Pharmacy Education (2022) 22(4) 42 - 62
https://doi.org/10.46542/pe.2022.224.4262

ACADEMIC PHARMACY SECTION SPECIAL ISSUE

REVIEW

Describing competency requirements for competency-based regulatory sciences education in sub-Saharan Africa – A qualitative systematic review

Abigail Ekeigwe[1], Bethany McGowan[2], Loran Parker[3], Steven Byrn[1], Kari Clase[1]

[1] Biotechnology Innovation and Regulatory Sciences, School of Agricultural and Biological Engineering, Purdue University, West Lafayette, Indiana, United States

[2] Libraries and School of Information Studies, Purdue University, West Lafayette, Indiana, United States

[3] Evaluation and Learning Research Centre, West Lafayette, Indiana, United States

Keywords
Competency
Regulatory Scientist
Sub-Saharan Africa
Qualitative systematic review

Correspondence
Abigail Ekeigwe
Agricultural & Biological Engineering
University Street
Purdue University
Indiana
United States
abigail.a.ekeigwe@gmail.com

Abstract

Background: Competency-based regulatory sciences education could expand the workforce of regulatory scientists in sub-Saharan Africa. A competency framework is foundational to developing competency-based education. **Objective:** To identify the entry-level competency requirements of regulatory scientists in sub-Saharan Africa. **Method:** This research was a systematic review of the literature based on a pre-registered protocol. The research used the "framework synthesis" systematic review model to deductively identify competencies and code them into clusters with NVivo 12 software. **Result:** Three broad clusters of competencies were identified – enabling behaviours, knowledge, and skills. The knowledge and skills clusters were further subdivided into sub-clusters: the knowledge cluster into administrative, regulatory governance/framework, and scientific knowledge, and the skills cluster into functional and technical skills. **Conclusion:** The identified competencies will assist in developing an entry-level competency framework required for competency-based regulatory sciences education in sub-Saharan Africa.

Introduction

African Union's Agenda 2063 goal number two and the United Nations Sustainable Development Goal (SDG) number three are concerned with ensuring health and nutrition for persons (African Union, 2021). The African Union (A.U.) is approaching this goal through programs such as the African Medicines Regulatory Harmonization Initiative (AMRHI), the establishment of the African Medicines Agency (AMA), and the Pharmaceutical Manufacturing Plan for Africa (PMPA) (Ncube, Dube, & Ward, 2021). These initiatives aim to strengthen Africa's pharmaceutical and regulatory sectors to ensure access to safe, quality, and effective medical products. A contributing pillar for attaining these initiatives' goals is a reinforced, portable workforce of regulatory scientists equipped with the requisite training in drug development, pharmaceutical manufacturing, and regulatory sciences. Thus, building the capacity of regulatory scientists in sub-Saharan Africa is part of the World Health Organization's (WHO) five-year plan (2019 – 2023) for developing effective and efficient regulatory systems in sub-Saharan Africa and ensuring access to "quality-assured medical products (World Health Organization, 2019a).

Scholars have suggested that expanding and strengthening regulatory scientists' workforce in sub-Saharan Africa is attainable through competency-based education (CBE) — matching curricular, instructional methods and assessments to competencies required in the profession (Kerpel-Fronius *et al.,* 2015; Semete-Makokotlela *et al.,* 2021). CBEs are based on clearly defined competencies in a

competency framework. Therefore, competency-based regulatory sciences education would require a robust competency framework for regulatory scientists in sub-Saharan Africa, reflecting its socio-cultural and economic diversity. The WHO has published a draft condensed global competency framework for regulators of medical products (World Health Organization, 2019b). It is challenging to translate this condensed model to specific curriculum items. To develop and implement competency-based regulatory sciences education for sub-Saharan regulatory scientists, an expanded framework is needed. A barrier to the development of an over-arching competency framework for regulatory scientists in sub-Saharan Africa is the absence of a unified regional body for regulatory sciences (Ncube *et al.,* 2021). Semete-Makokotlela and authors (2021) suggested the establishment of *"a Regional Institute (or Academy) of Regulatory Sciences in Africa"* to house an across-the-board competency framework, an idea yet to be implemented.

Regulatory sciences

Regulatory science is an emerging field with evolving definitions and descriptions. The Institute of Medicines (IOM) of the National Academies describes regulatory science through the lens of translational science as *"the application of the scientific method to improve the development, review, and oversight of new drugs, biologics, and devices that require regulatory approval before dissemination."* (Institute of Medicine, 2012). Thus, regulatory scientists are at the decision points (throughout the lifecycle of a medical product) of fostering access to safe, quality, and effective medical products while preventing harmful, substandard, or falsified medical products from getting to the public.

Competency Framework

Competency Framework (CF) is a collection of competencies required to perform a given task or job function within an organization or professional entity (Benayoune, 2017; International Atomic Energy Agency). The modern competency movement is attributed to David McClelland (1973), who defined competence as *"a personal trait or set of habits that lead to more effective or superior job performance."* Subsequently, other scholars have defined competence variously; their educational background often influences their definitions (Boyatzis, 1982; Gonczi *et al.,* 1990; Hager & Gonczi, 1996; Wiek, Withycombe, & Redman, 2011; Mulder, 2014; Gilbert, 2019). For direct relevance to this workforce group and to foster understanding, this research adopts the WHO's definition of competency: *"Competency is the knowledge, skills, attitudes, and behaviours developed through education, training, and experience."* (World Health Organization, 2019b).

CFs have varied uses, including recruitment and selection of new staff, provision of precise, understandable performance requirements and behaviours for staff, training, performance evaluation and promotion, and deployment of staff (Fouad & Grus, 2014; Benayoune, 2017; Bernard *et al.,* 2018; International Atomic Energy Agency, n.d). This research focuses on using the CF to build initial and continuous professional development training curricula.

Aim

Sub-Saharan Africa does not have a comprehensive CF for regulatory scientists involved in regulatory registration and inspections for medical products nuanced with its socio-cultural and economic diversity. A recommended first step in developing a competency framework is to review the literature (Rodriguez *et al.,* 2002; Marrelli, Tondora, & Hoge, 2005). Thus, through a systematic review of the literature, this research aims to identify the competency requirements of regulatory scientists for inclusion in a competency framework for regulatory scientists in sub-Saharan Africa involved in regulatory registration and inspections of medical products (pharmaceuticals, medical devices, and in-vitro diagnostics).

Methods

A "framework synthesis" systematic review model guided this research. It *"involves establishing an a priori conceptual model of the research question by which to structure the coding of the literature"* (Xiao & Watson, 2019). The systematic review followed the PRISMA guidelines for systematic reviews (Supplementary Material 1) (Moher *et al.,* 2009). The literature was coded on the basis of the WHO's Conceptual Model of Competency. This model describes competency as knowledge, skills, behaviours, and attitudes needed to perform a task (World Health Organization, 2019b).

Literature search

The search was conducted in March 2020 following the search strategy documented in the preregistered protocol that was designed by Ekeigwe and the team. (Ekeigwe *et al.,* 2020). The search strategy was developed in collaboration with a librarian from Purdue Libraries and the School of Information

Studies. The databases searched included Web of Science: All Databases (at Purdue University), Engineering Village, and PubMed. To identify institutional publications, reports, and conference papers, a grey literature search was also conducted using Google Scholar (for publications between January 2016 and March 2020) and the following targeted institutional websites: World Health Organization (WHO), United States Food and Drugs Administration (US FDA), International Medical Devices Regulators Forum (IMDRF), Regulatory Affairs Professional Society (RAPS), and The Organization for Professionals in Regulatory Affairs (TOPRA).

A combination of controlled vocabulary and free text terms was used when appropriate. Common search terms included: *'pharmaceutical education', 'regulatory science', 'professional competence', 'competence', 'drug quality', 'drug control', 'competency', 'regulatory competence', 'competency framework', 'professional competence', 'pharmaceutical regulators', 'drug regulators', 'regulatory affairs professionals', 'medicines regulators', 'competency-based education', and 'skills framework'.* Details of the search strategy are documented in the systematic review protocol (Ekeigwe *et al.,* 2020).

Screening of the literature

Duplicates of the retrieved publications were removed. The removal of duplicates was followed by the first level of publication screening (titles, abstracts, table of content and executive summaries) for relevance to the research purpose. Then a second level screening (full-text screening) based on the inclusion and exclusion criteria stated in the systematic review protocol and listed below (Ekeigwe *et al.,* 2020). The screening was done in Excel.

Inclusion criteria:

- Must include a discussion of potential competencies or competencies in use or areas of need for training and capacity development of regulatory scientists in the medical products industry.
- Must be the most current version of the document
- Must be the complete and final version of the document, not a draft or summary
- Publications in English

Exclusion criteria:

- Literature does not discuss potential competencies in use or areas of need for training regulatory scientists in the medical products industry.
- Documents in draft or summary versions or versions that have been replaced (Ekeigwe *et al.,* 2020)
- Documents not in English
- Commentaries, news articles, reviews, and opinion papers.

Publications excluded at the full-text screening stage and the reasons for exclusion are documented in the excluded publications file (see Supplementary Material 2). The publications that survived this second screening level were then subjected to quality assessment using the Joanna Briggs Institute (JBI) Critical Appraisal Tool for Text and Opinions (Joanna Briggs Institute, 2020). Publications were assigned a rating of ** or * based on the checklist criteria (see quality assessment of publications, Supplementary Material 3). Although some publications met only five out of the six quality assessment criteria, they were included in the systematic review's final data set because these publications were from credible institutions. No publications were rejected based on quality assessments. The PRISMA flow chart (Figure1) adapted from "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement" (Moher *et al.,* 2009) illustrates the data set selection process. All screening levels were completed by the lead author and independently assessed by a second reviewer. Differences were resolved by discussion with a third reviewer.

