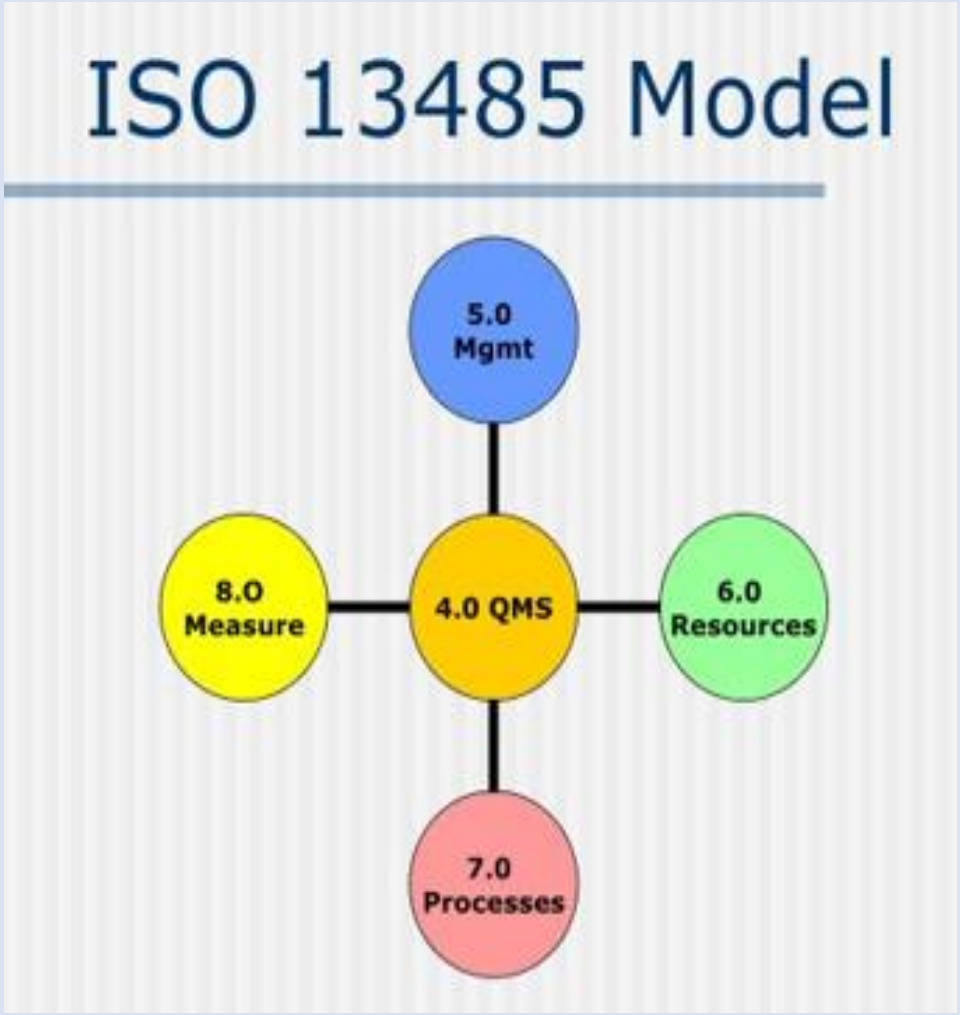
IBRATSA
Institute of Bio Research, Auditing and Training in Southern Africa.

SAATCA CORPORATE MEMBER
Membership Number : M058

IBRATSA offers Public Training on:
Understanding & Implementation of ISO 13485 Standard



ISO 13485 Course Outline

- Introduction to ISO 13485 Medical Devices Quality Management System (MDQMS)
- Initiation of and Planning for the Implementation of a MDQMS
- Implementation of a MDQMS
- Monitor, Measure & Analyse Data
- Continually improve MDQMS processes

Course Structure

- This is a 5-day course. The pre-requisite for this course is a Secondary education or equivalent.
- Theory & Activities & End of day Formative assessment – Day 1 to Day 4
- Summative assessment – Day 5.

Significance of the Course

This course provides in-depth understanding of the ISO 13485 Standard. Additionally, it offers an Implementation approach that has led to project completion in defined timeframes.
This is a pivotal course for any economic player in the Medical Devices industry planning on implementing ISO 13485 QMS.

With the Certification deadline timeframe of 2025, as issued by the regulator, SAHPRA, there is no better time to embark on training as the first step towards the Certification goal.

Objectives

To produce competent individuals with the confidence to develop & implement their organisational QMS by using up-to-date theory, industry expert lecturers and syndicate working groups to ensure direct application to the business.
Activities & Assignments are “fit for purpose” and will be able to be taken back to the business for implementation.

Who should attend?

