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MedDevREG AFRiSUMMIT

4th - 5th November 2025

Hilton Grand Nile Hotel, Cairo - Egypt

MDMSA

VOICE of the Industry Medical Device associations & strategies

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The **Medical Device Manufacturers** industry association of **South Africa (MDMSA)** is a local medical technology, not for profit, membership-based association.

When a member company joins MDMSA, there are 3 main areas that thev benefit from namely:

Strategy

to provide this industry with a unified and respected **VOICE** in order to champion the use of safe and effective locally manufactured medical devices to deliver affordable high-quality patient outcomes.

to **ENGAGE** with government, regulators, key industry stakeholders and other industry related associations, both in South Africa and abroad, in order to represent the local manufacturing industry and ensure that locally made devices meet International Standards and requirements.

to ensure that we identify the key issues and opportunities, develop and propose practical **SOLUTIONS** that protect the balance between patient benefits, safety, ethics, technological innovation and market access in a global market.

PRODUCTION supply chain

- The network of all the individuals, organizations, resources, activities and technology involved in the creation and sale of a product.
- A supply chain encompasses everything from the delivery of source materials from the supplier to the manufacturer through to its eventual delivery to the end user.

Local Manufacturing

The role of manufacturers;

- Manufacturers – a legal entity with legal obligations
  - Where medical device [inc IVD] is “**placed on the market** under the natural or legal person's own **name**, or in the name of a firm”
- Manufacturers aligned to definition of “medical device”
  - (a) intended by the **manufacturer** to be used, ….
- **Economic Operators** are not restricted to the word “manufacture” where;
  - many activities of production (inc Distribution/ delivery) can be “Outsourced” Clause 4.1.4. ISO13485
  - Installation, servicing, packaging – part of manufacturing “realisation” ISO13485 Clauses 7.5.3 & 4
  - Labelling, packaging and delivery (distribution) ISO13485 Clauses 7.5.1 e) & f)
- **Product compliance and Labelling**
  - Aligned to clinical evidence and safety and performance principles (Declaration of Conformity)

REGULATORY considerations

✓**medicines produce a pharmacological, metabolic, or immunological effect on the body by interacting with its chemistry**
✓ **medical devices work mechanically, or through other non-chemical means, to diagnose, prevent, monitor, or treat a condition**

Using old legislations from Pharmacopeial history to modern standards and technology aligned to quality management

Aligning establishment licensing and product registration to medicines not appropriate as medical devices are not medicines

3 pillars of legislation for AFRICA to enable affordability and access

1. Unified

2. Smart

3. Impact Driven

✓**medicines dispensed and sold through by pharmacies / pharmacist**
✓ **medical devices depend on intended use which can be HCP / layperson and navigate through retail and healthcare market**

www.researchgate.net/figure/**Comparison-of-industry**-characteristics-between-the-pharmaceutical-and-medical-technology_tbl1_262872003

Pharmaceutical industry	Medical technology industry
Established, old industry	Relatively young industry
Dominated by large multinational companies	80 % SMEs
Limited number of products	500,000 products in 10,000 generic product groups
Innovation occurs in laboratories	Innovation occurs from clinicians' insights
Product lifetime and investment recovery period is rather long	Investment recovery period can be as short as 18 months for medical devices with incremental improvements
Rather low distribution costs	Rather high distribution costs
Limited training, education and service requirements	High training, education and service requirements
Efficacy and efficiency of product proven in clinical tests before product launch	Efficacy and efficiency more difficult to prove; results obtained depend on skills and experience of the physician

Activities of manufacturers

- Place the product in the market
- Compliance to the essential principles of Safety and Performance
- Compliance to regulatory pre and post market requirements (labelling, safety and performance principles – GMP
- Operational production and market access interventions; QMS
- Attest the “declaration of Conformity”

Management system differences

medical devices typically having shorter product life cycles and requiring a quality management system aligned with ISO 13485 to manage risk (classification of device), while medicine manufacturers operate under different pharmaceutical Good Manufacturing Practices (GMP) and follow different scheduling systems based on active ingredients and safety profiles.

