SAMED
advancing patient care through MedTech

SAMED 2023

ANNUAL CONFERENCE

ACCELERATE | CONNECT | CONVERGE | REBUILD

12 & 13 September 2023

Deloitte, Waterfall City, Midrand

DAY 1 12 SEPTEMBER 2023

MAIN ROOM

08:30 ***Arrival and Registration***
Arrive early to check in or register and enjoy some refreshments in the exhibition room.

09:00 **OPENING**

Welcome / Opening
- **Peter Mehlape**, SAMED Chairperson

09:20 **KEYNOTE**

The impact of healthcare in times of disaster
- **Dr Imtiaz Sooliman**, Gift of the Givers

10:05 **PLENARY**

Executive Straight Talk
Leaders from medical technology companies speak openly about challenges and opportunities, including market potential, supply chain disruptions, local manufacture, ESG, innovation, transformation, and investments.

- **Patrick Godard**, Chief Commercial Officer, Vertice Medtech
- **Merilynn Steenkamp**, General Manager: Southern Africa, Roche Diagnostics
- **Graham Blackbeard**, Managing Director, Southern Implants
- **Mkateko Charlotte Mangalana**, Chief Executive Officer, Lechoba Medical Technologies

BROUGHT TO YOU BY:

MAIN ROOM

10:55 ***Break***
Enjoy some refreshments in the exhibition room.

11:15 **PARELLEL**

Connecting on the corruption effect
Corruption is a complex social, political, and economic phenomenon that undermines democratic institutions, erodes economies, contributes to political instability, and impacts provision of healthcare. In this session we unpack the short- and long-term repercussions of corruption on health provision, the risk areas, and the role of stakeholders in combating corruption.

- **Rob Millar**, Chairperson, Project 18C
- **Pranesh Maharaj**, Chief Programme Portfolio Officer, Special Investigations Unit / Health Sector Anti-Corruption Forum
- **Dr Katlego Mothudi**, Managing Director, Board of Healthcare Funders

BREAKAWAY

PARELLEL

Ask the Experts: Medical Device and IVD Regulatory Requirements
In this session, we cover how to and what to expect under the amended regulations: licence types, applications, amendments, renewals, listing updates, recalls and vigilance, labelling, advertising, product registration and fees.

- **Khatija Suleman**, SAMED Regulatory Vice-Chairperson
- **Dr Dimakatso Mathibe**, Senior Manager: Medical Devices, The South African Health Products Regulatory Authority / Co-chairperson of the African Medical Device Forum
- **Colbert Ditsepu**, Deputy Manager: Non-ionising radiation medical devices, South African Health Products Regulatory Authority
- **Johan Uys**, Senior Scientist, South African Health Products Regulatory Authority
- **Natalie De Koker**, Radiation Scientist, South African Health Products Regulatory Authority

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MAIN ROOM

12:15 **PARELLEL**

Ask the Expert: Determining Fair Market Value

Determination of Fair Market Value (FMV) rates and HCP tier assignments enable appropriate and defensible payments to consultants, industry influencers, managed markets programs, grants, and clinical trials. Ensuring FMV is paramount to ensuring that payments are not used or construed as undue influence or perverse incentives. In this session we look at best practice and latest innovations around methodologies, criteria, compensation models, documentation, transparency, disclosures, and patient input for FMV determination.

- **Sada Wood**, SAMED Code Vice-chairperson
- **Natasha Naidoo**, Director, Norton Rose Fulbright
- **John Moose**, Senior Principle Global FMV, IQVIA

BREAKAWAY

PARELLEL

Accelerating value-based procurement and funding of medtech

The SA healthcare system faces significant challenges: how to match increased demand for healthcare services with an increased lack of healthcare workers and how to improve patient outcomes while managing the total cost of care delivery. Collaborative solutions are required to move from the traditional medtech volume/price-based procurement and reimbursement models to value-based ones. How do we take the risk out of risk sharing agreements and leverage real world evidence?

- **Barry Childs**, Joint Chief Executive Officer, Insight Actuaries
- **Ayanda Mbuli**, Health Policy and Clinical Advisory General Manager, Medscheme
- **Dr Zaheen Omar**, Clinical Head, Momentum Health Solutions
- **Fundile Gebremebhin**, Director of Medical Devices and Health Technology Procurement Management, National Department of Health

13:05 ***Networking Lunch***

Collect your lunch voucher from the exhibition space and enjoy a variety of tasty options from the canteen.

14:00 **PARELLEL**

Breaking down barriers: collaborative convergence of medical device and IVD regulations

Regulatory convergence and reliance accelerate access to medtech and strengthen the regulatory capacity for global oversight. Convergence initiatives such as IMDRF, GHWP and AMDF play in achieving this. So too good regulatory practices seek to support this but even small differences in standards and technical regulations can lead to major differences and impact access. In this panel discussion, regulators and industry experts explore the challenges and opportunities for convergence and give practical examples of what has worked and what still needs to be done.

