ISO 13485

MEDICAL DEVICES

Quality Management System

JC AUDITORS

www.jcauditors.com

info@jcauditors.com

+27 33 342 0529

+27 82 858 9995

ISO 13485
REGULATIONS

ACT 72 OF 2008; SEC 22C(1)(B)

the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device establishment, manufacturer, wholesaler or distributor of a medicine, scheduled substance, medical device, a license to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such medicine, scheduled substance, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.

ACT 101

The Medicines and Related Substances Act 101 as amended, requires a medical device establishment to hold an establishment license in recognition of the activities conducted by the organization. Such a license is issued upon the fulfilment of the regulatory model requirements that includes, but not limited to, managing a (scope-relevant) quality management system which meets the recognized international standard for medical device establishments, i.e. ISO 13485.

UNDERSTANDING ISO 13485

WHAT IS ISO 13485?

The international standard, ISO 13485:2016 Medical Devices – Quality Management Systems Requirements for regulatory purposes identifies the requirements for a quality management system that is used by an organization involved in one or more stages of the life-cycle of a medical device, including the design and development, production, storage and distribution, installation, servicing, final decommissioning and disposal of a medical device, design and development, or provision of associated activities.

While ISO 13485 is based on the ISO 9001 process model concepts of Plan, Do, Check, Act, it is designed for regulatory compliance; therefore it is more prescriptive in nature and requires a more thoroughly documented Quality Management System.

THE IMPORTANCE OF ISO 13485

ISO 13485 provides the manufacturer with a higher level of confidence in the ability to consistently achieve and maintain compliance with regulatory requirements. It can also help to minimize surprises and failures which might adversely affect patient safety and damage a manufacturer's reputation & marketability.

When it comes to medical device manufacturing, patient safety greatly depends on the quality and consistency of medical products, and ensuring effectiveness, control and maintenance of your QMS is critical to customers, stakeholders, patients and users, and regulatory agencies.

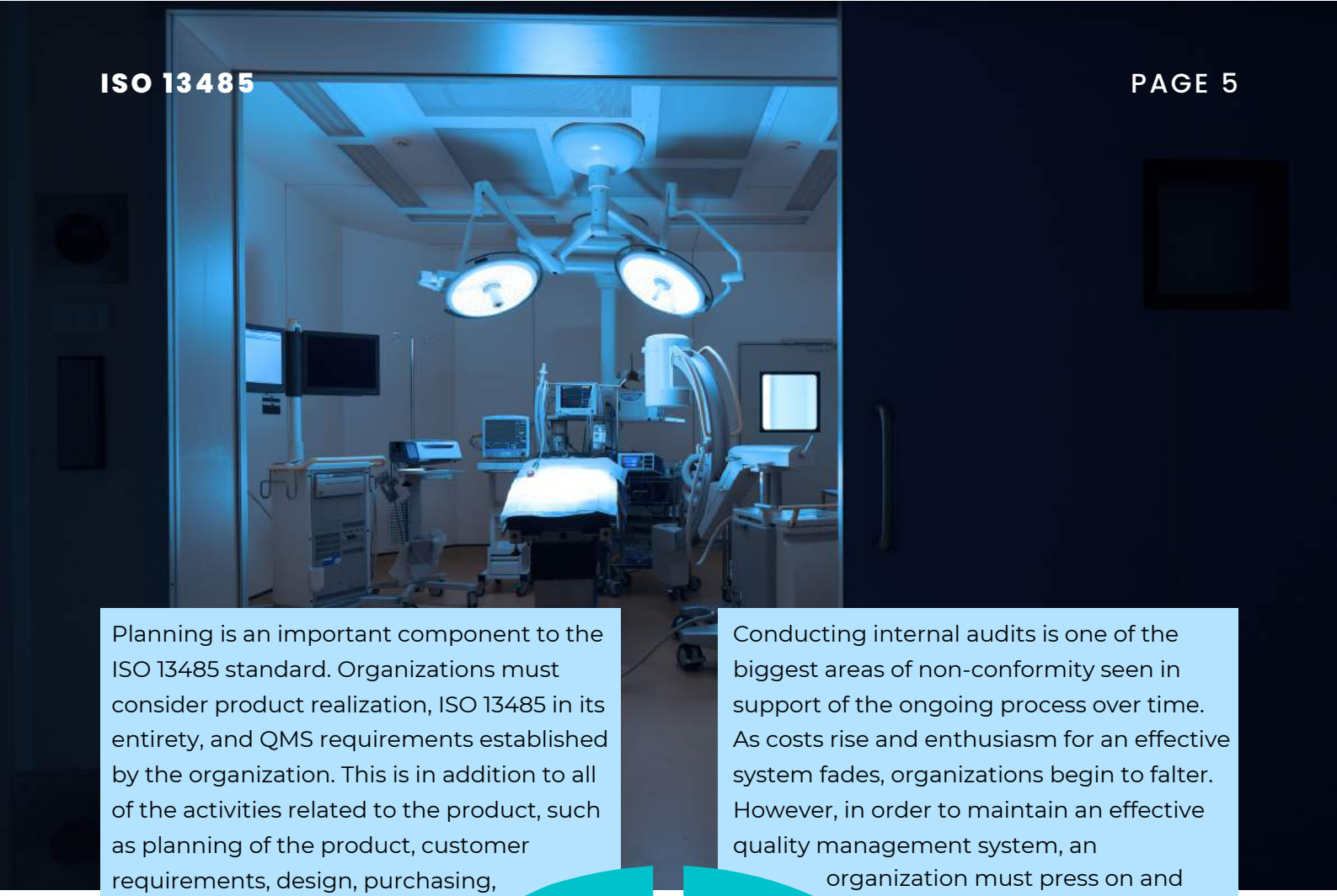
ISO 13485
ADVANTAGES

KEY BENEFITS OF ISO 13485

- Improve your company's credibility & identity
- Evidence-based decision making
- Continual improvement
- Increased employee involvement
- Enhanced customer satisfaction
- Increases your company's marketability
- Minimizes surprises & failure of devices
- Increased quality and consistency of medical products

THE PROCESS APPROACH

Rather than focusing on each individual clause of the standard, read the requirements in terms of inputs and outputs. ISO 13485 uses the Plan, Do, Check, Act methodology; each key area of the standard, such as quality system, management responsibility, resource management, product realization, and measurement, must be read in terms of inputs to the requirement (i.e. resource requirements) and outputs to the requirement (i.e. measurements). Only through careful study and understanding of the process model can you achieve this effective thinking approach.



Planning is an important component to the ISO 13485 standard. Organizations must consider product realization, ISO 13485 in its entirety, and QMS requirements established by the organization. This is in addition to all of the activities related to the product, such as planning of the product, customer requirements, design, purchasing, production, storage, and measuring, and any additional requirements

Conducting internal audits is one of the biggest areas of non-conformity seen in support of the ongoing process over time. As costs rise and enthusiasm for an effective system fades, organizations begin to falter. However, in order to maintain an effective quality management system, an organization must press on and conduct its internal audit plan.

The final step in conducting an effective internal audit focuses on understanding and measuring the effectiveness of the actions taken, and understanding and measuring the effectiveness of the internal audit process.

Once an internal audit is conducted, the results are reported, and actions to correct deficiencies must be processed immediately. Any causes for non-conformities must be eliminated.

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JC Auditors have conducted in excess of 5000 audits over the last 15 years. We are tried & trusted, upholding ethics and adding value.

CONTACT US

+27 33 342 0529

info@jcauditors.com

www.jcauditors.com

+27 82 858 9995

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