Towards a global competency framework for regulators of medical products

Introduction
The human being is key in any chain of operations, including public health, but is also by nature the most flexible and variable impacting on predictability, consistency, transparency, and quality of decisions. Predictably, the low regulatory capacity in low- and middle-income countries (LIMC) is partly due to the lack of appropriately qualified, trained and experienced regulators to ensure access to quality, safe and efficacious medical products in those settings. The Institute of Medicine (IOM) report described the current mishmash of inconsistent training offered to LMICs as part of the problem. Consequently, systematic regulatory workforce development was identified as one of the critical areas to address the gaps in regulatory capacity for medical products in LMICs.

Although there is progress in harmonizing technical standards, joint activities, and information and work sharing, having an internationally accepted set of competencies will maximize the benefits of collaboration and cooperation in medical product regulation. While the World Health Organization (WHO) has established a well-recognized process for benchmarking and strengthening regulatory systems, there is a growing recognition that the current approach in regulatory capacity development must include a common global competency framework if the desired public health outcomes are to be achieved.

To this end, as part of the regulatory systems strengthening, WHO is working with partners to develop a global competency framework and global curricula to support training and professional development of regulatory staff. The focus of this paper is to highlight the progress on the development of the global competency framework, and the proposed competency framework for medical product regulation.

Development of the global competency framework
There are various definitions for competency; in this case, competency is defined as the knowledge, skills, attitudes, and behaviours developed through education, training, and experience. Moreover, in other professions such as medicine and aviation industry, not only is the use of competency for training and professional development well-established and recognized, but also the set of required competency is universally accepted and globally applicable. Similarly, taking into account the global nature of the pharmaceutical industry and the need to ensure universal promotion and protection of public health and that all people have access to safe, efficacious and quality medical products, a universally applicable, adaptable, flexible global competency framework to support regulatory professionals is imperative.
A competency model is defined as an organizational framework that lists the competencies required for effective performance in a specific job, job family, organization, function or process. Moreover, the WHO Global Benchmarking Tool (GBT) applies a maturity model approach for strengthening national regulatory authorities (NRAs). This maturity level approach is consistent with the International Organization for Standardization (ISO) 9004:2009 management system. Accordingly, NRAs are classified from maturity level 1 to 4, with 1 being the lowest maturity and 4 the highest maturity. Additionally, the maturity model represents not only a tool for NRA development, but also a continuum of the NRA’s capabilities in performing regulatory functions. Thus, the global competency framework for regulators allows competency modelling by individual NRAs across the maturity levels, in particular, level 1 to 3, aligning individual capabilities with the organizational strategy and business processes.

**Approach**

There are wide-ranging approaches in developing competency frameworks. For this purpose, the following approach was followed:

a) a multi-stakeholder group that included representatives from the United States Food and Drug Administration (US FDA), WHO, Pan American Health Organization (PAHO), professional societies involved in medical product regulation and donor organizations developed the strategies and approaches for building a global competent regulatory workforce and global curricula to educate and train regulators.

b) A panel of experts in the regulation of medical products from academia, industry, government, and non-governmental organizations (NGOs) defined the basic competency needed by regulatory professional staff in LMICs. The first draft framework includes general and technical competencies needed by regulators involved in medical products and food, and competencies specific to medical products;

c) The competencies formed the basis for creating a curricular framework for training and educating regulatory professionals;

d) Tools for reviewing the current knowledge and competencies of regulatory agency staff and comparing staff competencies with current agency operations and plans for the regulatory agency were developed and piloted in Ethiopia and Indonesia.

e) Based on the results of the pilot, the competency framework was revised accordingly. In addition, the revision took into account the advances made with the GBT. Thus, the revised model covers not only basic competencies, but the range of functions as defined in the GBT, the maturity levels of NRAs and good regulatory practices, as well as flexibility and adaptability by different users at different levels.

f) A validation meeting of the updated framework was held with representatives of regulators and academia in Africa. In addition, feedback was received from subject matter experts. Changes to the framework were incorporated based on the feedback.
Updated competency framework

Diverse competency frameworks exist. On that account, the competency framework for the regulators is modelled as follows: (a) Mandatory workplace competencies, (b) Core or generic competencies, and (c) Role-specific or occupation-related competencies.

Mandatory competencies form the base of the model and provide the foundation for success in a regulatory work environment and are essential to perform the specific regulatory work functions.

Core or generic competencies are specific to the regulation of medical products and cut across all the regulatory functions. This is important to support the development of an agile workforce and facilitate movement not only between regulatory functions, but also between sectors, e.g., from industry to government and vice versa.

All regulatory staff within the NRA should have mandatory and core competencies appropriate for their level. Notwithstanding this, the core competencies may be adapted accordingly by agencies, depending on their specific structure, context and needs.

The role/occupation specific competencies are initially defined for analysts, reviewers/assessors, inspectors and vigilance personnel.

The acquisition or development of the competencies for regulators of medical products is organized in three stages of professional development or proficiency levels adapted from the five-stage model of skill acquisition. The three stages / levels are basic (Level I), competent (Level II) and proficient / expert (Level III).

The framework defines the specific work functions (tasks/roles), underlying knowledge, and the skills or abilities to perform the detailed tasks/roles for the core and role specific competencies. The model is summarized in Figure 1.
Next steps

The updated competency framework will be piloted in different settings, which includes, as part of the NRA assessment in the GBT, individual NRAs across different maturity levels, in regional economic communities involved in joint activities, in particular assessment and inspection activities, as well as training institutions. Based on the outcomes of the pilot exercise, the framework will be revised before finalized and made publicly available for implementation.

Conclusion

A globally accepted competency framework that is adaptable is essential to ensure standardized training approach and systematic development of competent regulatory professionals not only in LMICs but globally taking into account the globalization of the medical product regulation and the need for collaboration and information sharing. The work achieved to date, highlight the complexity of the matter and affirms the need for wider consultations with the target audience and a pragmatic approach to ensure the outcome achieves the desired objectives.

Funding

Part of this work was funded by an FDA Cooperative Grant U01FD005031-05.

References