TOPCERTIFIER

Governance, Risk & Compliance Consultants

ISO 9001 GAP ANALYSIS TEMPLATE

INTRODUCTION:

TopCertifier presents a Simplified ISO 9001 Gap Analysis Checklist to assist you in pinpointing areas where your organization might require enhancements to conform with ISO 9001 standards. This checklist offers a fundamental framework for evaluating your alignment with ISO 9001:2015 and serves as an initial step in assessing your compliance.

SECTION 1: LEADERSHIP AND COMMITMENT

- ☐ Is there clear leadership commitment to quality and ISO 9001 compliance?
- ☐ Are quality objectives established and communicated to relevant personnel?
- ☐ Is there a defined quality policy reflecting ISO 9001 principles?

SECTION 2: PLANNING

- ☐ Are risks and opportunities related to the QMS identified and addressed?
- ☐ Are quality objectives measurable and consistent with the quality policy?
- ☐ Is there a documented process for QMS planning?

SECTION 3: SUPPORT

- ☐ Are resources (human, infrastructure) available for QMS implementation?
- ☐ Is there an awareness program for employees regarding ISO 9001?
- ☐ Are documented procedures in place for competence, awareness, and communication?

SECTION 4: OPERATION

- ☐ Are processes determined, documented, and consistently followed?
- ☐ Are criteria for product and service conformity defined and monitored?
- ☐ Is there a process for handling non-conforming products or services?

SECTION 5: PERFORMANCE EVALUATION

- ☐ Are internal audits conducted to assess QMS compliance?
- ☐ Are data and information collected and analyzed to evaluate QMS performance?
- ☐ Is there a process for conducting management reviews?

SECTION 6: IMPROVEMENT

- ☐ Are corrective actions taken when non-conformities are identified?
- ☐ Is there a process for continuous improvement based on QMS performance data?
- ☐ Is there a process for conducting management reviews?

SECTION 7: DOCUMENTATION AND RECORDS

☐ Are procedures and processes documented as required by ISO 9001?
☐ Are records maintained to demonstrate QMS conformity and effectiveness?
☐ Is document control in place to ensure the latest versions of documents are used?

Please note that this checklist provides a high-level overview, and it's essential to perform a thorough analysis specific to your organization's processes and context. Additionally, it's recommended to engage with ISO 9001 experts or consultants to conduct a comprehensive gap analysis for your organization.