Data extraction and synthesis

Data extraction involved coding the publications included in the qualitative review using the NVivo™ 12 software. The coding was done deductively based on a pre-existing concept of competency - the WHO competency concept (World Health Organization, 2019b). A codebook was developed a priori based on this concept by the team of researchers. The codebook was expanded as the coding proceeded (Supplementary Material 4). Generally, coding involves gathering similar materials by topic into 'buckets' called codes and interpreting and generating new ideas by reflecting on these materials (Richards, 2014; Saldana, 2009). Descriptive coding was done to describe the primary attributes (author (s), title, or purpose of the publication, publication type) of the publications (Supplementary Material 5). Topic coding, or allocating similar materials into codes (Richards, 2014), was done by identifying entry-level competencies likely suitable for sub-Saharan regulatory scientists in the publications and assigning them to predefined codes as stated in the codebook. For example, competencies related to attitudes were

assigned to the *'Enabling Behaviors'* code, while competencies related to comprehension of a concept were assigned to the 'Knowledge' code. Coded data were further analysed, interpreted, and synthesised using analytical coding (Richards, 2014) - to propose the list of competencies for inclusion in a CF. The coding was done by the lead author and discussed with the team.

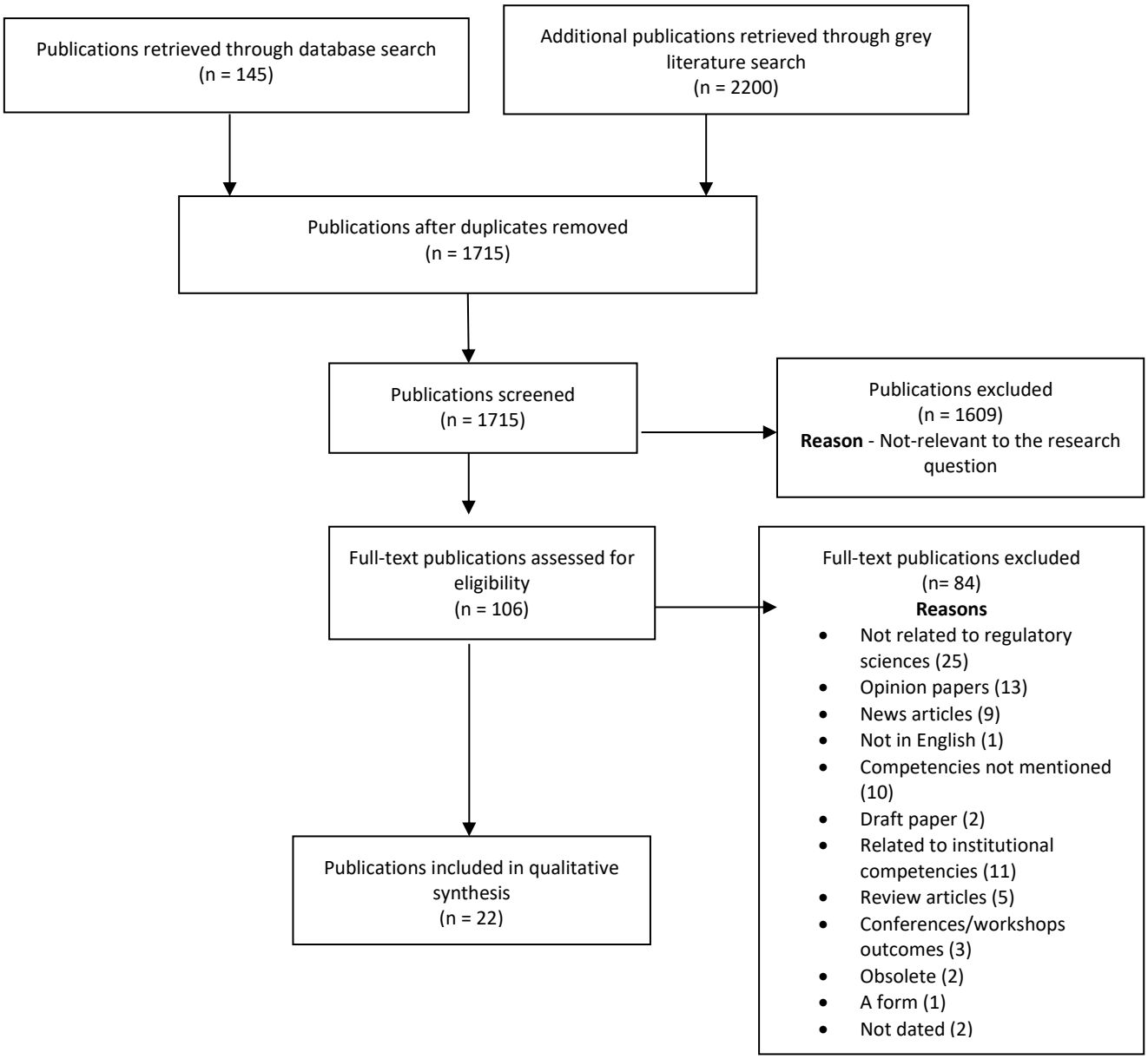

Figure 1: PRISMA flow chart for the qualitative systematic review

Results

Publications' characteristics

Databases and grey literature searches yielded a total of 2,345 publications. Following the deduplication and screening processes (Figure1), 22 publications were included in the qualitative review dataset (Supplementary Material 5). The dataset's descriptive coding shows that institutional papers made up 30% (n=7), and articles authored by individuals made up 70% (n=15) of the data set.

Quality assessment of publications

81% (n=18) of the publications met all six of JBI's quality assessment criteria. The others, 29% (n=4), were institutional papers that did not meet the JBI's criteria for reference to extant literature (Supplementary Material 3). However, these institutional papers were included in the study because they were from a credible organisation (International Medical Devices Regulators Forum), and thus assumed to confer no additional risk to the research.

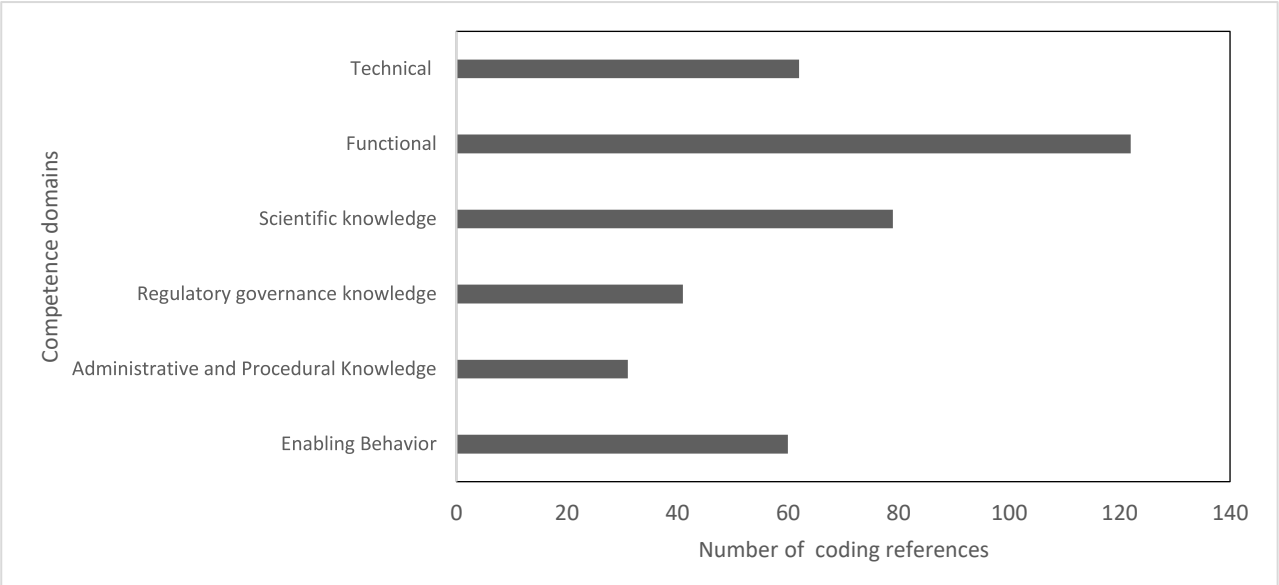

Figure 2: Number of coding references for identified competence clusters

Identified competencies

The research identified 89 competence statements in three competence clusters: enabling behaviour, knowledge, and skills for entry-level regulatory scientists involved in regulatory registration and inspections of medical products. This research expanded the knowledge and skills competence clusters to include sub-clusters. The sub-clusters for knowledge are administrative, regulatory framework, and scientific knowledge; the sub-clusters for skills are functional and technical skills. The details of all the competence clusters, competencies, and their associated sources can be accessed in the supplementary file (Supplementary Material 6).

The competence cluster with the highest coding references (the number of references coded at the cluster across the study publications) is functional skills (n=122, 30.88%). Other competence clusters have the following coding references in descending order: scientific knowledge (n=79, 20%), technical skills (n=62, 15.69%), enabling behaviours (n=60, 15.19%), regulatory governance knowledge (n=41, 10.38%), and administrative and procedural knowledge (n=31, 7.85%). Figure 2 above shows the distribution of coding references for the competence clusters. Competencies mentioned five times or more across the publication data set for each cluster were also identified (Table I). These competencies were extracted from both institutional and individually authored publications.

Discussion

The review identified the resonating competencies for inclusion in a competency framework for regulatory scientists in sub-Saharan Africa in the three conceptual categories (Behaviours, Knowledge, and Skills) of the WHO's definition of competency (Table I). The results show that the priority competence cluster is functional skills. The foremost competencies under the functional skills competence cluster are communication skills, teamwork, leadership, interpersonal relationships, time management, project management, and the use of technology. The following sub-headings discuss top competencies identified within the competence clusters and sub-clusters.

