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AI-generated content may be incorrect.

QMS Checklist

Preparing your Quality Management System for ISO9001 certification

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| **Clause 4 Context of the organisation** | | | **Yes/No** | | **Evidence & Comments** |
| Have you identified internal & external issues that will impact on your Quality Management System (QMS), including Climate Change? | | |  | |  |
| Have you identified interested parties & which stakeholder requirements will be addressed through the QMS, including requirements relating to Climate Change? | | |  | |  |
| Have you determined and documented the scope and boundaries of the QMS? | | |  | |  |
| Have you identified and justified exclusions from the scope of the QMS? | | |  | |  |
| **Clause 5 Leadership** | **Yes/No** | | | | **Evidence & Comments** |
| Can your organisation demonstrate that top management is providing leadership and commitment to the QMS? |  | | | |  |
| Have you established and documented a Quality Policy? |  | | | |  |
| Has management assigned roles and responsibilities for the QMS’s implementation, operation, performance reporting? |  | | | |  |
| **Clause 6 Planning** | **Yes/No** | | | | **Evidence & Comments** |
| Have you established a plan to address identified risks and opportunities related to the QMS? |  | | | |  |
| Have you established a documented risk assessment process that considers internal and external issues and the needs and expectations of interested parties relevant to the organisation? |  | | | |  |
| Have you established and documented measurable quality objectives? |  | | | |  |
| Have you established plans to monitor, measure, communicate and achieve objectives and determined processes for maintaining related records? |  | | | |  |
| Have you established processes to ensure changes to the QMS are carried out in a planned manner? |  | | | |  |
| **Clause 7 Support** | | **Yes/No** | | **Evidence & Comments** | |
| Have you determined the resources needed to establish, implement, continuously improve and maintain the QMS? | |  | |  | |
| Have you determined and documented the competencies required by personnel to undertake their roles and responsibilities in compliance with the QMS? | |  | |  | |
| Do you retain documented records of education, training experience, competence and qualification? | |  | |  | |
| Is QMS documentation protected from loss of confidentiality, loss of integrity and improper use? | |  | |  | |
| **Clause 8 Operation** | | **Yes/No** | | **Evidence & Comments** | |
| Have you established operating procedures, including criteria and implementation of process controls in accordance with criteria, as needed to ensure customer requirements are met? | |  | |  | |
| Have you established change management procedures and processes for reviewing the consequences of unintended change? | |  | |  | |
| Have you determined any/all outsourced processes and established related controls for external providers (suppliers/subconsultants/subcontractors) of products and services? | |  | |  | |
| Have you determined the documented information to be retained to the extent necessary to have confidence that the processes have been carried out as planned? | |  | |  | |
| **Clause 9 Performance Evaluation** | | **Yes/No** | | **Evidence & Comments** | |
| Have you established processes and methods for monitoring, measuring, analysing and evaluating QMS performance and effectiveness i.e., what, when, how, and by whom? | |  | |  | |
| Have you determined how evidence will be preserved? | |  | |  | |
| Clause 9.2 Internal Audit | | **Yes/No** | | **Evidence & Comments** | |
| Have you established a documented audit programme that defines timing, responsibilities, reporting, audit criteria and scope? | |  | |  | |
| Have you established a process to ensure results and evidence of implementation of the internal audit program/process are documented and available? | |  | |  | |
| Have you conducted internal audits to ensure that the organisation audits its own quality requirements and the requirements of the Standard? | |  | |  | |
| Clause 9.3 Management Review | | **Yes/No** | | **Evidence & Comments** | |
| Do you conduct and document regular management reviews of the QMS? | |  | |  | |
| **Clause 10 Nonconformity & Continuous Improvement** | | **Yes/No** | | **Evidence & Comments** | |
| Do you record all nonconformities, including initial correction, root cause and corrective actions? | |  | |  | |
| Do you continually improve the effectiveness of QMS using quality policy, audit results, analysis of events, corrective actions and management review? | |  | |  | |

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| **Mandatory QMS Documented Information** | **Yes/No** | **Evidence & Comments** |
| *Do you maintain the following mandatory documentation?* | | |
| Documented scope of the QMS (4.3) |  |  |
| Documented information to support operation of processes (4.4) |  |  |
| Quality Policy (5.2) |  |  |
| Organisational roles and responsibilities (5.3) |  |  |
| QMS Objectives, targets and plans to achieve them (6.2) |  |  |
| Competency evidence (7.2) |  |  |
| Operating Procedures (8.1) |  |  |
| Review of the Requirements for Products and Services (8.2.3) |  |  |
| Design and Development requirements (8.3.2) |  |  |
| Design and Development Inputs (8.3.3) |  |  |
| Design and Development Controls (8.3.4) |  |  |
| Design and Development Outputs (8.3.5) |  |  |
| Design and Development Changes (8.3.6) |  |  |
| Criteria For Evaluation, Selection, Monitoring of Performance, and Re-Evaluation of External Providers and Actions Arising From Evaluations (8.4.1) |  |  |
| Identification and Traceability (8.5.2) |  |  |
| Control of Changes for Product/Service Provision (8.5.6) |  |  |
| Release of Products/Services (8.6) |  |  |
| Control of Nonconforming Output (Products/Services) (8.7.2) |  |  |
| Evaluation, Measurement, Analysis and Evaluation Results (9.1) i.e., QMS Performance Including Trends and Performance against Objectives. |  |  |
| Internal audit (9.2) i.e., Schedule, Internal Audit Reports |  |  |
| Management Review (9.3) i.e., Agenda and Minutes |  |  |
| Records relating to Nonconformity and Corrective Action (10.2) |  |  |

##End of Checklist##