

# Medical Device Regulatory Convergence Project (MDRC)

## Africa Medical Device Forum (AMDF) – USFDA Workshop

# Goals for the Week – Training Activities

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- **Provide an exchange of information and capacity building between AMDF, member and partner NRAs, Africa CDC and industry**
- **Provide as a focused reference the USFDA experience in the Regulation of Medical Devices**
- **Cover the core international references for medical device regulatory frameworks**

# Goals for the Week – Training Topics

## Core international references for medical device regulatory frameworks

- International Medical Device Regulators Forum (IMDRF)
- International Standards
- Conformity Assessment
- Medical Device Single Audit Program (MDSAP)
- Post-Market Activities
- Good Reliance Practices
- Proper Legal Foundations for Rulemaking
  - Good Regulatory Practices (GRP)
  - Technical Barriers to Trade (TBT)

# Goals for the Week – Purpose & Outcomes

- To support and advance the AMDF 2023 Workplan and Training Plan in furtherance of the AMDF 5-year strategic plan accelerating African MD NRA capacities
- To support the AMDF application as a Regional Harmonization Initiative (RHI) of the IMDRF
- To strengthen the soft infrastructure of medical device regulatory frameworks on the continent to incorporate global lessons learned from the COVID-19 pandemic
- To better prepare for future health emergencies
- To prevent the implementation of unnecessary regulatory barriers to medical technologies
- To improve general MD NRA public administration and general public health
- To support acceleration of diagnostics access in Africa in collaboration with the Africa CDC through the Diagnostic Advisory Committee (DAC)