Table I: Identified high-frequency competencies of competency clusters for inclusion in a competency framework for regulatory scientists in sub-Saharan Africa

Competency cluster	Competencies	Frequency*
Enabling behaviour	Ethical intelligence	9
	Cultural awareness	7
	Adaptability	6
	Personal and professional integrity	5
Administrative and procedural knowledge	Understanding QMS	7
	Organization's vision, mission, mandate, and values	5
Regulatory framework knowledge	Identify, thoroughly comprehend, interpret, evaluate, and analyse the relevant laws, regulations, guidance, standards (national and international) that affect all aspects of the lifecycle management (pre-and post-market) of medical products	14
Scientific knowledge	Knowledge of medical products life cycle	12
	Clinical trials	9
	Statistics	5
	Drug safety and principles	5
Functional skills	Communication	15
	Working in teams	9
	Leadership	8
	Interpersonal relationship	8
	Time management	5
	Project management	5
	Proficient use of technology	5
Technical skills	Contributes to regulatory strategies for the life cycle management of new medical products	5
	Contributes to ethical design and conduct of preclinical and clinical trial designs	5

*Number of times the specific competency is mentioned across the publication dataset

Skills

Two skills (the capability to apply knowledge to execute a given task) were distinguished – functional and technical skills.

- Functional skills are viewed in this paper as skills that enable a regulatory scientist to work in any team while
- Technical skills are defined as applying or translating scientific knowledge to the performance of tasks in medical products regulatory practice either in the industry or regulatory agency.

Interestingly, the foremost of the functional skills identified was communication (both written and verbal) skills; this is not surprising as communication skill is a universally required skills for all professionals. Additional functional skills identified included: working in teams, leadership, systems, strategic and critical thinking, project management, organisational, and efficient use of technology skills.

The technical skills highlighted included conducting regulatory due diligence, developing regulatory strategy, and designing and assessing clinical trials (Table I).

Knowledge

Knowledge is described as education or information all regulatory scientists in sub-Saharan Africa need at the entry-level (Supplementary Material 4). The foundation of the regulatory science profession is knowledge. As a start, a regulatory scientist should possess a minimum of a bachelor's degree in any of the sciences such as Biology, Chemistry, Physics, Pharmacy, Medicine, Engineering, or related disciplines (International Medical Devices Regulators Forum, 2013; Danysz *et al*., 2019). As stated above, the knowledge cluster is further subdivided into

- Administrative – described in this paper as awareness of how peoples, processes, and procedures interact as part of a system, such as the relationship of a role to other functional roles, good documentation practices, Quality Management Systems (QMS), process improvements, organisational policies, and values.
- Regulatory framework – described as an awareness of regulatory governance processes, the laws, policies, regulations, and guidance related to the regulation of medical products and
- Scientific knowledge – is the comprehension of the fundamental scientific principles of medical products from conception to discontinuation.

Identified administrative knowledge includes understanding the organisation's vision, mission, mandate, values, organisational structure, and working relationships. However, understanding the role of quality management systems and how they support the organisation's systems to ensure smooth operations and continuous improvement stood out as the most crucial competence in this sub-cluster; this aligns with the critical position of QMS for driving efficiency and

effectiveness in organisations (Movahedi, Teimourpour, & Teimourpour, 2013; Anyakora *et al.,* 2017; World Health Organization, n.d.-b).

Essential regulatory framework knowledge that emerged includes identification, thorough comprehension, interpretation, evaluation, and analysis of relevant laws, regulations, guidance, and standards (national and international) that affect all aspects of the lifecycle management (pre-and post-market) of medical products. It was observed that regulatory scientists need to understand and contribute to reviewing and developing policies, regulations, guidance, and standards to ensure consistency, the achievement of purpose, and alignment with ethical principles.

The review also identified the following critical scientific knowledge: comprehension of medical products, their life cycles (discovery/research, development, preclinical, clinical, regulatory approval processes, post-marketing regulations, and discontinuation), and the roles of different stakeholders and professionals in the management and regulation of medical products throughout their life cycles; understanding of statistics; clinical trials; and medical products safety principles. These identified competencies are essential for sub-Saharan African regulatory scientists because medical products discovery, research and development, clinical trial management, and safe medical products are at developmental stages (Zannad *et al.,* 2019; Surur *et al.,* 2020).

Enabling behaviours

Enabling behaviour is defined in this paper as attitudes and traits regulatory scientists should possess and demonstrate (Supplementary Material 4). Enabling behaviours identified as outstanding for regulatory scientists were adaptability, cultural awareness, ethical intelligence, and personal and professional integrity (Table I).

The findings above are similar to other documents and articles that have been developed to define competency requirements for regulatory scientists in different sub-regions. For example, the European Medicines Agency's (EMA) requirements for competence and training of quality assessors include the following competencies – *"personal characteristics" such as "self-organisation," "self-dependence," "ability to follow standardized procedures," "basic informational technology (IT)," "communication skills," "knowledge of the quality regulatory framework," and "sufficient knowledge and understanding of GMP"* (European Medicines Agency, 2011). Similarly, the IOM, in their workshop summary on "Strengthening a workforce for innovative regulatory science in therapeutics development," have listed similar competencies (IOM (Institute of Medicine), 2012). Other articles or documents that agree with the findings in this paper are the United States Food and Drug Administration's "Competencies for All CDER (Centre for Drug Evaluation and Research) Staff" (United States Food and Drug Administration, n.d), the WHO competencies for employees (World Health Organization, n.d.-a), and "Core competencies for graduates of MS (Master of Science) programs in regulatory studies" (Association of Graduate Regulatory Educators, 2020).

Research limitations

Publication bias is a limitation of this research. The research relied heavily on a grey literature search because the available literature in this area is rarely published in peer-reviewed journals. However, the research applied a robust methodological grey literature search strategy, which helped identify rich web-based resources that are vital sources of information for large-scale reviews. The literature provides guided support for searching grey literature in systematic reviews (Godin *et al.,* 2015; Paez, 2017). A second limitation is that only publications in the English language were included. Restriction to only English language publications may not have significantly impacted the research since only one publication was excluded because of this criterion.

Conclusion

This review has identified through the critical appraisal of several publications the competencies for inclusion in an expanded competency framework for sub-Saharan regulatory scientists involved in regulatory registration and inspections of medical products. A recommended next step is to obtain expert opinion for the inclusion of these competencies in the expanded competency framework. Expert opinions can be obtained through, but are not limited to, focused group discussions, structured interviews, surveys, and observational studies (Rodriguez *et al.,* 2002; Marrelli *et al.,* 2005).

A competency framework will serve as a backbone for the development of a curriculum and Competency-Based Regulatory Sciences Education (CBRSE) for the professional development of regulatory scientists in sub-Saharan Africa (Semete-Makokotlela *et al.,* 2021). CBRSE may play a pivotal role in achieving the goal of the African Medicines Agency (AMA) to develop 'regulatory science specialists' in Africa (Ncube *et al.,* 2021).

Conflict of interest

AE has been a regulatory officer with the National Agency for Food and Drug Administration (NAFDAC), Nigeria, for 18 years before starting her Ph.D. at Purdue University. KC, SB, and LP are academic advisors to AE. The authors declare that they have no competing interests.

Authors' contributions

Conceptualization: AE KC BM LP SB.

Data curation and analysis: AE KC LP.

Development of methodology: BM AE LP KC SB.

Paper writing: AE.

Writing – Review & Editing: AE KC BM LP SB.

Final review: KC LP BM SB.

References

African Union. (2021). Linking Agenda 2063 and the SDGs | African Union. Retrieved *1* January 2021 from https://au.int/agenda2063/sdgs

Anyakora, C., Ekwunife, O., Alozie, F., Esuga, M., Ukwuru, J., Onya, S., & Nwokike, J. (2017). Cost benefit of investment on quality in pharmaceutical manufacturing: Who gmp pre- and post-certification of a nigerian pharmaceutical manufacturer. *BMC Health Serv Res*, **17**(1), 665-665. https://doi.org/10.1186/s12913-017-2610-8

Association of Graduate Regulatory Educators. (2020). Core competencies | agreglobal. Retrieved 28 October 2020 from https://www.agreglobal.org/core-competencies

Benayoune, A. (2017). Competency-based framework: The benefits and the challenges. *International Journal of Management and Applied Science*, **3**(9), 6-11

Bernard, H., Hackbarth, D., Olmsted, R. N., & Murphy, D. (2018). Creation of a competency-based professional development program for infection preventionists guided by the apic competency model: Steps in the process. *Am J Infect Control*, **46**(11), 1202-1210. https://doi.org/10.1016/j.ajic.2018.04.225

Boyatzis, R. E. (1982). The competent manager: A model for effective performance. New York: Wiley

Danysz, K., Cicirello, S., Mingle, E., Assuncao, B., Tetarenko, N., Mockute, R., Desai, S. (2019). Artificial intelligence and the future of the drug safety professional. *Drug safety*, **42**(4), 491-497

Ekeigwe, A., Clase, K., Byrn, S., Shivanand, P., McGowan, B., & Parker, L. C. (2020). Protocol - describing the competences of regulatory scientists in sub-saharan africa for regulatory registration and inspection to improve the safety, quality and efficacy of medical products – a qualitative systematic review. Retrieved 1 January 2021 from https://osf.io/eug53/

European Medicines Agency. (2011). Competence requirements and training needs for quality assessors. Retrieved 26 March 2019 from https://www.ema.europa.eu/en/documents/other/competence-requirements-training-needs-quality-assessors_en.pdf

Fouad, N. A., & Grus, C. L. (2014). Competency-based education and training in professional psychology. The Oxford Handbook of Education and Training in Professional Psychology, 105-119