MEDICINES	**GMP** **SMF** **Product technical cycle the same (recipe, clinical trials, Pharmacopoeia standards** Pharmacokinetics - the study of what the body does to the drug Pharmacodynamics - the study of what the drug does to the body.	**Medical Device**	**QMS [ISO13485]** **Manufacturers obligation to principles of safety & performance** **Usability, ISO performance standards**

Progression

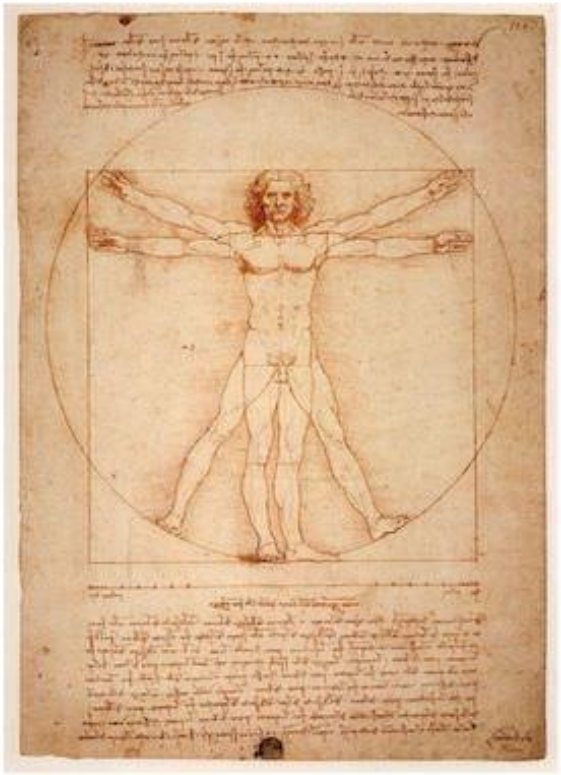
"the process of developing or moving gradually towards a more advanced state"

Renaissance

- Learn from the past - History
- Embrace the present – move with Technology
- Keep it Simple - minimizing complexity to make something easier to understand, use, or achieve.
- Keep up to Date - stay informed about the latest or most current information, trends, or developments.

Quality Management System Pu

1. determining the needs and expectations of **customers** and other interested parties;
2. establishing the quality **objectives** for the organization;
3. determining the **processes, resources and responsibilities** necessary to attain the quality objectives;
4. establishing and applying methods to **measure and determine the effectiveness and efficiency** of each process;
5. determining the means of **preventing nonconformities and eliminating their causes**; and
6. establishing and applying a process for **continual improvement** of the quality management system.
7. creates **confidence** in the consistent capability of its processes and the quality of its products, and it provides the basis for continual improvement.
8. leads to increased satisfaction/ confidence of customers and other interested parties and to the **success of the organization**



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SIMPLICITY IS THE ULTIMATE SOPHISTICATION.

LEONARDO DA VINCI

Smart & Impact driven

“a major problem or controversial issue which is obviously present but is avoided as a subject for discussion”

1. Device regulations an off shoot of historical drugs legislation (scissors can be stationery, needles, screws, nails are also home items … but also packed and sterilized for surgery - stationery & home items have no risk restrictions)
2. NRA fees for each country can not be the same as the high population mature of jurisdictions as in FDA, EU can fund a regulator empire but low AFRICAN populated countries can no afford

RISK class the basis of regulation and conformity assessment

Table 1. A common framework for medical device regulations

STAGE	PRE-MARKET	PLACING ON-MARKET	POST-MARKET
CONTROL/MONITOR	PRODUCT	SALE	AFTER-SALE/USE
PERSON	MANUFACTURER	VENDOR	VENDOR/USER
Items or activities regulated	**Device attributes** • Safety and performance **Manufacturing** • Quality systems (see 3.4.4) **Labelling** (representation) • Accurate description of product • Instructions for use	**Establishment registration** • List products available or in use • Requires vendor to fulfil after-sale obligations **Advertising** (representation) • Prohibits misleading or fraudulent advertisement	**Surveillance/vigilance** • After-sale obligations • Monitoring of device's clinical performance • Problem identification and alerts

- WHO MEDICAL DEVICE REGULATIONS Global overview and guiding principles

THANK YOU

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