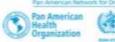
Global regulatory curriculum – a joint effort

Regulatory Systems Strengthening [RSS]
Regulation of Medicines and Other Health Technologies [RHT]
Department of Essential Medicines and Health Products [EMP]
World Health Organization











Background

- Numerous WHO assessments of regulatory systems for medical products worldwide have demonstrated that regulatory workforce is one of the main gaps in regulatory systems in LMIC;
- Various factors contribute to this gap:
 - Lack of trained staff;
 - Inadequate incentives to retain the staff;
 - inadequate technical training, etc.









Regulatory Workforce development – **Global effort**

Project Objectives:

- Define the basic competencies needed by new to mid-level staff in developing regulatory agencies;
- Develop education/training curriculum framework for preparing competent regulatory staff;
- 3. Develop tools to allow staff and supervisors to develop training plans for regulatory staff.









Regulatory workforce development (1)

- A multi-stakeholder working group (US FDA, COFEPRIS, WHO, PAHO, RAPS, IFPTI and others) met to discuss a 2012 report by the Institute of Medicine of US National Academies that called for standards for the food and medical product regulatory workforce in low- to middle-income countries (LMICs).
- The working group identified a project to define minimal core competencies for Basic Level food and medical product regulatory professionals in LMICs i.e., the knowledge, skills, and abilities necessary for successful job performance, and to develop a curriculum framework to educate/train the regulatory workforce to the competencies.

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Regulatory workforce development (2)

- International expert panels was established in 2014 to develop/review basic competencies for medical products and foods;
- Survey of regulatory professionals around the world to review competencies;
- Expert panel refines competencies and domains;
- Expert panel develops basic curricula based on competencies;
- Tool to assess individual competencies developed;









Regulatory workforce development (3)

- Competencies aligned with WHO assessment/ benchmarking tool;
- Pilot self-assessments conducted in Ethiopia and Indonesia conducted in 2015-20116 and site visits conducted to evaluate the results and to test the competencies and tools;
- After two years of work the competency framework for Basic Level regulators was completed.











Regulatory workforce development (4)

The competencies are classified accordingly:

- General: knowledge, skills, and abilities required by the entire food and medical product regulatory workforce in LMICs
- Technical: knowledge, skills, and abilities specific to both the food and medical product regulation
- Food: knowledge, skills, and abilities specific to the food regulatory workforce
- Medical Product: knowledge, skills, and abilities specific to the medical product regulatory workforce. Medical Product competencies were further classified into three categories: Regulatory Information and Strategy, Pre-approval/ Approval, and Post-approval.











Regulatory workforce development (5)

Phase II of the Project is currently underway to:

- Implement and evaluate pilot programs with partner organizations and with LMIC regulators to implement training based on the assessments;
- Recommend strategies for expanding and sustaining training for regulatory professionals in low- and middle-income countries;
- WHO to host the final product once finalized and to facilitate rolling out in the Member States.
- The project is in "work-in-progress" status...











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