Gilbert, M. B. (2019). Human performance technology: Further reflections on human competence. *Journal of Organizational Behavior Management*, **39**(1-2), 7-112. https://doi.org/10.1080/01608061.2019.1596864

Godin, K., Stapleton, J., Kirkpatrick, S. I., Hanning, R. M., & Leatherdale, S. T. (2015). Applying systematic review search methods to the grey literature: A case study examining guidelines for school-based breakfast programs in canada. *Systematic Reviews*, **4**(1). https://doi.org/10.1186/s13643-015-0125-0

Gonczi, A., Australia National Office of Overseas Skills Recognition, Australia Department of Employment Education and Training, University of Technology Sydney

Hager, P., & Oliver, L. (1990). Establishing competency-based standards in the professions. In (pp. 70 p.). Canberra: Australian Government Publishing Service

Hager, P., & Gonczi, A. (1996). What is competence? *Medical Teacher*, **18**(1), 15-18. https://doi.org/10.3109/01421599609040255

International Atomic Energy Agency. (n.d.). The competency framework: A guide for iaea managers and staff. Retrieved 1 October 2020 from https://www.iaea.org/sites/default/files/18/03/competency-framework.pdf

International Medical Devices Regulators Forum. (2013). Competence, training, and conduct requirements for regulatory reviewers. Retrieved 1 October 2020 from http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf#search=%22Competency%20%22

IOM (Institute of Medicine). (2012). Strengthening a workforce for innovative regulatory science in therapeutics development: Workshop summary. Washington, D.C.: National Academies Press

Joanna Briggs Institute. (2020). Checklist for text and opinion critical appraisal tools for use in jbi systematic review. Retrieved 3 October 2020 from https://joannabriggs.org/sites/default/files/2020-08/Checklist_for_Text_and_Opinion.pdf

Kerpel-Fronius, S., Rosenkranz, B., Allen, E., Bass, R., Mainard, J. D., Dodoo, A., . . . Whitty, J. (2015). Education and training for medicines development, regulation, and clinical research in emerging countries. *Frontiers in*

Pharmacology, **6**. https://doi.org/10.3389/fphar.2015.00080

Marrelli, A. F., Tondora, J., & Hoge, M. A. (2005). Strategies for developing competency models. *Administration and Policy in Mental Health and Mental Health Services Research*, **32**(5-6), 533-561

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & Prisma, G. (2009). Preferred reporting items for systematic reviews and meta-analyses: The prisma statement. *PLoS med*, **6**(7), e1000097

Movahedi, M. M., Teimourpour, M., & Teimourpour, N. (2013). A study on effect of performing quality management system on organizational productivity. *Management Science Letters,* **3**(4), 1063-1072. https://doi.org/10.5267/j.msl.2013.03.022

Mulder, M. (2014). Conceptions of professional competence. In S. Billett, C. Harteis, & H. Gruber (Eds.), International handbook of research in professional and practice-based learning (pp. 107-137). Dordrecht: Springer Netherlands

Ncube, B. M., Dube, A., & Ward, K. (2021). Establishment of the african medicines agency: Progress, challenges and regulatory readiness. *Journal of Pharmaceutical Policy and Practice*, **14**(1). https://doi.org/10.1186/s40545-020-00281-9

Paez, A. (2017). Gray literature: An important resource in systematic reviews. *Journal of Evidence-Based Medicine*, **10**(3), 233-240. https://doi.org/10.1111/jebm.12266

Richards, L. (2014). Handling qualitative data: A practical guide (3rd ed.): SAGE Publications

Rodriguez, D., Patel, R., Bright, A., Gregory, D., & Gowing, M. K. (2002). Developing competency models to promote integrated human resource practices. Human Resource Management: Published in Cooperation with the School of Business Administration, The University of Michigan and in alliance with the Society of Human Resources Management, **41**(3), 309-324

Saldana, J. (2009). Coding manual for qualitative researchers (1st ed.): SAGE Publications

Semete-Makokotlela, B., Mahlangu, G. N., Mukanga, D., Darko, D. M., Stonier, P., Gwaza, L., . . . Pillai, G. C. (2021). Needs-driven talent and competency development for the next generation of regulatory scientists in africa. *British Journal of Clinical Pharmacology*. https://doi.org/10.1111/bcp.15020

Surur, A. S., Fekadu, A., Makonnen, E., & Hailu, A. (2020). Challenges and opportunities for drug discovery in developing countries: The example of cutaneous leishmaniasis. *ACS Medicinal Chemistry Letters*, 11(11), 2058-2062. https://doi.org/10.1021/acsmedchemlett.0c00446

United States Food and Drug Administration. (n.d). Competences for all cder staff. Retrieved 10 September 2020 from https://www.fda.gov/media/87320/download

Wiek, A., Withycombe, L., & Redman, C. L. (2011). Key competencies in sustainability: A reference framework for academic program development. *Sustainability Science*, **6**(2), 203-218

World Health Organization. (2019a). Delivering quality-assured medical products for all 2019-2023: who's five-year plan to help build effective and efficient regulatory systems. Retrieved 13 September 2019 from https://apps.who.int/iris/handle/10665/332461

World Health Organization. (2019b, 2019). Towards a global competency framework for regulators of medical products. Retrieved 8 September 2020 from https://apps.who.int/iris/handle/10665/330894

World Health Organization. (n.d.-a). WHO competences. Retrieved 28 October 2020 from https://www.who.int/employment/WHO_competencies_EN.pdf

World Health Organization. (n.d.-b). WHO global benchmarking tool (gbt) for evaluation of national regulatory systems. Retrieved 25 January 2021 from https://www.who.int/medicines/regulation/benchmarking_tool/en/

Xiao, Y., & Watson, M. (2019). Guidance on conducting a systematic literature review. *Journal of Planning Education and Research*, **39**(1), 93-112

Zannad, F., Sobhy, M., Almahmeed, W., Balghith, M., Butler, J., Dziri, S., . . . Gamra, H. (2019). Clinical research in africa and middle east: Roadmap for reform and harmonisation of the regulatory framework and sustainable capacity development. *Journal of global health reports*, **3**. https://doi.org/10.29392/joghr.3.e2019082

Supplementary materials

Paper title - Describing the competency requirements for competence-based regulatory sciences education in sub-Saharan Africa – A qualitative systematic review

Journal – FIP Pharmacy Education journal

Supplementary material 1: PRISMA 2009 Checklist - Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Abigail Ekeigwe[1]*, Bethany McGowan[2], Loran Parker[3], Steven Byrn[1], Kari Clase[1]

[1]Biotechnology Innovation and Regulatory Sciences, School of Agricultural and Biological Engineering, Purdue University, West Lafayette, Indiana, United States.

[2]Libraries and School of Information Studies, Purdue University, West Lafayette, Indiana, United States.

[3]Evaluation and Learning Research Center, West Lafayette, Indiana, United States.

* Corresponding author

E-mails – aekeigwe@purdue.edu (AE)

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2 - 3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4 - 6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	7
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6 - 8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Preregistered protocol
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6 - 8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8, 9
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	8, 9 and Supplementary file 4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9

Section/topic	#	Checklist item	Reported on page #
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	9, 10
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	9
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	9,10
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Fig 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Supplementary file 5 and 8
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9, Supplementary file 3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Table 1
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	11, 12 Table 1
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Supplementary file 3
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	11, 12 Table 1
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13 - 16
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	16
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	18

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

Supplementary material 2: Articles excluded after the full-text screening

S/N	Title	Author(s)	Type of paper	Reasons for exclusion
1.	Making the profession better & fulfilling our mission.	Louisiana State Board of Dentistry, USA.	Opinion paper	Not related to regulatory sciences. Related to Dentistry and an opinion paper
2.	[Questions about pharmaceutical expertise]. [Article in French]	Sauer F	Opinion paper	Opinion paper
3.	FDA proposes "regulatory science" initiatives.	No authors listed	News	News article
4.	A pharmacy preregistration course using online teaching and learning methods.	Elliott RA, McDowell J, Marriott JL, Calandra A, Duncan G.	Research paper	Not related to regulatory sciences. Related to Pharmacy practice in hospital and community settings
5.	[Controversial expertise. The "Scientific Advisory Committee for Drug Safety" and its role in drug regulation in the Federal Republic of Germany, 1968-1976]. [Article in German]	Kessel N.	English Abstract	The publication is not in English
6.	Credentialing.	Ogle OE	Review paper	Not related to regulatory sciences. Related to Dentistry
7.	The unfinished business of US drug safety regulation.	Evans BJ	Review paper	No mention of competencies or skills for regulatory scientists
8.	Data audit by a regulatory agency: its effect and implication for others.	Shapiro, Martin F	Research paper	No mention of competencies or skills for regulatory scientists
9.	Understanding the medical product development process: Continuing professional development for life science professionals	Rodriguez, Rogelio	Conference article	No mention of competencies or skills for regulatory scientists
10.	Arbiter of science: Institutionalization and status effects in FDA drug review 1990-2004	Kim, Jerry W.	Research paper	No mention of competencies or skills for regulatory scientists
11.	A Shared Focus: Comparing the Australian, Canadian, United Kingdom, and United States Pharmacy Learning Outcome Frameworks and the Global Competency Framework.	I Stupans, J Atkinson, A Meštrović, R Nash, MJ Rouse	Research paper	Not related to regulatory sciences. Related to Pharmacy practice
12.	The development of the Croatian competency framework for pharmacists	I Mucalo, MO Hadžiabdić, T Govorčinović...	Research paper	Not related to regulatory sciences. Related to hospital and community Pharmacy practice competences
13.	Assessment and self-assessment of the pharmacists' competencies using the Global Competency Framework (GbCF) in Serbia (Serbian Language)	S Stojkov, I Tadić, T Crnjanski, D Krajnović - Vojnosanitetski pregled	Research paper	Not related to regulatory sciences. Related to hospital and community Pharmacy practice competencies
14.	A preceptor competency framework for pharmacists. Part 2 of a 3-part series	S Walter, K Mulherin,	Qualitative Review paper	Not related to regulatory sciences. Related to preceptor competencies
15.	Competency-based pharmacy education in the Eastern Mediterranean Region—A scoping review	D Bajis, B Chaar, J Penm, R Moles	Qualitative review paper	Not related to regulatory sciences. Related to hospital and community Pharmacy practice competencies
16.	Increasing the odds of effective drug development: Elevating regulatory affairs professionals to strategic partners	D Drago, M Yap, O Ekmekci	Regulatory perspective	Opinion paper
17.	Specialty education for student pharmacists and PharmD graduates in US colleges and schools of pharmacy	MA Islam, SA Khan, S Gunaseelan	Research paper	Not related to regulatory sciences. Discussing the status of dual degrees in US Pharmacy schools
18.	The rise of regulatory affairs in innovative startups	E Pollman	Draft Book Chapter	Draft publication
19.	Educating a new generation of professionals in aging worldwide	NM Silverstein, KG Fitzgerald	Forward to conference Proceedings	Forward to conference proceedings
20.	A survey of pharmacists' perception of foundation level competencies in African countries	A Udoh, A Bruno, I Bates	Research paper	Not related to regulatory sciences. Related to hospital and community Pharmacy

