Promoting excellence in the regulatory affairs profession: a competency framework

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Keywords
Competency framework; Regulatory affairs education; Professional development; Skills.

Abstract
In this article, we discuss the evolution of the Regulatory Affairs Competency Framework, and its significance. Our goal is to stimulate discussion about the current status of the profession and the knowledge, skills, and abilities that regulatory professionals need today, and in the future. As innovation occurs, it is important that regulatory professionals stay relevant and have the necessary skills and competencies to make substantive contributions to their organisations. We believe that this framework is an important contribution towards this goal. In addition, it offers guidance on the role of the regulatory professional in the delivery of safe, high quality, and accessible healthcare products for human and animal use to patients and consumers worldwide.

Background

The healthcare products landscape has evolved substantially in the past few decades. Today there are new emerging technologies, an improved understanding of patients' and consumers' needs, and a truly global marketplace. Regulatory professionals who can successfully navigate this new landscape are in high demand and short supply. Organisations that focus on the oversight, development, manufacture, and/or commercialisation of healthcare products, for human and animal use, face the significant challenge of developing a skilled regulatory workforce. As the complexity of the tasks regulatory professionals face has increased, many have argued that more tools and resources should be devoted to the preparation of a new generation of regulatory professionals.[1–2]

When individuals are not adequately equipped with the necessary knowledge, skills, and behaviours, they encounter challenges in helping their organisations perform effectively. It can be argued that regulatory professionals will serve organisations and society effectively only if an improved, efficient, and rigorous system of professional development is established. To accommodate the demands of an evolving healthcare system, there is a need for a sustained workforce capability development and hence a competency-based performance measurement to demonstrate quality and accountability in the regulatory profession. Such a framework provides a means to achieve accountability through imparting practice-based clusters of knowledge and skills, the mastery of which builds the foundation for individual performance evaluation.

The concept of academic education based on a set competencies dates back to the 1920s. However, it was in the 1970s that a competency-based approach gained more interest, largely due to the work of David McClelland on human motivation and achievement.[3] McClelland's approach has been embraced by many educational programmes specifically in the healthcare field.[4–7]

A number of competency frameworks have been developed, and TOPRA has had regulatory competencies for its members for many years. In 1990, RAPS developed a professional competency framework and this was followed in 2010 by the Association of Graduate Regulatory Educators (AGRE) which, in collaboration with other stakeholders, initiated the development of core competencies for graduates of Master of Science programmes in regulatory studies.[8,9] This was an important step forwards because a competency-based approach for the development and assessment of academic curricula helps to ensure graduates have the skills and competencies to excel as professionals in the workplace. Professional societies started to use practice-based competency frameworks to define the knowledge, skills, and abilities that their members needed to have, and there has been some interesting work to create some overarching competency frameworks. For instance, Vitae developed a Researcher Development Framework for all lab-based scientists at all levels, creating some overall competencies that spanned the many different scientific disciplines. Of more relevance to regulatory professionals, the European Medicines Research Training Network has been working on competencies for people working in the safety sciences for medicines and devices, but this work is not yet complete.[10] The European Medicines Agency (EMA) and other regulatory authorities such as the UK's Medicines and Healthcare products Regulatory Agency (MHRA) have also developed competency frameworks.

In this article, we build on the growth of advocacy for excellence in the regulatory affairs profession.[11] We also describe the recent work of the International Competency Framework Development Committee and discuss the committee's work on the Regulatory Affairs Competency Framework, a framework that brings together the competencies embedded in the curricula and assessment of regulatory qualifications and the competencies professionals need at different stages of their regulatory careers.

Developing the Regulatory Affairs Competency Framework

The Regulatory Affairs Competency Framework is the result of research conducted over many years across regulatory professionals working in different sectors, and based in different geographies. It is important that regulatory competency frameworks develop along with the profession. The TOPRA Professionalism Committee began the process of updating the regulatory competencies for TOPRA members and identified the need to have a competency framework that mapped to the TOPRA professional development framework. They carried out a needs assessment and initial data collection. This was followed by a period of informal consultation with a wider group of TOPRA members. In response to this consultation, an International Competency Framework Development Committee was established as an international, interdisciplinary group of regulatory experts, including representatives of the regulated industry, health authorities, and academia. In 2016,

Table 1 – Regulatory Affairs Competency Framework.

