

# SAMARTH CONSULTANTS

## ISO 9001:2015- Quality management System

### Overview

- It's a Quality Management System (QMS) Standard, published by the International Organization of Standards (ISO)
- It can be used by any organization, large or small, regardless of its field of activity.
- It provides guidelines for the development, implementation and management of a QMS
- It's the world's most popular ISO Standard
- It's updated every 5 years, and 2015 is the most up-to-date Standard

### Benefits

- The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.
- It ensures the ability of the organisation to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
- It facilitates opportunities to enhance customer satisfaction;
- It addresses risks and opportunities associated with context and objectives of the Organisation;

### Approach of Standard

- This standard is based on a number of **quality management principles (QMP)** including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement.
  - QMP 1 – Customer Focus
  - QMP 2 – Leadership
  - QMP 3 – Engagement of people
  - QMP 4 – Process approach
  - QMP 5 – Improvement
  - QMP 6 – Evidence-based Decision Making
  - QMP 7 – Relationship management
- This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.
- The process approach enables an organization to plan its processes and their interactions.
- The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement

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are determined and acted on.

- Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise
- Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

## **Implementation Steps**

1. Gap Analysis
2. Awareness Training
3. Quality Policy and Quality Objectives Finalization
4. Documentation/Process Design
5. Documentation / Process Implementation
6. Internal Audit
7. Corrective Action to close non conformances
8. Management Review Meeting
10. Stage 1 Audit by Certification Body
11. Corrective Action to close non conformances if any
12. Stage 2 Audit by Certification Body

## **Cost**

Cost of consultancy is ultimately determined by factors such as the organisation's size, its industry, number of employees, number of locations and choice of Certification Body.