

Doc Number: QMS01	QUALITY POLICY STATEMENT	SAHPRA South African Health Products Regulatory Authority
Revision: 2.0		Effective date: 06 June 2025

The South African Health Products Regulatory Authority (SAHPRA) is responsible for the:

- Regulation of health products intended for human and animal use.
- Licensing of manufacturers, wholesalers and distributors of medicines, medical devices, radiation emitting devices and radioactive nuclides; and
- Conduct of clinical trials.

Our organisation is committed to providing the highest standard of regulatory services to all customers. This will be achieved through the use of guidelines, policies, processes, and procedures, which guarantee an effective quality management system that conforms to the requirements of ISO 9001:2015 and other applicable requirements.




Continual improvement, reliable service and meeting customer requirements inspire all our efforts in ensuring quality, safety and efficacy of all regulated health products used in South Africa.

SAHPRA shall therefore commit adequate required resources for implementing, maintaining, and continually improving the quality management system to achieve set objectives; and maintain an adequate workforce that is trained, motivated, and empowered to achieve results.

Actions required for Top Management includes:

- Supporting the QMS and actively promoting the agenda by defining and communicating the Quality Policy, by communicating the importance of effective quality management and of conforming to the quality;
- management system requirements;
- encouraging the establishment and monitoring of Quality objectives;
- ensuring appropriate resources are available; and
- ensuring the focus on enhancing customer satisfaction is maintained.

This quality policy shall be communicated to all SAHPRA employees and shall be reviewed annually for continuing suitability.

AUTHORISATIONS			
Role	Name and Surname	Signature	Date
Prepared by QMS Manager:	Ms Duduzile Ntoko	 <small>Duduzile Ntoko</small>	
Reviewed and recommended for approval by COO:	Ms Christelna Reynecke	 <small>Christelna Reynecke</small>	
Approved by CEO:	Dr. Boitumelo Semete Makokotlela	 <small>Boitumelo Semete Makokotlela</small>	