

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

VIII Conference of the Pan American Network on Drugs Regulatory Harmonization | Mexico City | 19 to 21 October

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.

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Regulatory Workforce development – Global effort

Project Objectives:

1. Define the basic competencies needed by new to mid-level staff in developing regulatory agencies;
2. 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.

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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;

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Regulatory workforce development (3)

- Competencies aligned with WHO assessment/benchmarking tool;
- Pilot self-assessments conducted in Ethiopia and Indonesia conducted in 2015-2016 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.

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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.**

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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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17th ICDRA in Cape Town, South Africa

29 November – 2 December 2016

"Patients are waiting: How regulators collectively make a difference"

Days

Hours

Minutes

Seconds

4 0 : 1 6 : 1 8 : 3 9



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Registration

Registration for the Pre-ICDRA conference event, the 17th ICDRA and relevant social events will be facilitated through the online registration process.

Register



**Registration is open
until 13 November**

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