- **Diana Kanecka**, Senior Manager: International Affairs, Medtech Europe
- **Ofentse Ramokgopa**, Medical Device Technical Officer: Compliance, The South African Health Products Regulatory Authority
- **Oneaho Monyileote**, Medicine Registration Officer (Licensing Medical Devices), The South African Health Products Regulatory Authority
- **Batlegang Dallas Mosweu**, Manager Medical Devices, Botswana Medicines Regulatory Authority

PARELLEL

Growing medtech: Developing critical medtech skills and talent pipelines.

The Medical technology industry requires certain critical skills such as manufacturing, regulatory and quality management, reimbursement, and health technology assessment expertise. It is vital that these skills sets are grown as part of capacity development to ensure skills transfer and sustainability. In this session we look at recent developments such as the health products regulatory affairs assistant qualification, the YES programme and other courses/training available that can be used to develop critical skills and talent pipelines.

- **Reinet van Graan Oerlemans**, Chief Executive Officer, Diverse Conversations (Moderator)
- **Ahmed Vawda**, Executive Director, Creative Consulting
- **Yanga Nozibele**, Business Development Associate, Youth Employment Service
- **Dr Martin Neiuwoudt**, Extraordinary Associate Professor, Institute for Biomedical Engineering, Stellenbosch
- **Tanya Vogt**, Executive Officer, SAMED

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MAIN ROOM

15:00 **PARELLEL**

Economic and Social infrastructure: health impact

There are many factors that contribute to quality and effective healthcare provision. Country infrastructure constraints and developing robust contingency solutions is central to these discussions within the South African context. In this session, we engage on the social and policy requirements for building robust, sustainable, and transparent supply chains within constrained infrastructure.

- **Cas Coovadia**, Chief Executive Officer, Business Unity South Africa
- **Paola Desogus**, Head: Competency Centre, DHL
- **Professor Alex van den Heever**, Chair of Social Security Systems Administration and management studies, WITS School of Governance

15:50 *Break*

16:10 **PARELLEL**

Conscience over compliance

It is essential to promote conscious leadership in the pursuit of value creation and the development of healthy, purpose-driven organisations within the context of inclusive capitalism and sustainable development across the dimensions of economy, society, and the environment. In this session we discuss the role of ethical leadership, the power of good governance, and purpose of humanity in healthcare.

- **Guru Kali**, Director, Conscious Leadership Academy
- **Professor Mervyn King**, Partner, Mervyn E King SC
- **Dionne Kerr**, Chief Executive Officer, Siyakha Consulting

17:10 **KEYNOTE**

National Department of Health

- **Dr Sibongiseni Dhlomo**, Deputy Minister of Health, National Department of Health

17:40 *Networking Cocktail Dinner*

Skip the traffic and stay on for some networking and cocktail refreshments

BREAKAWAY

PARELLEL

Localisation and local manufacture: can it be done and how to do it

Explore LM and export challenges and how to overcome them. Value and place of trade agreements such as AGOA and others. Who are South Africa's major trading partners and which markets are opening up. What other countries are doing to expand/attract local manufacture (Saudi Arabia and Ireland). How can multinationals and distributors get involved?

- **Vic van Vuuren**, Consultant, Health Products Master Plan
- **Dylan Hill**, General Manager, Priontex (alt. Graham Blackbeard, Managing Director, Southern Implants)
- **Stefan Beier**, General Manager, Beier
- **Tracy Moonsamy**, Group Quality Executive, Beier

PARELLEL

Impact of nursing regulatory landscape on medtech

Recent regulatory changes to the landscape will significantly change the way in which medtech companies engage and contract with private nurse practitioners. We look at the implications if the current regulations are implemented unchanged, the guidelines and comments proposed by SAMED on behalf of the industry and the wider healthcare impact.

- **Elsabe Klinck**, Partner, Elsabe Klinck & Associates
- **Dr Febe Bruwer**, Society of Private Nurse Practitioners of South Africa
- **Brinsley Davids**, Vice President, Wound Healing Association of South Africa

DAY 2 13 SEPTEMBER 2023

MAIN ROOM

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09:00 **PLENARY**

Climate change, Environment, Societal Governance and Medtech sustainability: a matter of compliance or necessity?

Medtech is faced with emerging opportunities and challenges as healthcare systems are increasingly expected to serve not only patients but the planet and social society. To accelerate real action, business and government must align and collaborate – both in intent and action. Join this session to hear from leaders on building a climate zero medtech including extended producer responsibility (EPR), the notion of circularity, environment, societal and governance (ESG) responsibilities, how to design and manufacture for carbon zero, and empowering diversity, equity, and inclusion.

