# MALARIA RAPID DIAGNOSTIC TESTS

Imperial botanical beach Entebbe
20TH-21st-Oct-2015

**By: Denis William Mwesigwa**
**Senior Inspector of Drugs-GMP**

# Scope of Presentation:

**The presentation shall proceed as follows:**

- What has been done
- What has been effective
- What are the main challenges
- What should be done next

# What has been done

- Several documents have been developed to regulated the sector
- Inspection of premises for distribution and storage of mRDT's.
- All local manufacturers of mRDT's are inspected and certified by NDA.

- All mRDT's on the market are subjected to Pre-import and export approval by the NDA.

- The 2 project. mRDT brands passed the WHO- lot QC assessment criterion.

- 178 (83%) n=215, mRDT outlets satisfactorily practice bio-safety and waste mgt.
- Hazardous waste generated is safely transported for offsite for final disposal in NEMA certified sites

# What has been effective

- Throughout, adequate methods for distribution including transportation has be maintained to achieve quality, safety and security of mRDT's.

- Each manufacturer of mRDT shall demonstrate its ability to provide mRDT' and its accessories that consistently meet ISO, 13485:2003- (collaboration with WHO and other strong DRAs)

- Lot testing has be carried out on only 2 RDT's prior to placement on the market- this is an assurance to quality

# What are the main challenges

- failure to adherence by distributors of mRDT's to Good medical devices distribution and storage practices to assure quality
- Lack proper mechanisms to track consumer complaints and performance for corrective action
- Capacity to inspect all manufacturer of mRDT placed on the market for conformity to ISO, 13485:2003 & GMP
- The relevant legislation to enable regulators(NDA) properly regulate the sector
- capacity to adequately perform Lot testing locally on all RDT's ( at the ports of entry , PMS)

# What next & Conclusion

with the advance in medical technology, it is increasingly imperative for the government hasten the promulgation of the law to enable NDA adequately regulate and control the area of medical devices to ensure maximum benefits are derived from their use while the risks to the patients and users are kept minimum