked="" type="checkbox"/> External Auditor		
Business Partner	Stylo gold unit B	Auditee	Prasanth
QMS_Result	Ok		
Observation	All the points document control verified		
remarks			

Reference

Purchase Order	800508_17/07/2019	Inspection	1000006_1000000_Logitech Mouse
Manufacturing Order	80004_Fabrication	Receipt	



# Document Actions

# Validation

## **Save :**

1.System will check the all mandatory fields

## **Delete :**

1.System will delete the Document and its history details

## **Document action prepare :**

1.System will check the period details and master data's checking

## **Document action complete :**

1.Once document action is complete ,all fields are update in read only

## **Document action void/reverse correct actual :**

1.Void- system will reverse all the transaction data's and change the document status to Void

## **Document action close :**

1.system will check whether all the activity for the document is completed and change the Document status to close.

# Video