International Standards Supporting Businesses

Quality Management Systems (ISO 9001)

UKaid
from the British people

Commonwealth Standards Network

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Challenges	Solutions
Over 90% of businesses globally are Small and Medium sized Enterprises (SMEs), they represent the majority of global employment and are an essential contributor to economic development in low and middle-income countries. However, some SMEs are not working at optimal levels of productivity, efficiency, safety, innovation, and compatibility and are therefore not gaining access to new markets and are not achieving their potential for growth and development.	International standards are primarily designed to address market needs, they are written for the benefit of users and their stakeholders and are applicable regardless of business size and location. They play an important role for SMEs by promoting productivity, efficiency, safety, supporting innovation, reducing costs, removing barriers to trade, and driving economic growth and development.
Poor management processes leads to SMEs not providing optimal quality, service, and price. This can result in SMEs being uncompetitive and cause reputational damage if customer and other stakeholder expectations are not met. Using management processes that are not internationally applicable can stifle trade and restrict access to new markets.	ISO 9001 'Quality Management systems' is internationally recognised and respected. It is one of the world's most widely used standards because businesses of all sizes and locations recognise that it helps them improve the quality of their products and services and consistently meet expectations of their customers and other stakeholders.
International standards are sometimes regarded by SMEs as a burden because there is a poor understudying of the likely costs and effort as well as the benefits that can be achieved.	The Commonwealth Standards Network (CSN) works in partnership with National Standards Bodies throughout the Commonwealth to communicate the benefits that can be achieved by SMEs through the use of international standards.

Standards are agreed ways of doing things

Standards

There are a huge range of subjects and activities covered by standards, such as: making a product, managing a process, delivering a service, or supplying materials. Standards are designed to make life simpler.

Like a good cookbook, standards are written by experts to help us complete processes in effective, tried and tested ways to achieve efficient, high-quality, repeatable outcomes that consistently meet expectations.

International standards

While standards are sometimes only applicable to specific countries and stakeholders, international standards (e.g. ISO and IEC) are designed to be globally applicable and widely available.

Key features of international standards:

- International standards are written as voluntary documents to assist users meet global market needs.
- They provide a vital tool for reducing barriers to trade by assisting businesses speak a common technical language, enhancing trust in supply chains and giving consumers and businesses confidence that goods and services meet their expectations.
- Although they are written as voluntary documents, they can be used to demonstrate compliance with mandatory regulations and therefore relieve regulatory burdens.
- They provide globally recognised legitimacy through being collaboratively developed by experts via an open and transparent process of global public consultation and consensus building.
- They can be supported through Quality Infrastructure*.

Trading relationships are built on trust.

International standards have become the international language of trade by providing confidence in products and processes to regulators, business partners and consumers locally and globally. They ensure everyone gets what they expect.

*Quality infrastructure

For standards to carry additional authority, they need to be correctly used in ways that give everyone involved a high level of confidence in the outcome. It is to enable that consistent rigour that the concept of National Quality Infrastructure (NQI) has emerged.

National Quality Infrastructures form a foundation for economic development and greater prosperity.

Standardization

Agreed, repeatable ways of doing something. Can be used as a voluntary tool to demonstrate compliance with mandatory regulations.

Conformity Assessment

Testing, verification, and certification processes for formal recognition that show the requirements of standards are being met.

Accreditation

Formal recognition that organisations can perform conformity assessment.

Metrology

Science of accurate measurement.

Market Surveillance

Checking and ensuring compliance of regulations.

International standards support SMEs

SMEs represent more than 90% of businesses and the majority of employment globally. They play an essential role in low and middle-income countries where they account for approximately 70% of jobs[2] and contribute up to 40% of national income[1].

Businesses are more successful with effective processes in place, regardless of size, location, or sector. International standards provide globally recognised best practice for effective processes, this brings benefits to SMEs, including:

- Enhance confidence by demonstrating to business partners, regulators, staff, and customers that your products and services consistently and measurably meet expectations.
- Access to markets is improved locally, regionally, and internationally when stakeholders all use the same international standard.
- Resilience is improved by using processes to identify, analyse, and evaluate risks.
- Profitability and competitiveness are increased through efficiency and productivity improvements.

International standards provide business development opportunities to SMEs and help them reduce risks.

