TFDA PEPFAR FELLOW EXPERIENCE AT CBER, FDA

TRAINING IN THE EVALUATION AND REGULATION OF HIV TEST KITS AND BLOOD DONOR SCREENING ASSAYS

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Objectives of the PEPFAR Fellowship

- Learn the laws, regulations and review principles that govern FDA regulatory review and oversight of HIV diagnostics and blood donor screening tests
- Contribute to the establishment of a review function for these products within the TFDA to build regulatory capacity for IVDs.

Overview of FDA and Fellowship

- FDA is an agency within the Department of Health and Human Services (DHHS) responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation.
- CBER is the Center within FDA that regulates HIV tests.
- CBER received a grant from PEPFAR (*U.S*. President's Emergency Plan for AIDS Relief) to support the regulatory capacity building specifically for HIV test kits.
- Through the PEPFAR grant, CBER sponsored two staff from Tanzania FDA to be trained at US FDA for three months.

Training Aspects of PEPFAR Fellowship

- Senior Staff Member as Mentor
- Lecture and hands-on training
  - Standardized new reviewer training (classroom, on-line)
  - HIV-specific regulatory review training
  - Participation in Branch and Division Meetings
  - Participation in meetings with test developers
  - Participation on active review teams
    - Product Manufacturing Information
    - Pre-Clinical Studies
    - Clinical Studies
    - Review of labeling

Challenges

- HIV IVDs vary in complexity, ranging from simple Point of care rapid dip-stick devices to sophisticated computerized instruments based test
- Regulation and review encompass diverse professions including; Biologists, Microbiologists, Molecular Biologists, Immunologists, Statisticians, Engineers, Medical Doctors, and Pharmacists. While in our setting at TFDA we may not have these experts.
- Directly control of manufacturing from the design to the finished product is challenging and would require significant resources.
- There are or very limited courses on the review/regulation of IVDs. The Regulatory Authority should continue the collaboration with the appropriate Authorities to assist in strengthening regulatory capacity

Lessons learned during PEPFAR Fellowship

- Training in key areas is considered essential to strengthening regulatory capacity for IVDs.
- Involvement of multidisciplinary professionals is vital in regulation of IVDs.
- Emphasis should be placed on leveraging existing efforts and post-market surveillance activities.
- Regulation of IVDs, including those for HIV, should be done in a controlled and well governed manner.

Thank You