S/N	Title	Author(s)	Type of paper	Reasons for exclusion
				practice competencies
21.	Core competencies in evidence-based practice for health professionals: consensus statement based on a systematic review and Delphi survey	L Albarqouni, T Hoffmann, S Straus, NR Olsen	Research paper	Not related to regulatory sciences. Related to the Practice of Medicine
22.	Value creation in the pharmaceutical industry: the critical path to innovation	A Schuhmacher, M Hinder, O Gassmann	Book	Not related to regulatory sciences. Discussing Research & Development in the Pharmaceutical industry, not competencies
23.	Entrustment decision making in clinical training	O Ten Cate, D Hart, F Ankel, J Busari	Article	Not related to regulatory sciences. Related to the Practice of Medicine
24.	Competency-Based Pharmacy Education: An Educational Paradigm for the Pharmacy Profession to Meet Society's Healthcare Needs	MG Katoue, TL Schwinghammer	Book chapter	Not related to regulatory sciences. Related to hospital and community Pharmacy practice competences
25.	Specialty tracks in Pharm. D. curricula of US colleges and schools of pharmacy	MA Islam, G Chen, R Talukder	Research paper	Not related to regulatory sciences. Discussing the status of dual degrees in US Pharmacy schools
26.	Medicines regulation in Africa: current state and opportunities	M Ndomondo-Sigonda, J Miot, S Naidoo... - ...	Opinion paper	Opinion paper
27.	Improving safety, quality, and efficacy of medicines in the Americas	R Bolaños, K Bond, R Child, JV Coto	Overview paper	Overview paper (Opinion paper)
28.	The European Medicines Agency's goals for regulatory science to 2025	PA Hines, RH Guy, AJ Humphreys, M Papaluca-Amati	Commentary	Commentary (Opinion paper)
29.	Evolution to a Competency-Based Training Curriculum for Pharmaceutical Medicine Physicians in Switzerland	G Schnetzler, MF Bremgartner	Opinion paper	Opinion paper
30.	Competency-Based Education Frameworks Across Canadian Health Professions and Implications for Multisource Feedback	MS John, B Tong, E Li, K Wilbur	Qualitative Review paper	Not related to regulatory sciences. Related to hospital practice
31.	ICDRA: 17th International Conference of Drug Regulatory Authorities	World Health Organization	conference report	Conference report
32.	WHO competency framework for health workers' education and training on antimicrobial resistance	E Castro Sanchez, A Holmes	Institutional Paper	Not related to regulatory sciences. It is related to other health workers - prescribers, Non-prescribers, and others working in hospitals and other clinical settings.
33.	Importance of communication in pharmaceutical regulatory affairs	DR Sumana, A Dubey, GS Ravi...	Review article	Review article
34.	Skill development in the pharmaceutical sector in India	G Patani	Editorial	Editorial (Opinion paper)
35.	Towards a global competency framework for regulators of medical products	World Health Organization	Regulatory News	Regulatory News
36.	Correlation between tertiary education and pharmaceutical industry requirements for regulatory affairs pharmacists	MR Moonsamy	Dissertation	No mention of competencies. It is related to curriculum deficiencies in pharmacy programs.
37.	Perspective on how regulators can keep pace with innovation: Outcomes of a European Regulatory Preparedness Workshop on nanomaterials and nano-enabled ...	LG Soeteman-Hernández, C Bekker, M Groenewold	Workshop outcome paper	Workshop outcome paper
38.	Medical Writing Competency Model—Section 1: Functions, Tasks, and Activities	DB Clemow, B Wagner, C Marshallsay	Analytical report	No mention of competencies.
39.	Regulatory Affairs Professionals in Early Clinical Trials	LM Muñoz - pdfs.semanticscholar.org	Review article	Review article
40.	Continuous professional development of healthcare workers- analysis of the current state.	A Undilashvili, K Ebralidze, R Beriashvili	Opinion paper	Opinion paper
41.	Can Source Triangulation Be Used to Overcome Limitations of Self-Assessments? Assessing Educational Needs and Professional Competence of Pharmacists.	N Kheir, MS Al-Ismail, R Al-Nakeeb	Research paper	Not related to regulatory sciences. Related to hospital and community Pharmacy practice competences
42.	Curriculum transformation: from didactic to competency-based programs in Pharmaceutical	O Chisholm - Frontiers in Pharmacology	Opinion paper	Opinion paper

S/N	Title	Author(s)	Type of paper	Reasons for exclusion
	Medicine			
43.	Building Quality Assurance (QA) and Risk-Based Quality Management (RBQM) Systems into Clinical Research Operations. An Academic Site Perspective	Marina A Malikova*	Review article	Review article
44.	Administering a US Based MS Degree in Kilimanjaro, Africa–A Global Benchmarking in Regulatory Science	ML Springer, L Terruso, M Speer	Research paper	No mention of the competencies of regulatory scientists. Comparing institutions providing regulatory science education in the US
45.	Mapping and assessment of personal and professional development skills in a pharmacy curriculum	E Ramia, P Salameh, IF Btaiche, AH Saad	Research paper	Not related to regulatory sciences. Related to Pharmacy practice
46.	The development of a foundation-level pharmacy competency framework: An analysis of country-level applicability of the Global Competency Framework	N Arakawa, S Yamamura, C Duggan, I Bates	Research paper	Not related to regulatory sciences. Related to Pharmacy practice
47.	Preparation for future learning: a missing competency in health professions education?	M Mylopoulos, R Brydges, NN Woods... -	Opinion paper	Not related to regulatory sciences. Related to systems of instruction and learning
48.	The difference between competency and competence: A regulatory perspective	R Moghabghab, A Tong, A Hallaran	Research paper	Not related to regulatory sciences. Definition of the terms competency and competence
49.	Competency, programming, and emerging innovation in graduate education within schools of pharmacy: the report of the 2016-2017 research and graduate affairs.	SM Poloyac, KF Block, JE Cavanaugh...	Research paper	Not related to regulatory sciences. Related to Pharmacy Practice
50.	Development of a teaching model to advance skills in industrial pharmaceutical formulation and regulatory aspects	G Laverty, L Belaid, C Coulter, S Porter -	Research paper	Not related to regulatory sciences. Evaluation of a teaching method
51.	Competencies: A new currency for continuing professional development	A Aperia, J Dirach, M Hardman	Review article	Review article
52.	Competency and Its Many Meanings	Z Austin	Commentary	Commentary (Opinion paper)
53.	Health workforce cultural competency interventions: a systematic scoping review	C Jongen, J McCalman, R Bainbridge	Research paper	Related to professional practice in clinical settings
54.	Development of an interprofessional competency framework in Japan	J Haruta, I Sakai, M Otsuka, H Yoshimoto	Research report	Related to professional practice in clinical settings
55.	What future healthcare professionals need to know about Pharmacovigilance: introduction of the WHO PV Core curriculum for university teaching with focus ...	R van Eekeren, L Rolfes, AS Koster, L Magro	Opinion paper	Opinion paper
56.	https://www.who.int/medicines/regulation/09_GBT_LR_RevVI.pdf	World Health Organization	Institutional document	Related to institutional competencies
57.	https://www.who.int/medicines/regulation/06_GBT_RI_RevVI.pdf pdf	World Health Organization	Institutional document	Related to institutional competencies
58.	https://www.who.int/medicines/regulation/02_GBT_MA_RevVI.pdf	World Health Organization	Institutional document	Related to institutional competencies
59.	https://www.who.int/gho/medicines/regulation/05_GBT_LI_RevVI.pdf	World Health Organization	Institutional document	Related to institutional competencies
60.	https://www.who.int/hrh/documents/15-295Strategy_Report-04_24_2015.pdf pdf	World Health Organization	Institutional document	No mention of competencies. Related to human resource strategy to develop and retain skilled health workers
61.	https://www.who.int/medicines/areas/regulation/01_GBT_RS_RevVI.pdf pdf	World Health Organization	Institutional document	Related to institutional competencies
62.	WHO | The promise of competency-based education in the health professions for improving global health	Larry D Gruppen , Rajesh S Mangrulkar and Joseph C Kolars	Review article	Review article
63.	Code of Ethics	Regulatory Affairs Professionals Society	Institutional document	No mention of competencies
64.	RAPS' New Regulatory Competency Framework Helps Organizations, Individuals Plan Professional Development,	Zachary Brousseau	News Article	News Article