- Quality Managers; Regulatory Managers ; Section Heads
- Others as Identified by the Organisation

Contact details *email: info@ibratsa.co.za ; Tel: 012 472 0033; Web: www.ibratsa.co.za*

APPENDIX 1: TRAINING COURSE: MODULE 1 CONTENT

The Proposed training course outline is given below:

ISO 13485 Understanding & Implementation Training Course Outline

PART 1		
DAY 1	**Specific Outcome 1**	**Introduction to ISO 13485 Medical Devices Quality Management System (MDQMS)**
	Assessment Criteria	• Standards and regulatory frameworks ➢ Management System Standards & ISO Structure. ➢ Benefits of QMS. ➢ Brief History of ISO13485 & Scope of ISO 13485 ➢ Key Terms & Definitions. • The principles of quality and their applications are discussed to ensure their effective implementation within an organisation • Key quality concepts ➢ The concept of Plan-Do-Check-Act (PDCA) is discussed using examples. ➢ The process approach. ➢ Risk-based Approach • Understanding ISO 13485 MDQMS Clauses 4-8. • Classroom Activities
PART 2		
DAY 2	**Specific Outcome 2**	**Initiation of and Planning for the Implementation of a MDQMS (PLAN)**
	Assessment Criteria	• Re-Cap of Day 1 • Initiate the MDQMS • Understanding and analysing the Organisation and its context • Management Commitment • Define Scope of MDQMS • Required QMS Documentation • Risk Management • Classroom Activities •

DAY 3	**Specific Outcome 3**	**Implementation of a MDQMS (DO)**
	Assessment Criteria	• Manage resources • Bring awareness and communication • Manage Documents • Plan for Product realization • Determine Product & Service Requirements • Design and Development processes • Purchasing processes • Provide products & services • *Formative Assessment*
DAY 4 :	**Specific Outcome 4**	Monitor, Measure & Analyse Data (**CHECK**)
	Assessment Criteria	• Monitor and Measure products and processes • Conduct internal audit • Conduct Management Reviews • Report to regulatory authorities
	Specific Outcome 5	Continually improve MDQMS processes (**ACT**)
		• Control non-conformities • Continual Improvement • Revision
	DAY 5 :	
	Summative Examination	

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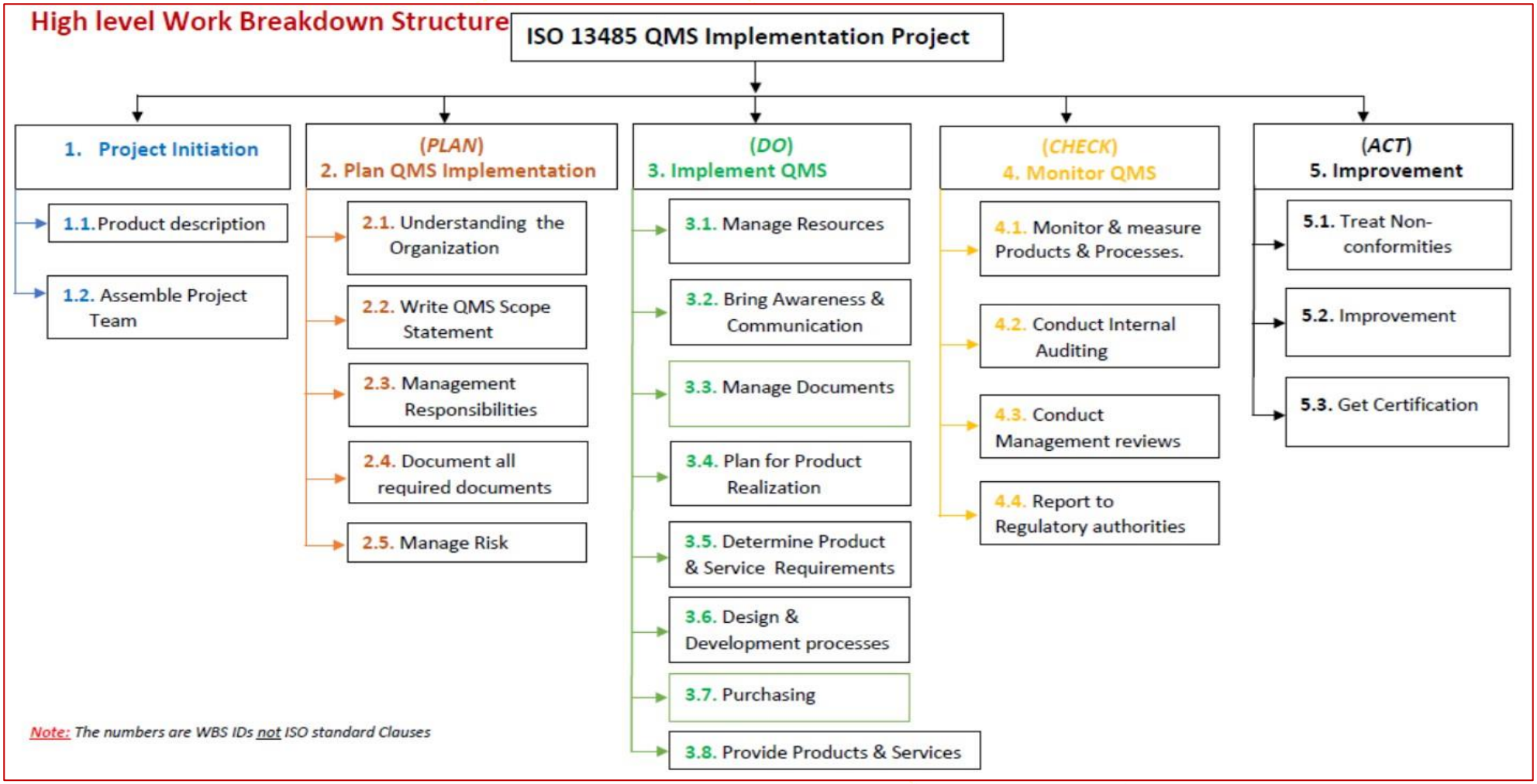

222 Corobay Avenue,Waterkloof Glen, Pretoria 0100.
Email: info@ibratsa.co.za, Tel: +27 12 427 0033,
Director: Dr Felistas Mashinya Ph.D