

Workshop Introduction

Ginette Y. Michaud, MD

US Food and Drug Administration

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Outline

- Purpose of Workshop
- US FDA's Global Mission
- Major Workshop Topics
- What is an *In Vitro* Diagnostic Test (IVD)?
- Why Do We Regulate IVDs?
- Responsibilities of the Regulatory Authority
- General Principles of IVD Regulation
- Open Discussion
- Presentation by TFDA Fellows



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Purpose of Workshop

- Strengthen capacity of PEPFAR nations to lead response to HIV epidemic
- Assist in transition from emergency response to promotion of sustainable country programs
- Support the goal of nations to regulate HIV tests in their particular jurisdiction



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Purpose of Workshop

- FDA recognizes and supports, through this workshop, the region's efforts to enhance regulatory systems
- PAHWP's goal of advancing harmonized regulation of medical devices and diagnostics
- 2014 World Health Assembly resolution to support the strengthening of regulatory systems



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Purpose of Workshop

- Each nation has the opportunity to:
 - control HIV tests within its own jurisdiction
 - determine which tests are suitable for its particular circumstances
- FDA wishes to support the availability, quality, effectiveness and safety of medical products through the advancement of sustainable regulatory programs



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US FDA's Global Mission

FDA's global mission is to improve global public health through:

- international information sharing & regulatory cooperation
- sharing of technical & scientific expertise
- international research collaboration
- global standards setting & development



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Arusha Workshop

- Workshop will build on past efforts to increase regulatory capacity in the region
- Trainers:
 - current or past regulators of medical devices and diagnostic tests (USA or UK)
 - experienced in international cooperation, regulatory capacity building and regulatory harmonization



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Major Workshop Topics

- HIV tests for diagnosis, confirmation, viral load
- Principles and benefits of regulating IVDs
- Common elements of regulatory systems
- Review of information provided to a Regulatory Authority for marketing authorization
- Value of Quality Management Systems
- The role of post-marketing regulatory activities
- Practical exercises and group discussions



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What is an In Vitro Diagnostic Test?

IVD = Test Kit = Assay = Test

IVD Medical Device: A device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body...



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What is an In Vitro Diagnostic Test?

...solely or principally to provide information for diagnostics, monitoring or compatibility purposes....



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What is an In Vitro Diagnostic Test?

...This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

GHTF/SC/N4:Glossary and Definitions of Terms Used in GHTF Documents 2012
(Edition 2)



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Why Do We Regulate IVDs?

What is the risk?

- IVDs produce no side-effects and are not toxic - unlike drugs.
- IVDs do not contact the body, unlike many other medical devices.
- IVDs do not deliver energy to the body.



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Why Do We Regulate IVDs?

We rely on IVDs to generate correct results to:

- diagnose disease
- stop the spread of disease
- monitor response to treatment

Incorrect results have negative consequences for patients and for public health such as:

- delay in treatment
- incorrect treatment
- the opportunity for disease transmission
- wasted resources



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Why Do We Regulate IVDs?

We regulate IVDs to ensure they are safe & effective for:

- their intended use
- by intended user
- in intended environment.

A test that is safe and effective will give you the correct answer, consistently and in a way that can be understood.



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Why Do We Regulate IVDs?

Benefits to public health of safe and effective IVDs:

- identifying individuals in need of health services
- providing more timely and effective therapies
- empowering individuals to make decisions about their health
- preventing spread of disease (e.g., through education)



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Why Do We Regulate IVDs?

Benefits to public health of safe and effective IVDs:

- ensuring that the test kits are what they claim to be (traceability, version control)
- ensuring that language of labeling is suitable and that text is clear and unambiguous

Identifying which devices meet regulatory requirements is a separate procedure from that of deciding which should be procured.



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Role of Regulatory Authority (RA)

- Development and enforcement of regulations governing medical device
 - manufacturing
 - safety, effectiveness, labeling
 - sales and distribution
- Granting marketing authorization to the device manufacturer
- Removing unsafe devices from the market



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Responsibilities of RA

- Protecting public health through regulatory oversight
- Promoting public health
- Generating speedy and transparent regulatory decisions
- Acting within the boundaries of the legislation
- Maintaining administrative record and regulatory consistency



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Responsibilities of RA

Unnecessary regulations may:

- delay novel technology
- drive manufacturers out of the market
- increase healthcare costs



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General Principles of IVD Regulation

- Public health focus
- Science based decision-making
- Assessment of benefit versus risk
- Risk based regulatory controls (greater controls for higher risk)
- National considerations (e.g., language, epidemiology)
- International collaboration and leveraging
- Harmonization and convergence of regulatory practices



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Medical Device Regulatory System

- Establishing a regulatory system is a major initiative requiring the firm will and commitment of government leaders
- Authority for development and enforcement of regulations is assigned by law to the Regulatory Authority (RA)



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Open Discussion

We invite you to share the challenges you have encountered in your jurisdiction.



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