SAMED

advancing patient care through MedTech

CHEAT SHEET GUIDANCE FOR MEDICAL DEVICES

Frangie Letsoalo

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PRIVILEDGED & CONFIDENTIAL

FINAL MEDICAL DEVICE REGULATIONS AND IMMINENT REGISTRATION

- Are you concerned that the clock is moving too slow or moving forward and backwards with no progress?
- Do you feel as though your business is swimming just above the sharks and oblivious of what is happening at the bottom of the ocean?
- Are you anxious about the impending final regulations and registration call up?
- No need to panic the clock might be on time instead you need to:-
  - ✓ Stay Compliant
  - ✓ Stay informed
  - ✓ Stay Prepared
  - ✓ Actively Participate
  - ✓ Establish sound relationship

CHEAT SHEET GUIDANCE FOR MEDICAL DEVICES

- **Stay Compliant** – Even though devices are not registered and no active surveillance, we still need to avoid violating the act, existing rules & regulations {**Reg 29(3)}.**
- **Stay Informed** – learn about the Global harmonized standards and understand regulatory and technological changes.
- **Stay Prepared** - Conduct Regulatory self-audit. Make scenarios, what will we do if this happens?
- **Active Participation** – network, forums, webinars, training, conferences etc.
- **Establish Relationship** – engagement with regulatory authorities and notified bodies, industry forums to foster a common understanding.

NAVIGATING THE REGULATORY FIELD

- **Establishment Licenses**:
  - ✓Monitor your channel partners (SAHPRA registry/request)
  - ✓Authorized representative – adequate skills to align with responsibilities
  - ✓**License renewal: QMS certification requirements - request for extension**?
- **Listing : classification**
  - ✓ Ensure you get the right classification and consider all the rules
  - ✓ Instances where classification in SA is different to the one in other countries – *local will take precedence*
  - ✓ Attention to Rules 13, 14, 15 & 16—Additional rules, as these rules may not be applied consistently internationally

MAINTAINING REGULATORY COMPLIANCE

- **Change Management**

  ✓Capture, Trigger Alerts and "Automate" Risk/Impact Assessments

  ✓Map Tasks and Determine the Effects of Changed Requirements

- **License amendment**:

  ✓ Notification versus Approval process

  ✓Modification of and change in the approval status or certification of the Class C or Class D medical device in the jurisdiction/s submitted for support of license application

  ✓Modification of GMDN term – you can consider whether or not to chose an alternative Term for your product. Notification

NAVIGATING THE REGULATORY FIELD

- Compliance with local and international Medical Device and Conformity Assessment Standards
  - ✓Essential Principles for quality, safety and efficacy
  - ✓Verification, Validation, sterilization validation report,
  - ✓PMS, PMCF plans/reports. PSUR
  - ✓Risk Management Report
  - ✓Vigilance – adverse event reporting and recalls

Optimism and confidence is not evidence; Regulator and auditors will be looking for plans, data, records and reports.

“If you think Compliance is expensive, try Non-compliance”

NAVIGATING THE REGULATORY FIELD

Quality Management System

- Should not be seen as the set of procedures that define the rules and restrictions that must be followed
- Avoid implementing a QMS that is largely rule-based, restrictive, cumbersome, and largely ineffective.
- Don't implement a QMS because you feel you are more or less forced to comply with applicable regulations governing medical device industry.

QUALITY MANAGEMENT SYSTEM

- Improve the conventional approach for establishing a QMS that addressing compliance to regulations
- Your QMS must be set of processes ensuring that you run a better and more efficient business.
- focus on true quality and what is best for the patients – the recipients of the medical devices.
- When you shift your focus to what is best for the patient, then compliance becomes a natural by-product.

Should you follow the requirements defined in ISO 13485:2016 and become certified? Technically, no you don't have to.

But……doing so will help you run a better business where patients will receive benefits.

REGULATORY REQUIREMENTS IN ISO 13485:2016

- Clause 4.1.: QMS must include the requirements for roles undertaken by the organization for **applicable regulatory bodies**.

- Clauses 5.6.2 & 5.6.3 - management review must include reports **to regulatory bodies** as inputs; and, as outputs, any necessary changes in response to new or changing issues with regard to relevant **regulatory bodies**.

- Clause 7.5.9.1: traceability of measurement must be maintained according to the needs of relevant **regulatory bodies.**

REGULATORY REQUIREMENTS IN ISO 13485:2016

- Clause 7.2.2 : requirements for products and services should include requirements from **applicable regulatory bodies**.
- Clause 7.3.3, 7.3.7 & 7.3.9 : the design and development process to consider **the requirements of regulatory bodies,** such as the level of control that is expected in the process.
- Clause 8.2.3: advisory notices must be made available to applicable **regulatory bodies** as appropriate.

TO CONCLUDE

“Not to know is bad. Not to wish to know is worse”

“Ignorance of the Law excuses no man”

“Beware of false Knowledge; it is more dangerous than ignorance”

THANK YOU