[2] https://www.worldbank.org/en/topic/smefinance

ISO 9001 'Quality Management Systems' supports SMEs

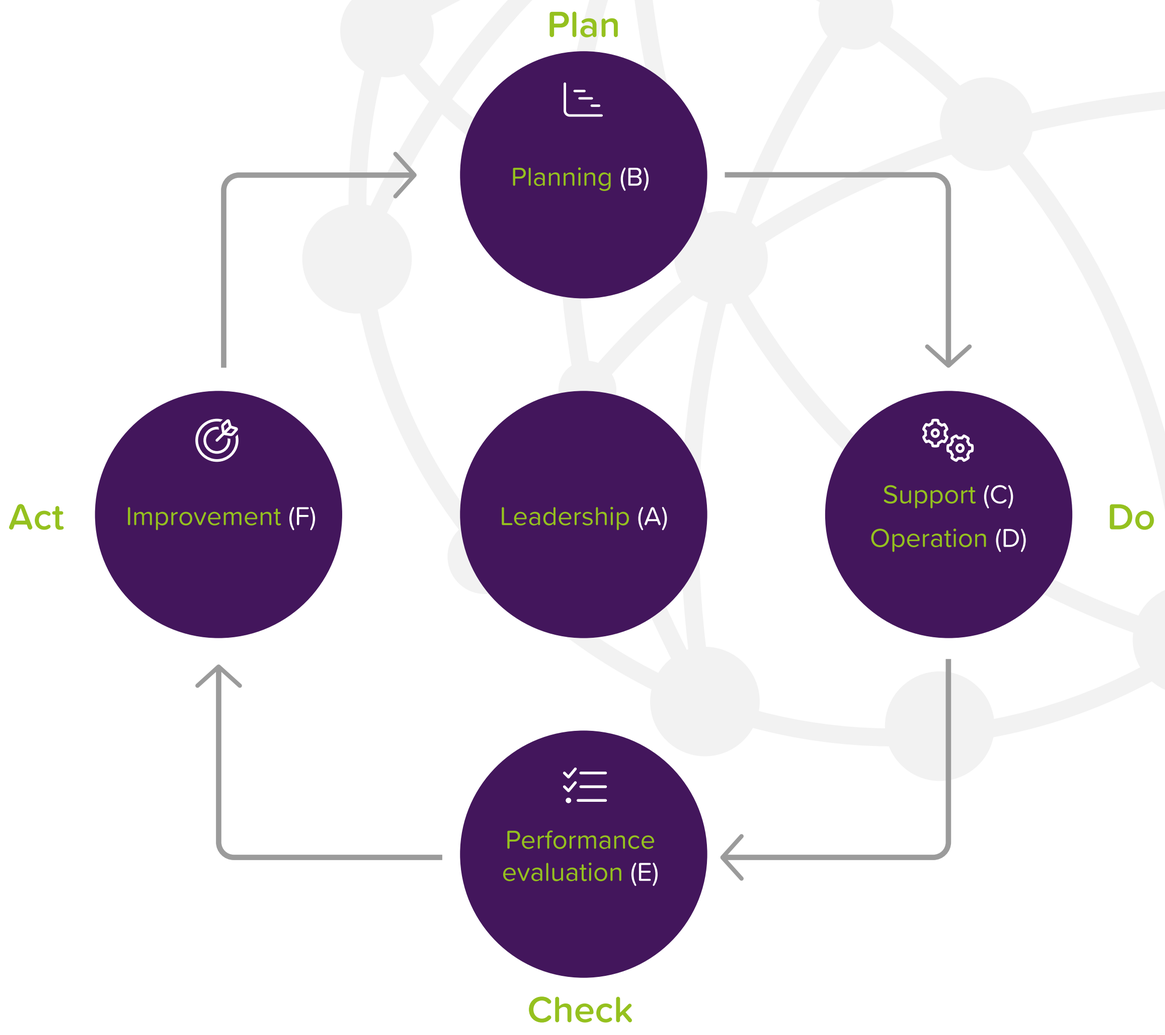
- Quality Management Systems (QMS) are ways of organising activities to achieve desired results.
- Effective QMS help SMEs ensure that their products and services consistently meet expectations for quality resulting in them being more competitive through gaining access to new markets, increased efficiency and productivity, and improving their reputation with business partners, regulators, employees, and customers.
- ISO 9001 'Quality Management Systems' is one of the most widely used international standards: used in almost every country on the planet by organisations of every size and sector because of the universal benefits it provides.
- The standard provides a framework to help organisations improve management practices that apply to them. It provides flexibility by highlighting processes that might need to be considered - but it does not specify exactly how to do them.
- ISO 9001 is designed to be applicable to any organisation in any location, and for any product or service type.
- A well applied QMS will add value and should not be an excessive burden or cost to an SME, it is investment that leads to a path of performance benefits. ISO 9001 helps SMEs follow a systematic approach to making improvements.

ISO 9001 is a business opportunity for SMEs to provide products and services that consistently meet expectations – leading to enhanced reputations with business partners, customers, and regulators.

Benefits to SMEs using ISO 9001:

- Consistently provide products and services that meet expectations of customers, business partners and regulators.
- Demonstrate conformity. Improved assurance, compliance, confidence and support for stakeholders.
- Process improvements via frameworks of continual improvement.
- Improved efficiencies.
- Enhanced customer satisfaction.
- Enhanced reputation with stakeholders including customers, regulators, and business partners.
- Effective identification and management of risks and opportunities.
- Increased employee engagement through improved awareness and clarity of roles and responsibilities.
- Improved access to global supply chains and markets.

