

Towards Competence-Based Regulatory Sciences Education in Sub-Saharan Africa: Identification of Competencies

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Abstract : There are growing calls in the literature to develop and implement competency-based regulatory sciences education (CBRSE) in sub-Saharan Africa to expand and create a pipeline of a competent workforce of regulatory scientists. A defined competence framework is an essential component in developing competency-based education. However, such a competence framework is not available for regulatory scientists in sub-Saharan Africa. The purpose of this research is to identify entry-level competencies for inclusion in a competency framework for regulatory scientists in sub-Saharan Africa as a first step in developing CBRSE. The team systematically reviewed the literature following the PRISMA guidelines for systematic reviews and based on a pre-registered protocol on Open Science Framework (OSF). The protocol has the search strategy and the inclusion and exclusion criteria for publications. All included publications were coded to identify entry-level competencies for regulatory scientists. The team deductively coded the publications included in the study using the 'framework synthesis' model for systematic literature review. The World Health Organization's conceptualization of competence guided the review and thematic synthesis. Topic and thematic codings were done using NVivo 12™ software. Based on the search strategy in the protocol, 2345 publications were retrieved. Twenty-two (n=22) of the retrieved publications met all the inclusion criteria for the research. Topic and thematic coding of the publications yielded three main domains of competence: knowledge, skills, and enabling behaviors. The knowledge domain has three sub-domains: administrative, regulatory governance/framework, and scientific knowledge. The skills domain has two sub-domains: functional and technical skills. Identification of competencies is the primal step that serves as a bedrock for curriculum development and competency-based education. The competencies identified in this research will help policymakers, educators, institutions, and international development partners design and implement competence-based regulatory science education in sub-Saharan Africa, ultimately leading to access to safe, quality, and effective medical products.

Keywords : competence-based regulatory science education, competencies, systematic review, sub-Saharan Africa

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