	Strategy (Competencies related to assessing information – by using an analytical thought process – and achieving a defensible conclusion)	**Communication** (Competencies related to communicating with diverse populations through verbal, written and non-verbal means)	**Business and Organisational Awareness** (Competencies related to the understanding of the business and/or regulatory agency's authority, structure and activities)
Establishing	● Identify relevant law, regulations, and guidance documents covering pre- and/or post-market requirements for healthcare products ● Collect data relevant to the essential regulatory question, issue, or problem ● Identify factors leading to regulatory recommendations.	● Co-author basic regulatory documents and reports ● Use appropriate questions to verify complete understanding ● Recognise the importance of negotiation skills.	● Explain the role of a regulatory agency, their authority, structure, and activities ● Explain the ethical behaviour expectations of working in the regulated industry and/or for governmental agencies ● Recognise and respect confidentiality and comply with relevant codes of conduct ● Recognise the meaning and significance of conflicts of interest ● Ensure personal compliance with relevant quality standards ● Explain the role of regulatory professionals and their interrelationships with other functions in the organisation.
Consolidating	● Contribute to the development of regulatory recommendations and decisions ● Recognise potential regulatory issues, solutions, and opportunities ● Identify the underlying processes and principles for developing product claims.	● Use communication skills to transfer knowledge to entry-level employees ● Review written correspondence from peers and entry-level employees ● Employ effective technical and regulatory writing skills to author standard regulatory documents and reports ● Explain complex technical regulatory issues into plain language to nontechnical audiences.	● Identify the ethical principles and requirements related to the development of new healthcare products ● Identify potential conflicts of interest and their significance.
Driving	● Develop regulatory strategies to bring new healthcare products to market that support business objectives and are in compliance with regulatory requirements ● Apply lessons from the history of domestic and international regulatory and product requirements ● Identify new regulatory trends that could affect future requirements ● Explain the role of risk management in regulatory strategy and operation ● Explain evidence-based decision-making in the assessment of benefit–risk of healthcare products.	● Prepare and deliver effective presentations ● Analyse communications from health authorities and respond appropriately ● Explain relevant regulatory issues clearly.	● Manage regulatory plans for complex projects ● Appraise the chance of regulatory success in bringing a new healthcare product to the market ● Evaluate the global healthcare environment and its potential impact on the organisation.
Influencing	● Explain implications and the consequences that emerge from proposed regulatory recommendations ● Formulate defensible regulatory strategies and recommendations for complex issues ● Predict the effect of changes to regulations, policies, or procedures ● Explain data requirements to support product claims ● Contribute to the development of new or revised legislations and guidance documents.	● Formulate regulatory and public health information to obtain a desired outcome ● Use effective communication skills for public speaking ● Advocate organisational position to decision-makers ● Effectively communicate the value of the regulatory profession to stakeholders ● Review and approve inspection and audit communications.	● Perform due diligence ● Analyse regulatory guidelines, policies, and actions to determine potential business impact on the organisation ● Assess regulatory impact and risk, and develop risk management recommendations ● Explain opportunities for alignment of business objectives with regulatory requirements ● Manage organisational change.

NOTE: For the scope of this framework, the term "healthcare products" includes pharmaceuticals, biologics, medical devices, veterinary products and in vitro diagnostics.

Table 1 – Regulatory Affairs Competency Framework (Cont'd).

