

A word from the experts

What Standard is Right for You?

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The one thing in life we all know is that change is constant. Change can happen in every aspect of our lives whether it be personally or professionally. The world of standards and regulations is no different. There is a constant evolution of changes to existing standards and the creation of new standards to reflect changes in the ever-evolving regulatory landscape.

We often get asked why do we need certification to a standard? What standard should our company be certified to? What are the benefits of certification?

These are all great questions. The first point to consider is the type of business you are in. For some businesses, it is a legal requirement to have certification. An example would be for the sale of Medical Devices in Canada (ISO 13485:2016). Another factor to consider would be a business necessity. For example, some customers require their suppliers to have ISO certification in order to be qualified as a preferred supplier. Another reason for ISO certification is to remain competitive. These are all valid reasons but one of the best reasons in my opinion are the business benefits that are an output from building a certified quality management system.

Typical benefits include but are not limited to:

- Providing organizational structure and a standardized approach to procedures by adopting Standard Operating Procedures, Work Instructions and related training
- Key Performance Index (KPI) for monitoring, measurement and feedback for corrective actions if needed
- Adoption of a customer centric approach by engaging tools such as customer feedback, complaints management, internal audits, CAPA, etc.
- Common goals through the setting of a quality policy and communication of the company strategic vision
- Audit readiness for identifying and correcting issues BEFORE customer and compliance audits happen
- Personal ownership and accountability of issues
- Evidence that a 3rd party (ISO Registrar) has deemed your QMS to be effective by awarding the ISO certificate

The top three types of ISO certification are:

- **ISO 9001: 2015 Quality Management.** The **ISO 9000** family addresses the various aspects of quality management, and is one of the **ISO's best-known standards**
- **ISO 14000 – Environmental Management**
- **ISO 2700 Information Security Management Systems (ISMS)**

Did you know there are over 21,000 published ISO Standards? ISO certification will continue to evolve and change as our world changes and businesses need to understand and deploy as required.

Next month's blog will be how to implement change within a quality focused organization to ensure success. Stay tuned!

If you have any questions, please feel free to contact me at kelly.huckabone@thermofisher.com