

Features and Challenges of Regulatory Systems

Ginette Y. Michaud, MD

US Food and Drug Administration

December 14, 2015

Arusha, Tanzania



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



Sustainability of Regulatory Systems

Sustainability requires adequate resources to carry out and enforce regulatory functions:

- stable and sufficient funding
- human capital and expertise
- adequate infrastructure

Sustainability depends on:

- strong leadership
- a clear mission
- well defined strategic goals



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



Regulatory Systems are Dynamic

They evolve with:

- technological advances
- public demands
- changes in the marketplace
- changes in the industry
- globalization



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



Regulatory Systems are Dynamic

Examples of changes in the past twenty years:

- point of care, rapid tests
- combination products
- global manufacturing
- software driven devices
- sophisticated instrumentation
- needs for traceability



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



Stepwise Approach to Regulation

Regulatory Systems are built over time and change over time. This is true of all regulatory systems.

Strategic approach:

- develop a stepwise plan
- start with critical elements
- set realistic goals and timescale
- prioritize country specific needs
- leverage existing international resources when possible



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



Need for Regulatory Autonomy

- Independence of RA in decision-making
- Autonomy to regulate without interference or inducements
- Independence from industry
- Absence of conflict of interest, apparent or real
- Expert advisory committees that are free of conflict

Regulatory autonomy enhances public's confidence in regulatory decision-making



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



Communication by RA

Communication and/or publication of:

- regulatory requirements to promote understanding of, and compliance with, regulations
- process for soliciting guidance from RA and for having RA's decisions reviewed
- progress of regulatory activities
- regulatory decisions
- draft regulations and draft guidance to provide an opportunity for public input



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



Communication by RA

Communication with:

- public, including patient groups
- regulated industry
- other public health organizations
- end users

Communication must comply with rules on disclosure and protection of information.

Trade secret and commercial confidential information must be protected.



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



Collaboration Between RAs

- Leveraging of knowledge and expertise among peers
- Harmonization and promotion of best practices
- Dissemination of critical public health information



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



RAs and Regulated Industry

Dynamics between RA & industry may be:

- collaborative (e.g., symposium or workshop)
- cooperative (e.g., investigating cause of device failure)
- contentious (e.g., adverse regulatory decision)

RA must fulfill its mission, meet its regulatory obligations through fair and transparent action, while operating within legislative boundaries.



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF



Thank you for your
participation.



U.S. FOOD AND DRUG ADMINISTRATION
U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF

