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ISO 13485

BENEFITS, REQUIREMENTS, AUDIT PROCESS

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WHAT IS ISO 13485?

ISO 13485:2016 is an international standard that sets out the requirements for a quality management system (QMS) specific to the medical devices and IVD industry.

The standard focuses on meeting customer and applicable regulatory requirements and is intended for any organization partially or fully involved in the medical device and IVD life-cycle.

BENEFITS OF ISO 13485?

- *Improve Credibility*
- *Assurance of high quality and safe medical devices*
- *Excellence in service delivery*
- *Evidence-based decision making*
- *Continual improvement*
- *Better communication*

BENEFITS OF ISO 13485?

- *Enhanced customer satisfaction*
- *Training and qualification with increased competence*
- *Increase profitability, reduction in wastage*
- *Control and evaluation of suppliers and service providers*
- *Implement effective risk management*

WHY DO WE NEED ISO 13485?

Enables compliance with relevant laws & regulations

Requirement to be certified by 16 January 2025 to renew or apply for an establishment license issued by the medical device and IVD regulator, South African Health Products Regulatory Authority (SAHPRA).

Documented in the medical device and IVD regulation published in 2016, included in the updated draft regulation open for comment until 25 November 2023.

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REQUIREMENTS

ADMINISTRATIVE CLAUSES

CLAUSE 1 - 3

Not auditable

REFERENCE

OPERATIVE CLAUSES

CLAUSE 4 - 8

Auditable

REQUIREMENTS

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REQUIREMENTS

CLAUSE 4 – GENERAL

4.1 General Requirements

4.2 Documentation Requirements

CLAUSE 5 – MANAGEMENT RESPONSIBILITIES

5.1 Management Commitment

5.2 Customer Focus

5.3 Quality Policy

5.4 Planning

5.5 Responsibility, Authority and Communication

5.6 Management Review

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REQUIREMENTS

CLAUSE 6 – RESOURCE MANAGEMENT

6.1 Provision of resources
6.2 Human Resources
6.3 Infrastructure
6.4 Work Environment and Contamination Control

CLAUSE 7 – PRODUCT REALIZATION

7.1 Planning of Product Realization
7.2 Customer Related Processes
7.3 Design and Development
7.4 Purchasing
7.5 Production and Service Provision
7.6 Control of Monitoring and Measuring Equipment

