The QUARTET

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ISO 13485 MEDICAL DEVICES

In the complex and crucial field of healthcare, maintaining high standards of precision, safety, and reliability is of utmost importance. Adherence to strict quality standards is non-negotiable. One of the most critical certifications in this domain is **ISO 13485**. This globally recognised standard is specifically designed for the medical device industry. **SANCERT** has obtained accreditation for this standard from SANAS and is in the process of registering with SAHPRA (South African Health Products Regulatory Authority) as an accredited certification service provider. We have developed a cost-effective approach for carrying out ISO 13485 accredited certifications for all SAHPRA members. This will become a mandatory requirement by the end of 2025, therefore anyone operating in the medical devices space should consider this.

ISO 13485 outlines the complete requirements for creating and maintaining a quality management system (QMS) that is tailored to the needs of medical device manufacturers, repair operations, importers, and suppliers. Being compliant with this standard shows the commitment of an organisation to maintain the **highest standards of quality, safety, and regulatory compliance** throughout the lifecycle of its products.

In an industry subject to stringent regulatory oversight across jurisdictions, ISO 13485 certification serves as a **foundational framework for meeting regulatory requirements**. It harmonizes with regulatory frameworks worldwide, including the European Medical Device Regulation (MDR) and the U.S. Food and Drug Administration (FDA) Quality System Regulation (QSR), facilitating smoother regulatory approvals and market access.

ISO 13485 certification assures healthcare providers, patients, and regulatory bodies that medical devices are reliable and safe. It signifies rigorous quality assurance processes, and adherence to industry best practices and standards, leading to improved patient outcomes and satisfaction.

ISO 13485 places a strong emphasis on **risk management** throughout the product lifecycle. By systematically identifying, assessing, and mitigating risks associated with medical devices, manufacturers can proactively address potential hazards and ensure the safety and efficacy of their products, minimizing the likelihood of adverse events or recalls.

ISO 13485 certification serves as a passport to **global markets**, facilitating access to international markets and enhancing competitiveness on a global scale. In an industry where even the smallest oversight can have profound consequences, ISO 13485 certification stands as a beacon of **quality, safety, and reliability in medical device manufacturing**.

By adhering to this rigorous standard, organizations demonstrate their unwavering commitment to excellence, regulatory compliance, and the well-being of patients worldwide.

QUality and Reliability Through Expertise and Teamwork

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