

#### **Document Control Procedure Template**

#### 1. Purpose:

The purpose of this document control procedure is to ensure the effective management of documented information within [Organization Name], in accordance with ISO 9001:2015 requirements. This procedure establishes the processes for creating, reviewing, approving, distributing, and revising documents to maintain accuracy, consistency, and compliance with quality management standards.

#### 2. Scope:

This procedure applies to all documented information generated, utilized, or maintained by [Organization Name] as part of its Quality Management System (QMS).

#### 3. Responsibilities:

- Quality Manager: The Quality Manager is responsible for overseeing the implementation of this document control procedure and ensuring compliance with ISO 9001 requirements. Responsibilities include:
  - Establishing document control processes and procedures.
  - · Providing training and guidance on document control requirements.
  - Monitoring the effectiveness of document control activities and initiating improvements as necessary.
- Document Owners: Document Owners are responsible for creating, updating, and maintaining documents within their area of expertise. Responsibilities include:
  - Ensuring that documents are accurate, up-to-date, and aligned with relevant standards and procedures.
  - Reviewing and approving documents before distribution.
  - Notifying the Quality Manager of any changes or updates to documents.
- Document Controllers: Document Controllers are responsible for managing the day-today activities related to document control. Responsibilities include:
  - Maintaining a central repository of all documents and records.
  - Ensuring that document numbering, naming, and version control are maintained consistently.

# **Sample Document Control Procedures**

**Anthony S. Fauci** 

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