S/N	Title	Author(s)	Type of paper	Reasons for exclusion
	Training, Career Advancement			
65.	About the Regulatory Profession	Regulatory Affairs Professionals Society	Commentary	Commentary (Opinion paper)
66.	Competency Expectations for the Regulatory Professional: A Changing Paradigm	Andrey Mladenov, Siegfried Schmitt, PhD	News Article	News Article
67.	Core Competencies Provide Roadmap for Strengthening Regulatory Education	Sra Shire, DMD, MPA, Charles H. Swanson, Ph.D., Daniela Drago, Ph.D., Jean E. Feagin	News Article	News Article
68.	Writing Skills for the Regulatory Professional	Mukesh Kumar,	News Article	News Article
69.	Harmonization Creates Opportunities for Both Regulatory Professionals and Agencies in Developing Countries	Obaid Ali, RPh, MPhil, Ph.D., Roohi B. Obaid	News Article	News Article
70.	Teaching: An Integral Responsibility for Regulatory Professionals	Max Sherman	News Article	News Article
71.	Practical Document Writing and Management	The Organization of Professionals in Regulatory Affairs	An event advert	An event advert (News Article)
72.	Regulatory Authority Assessment method for the recognition and monitoring of medical device auditing organizations [PDF file]	International Medical Devices Regulatory Forum	Institutional document	Related to institutional competencies
73.	GHTF SG4 Training Requirements for Auditors	International Medical Devices Regulatory Forum	Institutional document	Obsolete version
74.	Consultation: Competence, Training, and Conduct Requirements for Regulatory Reviewers	International Medical Devices Regulatory Forum	Institutional document	Draft publication
75.	Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations	International Medical Devices Regulatory Forum	Institutional document	Related to institutional competencies
76.	Good Regulatory Review Practices	International Medical Devices Regulatory Forum	Presentation	Presentation (Opinion paper)
77.	Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition	International Medical Devices Regulatory Forum	Institutional document	Related to institutional competencies
78.	Archived: GHTF SG4 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 1: General Requirements [Word file]	International Medical Devices Regulatory Forum	Institutional document	Obsolete version
79.	42. GHTF SG4 Auditing of QMS Medical Device Manufacturers-Part 3 Audit Reports	International Medical Devices Regulatory Forum	Institutional document	Related to institutional competencies
80.	Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements	International Medical Devices Regulatory Forum	Institutional document	Related to institutional competencies
81.	GHTF SG4 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategies	International Medical Devices Regulatory Forum	Institutional document	Related to institutional competencies
82.	Auditor and Technical Expert Competency Summary	US Food and Drugs Administration	Institutional document	A form
83.	https://www.who.int/employment/WHO_competencies_EN.pdf	World Health Organization	Institutional document	Not dated
84.	Competencies for All CDER Staff	US Food and Drugs Administration	Institutional document	Not dated

Supplementary material 3: Quality assessment of publications

Key: 1. Is the source of the opinion clearly identified? 2. Does the source of opinion have standing in the field of expertise? 3. Are the interests of the relevant population the central focus of the opinion? 4. Is the stated position the result of an analytical process, and is there logic in the opinion expressed? 5. Is there reference to the extant literature? 6. Is any incongruence with the literature/sources logically defended?

Author(s) and year	1	2	3	4	5	6	Ranking
Adamo J.E, Wilhelm E.E, Steele S.J 2015	Yes	Yes	Yes	Yes	Yes	N/A	**
Wipfli HL, Berman M, Hanson K, Kelder S, Solis A, Villanti AC, Ribeiro CM, Meissner HI, Anderson R. 2017	Yes	Yes	Yes	Yes	Yes	N/A	**
Allen, Gabrielle M., Chisholm, Orin 2019	Yes	Yes	Yes	Yes	Yes	N/A	**
Dubois, DJ; Jurczynska, A; Kerpel-Fronius, S; Kesselring, G; Imamura, K; Nell, G; Silva, H; Stonier, P 2016	Yes	Yes	Yes	Yes	Yes	N/A	**
Kerpel-Fronius, S; Rosenkranz, B; Allen, E; Bass, R; Mainard, JD; Dodoo, A; Dubois, DJ; Hela, M; Kern, S; Massud, J; Silva, H; Whitty, J. 2015	Yes	Yes	Yes	Yes	Yes	N/A	**
Stanley, AG; Jackson, D; Barnett, DB 2005	Yes	Yes	Yes	Yes	Yes	N/A	**
N Giangrande, RM White, M East, R Jackson, T Clarke 2019	Yes	Yes	Yes	Yes	Yes	N/A	**
J Wong, R Tong 2018	Yes	Yes	Yes	Yes	Yes	N/A	**
CA Hornung, CT Jones 2018	Yes	Yes	Yes	Yes	Yes	N/A	**
D Drago, S Shire, O Ekmekci 2016	Yes	Yes	Yes	Yes	Yes	N/A	**
NA Calvin-Naylor, CT Jones, MM Wartak 2017	Yes	Yes	Yes	Yes	Yes	N/A	**
CA Hornung, PA Ianni, CT Jones 2019	Yes	Yes	Yes	Yes	Yes	N/A	**
World Health Organization 2017	Yes	Yes	Yes	Yes	Yes	N/A	**
L Roth, D Bempong, JB Babigumira, S Banoo... – G 2018	Yes	Yes	Yes	Yes	Yes	N/A	**
D Drago, PL McDonald, GR Lotrecchiano – I 2018	Yes	Yes	Yes	Yes	Yes	N/A	**
DB Clemow, B Wagner, C Marshallsay 2018	Yes	Yes	Yes	Yes	Yes	N/A	**
D Drago, Samantha Alsbury, Tacye Connolly 2017	Yes	Yes	Yes	Yes	Yes	N/A	**
K Danysz, S Cicirello, E Mingle, B Assuncao 2018	Yes	Yes	Yes	Yes	Yes	N/A	**
Regulatory Affairs Professional Society 2017	Yes	Yes	Yes	Yes	No	N/A	*
International Medical Devices Regulatory Forum 2013	Yes	Yes	Yes	Yes	No	N/A	*
International Medical Devices Regulatory Forum 2013	Yes	Yes	Yes	Yes	No	N/A	*
International Medical Devices Regulatory Forum 2017	Yes	Yes	Yes	Yes	No	N/A	*

Supplementary material 4: Codebook for data extraction

Code Name	Description
Enabling behaviors	Attitudes and traits regulatory scientists should possess and demonstrate
Knowledge	Education or information all regulatory scientists need to have at entry-level
Administrative knowledge	Awareness of how peoples, processes, and procedures interact as part of a system, such as the relationship of a role to other functional roles, good documentation practices, quality management systems, process improvements, organizational policies, and values
Regulatory governance knowledge	Awareness of regulatory governance processes, the laws, policies, regulations, and guidance related to medical products regulation
Scientific knowledge	Comprehension of the fundamental scientific principles about medical products from conception to discontinuation
Skills	The capability to apply knowledge to execute a given task
Functional skills	Skills required to work in any team or organization
Technical skills	Ability to apply or translate scientific knowledge to the performance of tasks in medical products regulatory practice either in the industry or regulatory agency

Supplementary material 5: Included Publications: Overview of Publications for Qualitative Systematic Review

S/N	Publication title	Author(s)	Year	Type of paper	Quality[1]
1.	Advancing a Vision for Regulatory Science Training.	Adamo JE, Wilhelm EE, Steele SJ	2015	Research paper	**
2.	Postgraduate Education in Pharmaceutical Medicine in Australia: Evaluation and Evolution to a Global Program Over 20 Years	Allen, Gabrielle M., Chisholm, Orin	2019	Research paper	**
3.	Competency indices to assess the knowledge, skills, and abilities of clinical research professionals	CA Hornung, CT Jones	2018	Research paper	**
4.	Indices of clinical research coordinators' competence	CA Hornung, PA Lanni, CT Jones	2019	Research paper	**
5.	Promoting excellence in the regulatory affairs profession	D Drago, Samantha Alsbury, Tacye Connolly	2017	Research and institutional paper	**
6.	Communicating Transdisciplinary Characteristics in Global Regulatory Affairs: An Example From Health Professions Education.	D Drago, PL McDonald, GR Lotrecchiano - I	2018	Research paper	**
7.	Improving regulatory education: can we reconcile employers' expectations with academic offerings?	D Drago, S Shire, O Ekmekci	2016	Research paper	**
8.	Medical Writing Competency Model—Section 2: Knowledge, Skills, Abilities, and Behaviors	DB Clemow, B Wagner, C Marshallsay	2018	Analytical report	**
9.	Fostering Competence in Medicines Development: The IFAPP Perspective	Dubois, DJ (Dubois, Dominique J.); Jurczynska, A (Jurczynska, Anna); Kerpel-Fronius, S (Kerpel-Fronius, Sandor); Kesselring, G (Kesselring, Gustavo); Imamura, K (Imamura, Kyoko); Nell, G (Nell, Gerfried); Silva, H (Silva, Honorio); Stonier, P (Stonier, Peter)	2016	Research paper	**
10.	Competence and training requirements for auditing organizations [PDF file]	International Medical devices Regulators Forum	2013	Institutional document	*
11.	Regulatory Authority Assessor Competence and Training Requirements	International Medical devices Regulators Forum	2013	Institutional document	*
12.	Competence, Training, and Conduct Requirements for Regulatory Reviewers	International Medical devices Regulators Forum	2017	Institutional document	*
13.	Handbook of Medical Device Regulatory Affairs in Asia	J Wong, R Tong	2018	Book	**
14.	Artificial intelligence and the future of the drug safety professional	K Danysz, S Cicirello, E Mingle, B Assuncao	2019	Research paper	**
15.	Education and training for medicines development, regulation, and clinical research in emerging countries	Kerpel-Fronius, S (Kerpel-Fronius, Sandor); Rosenkranz, B (Rosenkranz, Bernd); Allen, E (Allen, Elizabeth); Bass, R (Bass, Rolf); Mainard, JD (Mainard, Jacques D.); Dodoo, A (Dodoo, Alex); Dubois, DJ (Dubois, Dominique J.); Hela, M (Hela, Mandisa); Kern, S (Kern, Steven); Massud, J (Massud, Joao); Silva, H (Silva, Honorio); Whitty, J (Whitty, Jeremy)	2015	Research paper	**
16.	Expanding global access to essential medicines: investment priorities for sustainably strengthening medical product regulatory systems	L Roth, D Bempong, JB Babigumira, S Banoo... - G	2018	Qualitative Review paper	**
17.	A competency framework to assess and activate education for sustainable development: Addressing the UN sustainable development goals 4.7 challenge	N Giangrande, RM White, M East, R Jackson, T Clarke	2019	Research paper	**
18.	Education and training of clinical and translational study investigators and research coordinators: a competency-based approach	NA Calvin-Naylor, CT Jones, MM Wartak	2017	Research paper	**
19.	Regulatory Competency Framework	Regulatory Affairs Professionals Society	2017	Institutional document	*
20.	The teaching of drug development to medical students: collaboration between the pharmaceutical industry and medical school	Stanley, AG (Stanley, AG); Jackson, D (Jackson, D); Barnett, DB (Barnett, DB)	2005	Research paper	**