	Technical (Competencies related to the regulatory oversight of healthcare products development and commercialisation)	**Core** (Competencies that cut across all domains)
Establishing	● Complete low-risk regulatory assignments under appropriate supervision ● Explain the interrelationship between law, regulation and guidance.	● Explain the importance of integrity while conducting work duties ● Use a systematic approach to accomplish assigned tasks ● Prioritise work to meet timelines ● Explain the importance of working as a team and operate effectively as a member of a multi-disciplinary team.
Consolidating	● Create submissions and technical reports with limited oversight ● Identify gaps in the evidence base supporting submissions ● Apply technical expertise in multi-disciplinary teams ● Explain key aspects of the healthcare product's development process ● Advise on risk -based approaches, as appropriate ● Review labelling and advertising for regulatory compliance ● Implement quality systems to support regulatory processes ● Describe clinical development plans commonly used to determine safety and efficacy/effectiveness ● Review regulatory submissions.	● Explain the importance of adapting to the changing regulatory environment ● Identify skills and abilities that allow a regulatory professional to represent the function effectively as a member of a multi-disciplinary team.
Driving	● Identify and interpret laws, regulations, and guidance documents for domestic and international agencies relevant to the development and commercialisation of healthcare products ● Describe the rationale of regulations related to healthcare products ● Lead regulatory activities for major projects ● Advise on the conduct of ethical safety, other nonclinical, and clinical studies according to international standards ● Identify quality requirements for the development and post-market maintenance of healthcare products ● Review the regulatory implications of the outcome of the analysis of quality, nonclinical and clinical data.	● Advise on requirements for healthcare product issues such as those that may require corrective and/ or preventive actions ● Develop standard operating procedures (SOPs) and policies ● Implement and appraise continuous performance improvements of personnel and/or processes ● Mentor junior professionals ● Develop negotiation strategies with regulatory agencies and/or the regulated industry ● Develop leadership skills that inspire high performance within the regulatory environment.
Influencing	● Evaluate benefit–risk balance of healthcare products ● Explain complex regulatory concepts such as the role of biomarkers and surrogate endpoints to address questions of efficacy/effectiveness and/or safety ● Develop, select and implement systems to ensure compliance ● Assess regulatory needs for pre- and post-marketing submissions.	● Identify innovative approaches to changes needed in the regulatory environment ● Advocate for necessary changes both internally and externally ● Evaluate emerging issues of trends in the development and commercialisation of healthcare products for area of expertise and assess their regulatory impact and risk ● Establish and maintain collaborative relationships with stakeholders ● Effectively manag resources ● Devise novel approaches to regulatory challenges ● Create and implement crisis management plans and procedures ● Apply leadership that inspires high performance, regulatory compliance, and continuous improvement.

the Steering Committee of the newly formed International Competency Framework Development Committee continued the work. Through an iterative process, members of the steering committee identified:

- Five high-level competency domains (Strategy, Communication, Business and Organizational Awareness, Technical, and Core)
- Four professional levels in the TOPRA career pathway, depending on the individual's current job position (Establishing, Consolidating, Driving, and Influencing).

The steering committee then drafted a set of competencies to map the high-level competency domains and the professional levels, based on the outcomes of the needs assessment and initial data collection.

The International Competency Framework Development Committee held a workshop on the draft competency framework on 20 July 2017 in London. The workshop included 15 leaders from health authorities (n=3), industry (n=6), consultancy (n=1), academia (n=2), and professional associations (n=4). Represented areas of focus included pharmaceuticals, biologics, medical devices, veterinary products, and in vitro diagnostics. The regulatory affairs field is very broad and, in some jurisdictions, it encompasses food, cosmetics, nutritionals, and tobacco products. However, for the scope of this framework, the term "healthcare products" only includes pharmaceuticals, biologics, medical devices, veterinary products, and in vitro diagnostics.

The Regulatory Affairs Competency Framework strives to align the desired outcomes or behaviour with the proficiencies regulatory professionals need. The focus is on observable and measurable competencies. This framework aims to be a model that broadly defines the blueprint for performance within the regulatory profession. It may be used to: develop needs assessments, baseline measures and performance standards for regulatory professionals; and to develop, refine, and evaluate their educational and training needs. The model should be considered as an integrated framework of knowledge, skills and abilities, and not as a prescriptive list of all the detailed responsibilities of regulatory professionals. The intent is to provide a foundation from which interested parties can create professional development plans that can apply to regulatory professionals working in the public and private sector (ie, heath authorities, industry, academia); with different types of healthcare product categories (ie, pharmaceuticals, biologics, medical devices, veterinary products, and in vitro diagnostics); and in different geographies.

Methods and results

The International Competency Framework Development Committee members were surveyed to rate on a five-point scale their level of agreement with the inclusion of each competency as part of the framework. Survey respondents were from industry (41%), health authorities (23.5%), academia (6%), consultancy (23.5%), and professional associations (6%). Responses were collected between 19 June and 18 July 2017. Informed consent was followed and no remuneration was provided to encourage participation. However, a reminder was used to encourage the participants to return the surveys and encouragingly a 100% response rate was achieved. The final list of competencies is provided in Table 1 and is based on the results of the survey and the workshop discussions.

