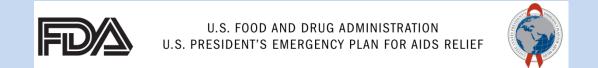
# Features and Challenges of Regulatory Systems

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## 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



### Regulatory Systems are Dynamic

#### They evolve with:

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

#### 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

### Stepwise Approach to Regulation

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

#### Strategic approach:

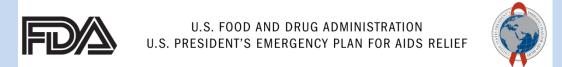
- develop a stepwise plan
- start with critical elements
- set realistic goals and timescale
- prioritize country specific needs
- leverage existing international resources when possible



#### 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

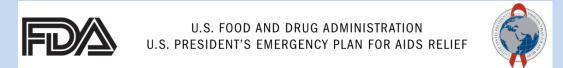
Regulatory autonomy enhances public's confidence in regulatory decision-making



## 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



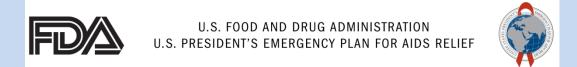
## Communication by RA

#### 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.



#### Collaboration Between RAs

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

## 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.

## Thank you for your participation.