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REQUIREMENTS

CLAUSE 8 – MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

8.2 Monitoring and Measurement

8.3 Control of nonconforming product

8.4 Analysis of data

8.5 Improvement

THE AUDIT PROCESS – WHAT TO EXPECT

STEP 1 - APPLICATION PROCESS

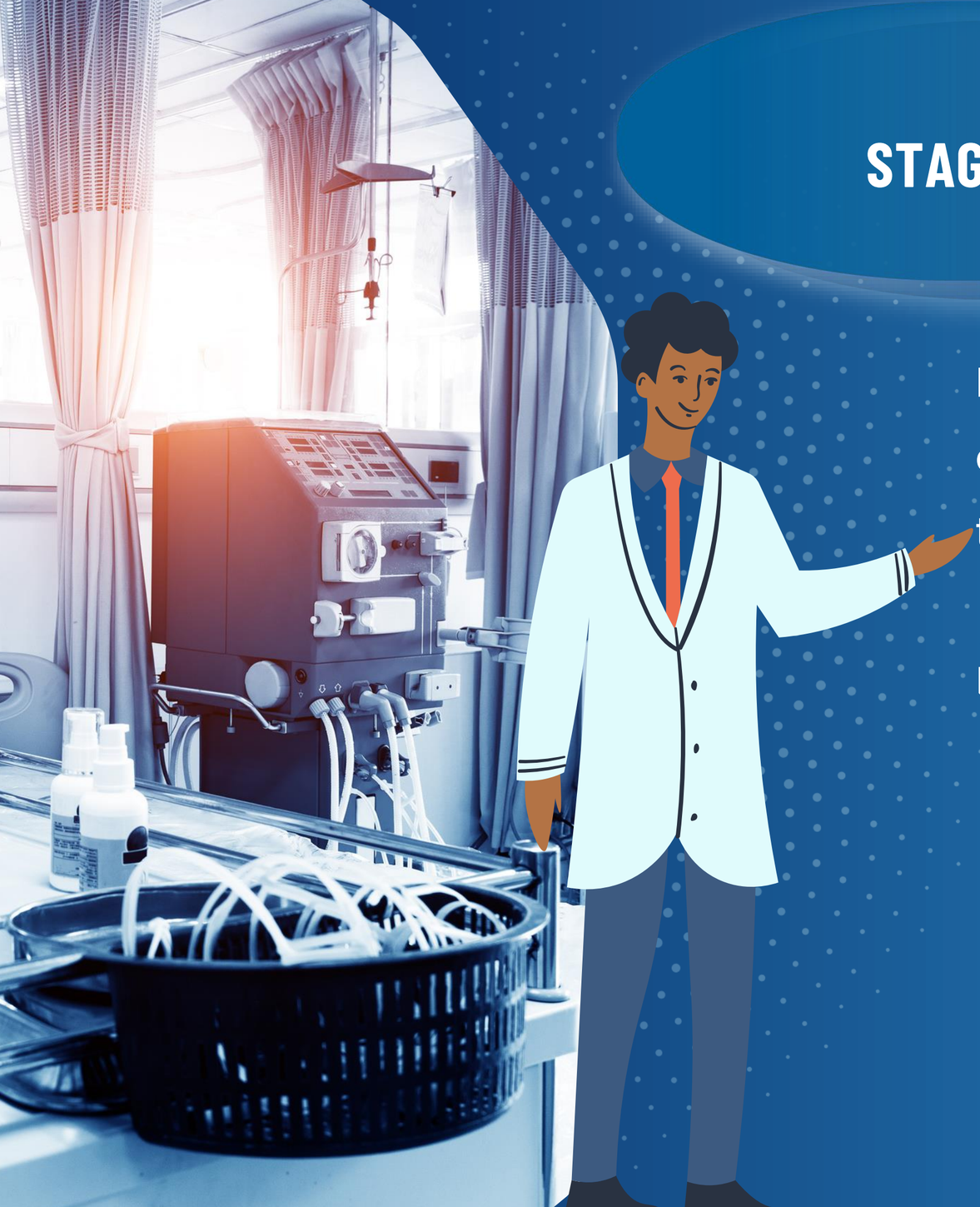
- ❑ Introductory Email
  - Application Form
  - Brochures
  - Certification Process
- ❑ Review
- ❑ Quotation
- ❑ Certification Agreement

THE AUDIT PROCESS - WHAT TO EXPECT

STEP 2 - CERTIFICATION PROCESS

- ❑ Audit Dates
- ❑ Prepare Audit Pack
  - Registers
  - Report Templates
- ❑ Stage 1 Audit
- ❑ Stage 2 Audit
- ❑ Review
- ❑ Certification

