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SERVICE METHODOLOGY ISO 9001:2015

QUALITY MANAGEMENT SYSTEM (QMS)

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INTRODUCTION TO ISO 9001

ISO 9001 defines the requirements for a Quality Management System (QMS). It helps businesses to consistently meet customer requirements by having well defined and documented policies and procedures, in turn improving the efficiencies and customer satisfaction. QMS assist companies in meeting statutory and regulatory requirements relating to their product while achieving excellence in their customer service and delivery. The standard can be used throughout an organization to improve the performance or within a particular site, plant or department

- An organization can meet the requirements of its customers and other stakeholders
- Promotes the idea of continual improvement
- Organizations to define the objectives and continually improve their processes and reduce the cost
- Reinforces use of the management system as a governance tool and will help identify business opportunities that contribute to bottom line improvements

KICKOFF

Kickoff meeting is an essential tool to communicate and plan for the execution of the project with minimal obstruction and to complete the project within planned time and cost.

Agenda for the kick off meeting is:

- Project plan discussion - This includes discussion about accountability and responsibility of stake holders. Milestones and deliverables in the project
- Scope of services and scope of certification
- Legal and regulatory requirements

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CREATION OF CORE TEAM

- Appointment of ISO Leader
- Appointment of Quality team
- Appointment of Internal Auditors

GAP ANALYSIS

During this phase we conduct a gap analysis to check how much of your current practices are in line with the requirements. Your current practices are verified against these four reference criteria.

- ISO 9001 standard requirements
- Legal, statutory, regulatory requirements
- Client requirements
- Internal policies and procedures

The results of this analysis are presented in the form of a Gap Analysis Report. This report acts as the list of action items for the reminder of the project.

QMS AWARENESS TRAINING

QMS awareness training will be conducted to the employees of your organization. The training session is to help employees to gain knowledge, understand the concepts of ISO 9001, and align processes and practice towards achieving higher customer satisfaction, via better understanding of the customer requirements and customer centered services. When staff have been trained they can think & act and contribute towards achieving the goals.

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QUALITY RISK ASSESSMENT (QRA)

A Risk Management procedure shall be documented and used as reference to manage the identified risks in consultation with all function heads. We use ISO 31000 techniques to identify, document, prioritize, quantify and the identify Internal and External risks. A thorough risk assessment is required to ensure effective risk control. This step creates a Risk Register.
Suitable mitigation plans are identified by using the hierarchy of risk control (Risk Management) based on the risk level, severity and likelihood. Establishment of proactive culture to improve the customer's satisfaction.

DOCUMENTATION

Our experts will list the policies, processes, SOPs, work instructions and records that need to be defined and documented as per ISO 9001.
By discussing with each department and function heads wecreate the necessary documentation. This would be followed by SOPs and record templates being made available for the team to operate and record the information.

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ESTABLISH CONTROLS

Once the policies, processes and SOPs, have been documented and list of records to be collected has been listed and personnel have been identified and trained on such activities, then the need is to operate, monitor and review the efficiencies of such processes.

INTERNAL AUDITOR TRAINING

ISO 9001 Internal Auditor (IA) Training will be provided to the identified personnel. This training will equip such personnel to analyze the need for IA, plan and schedule IA, prepare audit checklists, conduct an IA and to document and report their observations to the top management.

INTERNAL AUDIT

Our experts will oversee the conducting of internal audit by your internal audit team. This internal audit will identify still existing gaps in the system and demonstrate the level of preparedness to face the certification audit. This audit gives the organization a chance to identify and rectify all non-conformances before proceeding to the certification audit.

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ROOT CAUSE ANALYSIS (RCA) AND CORRECTIVE ACTIONS

All non-conformances identified during the internal audit, client or third party audits or from Risk Assessment, Customer Feedback, Complaints, Internal and External issues, daily walk through and any other sources have to be listed and a RCA to be performed using techniques like 5Why and Fish-Bone methods. The optimal correction and corrective actions are implemented and the effectiveness of such actions is documented and reviewed via a Corrective Action Report (CAR).
Our experts will be present with your team to guide through the process.

MANAGEMENT REVIEW MEETING (MRM)

The MRM is an opportunity for all stakeholders to meet on scheduled intervals to review, discuss and plan actions on the below agenda points.

- Risk Assessment
- Audit findings and non-conformances from all sources. Action plan to resolve any open items.
- Possible changes that might affect the system
- Improvements made to the system
- Resources, trainings required
- Opportunities for improvement
- External provider and supplier's performance
- Customer Satisfaction and Feedback from the relevant interested parties
- Statutory regulations
- Extent to which Quality objectives have been made
- Changes that could affect the system i.e. regulations or legislation

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CERTIFICATION AUDIT: STAGE 1

When the levels of preparedness has reached adequate levels, the process for certification begins. An appointed auditor of the Certification Body (CB) verifies the preparedness via a stage 1 audit. This involves the auditor reviewing the policies, processes, SOPs, Risk Assessment, critical operational records, IA and MRM records. Any major deviations from the CB's expectations will be notified at this point for brining in the necessary corrections.
This reduces the chances of major non-conformances during the certification audit.
TOPCertifier will by liaise with all stakeholders and oversee smooth completion of the audit.

CERTIFICATION AUDIT: STAGE 2

On successful completion of Stage 1 audit, the auditor embarks on a detailed audit of the practices and documentation of the QMS system of the organization. TOPCertifier would have trained your personnel on the audit requirements and on confidently facing the audit. Our experts will be present to assist in any means necessary for the smooth functioning of the audit. TOPCertifier will assist your team to close any non-conformances identified during the audit.
Upon successful completion of the certification audit, TOPCertifier will liaise with all stakeholders to draft, approve and release the final certificate.

CONTINUATION OF COMPLIANCE

TOPCertifier will be part of your organization's compliance journey and assist you at regular intervals with necessary trainings, system support and updations, internal and external audits and regular renewal of your certification.