Medical Device Regulatory Convergence Project (MDRC)
Workshop on Good Regulatory Practices and its implementation in the Medical Device Sector

Day 1

Date: 10 August 2022
Time: 14:00 – 17:00 (8:00-11:00 ET)
Language: English
Platform: Zoom

Time	Topic
14:00 – 14:05	**Welcome and Opening Remarks** Sandra Ligia González, Medical Devices Lead - MDRC
14:05 – 14:10	**Welcome Message** Dimakatso Mathibe, South African Health Products Regulatory Authority (SAHPRA)
14:10 – 14:35	**Introduction and Overview on Good Regulatory Practices (GRPs)** Speaker: Renata Amaral, GRP Lead – MDRC (15 min) Q&A: 10 min.
14:35 – 15:35	**International Benchmarks for Medical Device Regulatory Frameworks and Authorities: Health References & Recommendations** • WHO Global Model Regulatory Framework for Medical Devices and IVDs • WHO Good Regulatory Practices • WHO Good Reliance Practices Moderator: Dimakatso Mathibe, South African Health Products Regulatory Authority (SAHPRA) (5 min) Speaker: Agnes Sitta Kijo, Technical Officer, Regulatory and Safety Unit (REG), Regulation and Prequalification Department (RPQ), World Health Organization (WHO) (20 min) Speaker: Khanyisile Nkuku, Technical Officer, South African Health Products Regulatory Authority (SAHPRA) (20 min) Q&A: 15 min.
15:35 – 16:55	**International Benchmarks for Medical Device Regulatory Frameworks and Authorities: Trade & Legal References and Obligations** Moderator: Renata Amaral, GRP Lead – MDRC (5 min) Panelist: Lauro Locks, Legal Counsellor (Technical Barriers to Trade), World Trade Organization (WTO) (30 min) Panelist: Charles Sibiya, Manager Chemical Certification, South African Bureau of Standards (SABS) South Africa TBT Enquiry Point (30 min) Q&A: 15 min.
16:55 – 17:00	**Closing remarks** Dimakatso Mathibe, SAHPRA and Sandra Ligia González, Tier 2 Lead - MDRC

Workshop on Good Regulatory Practices and its implementation in the Medical Device Sector

Day 2

Date: 11 August 2022
Time: 14:00 – 16:00 (8:00-10:00 ET)
Language: English
Platform: Zoom

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14:00 – 14:05	**Welcome and Opening Remarks** Sandra Ligia González, Medical Devices Lead - MDRC
14:05 – 14:10	**Welcome Message** Dimakatso Mathibe, Snr Manager Medical Device Unit, South African Health Products Regulatory Authority (SAHPRA) , AMDF Vice Chair
14:10 – 15:00	**South African Legislative & Regulatory Framework for Medical Devices – Current Situation and Roadmap for the future** Moderator: Steven Bipes, AdvaMed, MDRC (5 min) Panelist: Bongani Ngcobo, Legislative Perspective – Health, South African Health Products Regulatory Authority (SAHPRA) (10 min) Panelist: Ms Lydia Motlogelwa, Manager Registration, Medical Device Regulation, South African Health Products Regulatory Authority (SAHPRA) (10 min) Panelist: Madeleine Pearce, South African Medical Technology Association (SAMED) (10 min) Q&A: 15 min.
15:00 – 15:55	**Review of South African Medical Device Technical Standardization & Stakeholder Participation** Moderator: Sandra Ligia González, Medical Devices Lead – MDRC (5 min) Panelist: Phollen Murivhula, South African Bureau of Standards (SABS) (20 min) Panelist: Dusty Miller, South African Medical Technology Industry Association (SAMED) (20 min) Q&A: 10 min.
15:55 – 16:00	**Closing Remarks** Dimakatso Mathibe, SAHPRA and Sandra Ligia González, Medical Devices Lead - MDRC