

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

QMS Audit Observation

The screenshot shows a web application window titled "QMS Audit Observation: QMS/...". The interface includes a toolbar with icons for navigation and editing. The form itself is titled "QMS Audit Observation" and contains the following fields:

- Client:** XYZ Foundation
- Organization:** MainHQ
- Document No:** QMS/1000015
- Document Type:** QMS Audit Observation (dropdown)
- Description:** (empty text area)
- QMS Audit Schedule:** QMS/1000010_Jun-21 (dropdown)
- User/Contact:** Selva (with a red arrow icon)
- QMS Audit Plan:** QMS/1000009
- Document Date:** 30/06/2021 (with a calendar icon)
- QMS Audit Master:** Internal Audit Department 2021
- Account Date:** 30/06/2021 (with a calendar icon)
- Audit Type:** InternalAudit
- Period:** Jun-21 (dropdown)
- Date Start Schedule:** 01/06/2021 (with a calendar icon)
- ISOCause:** (empty text area)
- Reason:** (empty text area)
- Document Status:** In Progress (dropdown)
- Document Action:** (button with a gear icon)
- Approval checkboxes:** ☐ Approved, ☐ Processed, ☐ Approved Level 1, ☐ 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

QMS Audit ObservationQMS/1000015_Jun-21

Line

DescriptionDocument Control

Product

DepartmentMarketing

☒ External Auditor

Business PartnerStylo gold unit B

QMS_Result*Ok

ObservationAll the points document control verified

remarks

Organization*MainHQ

QMS LineQMS/1000010_Jun-21_10

QMS Plan lineQMS/1000009_10

QMS Check ListDocument Control

Node

AuditeePrasanth

Reference

Purchase Order800508_17/07/2019

Manufacturing Order80004_Fabrication

Inspection1000006_1000000_Logitech Mouse

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