S/N	Publication title	Author(s)	Year	Type of paper	Quality[1]
21.	Defining Tobacco Regulatory Science Competencies.	Wipfli HL(1), Berman M(2), Hanson K(3), Kelder S(3), Solis A(4), Villanti AC(5), Ribeiro CM(6), Meissner HI(7), Anderson R(8).	2017	Research paper	**
22.	WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices	World Health Organization -	2017	Institutional Paper	**

[1]Assessment with the Joanna Briggs Institute (JBI) Critical Appraisal Tool for text and opinions.

** - Publications that met all six quality assessment criteria.

* - Publications that met at least five out of the six quality assessment criteria.

Supplementary material 6: Identified entry-level competency requirements for sub-Saharan African regulatory scientists involved in regulatory registration and inspections

List of competencies	Sources
Domain: Enabling behaviour	
1. Adaptability - ability to adjust to changing work demands, situations or environment, and new scientific findings	(Clemow et al., 2018; Drago, 2017; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c; Wong & Tong, 2018)
2. Learning Agility – ability to learn from experiences and different situations	(Clemow et al., 2018)
3. Autonomy – the ability to work independently with very little assistance	(International Medical Devices Regulators Forum, 2013a, 2013b, 2013c)
4. Commitment to continuous professional development	(Wong & Tong, 2018)
5. Commitment to public health	(International Medical Devices Regulators Forum, 2013b)
6. Compliant to laws, regulations, and policies	(Drago, 2017; Regulatory Affairs Professional Society, 2017)
7. Confidentiality – maintaining restricted information within the circle of authorized staff	(Drago, 2017; International Medical Devices Regulators Forum, 2013c; Regulatory Affairs Professional Society, 2017)
8. Cultural awareness – Recognize and respect different cultures	(Clemow et al., 2018; Giangrande et al., 2019; Hornung et al., 2018; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c; Regulatory Affairs Professional Society, 2017)
9. Ethical intelligence – applies a code of ethics and other professional guidelines and moral reasoning in professional work	(Clemow et al., 2018; Drago, 2017; Drago, Shire, & Ekmekci, 2016; Hornung et al., 2019; Hornung et al., 2018; International Medical Devices Regulators Forum, 2013b; Kerpel-Fronius et al., 2015; Regulatory Affairs Professional Society, 2017; Wipfli et al., 2017)
10. Mental wellness	(Giangrande et al., 2019)
11. Objectivity – ability to make judgments or decisions based on a balanced evaluation of situations or documents without undue influence from others or personal interest	(International Medical Devices Regulators Forum, 2013a, 2013b, 2013c)
12. Observant – alert and attentive to the environment and activities in it	(International Medical Devices Regulators Forum, 2013a)
13. Perceptive – naturally able to comprehend complex regulatory issues	(International Medical Devices Regulators Forum, 2013a, 2013b, 2013c)
14. Personal and professional integrity – behaves with the highest level of morals – honesty, fairness, respect, and responsibility.	(Drago, 2017; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c; Regulatory Affairs Professional Society, 2017)
15. Proactive – having the foresight and acting accordingly	(Clemow et al., 2018)
16. Tenacious – resolutely fixated on achieving goals and objectives	(International Medical Devices Regulators Forum, 2013a, 2013b, 2013c)
Domain: Knowledge	
17. Qualification – Bachelor's or its' equivalent in any sciences (for example, Pharmacy, Medicine, Biology, Physics, Chemistry, Biochemistry, Microbiology, Biophysics, Computer technology, engineering – biomedical, electrical, chemical, mechanical)	(Danysz et al., 2019; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c)
Sub-Domain: Administrative and procedural knowledge	
18. Understands and comprehends the vision, mission, mandate, and values of the organization	(Drago, 2017; Stanley, Jackson, & Barnett, 2005; Wipfli et al., 2017; Wong & Tong, 2018; World Health Organization, 2017)
19. Understands the structure, organizational charts, reporting lines, internal workings, functions of all parts of the organization, and their relationships	(Drago, 2017)
20. Understands the role of the regulatory scientists and their interrelationship with other functional units in the organization	(Drago, 2017; Stanley et al., 2005)
21. Understands and applies the laws, policies, regulations, guidance, procedures, and work instructions of the organization to their work	(Clemow et al., 2018; International Medical Devices Regulators Forum, 2013b, 2013c)
22. Understands Quality Management Systems (QMS), its significance, and how Standard Operating Procedures (SOP) are employed to drive QMS to	(Drago, 2017; Drago, McDonald, & Lotrecchiano, 2018; Drago et al., 2016; Hornung et al., 2018; International Medical Devices

List of competencies	Sources
support regulatory processes in their organizations	Regulators Forum, 2013c; Regulatory Affairs Professional Society, 2017; World Health Organization, 2017)
23. Understands the techniques and standards for assessing QMS	(International Medical Devices Regulators Forum, 2013a, 2013c)
24. Participates in developing SOPs, process improvements, change management, and project management	(Allen & Chisholm, 2019; Drago, 2017; Drago et al., 2018; Regulatory Affairs Professional Society, 2017)
25. Participates in the training of other colleagues and stakeholders to ensure organizational-wide compliance	(Regulatory Affairs Professional Society, 2017)
Sub-Domain: Regulatory Governance/ Framework Knowledge	
26. Understand the history, rationale, and structure of current global regulatory systems for medical products	(Adamo, Wilhelm, & Steele, 2015; Drago, 2017; Wipfli et al., 2017)
27. Describe the interconnection between law, regulation, and guidance	(Drago, 2017)
28. Identify, thoroughly comprehend, interpret, evaluate and analyze the relevant laws, regulations, guidance, standards (national and international) that affect all aspects of the lifecycle management (pre- and post-market) of medical products	(Adamo et al., 2015; Calvin-Naylor et al., 2017; Clemow et al., 2018; Danysz et al., 2019; Drago, 2017; Drago et al., 2018; Hornung et al., 2019; Hornung et al., 2018; International Medical Devices Regulators Forum, 2013c; Kerpel-Fronius et al., 2015; Regulatory Affairs Professional Society, 2017; Stanley et al., 2005; Wong & Tong, 2018; World Health Organization, 2017)
29. Understands and contributes to the process of reviewing and developing policies, regulations, guidance, and standards to ensure consistency, the achievement of purpose, and alignment with ethical principles	(Adamo et al., 2015; Drago, 2017; Wipfli et al., 2017)
30. Tracks, Identifies, and keeps abreast of novel regulatory trends that could affect medical products development and future requirements	(Drago, 2017)
Sub-Domain: Scientific Knowledge	
31. Understands public health principles	(World Health Organization, 2017)
32. Describes preclinical research, the rationale for preclinical research, and understands the basic principles of Good Laboratory Practice	(Adamo et al., 2015)
33. Understands clinical trials, their types, ethical issues related to clinical trials, elements of trial designs, analysis of trial outcomes to inform decisions, regulatory requirements, and comprehends the fundamentals of Good Clinical Practice	(Adamo et al., 2015; Allen & Chisholm, 2019; Calvin-Naylor et al., 2017; Drago, 2017; Hornung et al., 2019; Hornung et al., 2018; Kerpel-Fronius et al., 2015; Stanley et al., 2005; Wong & Tong, 2018)
34. Understands the concept of Real-World Evidence and its application in medical products regulation	(Adamo et al., 2015)
35. Knowledge of medical products, their life cycle (discovery/research, development, preclinical, clinical, regulatory approval processes, post-marketing regulations, and discontinuation), and the roles of different stakeholders and professionals in the management and regulation of medical products throughout their life cycle	(Adamo et al., 2015; Calvin-Naylor et al., 2017; Drago, 2017; Hornung et al., 2019; Hornung et al., 2018; International Medical Devices Regulators Forum, 2013a, 2013c; Kerpel-Fronius et al., 2015; Regulatory Affairs Professional Society, 2017; Stanley et al., 2005; Wong & Tong, 2018; World Health Organization, 2019)
36. Explains the role of quality requirements/standards in the life cycle of medical product	(Adamo et al., 2015; Drago, 2017; Drago et al., 2018; International Medical Devices Regulators Forum, 2013c)
37. Understands the fundamentals of bioequivalence, toxicology/pharmacology, pharmacokinetics, pharmacodynamics, biochemistry, chemistry, and dissolution testing	(Stanley et al., 2005)
38. Understands foundational statistics - including the formulation of research questions, hypothesis testing, experimental design, and inference of appropriate conclusions	(Adamo et al., 2015; Allen & Chisholm, 2019; Drago et al., 2016; International Medical Devices Regulators Forum, 2013a, 2013c)
39. Understand systematic, meta-analysis, and other scientific methods (focus groups, surveys, and experiments) to collect and validate data to inform regulatory decisions	(Adamo et al., 2015)
40. Understand the basis and use of "analytic tools and techniques such as bioinformatics, patient-reported outcomes, clinical effectiveness research, translational research, pharmacometrics"	(Adamo et al., 2015)
41. Tracks, identifies, describes, and keeps abreast of emerging technologies and innovations and how they may impact the regulation of medical products (e.g., innovations and technologies in manufacturing, testing, IT)	(Adamo et al., 2015; Regulatory Affairs Professional Society, 2017)
42. Understands the principles and science of drug safety and efficacy, and the history of significant events that guided safety and pharmacovigilance regulations	(Allen & Chisholm, 2019; Danysz et al., 2019; Kerpel-Fronius et al., 2015; Stanley et al., 2005; Wipfli et al., 2017)
43. Comprehends necessary medical, drug, and health terminologies such as, but not limited to those found in the "Medical Dictionary for Regulatory Activities (MedDRA) and World Health Organization Drug Dictionary (WHODrug) coding dictionaries and medical terminology"	(Danysz et al., 2019)
44. Comprehends the evidence-based regulatory decision process in the assessment of the benefit-risk ratio of medical products	(Drago, 2017; Wipfli et al., 2017)
45. Understands the concept of Good Distribution Practices	(Roth et al., 2018)
46. Knowledge of pharmacogenomics	(Allen & Chisholm, 2019; Stanley et al., 2005)

