

# QMS Audit Observation

- Introduction
- Tab
  - QMS Audit Observation
  - QMS Observation Line
- Document Actions
  - Validation
- Video

# 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 main form area 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

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

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