SIMTEK
ELECTRONIC MANUFACTURING
FROM CONCEPT TO DELIVERY

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The benefits of dual quality certification

Medical Electronics now accounts for over half of Simtek EMS Limited's turnover and the company has invested heavily in the training of key personnel in workmanship standards now demanded within this sector, such as IPC-A-610 and IPC-7711.

The company has also recently gained certification to the ISO 13485 medical equipment manufacturing quality standard further enhancing the ISO 9001 certificate held for over 8 years.

What is ISO 13485 certification?

Most global medical device market regulators require manufacturers to implement a quality management system (QMS) as part of their product registration effort. In most countries, ISO 13485 certification is the preferred or required method of meeting QMS requirements for medical devices.

What is ISO 13485?

This international standard is based upon the ISO 9001 standard with specific requirements to meet regulatory needs. This standard, applicable on a voluntary base, was designed in particular for medical device manufacturers; ISO 13485 addresses most or all of the quality system requirements in markets including Europe, Australia, Japan and Canada.

The US Food and Drug Administration does not formally recognize ISO 13485 certification, but US Good Manufacturing Practice requirements overlap with the standard in many areas. ISO 13485 is also the basis for quality system regulations in other markets such as South Korea and Brazil.
The ISO 13485 standard, officially named EN ISO 13485:2012, can be used by organisations in the design, development and production process for medical devices but also related services. It can also be used by notification bodies to meet regulatory requirements.

Though replicating the format of ISO 9001, ISO 13485 switches the focus from customer satisfaction and continual improvement to standardisation of regulatory requirements for medical device manufacturers. ISO 13485 can be achieved by either upgrading from ISO 9001 or as a standalone certification.

ISO 13485 Certification

In Europe, ISO 13485 (or EN ISO 13485) is seen as the de facto standard for the medical device industry. Based on the broader ISO 9001 standard, ISO 13485 was first implemented in Europe in 1996. Although ISO 13485 certification is voluntary, obtaining certification allows you to meet the quality system requirements of the European Medical Device Directive (93/42/EEC), In Vitro Medical Device Directive (98/79/EC) and Active Implantable Medical Device Directive (90/835/EEC) with less difficulty.

However, it is important to note that while ISO 13485 is an international standard, certification in Europe does not mean that ISO 13485 certification is valid in other markets such as Canada or Japan. Many countries impose their own additional QMS requirements on top of those outlined in the standard. A company must meet those additional requirements – on top of ISO 13485 – to be certified to sell in those markets.
ISO 13485 requirements

In order to achieve ISO 13485 certification, a company must develop written policies for the following functions:
• Document and record controls
• Internal auditing procedures
• Controls for non-conformance
• Corrective and preventative actions
• Process and design controls
• Record retention
• Accountability and traceability

As ISO 13485 is implemented, it is important to bear in mind that ISO standards are updated periodically — revisions and updates do occur. As quality system standards are updated, you must ensure that your own QMS keeps up with those updates in order to remain in compliance.

ISO 13485 benefits

What can medical device manufacturers hope to gain from having ISO 13485 certification?:
• Access to markets that recognise or require the certification
• Reduce operational costs by highlighting process deficiencies and improving efficiency
• Increase customer satisfaction by consistently delivering quality products and systematically addressing complaints
• Proven commitment to quality through an internationally recognized standard
• Adds transparency to the way complaints, surveillance or product recalls are handled

Medical device manufacturers can benefit from being both ISO 9001 and ISO 13485 certified. While such manufacturers are not required to have ISO 9001 certification, it can bring further business benefits, because it focuses on business aspects that are good for all businesses - for example, the emphasis on customer satisfaction and continuous process improvement that an ISO 13485 management system omits.

Likewise manufacturing control and component traceability practices gained from ISO 13485 can further enhance what can be offered to customers from other non-medical markets that only have ISO 9001 as a basic requirement.

If regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. This is especially useful for CEMs such as Simtek who focus entirely on manufacturing products.

COMPANY INFORMATION

EMPLOYEES: **46**
TURNOVER: **£3,200,000**
AREAS SERVED: **National and International**
APPROVALS & CERTIFICATION:
BS EN ISO 9001:2008 & EN ISO 13485:2012

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