ISO 13485 Certification

Certification of the quality management system is a confirmation from an independent, competent and accredited agency that the business adheres to the requirements of the internationally recognised quality management system standard. Certification by an external body creates trust and can increase revenue.

ISO 13485:2016 is designed to assist with the following:

- Meet customer and applicable regulatory requirements
- Safety and performance
- Identify and manage risks
- Enhance marketing
- Promote international trade

How does the certification process work?

The certification process consists of two phases:

- **Phase 1** includes of a visit to the business to review the status of the organisation, system documentation, infrastructure, etc. This assesses the maturity of the quality management system.
- **Phase 2** is the certification audit aiming to verify that the system documentation meets the requirements of ISO 13485 standard. The certification audit will give feedback to the organisation on issues that are not in conformance with the standard, and that need to be corrected before a certificate can be issued.

The certificate will be valid for three years after being granted. During this period, annual surveillance audits will be conducted.

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