- **Crystal Baloyi,** Hazardous Waste Management, Department of Forestry, Fisheries and the Environment
- **Andre Nortje**, National Environmental Sustainability Manager, Netcare
- **Peter Mehlape**, Managing Director: Southern Africa, Medtronic
- **Carolynn Chalmers**, Chief Executive Officer, ESG Exchange

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MAIN ROOM

10:00 **PARELLEL**

Transforming medtech procurement

Medtech procurement is evolving. Provinces are rethinking how to manage consignment stock. The Preferential Procurement Regulations require organs of state to identify "specific goals" in their procurement processes, including procuring from women, youth and disabled people owned entities, green procurement, and local content and production. These activities and goals ensure efficiencies, transparency, are a tool for economic stimulus and job creation and have the potential to meet procurement objectives set by the President for 40% of public procurement projects for women-owned businesses.

- **Vusi Memela**, Director: Inventory and logistics, KwaZulu-Natal Department of Health
- **Kealeboga Mokolabate**, Associate Director, Transcend
- **Professor Elizabeth Mayne**, Professor and Head of Division: Immunology, National Health Laboratory Service

BREAKAWAY

PARELLEL

Ask the Experts: ISO 13485 – Where to start and how to proceed

Medical technologies are designed to improve health and save lives. SAHPRA (South African Health Products Regulatory Authority) have strict requirements to ensure medical devices are created with quality products that are safe to use – which includes a ISO 13485 Management System. ISO 13485 doesn't just give a company the ability to comply with the SAHPRA licence requirement; it also will give your business a plethora of benefits, including system management, risk analysis and quality control.

- **Tracy Moonsamy**, Group Quality Executive, Beier
- **Andre ten Napel**, Founder, TNMC & TNMC Medical Devices UK
- **Felistas Mashinya**, Managing Director, IBRATSA
- **Oliver Naidoo**, Managing Director, JC Auditors

BROUGHT TO YOU BY: playbook® Medical

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10:50 ***Break***
Enjoy some refreshments in the exhibition room.

11:15 **PARELLEL**

Fast tracking medtech startups, SMMEs, investors, innovators, medtech clusters and incubators

We will explore the main challenges for value creation and how we can think out of the box to create value. We look at what businesses should be doing to attract funding and investment and how to overcome some of the common hurdles of bringing product to market. We explore the potential partners and support services that work to develop local medtech innovation.

- **Judy Vandell**, Founder, Kukuza Consulting
- **Grace Baloyi**, Manager: Global Health Innovation Accelerator (GHIA); Technology Transfer Office (TTO), MeDDIC & Grants Programmes, SAMRC
- **Rashmee Ragaven**, Director: Advanced Manufacturing, InvestSA
- **Maidei Matika**, Chief Investment Officer, Gauteng IDZ

PARELLEL

Ask the Experts: HTA how to and best practice.

The process of Health Technology Assessments (HTAs) can support decisions relating to benefit package design and service coverage both within medical schemes and national health insurance. HTA involves institutional cooperation with agreed methods and procedural standards. HTA awareness remains low, and HTA-related activities are uncoordinated and often disconnected from policy. In this session experts share best practice around developing real work evidence and how to best conduct HTAs within the context of both the funder and future NHI systems.

- **Mark Brand**, Founder, BRANDTECH Health Technology Consulting
- **Dr Sandile Mhlongo**, Clinical Director and Chief Health Economist, Curis Healthcare Consulting
- **Fundile Gebremebhin**, Director of Medical Devices and Health Technology Procurement Management, National Department of Health

BROUGHT TO YOU BY: VI Research — Real-World Evidence, Real Outcomes

12:15 **PLENARY**

The future of SA Healthcare

Achieving universal health coverage is one of the 2030 Sustainable Development Goals and a strategic priority for the World Health Organisation. It is imperative that we look at the future of healthcare within the South African context and the decided steps or changes that will facilitate increased coverage without stunting innovation or curbing product access. In this session we explore: National Health Insurance as a tool to achieve UHC; Challenges and opportunities in health policy landscape and how to overcome them; Building cyber safe healthcare systems; Accelerating public-private partnerships to co-create health access; Embracing change without compromising care; Digital Health; Artificial intelligence (Chat GPT and healthcare AI)

- **Rene Thompson**, Managing Director, Thompson Trust
- **Michelle Govender**, Cyber Emerging Technology Leader, Deloitte
- **Roseanne Harris**, Health Policy Actuary & B4SA/BUSA NHI Project lead, Business Unity South Africa

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13:05 **CLOSING**

Thanks / Closing

- Tanya Vogt, SAMED Executive Officer

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