- ISO 9001 is internationally recognised and promotes trade across national boundaries.
- Customers and regulators nationally and internationally can have confidence that they are provided with trusted information.
- ISO 9001 is a business opportunity for SMEs to provide products and services that consistently meet expectations – leading to enhanced reputations with business partners, customers, and regulators.
- ISO 9001 outlines quality management principles such as: Leadership, customer focus, relationship management, improvement, and process approach that support understanding of the value and importance of consistency of requirements, achieving effective processes, and implementing improvements based on effective evaluations.
- The 'Plan-Do-Check-Act' cycle supports the process approach and risk-based thinking. This approach establishes processes to achieve results and determines their risks/opportunities and mitigation:



The 'Plan-Do-Check-Act approach supports continual improvement through helping SMEs consider whether their processes are properly managed and resourced, that risks and opportunities are identified and managed, and that lessons learned are applied to future activities.

The risk-based thinking allows SMEs to regularly assess where their QMS processes are at risk – and how to prevent or minimise the effects of those risks.

Selected highlights of ISO 9001:

- Context of the organisation:
  - Understanding possible positive or negative influences on the organisation. These could include internal and external factors such as market changes, regulations, availability of resources or skills within the workforce.
  - Understanding the needs and expectations of interested parties can include anyone who has potential to impact on, or is impacted by the organisation. It is important to identify who these parties are and what their needs and expectations are.
  - Determining the scope of the QMS
  - QMS and its processes: Establish and maintain the QMS.
- A Leadership: Establish leadership commitment to ensuring that the QMS is effective and relevant to day to day operations of the business, that policies, processes and suitable resources are available with clear roles and responsibilities, and that the requirements of the system including focus on customer satisfaction and continual improvement are effectively communicated.
- B Planning: Activities must be planned with consideration to the identified risks and opportunities relevant to the QMS and achieve the expected requirements for products and services and the QMS objectives.
- C Support: To ensure the necessary resources are committed to the QMS.
  - People, infrastructure, environment of the processes, monitoring, measurement traceability, organisational knowledge, competence, awareness, communication, documented information.
- D Operation: Planning, implementing and controlling processes needed to meet requirements for products and services.
  - Requirements for products and services
  - Design and development
  - Control of nonconforming outputs.
- E Performance evaluation: To determine the performance and effectiveness of the QMS.
  - Monitoring, measurement, analysis and evaluation
  - Customer satisfaction
  - Internal audit and management review.
- F Improvement: Identification and implementation of opportunities to improve products or services, customer satisfaction or the effectiveness of the QMS.

ISO 9001 can be combined with other ISO management systems that use the Plan-Do-Check-Act cycle and risk-based thinking QMS standards such as ISO 22000 'Food Safety Management Systems' and ISO 45001 'Occupational Health and Safety Management Systems' to create an Integrated Management System, this enables SMEs to efficiently manage all Relevant Management Systems.

Evidence that you conform with the standard:

- ISO 9001 is a tool to support businesses. It is completely voluntary but can be further supported through Conformity Assessment, where testing, verification, and certification processes are carried out. This provides stakeholders with enhanced confidence and can lead to:
  - Improved opportunities within global markets.
  - Stronger collaboration with other certified organisations.
  - Further identification of improvements.
- SMEs should check that the organisation carrying out the Conformity Assessment is accredited by a reputable organisation[3], this will help ensure the quality of the assessment and reduce the risk of the assessment not being recognised by stakeholders.

Your ISO 9001 Journey

1. **Prepare:** Contact your National Standards Body (NSB), government departments, professional associations, ISO, or the CSN for more information on ISO 9001.
2. **Understand** Read the standard and build an understanding of how it sits within your existing activities, processes and objectives. Establish if any additional resources may be needed to implement standard requirements in your organisation.
3. **Implement:**
   a. Engage Top Management
   b. Identify how your business meets the requirements already and whether there are any areas that must be strengthened to implement an effective QMS.
   c. Train personnel (training programmes and gap assessments can usually be carried out by your NSB).
4. **Review** performance via the ISO 9001 Plan-Do-Check-Act cycle.
5. **Gain** certification via an accredited organisation, this can usually be arranged via your NSB.

Get involved:

- For international standards to be globally applicable and widely used it is important that the views of a diverse set of stakeholders (e.g. SMEs, consumers, academics) are represented in their drafting and revision processes.
- ISO 9001 is developed and maintained by an ISO Committee with working groups consisting of experts from across the globe that are nominated by their National Standards Bodies.
- Stakeholders that are interested in contributing to the development of international standards should contact their NSB, they generally manage National committees that 'mirror' the international committee to provide comments/ and formulate voting positions on the development of international standards.

About the Commonwealth Standards Network (CSN)

The CSN is a collaborative network that supports trade, economic growth and prosperity throughout the Commonwealth by promoting increased awareness, development and use of international standards.

To find out more about the network please see **www.commonwealthstandards.net** or contact the CSN Senior Programme Manager, Ben Hedley **ben.hedley@bsigroup.com**

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