ISOHealthSA and MDMSA

FREE WORKSHOP FOR SAAPI MEMBERS AND NON-MEMBERS
A FRANK DISCUSSION – WHAT DOES MY BUSINESS REALLY NEED FOR HEALTHCARE PRODUCTS

Workshop Outline:

A Frank Discussion – What Does My Business Really Need for Healthcare Products?
Practical Quality & Compliance for Healthcare Products.

Date and Time:
Thursday, 19 February 2026
09h00 to 10h00 (1 hour)

Venue: Online via MS Teams

Format: Open discussion, guided by presenter **Simone Rudolph-Shortt** from **ISOHealthSA**

Hosted by: SAAPI and the MDMSA as a Free Session for SAAPI Members and Non-Members.

Purpose
To provide industry professionals with a practical, candid exploration of key regulatory and quality considerations for healthcare products, highlighting differences, overlaps, and challenges in applying frameworks.

Discussion Flow:

1. **Welcome & Introduction**
   - Purpose of the session: an open, honest conversation about regulatory and quality requirements.
   - Setting the tone: interactive, questions encouraged.
2. **Foundations of Quality & Compliance**
   - **GMP vs QMS**: What each framework covers, and how businesses decide which applies.
   - Real-world implications for healthcare product companies.

3. **Corrective vs Preventive Approaches**
    - **CAPA vs Preventive Action**: Moving from reactive to risk-based thinking.
    - How documentation supports proactive compliance.
4. **Documentation & Processes**
    - **Documentation vs Records**: What's required, what's practical.
    - **Processes vs Procedures**: Understanding the difference and why it matters.
5. **Regulatory Submissions**
    - **Technical File vs Dossier**: Distinguishing requirements for medical devices vs medicines.
    - Why medicines quality is regulated more strictly than devices.
    - Practical tips for preparing submissions.
6. **Open Floor Discussion**
    - Questions, reflections, and shared experiences from delegates.
    - Key takeaways for businesses navigating healthcare product compliance.
7. **Closing Remarks**
    - Summary of main contrasts and insights.
    - Invitation to future SAAPI workshops.

Target Audience
- Healthcare product manufacturers / importers / distributors
- QA / RA staff
- Start-ups and growing businesses entering regulated healthcare markets
- Technical and operations managers