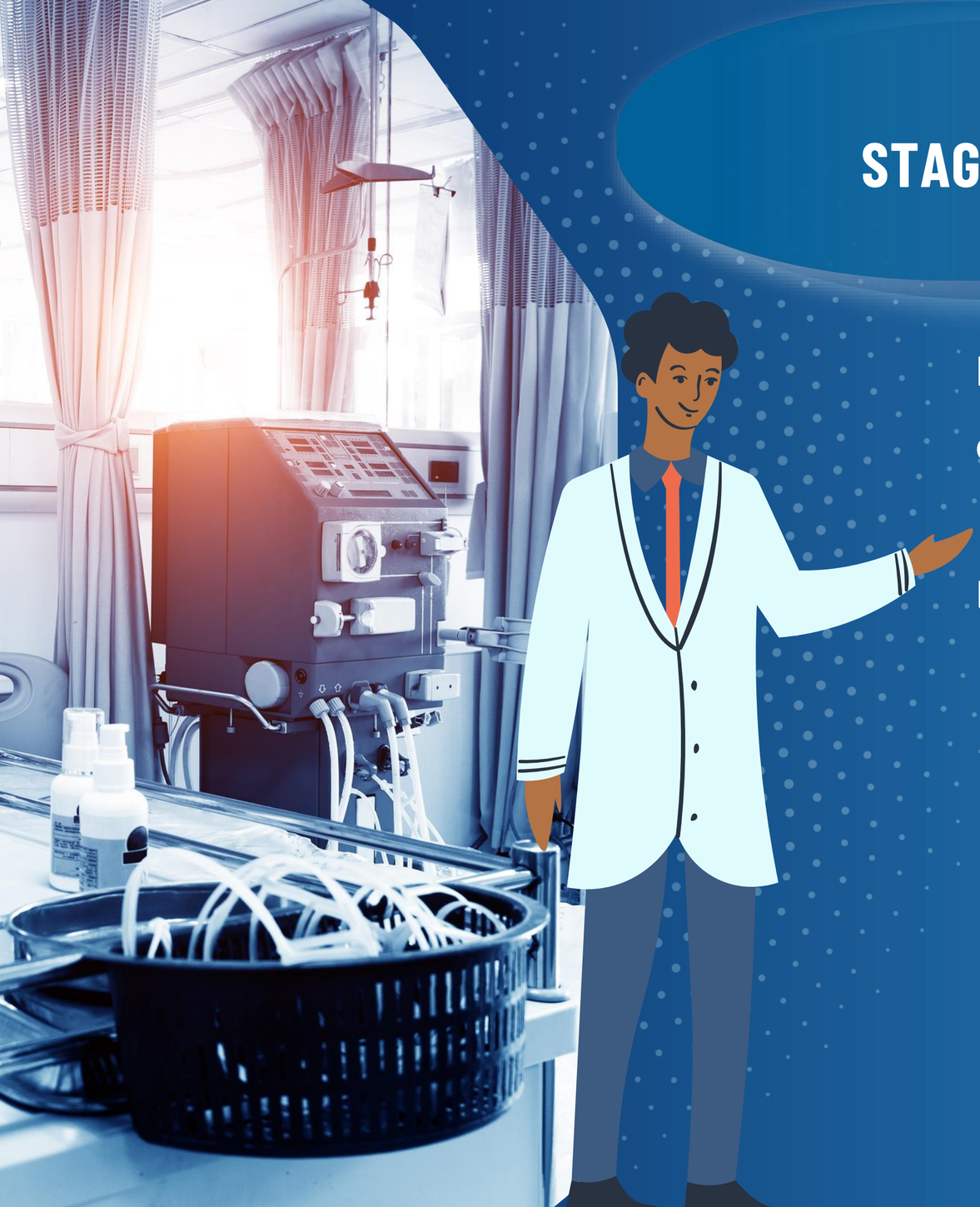
STAGE 1 OF THE AUDIT



Intended to - Assess that the auditee has a documented management system, which is compliant to applied standard.

❑ Ensure that:

- Documents are in place, required (manual, policy, objectives) and processed based
- Internal Audits and Management Review are conducted
- Communication from customers / external interested parties is documented / responded too



STAGE 2 OF THE AUDIT

Intended to - Address the implementation of all the elements in the standard

❑ Focus on:

- Implementation of the QMS
- Performance monitoring, measuring, reporting & reviewing (requirement, objectives, and targets)
- Operational control
- Improvement and its effectiveness
- Staff awareness, training, competence

THE AUDIT PROCESS – WHAT TO EXPECT

STEP 3 – POST CERTIFICATION PROCESS

- ❑ Client Pack
  - JCA Brochure
  - Use of Logo
  - Certification Marks
  - Certificate
  - Client Feedback

3 YEAR AUDIT CYCLE

YEAR 1 – CERTIFICATION AUDIT

YEAR 2 – SURVEILLANCE AUDIT

YEAR 3 – SURVEILLANCE AUDIT

ISO 13485 AUDIT CYCLE

FREQUENTLY ASKED QUESTIONS

1. **What is the cost of an audit?**
   Determined by scope, number of employees

2. **When selecting a certification body (CAB), what do I need to look for?**
   - *Must be accredited by South African National Accreditation System (SANAS)*
   - *Must appear on the List of Recognized Conformity assessment bodies by South African Health Products Regulatory Authority (SAHPRA)*
   - *Ask for auditor experience in medical devices and IVD industry*

3. **How much time elapse between Stage 1 and Stage 2?**
   - *Determined by the auditee*

FREQUENTLY ASKED QUESTIONS

4. How much time is allowed to address non-conformities raised during the audit?

- *For ALL non-conformities – Need to submit a plan to address after the audit*
- *Minor non-conformities – Must be addressed by the next audit*
- *Major non-conformities – Must be addressed within three (3) months*

5. How much time do I need to get a QMS and certification in place?

- *With a dedicated resource with expertise:*
  - *Create a QMS in three to six months*
  - *Implement the QMS in three to six months*
  - *Audit and certification process in three to six months*

TAKE NOTE: Minimum time – ±9 months to certification – Time is crucial!!!

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