List of competencies	Sources
47. Knowledge of Pharmacoeconomics	(Allen & Chisholm, 2019)
48. Understands the principles of risk management in all regulatory strategies and operations for medical products	(Drago, 2017; International Medical Devices Regulators Forum, 2013c)
49. Understands the fundamentals of labeling and advertisements	(Drago, 2017; Stanley et al., 2005)
Domain: Skills	
Sub-Domain: Functional Skills	
50. Communication skills - verbal and written (including active listening and regulatory writing); ability to communicate effectively to all stakeholders	(Adamo et al., 2015; Clemow et al., 2018; Danysz et al., 2019; Drago, 2017; Drago et al., 2018; Drago et al., 2016; Dubois et al., 2016; Giangrande et al., 2019; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c; Kerpel-Fronius et al., 2015; Regulatory Affairs Professional Society, 2017; Wong & Tong, 2018; World Health Organization, 2017)
51. Good presentation skills	(Clemow et al., 2018; Danysz et al., 2019; Drago, 2017)
52. Leadership skills	(Calvin-Naylor et al., 2017; Clemow et al., 2018; Danysz et al., 2019; Drago, 2017; Drago et al., 2016; Dubois et al., 2016; Giangrande et al., 2019; Regulatory Affairs Professional Society, 2017)
53. Teamwork and promoting teamwork across disciplines, roles, or departments - Cooperation, Collaboration	(Clemow et al., 2018; Danysz et al., 2019; Drago, 2017; Giangrande et al., 2019; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c; Regulatory Affairs Professional Society, 2017; Wipfli et al., 2017)
54. Interpersonal skills - empathy, compassion, mediation, participation, building positive and productive relationships	(Clemow et al., 2018; Danysz et al., 2019; Dubois et al., 2016; Giangrande et al., 2019; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c; Wong & Tong, 2018)
55. Systems thinking – understand how different components of a system interact and the feedback loops that exist among components	(Danysz et al., 2019; Giangrande et al., 2019)
56. Strategic thinking – planning for the future, based on inputs of all variables that lead to decision-making, implementing, addressing challenges, and organizational development	(Giangrande et al., 2019; Wong & Tong, 2018)
57. Critical/Analytical thinking skills – the logical analysis of objective facts/evidence/observations to competent knowledge to facilitate factual and logical judgment and decision making to draw informed conclusions with the minimal potential risk of judgment errors	(Clemow et al., 2018; Danysz et al., 2019; International Medical Devices Regulators Forum, 2013a, 2013b)
58. Data management skills - entry, quality control, coding, workflow, report producing, and data visualization	(Clemow et al., 2018; Danysz et al., 2019; Hornung et al., 2019; Wong & Tong, 2018)
59. Attention to details	(Clemow et al., 2018; Danysz et al., 2019; Wong & Tong, 2018)
60. Organizational skills – ability to manage multiple tasks concurrently and utilize resources effectively	(Clemow et al., 2018; Danysz et al., 2019; Drago, 2017; Wong & Tong, 2018)
61. Time management skills	(Clemow et al., 2018; Danysz et al., 2019; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c)
62. Project management skills	(Clemow et al., 2018; Drago, 2017; International Medical Devices Regulators Forum, 2013b, 2013c; Regulatory Affairs Professional Society, 2017)
63. Manages criticism and uses feedback to improve performance and learn	(Clemow et al., 2018; Regulatory Affairs Professional Society, 2017)
64. Seeks a variety of opinions, embraces diversity and inclusion, and promotes fairness in all dealings	(Clemow et al., 2018; Regulatory Affairs Professional Society, 2017)
65. Efficient use of technology, software applications such as Outlook, Excel, PowerPoint, OneNote, Publisher, Exchange, Teams, OneDrive, SharePoint, Skype, databases (regulatory and functional databases, e.g., Microsoft Access, Microsoft Excel), machine, and artificial learning	(Clemow et al., 2018; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c; Regulatory Affairs Professional Society, 2017)
66. Interviewing skills – a capability that enables the interviewer to elicit responses to achieve the interview's predetermined goals.	(Drago, 2017; International Medical Devices Regulators Forum, 2013a, 2013c)
67. Management of documents and records	(Clemow et al., 2018; International Medical Devices Regulators Forum, 2013a, 2013b, 2013c)
68. Networking skills - within the regulatory parlance (industry, regulators, academia, consultants)	(Roth et al., 2018)
69. Negotiation skills	(Clemow et al., 2018; Drago, 2017; Wong & Tong, 2018)
70. Literature search and review	(Clemow et al., 2018)
71. Use of citation management tools	(Clemow et al., 2018)
72. Judgment and decision-making skills	(Clemow et al., 2018)
73. Manage and facilitate meetings	(Clemow et al., 2018; Regulatory Affairs Professional Society, 2017)
74. Readiness to accept new and challenging tasks that extend and develop potential	(Regulatory Affairs Professional Society, 2017)
Sub-Domain: Technical skills	
75. Conducts local, regional, and international regulatory due diligence, projects potential impacts of regulatory changes, identifies and develops	(Drago, 2017; Drago et al., 2018; Regulatory Affairs Professional Society, 2017; Wong & Tong, 2018)

List of competencies	Sources
innovative approaches to such changes	
76. Contributes to regulatory strategies for the life cycle management of new medical products, evaluating regulatory pathways, opportunities, and challenges in alignment with current local, regional, or global regulatory frameworks	(Adamo et al., 2015; Drago, 2017; Drago et al., 2018; Dubois et al., 2016; Regulatory Affairs Professional Society, 2017)
77. Contributes to the ethical design and conduct of preclinical and clinical trial designs, applying statistical principles, modeling, and informatics to design and evaluate innovative trials that comply with global standards	(Adamo et al., 2015; Calvin-Naylor et al., 2017; Drago, 2017; Drago et al., 2018; Hornung et al., 2018)
78. Assess and explain clinical trial data and other scientific evidence to support the product's claims in alignment with the regulations	(Drago, 2017; Regulatory Affairs Professional Society, 2017)
79. Collates, interprets, and verifies data from a multidisciplinary team to create regulatory submissions (e.g., Common Technical Document, annual reports, technical files), make regulatory submission communication plans, and keeps track of all submissions, responding promptly to queries	(Clemow et al., 2018; Drago, 2017; Regulatory Affairs Professional Society, 2017; Wong & Tong, 2018)
80. Develops strategy for regulatory inspections, e.g., Good Manufacturing Practices (GMP), Good Clinical Practices inspections (GCP)	(Regulatory Affairs Professional Society, 2017)
81. Applies risk management principles in medical products development, manufacture, review, and inspection of manufacturing facilities	(Drago, 2017; Roth et al., 2018)
82. Contributes to and integrates multidisciplinary perspectives in the evaluation and interpretation of data to make decisions and solve complex issues during pre-and post-marketing regulatory processes	(Adamo et al., 2015; Drago, 2017)
83. Consistently applies critical/analytical thinking and relevant regulatory standards, regulatory history, published data, organizational, procedural, scientific knowledge, and methods in reviewing medical product submissions to ensure compliance, make objective conclusions and recommendations supported with rationale	(Calvin-Naylor et al., 2017; Drago, 2017; International Medical Devices Regulators Forum, 2013b; Stanley et al., 2005)
84. Applies the concept of safety first and benefit-risk analysis in the review of medical products' submissions	(Drago, 2017; Wipfli et al., 2017)
85. Demonstrate the application of quality management systems principles, relevant standards, regulations, and guidance documents to the life cycle management of medical products to ensure compliance with regulatory frameworks	(Drago, 2017; International Medical Devices Regulators Forum, 2013a; Regulatory Affairs Professional Society, 2017)
86. Evaluates inspection and review reports in public or shared domains	(Roth et al., 2018)
87. Participates in handling post-approval activities, e.g., complaints, recalls, reports of adverse events, annual reports, post-approval changes, in compliance with jurisdictional regulatory requirements	(Dubois et al., 2016; Regulatory Affairs Professional Society, 2017; Wong & Tong, 2018)
88. Reviews advertisement of medical products to ensure compliance	(Drago, 2017; Regulatory Affairs Professional Society, 2017; Stanley et al., 2005)