

ISO 9001:2015 Documentation Toolkit - Contents

The documents provided include these Instructions, an over-arching Environmental Manual, a series of supporting Procedures, a range of related Forms, Templates and Checklists, comprehensive Guidance and more.

Instructions - Doxonomy ISO 9001 2015 Toolkit

9001 Documentation:

- Quality Manual
- Table of Responsibilities and Authorities

Procedures:

- Control of Calibration and Verification
- Control of Competency
- Control of Customer Satisfaction
- Control of Design and Design Changes
- Control of Equipment Validation and Maintenance
- Control of Internal Auditing
- Control of Management System Documentation
- Control of Management System Records
- Control of Non-conforming Product
- Control of Non-conforming Service
- Control of Purchasing and Supply
- Control of QMS Corrective and Preventative Actions (CPAR)
- Control of QMS Management Reviews
- Control of Risks and Opportunities
- Identification of Quality Context

Forms, Templates, Logs and Registers:

- Approved Supplier List
- Calibration and Production Software Validation Register
- Calibration Register
- Controlled QMS Documents Register
- Controlled QMS Records Register
- Corrective and Preventative Action Request (CPAR) Form
- Corrective and Preventative Action Request (CPAR) Log
- Customer Feedback Form
- Design Change Request Form
- Design Software Validation Register
- Document Change Request Form
- Management Review Agenda Template
- Management Review Meeting Minutes Template
- Non-conforming Product Report and Resolution (NPRR) Form
- Non-conforming Service Report and Resolution (NSRR) Form
- PESTLE Template
- Preventative Maintenance Log
- Preventative Maintenance Register
- Process Definition Template

- Quality Context Log
- Receiving Inspection Log
- Risk Register
- Role Profile Form
- Role Profile Register
- Routine Maintenance Register
- Supplier Corrective Action Log
- Supplier Corrective Action Request (SCAR) Form
- Supplier Corrective Action Request (SCAR) Log
- Supplier Evaluation Form
- Supplier Questionnaire
- SWOT Template
- Training Evaluation Form

Internal Audit:

- Auditing Step-by-Step
- Auditor Code of Conduct
- Internal Audit Feedback Form
- Internal Audit Report Template
- Internal Audit Template - Process
- Internal Audit Questions - Process
- Internal Audit Questions - QMS
- Internal Audit Questions – Supplier
- Knowledge Requirements for QMS Auditors

9001 Training (PowerPoint Presentations)

- 9001 Training Module 1 - An introduction to Quality Management
- 9001 Training Module 2 - Quality Management Terminology
- 9001 Training Module 3 - CI1 to CI7 In Detail
- 9001 Training Module 4 - CI8 to CI10 In Detail

Auditor Training (To ISO19011:2011) (PowerPoint Presentations)

- Auditor Training Module 1 - Auditing Concepts
- Auditor Training Module 2 - Audit Management
- Auditor Training Module 3 - Conducting the Audit
- Auditor Training Module 4 - Competence and Training of Auditors

9001 Guidance:

- 9001 Step-by-Step
- Gap Analysis ISO 9001-2008 to 9001-2015
- Glossary of Terms ISO 9001-2015
- Mandatory Documents and Records ISO 9001-2015
- Risk Based Thinking ISO 9001-2015
- Quality Risk Management ISO 9001-2015

Example Process Maps:

- Example - Delivery of Services Process Map
- Example - Hiring Process Map
- Example - Ordering Process Map

- Example – Overall High Level Process Map

Selected Third Party Guidance:

- ISO 9001-2015 Debunking the Myths
- ISO 9001-2015 How to Use It
- ISO 9001-2015 Introduction to Documented Information
- ISO 9001-2015 Process Approach
- ISO 9001-2015 Quality Management Principles
- ISO 9001-2015 Reaping the Benefits
- ISO 9001:2015 Revision – FAQ's
- ISO 9001-2015 Technical Guide

Abacre:

- Instructions – Replacing Placeholders
- Placeholders

We have worked hard to create a “generic” document set that requires the minimum of tailoring to individual organisations. However, all businesses are different and you will inevitably, as described below, need to make changes to the documents we have provided and to fill in some “gaps”.