Discussion, recommendations, and conclusions

The workshop served to achieve consensus on the competencies. Interestingly, there is correspondence between the Regulatory Affairs Competency Framework (Table 1) and the previously cited AGRE competencies.[9] For instance, in the area of strategy, one of the AGRE's competency calls for graduates to "develop strategies to bring new medical products to market to support business objectives" and another one to "develop strategies to balance business objectives and compliance with regulatory requirements." The corresponding competency in the Regulatory Affairs Competency Framework (strategy domain; driving level) states: "develop regulatory strategies to bring new healthcare products to market that support business objectives and are in compliance with regulatory requirements."

Another example, in the area of communication, one AGRE competency asks graduates to be able to "analyze and respond appropriately to communications from the FDA and other entities." The corresponding competency in the Regulatory Affairs Competency Framework (communication domain; driving level) states "analyze communications from health authorities and respond appropriately."

Also, in the area of regulations, one AGRE competency states, "identify and interpret regulations and guidance documents for domestic and international agencies relevant to medical products." This correlates with the Regulatory Affairs Competency Framework (technical domain; driving level) to "identify and interpret laws, regulations, and guidance documents for domestic and international agencies relevant to the development and commercialization of healthcare products."

The list of competencies provided in Table 1, however, should not be taken as a static final product. The members of the International Competency Framework Development Network agreed there was a need for refinement and ongoing evaluation and validation to ensure the continued relevance of the framework to practice. As next steps, the Regulatory Affairs Competency Framework will be discussed at a session of the TOPRA Annual Symposium in October 2017. The presentation at the Symposium will include a call to action on how to disseminate the framework and get feedback about its utility. Indeed, an understanding of both the applications and the limits of competency frameworks is important. Those interested in the competency-based framework now face the challenge of validating and advancing the work already accomplished. This will include producing more detailed guidance to support the use of the framework by individual members and employers. We believe that the Regulatory Affairs Competency Framework is an important contribution to the establishment of a foundation that can be used by many in the profession to promote excellence.

References

1. D Berry, P Saias, B Williams. 'Unlocking hidden value within regulatory affairs', *KPMG Healthcare & Life Sciences,* 2014.
2. S Keramidas. 'Perspectives on the regulatory profession and its critical role in the global health product sector', *The Monitor,* 2013 (August):13–16.
3. A D Lucia, R Lepsinger. 'The Art and Science of Competency Models: Pinpointing Critical Success Factors in Organizations', San Francisco: *Jossey-Bass/Pfeiffer,* 1999.
4. J Frenk, L Chen, Z A Bhutta *et al.* 'Health professionals for a new century: transforming education to strengthen health systems in an interdependent world', *The Lancet*, 2010:1923–1958.
5. J R Frank, L S Snell, O Ten Cate *et al*. 'Competency-based medical education: Theory to practice', *Medical Teacher*, 2010, 32:638–645.
6. D S Tilley. 'Competency in nursing: A concept analysis', *Journal of Continuing Education in Nursing,* 2008, 39(2):58.
7. J G Calhoun, K Ramiah, E M Weist *et al.* 'Development of a core competency model for the master of public health degree', *American Journal of Public Health,* 2008, 98(9):1598-1607.
8. RAPS. Regulatory Affairs Professional Development Framework. Available at: www.raps.org/uploadedFiles/Site_Setup/Home_Page/About_RAPS/The_Regulatory_Profession/PDF_Framework_Whitepaper.pdf.
9. S Shire, C Swanson, D Drago *et al.* 'Core Competencies Provide a Roadmap for Strengthening Regulatory Education', *Regulatory Focus*, September 2014.
10. R Bray, S Boon. 'Towards a framework for research career development: An evaluation of the UK's Vitae Researcher Development Framework', *International Journal for Researcher Development,* 2011, 2(2):99–116.
11. D Drago, M Yap, O Ekmekci. 'Increasing the Odds of Effective Drug Development: Elevating Regulatory Affairs Professionals to Strategic Partners', *Clinical Research and Regulatory Affairs,* 2016, 1–7.