



Editorial

Regulatory Science and Regulatory Affairs

Ricardo Molins ^a

^a Office of the Texas State Chemist, Texas A&M AgriLife Research, Texas A&M University System, College Station, TX 77841, USA

Regulatory science is a relatively new field of study and practice, brought about by the need to develop and apply tools and guidelines designed to give laws and regulations a solid scientific basis. Without a scientific basis, guidelines, laws, regulations, and standards would hardly be objective and able to withstand the scrutiny and opposition that they often generate.

According to the U.S. Food and Drug Administration (FDA), “*Regulatory Science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.*”ⁱ According to the European Medicines Agency (EMA), “*Regulatory science is defined as a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied medicinal science and social sciences, and contributes to the development of regulatory standards and tools. So, a scientific discipline, but one conducted within a legal framework.*”ⁱⁱ Therefore, the EMA definition introduces a social element in addition to those in the FDA version, something that is ingrained in most European laws and regulations.

A more business-oriented definition of regulatory science is that by Volkers, “*The art and science of taking new medical and food products to market and keeping them on the market, under the constraints of a variety of laws and requirements. You're doing science, but you're doing it in a legal framework ... Regulatory science includes regulatory affairs, regulatory writing, risk management, compliance, and regulatory law.*”ⁱⁱⁱ

According to Moghissi *et al.*, three groups are involved in regulatory science: 1) Scientists who develop regulations; 2) people in the regulated community that must comply with the regulations; and 3) scientists that conduct the research underlining the regulations and develop the tools to determine compliance.^{iv}

Scientists who develop regulations and establish compliance benchmarks and standards must be highly trained in the particular area of concern. They must identify the scientific basis for a regulation, its scope, and its impact on the regulated community. The latter introduces economic and, frequently, social

aspects, that must be taken into account. (In the U.S., most regulations must be accompanied by an economic impact study.)

Although the development of regulations is primarily the purview of governmental regulatory agencies, there is also a large number of international organizations that, together, constitute a global regulatory establishment. The Joint Food and Agriculture Organization of the United Nation (FAO)/World Health Organization (WHO) Food Standards Program, of which the Codex Alimentarius is part of, is a good example of such an international standard-setting body. An example of international cooperation is the Global Summit on Regulatory Science (GSRS), a gathering of regulatory scientists involved in drug and food safety regulatory activities from all over the world. In the words of the FDA, the GSRS is, “*an international conference for discussion of innovative technologies and partnerships to enhance translation of basic science into regulatory applications within the global context ... The conference provides a platform where regulators, policy makers, and bench scientists from various countries can exchange views on how to develop, apply, and implement innovative methodologies into regulatory assessments in their respective countries, as well as harmonizing strategy via global collaboration.*”^v

The increasingly complex development and enactment process of national and international guidelines, laws and regulations, as well as the ever-growing array of such laws and regulation in many areas of human endeavor, including the food and feed industries, manufacturing of nutritional supplements and pharmaceuticals, environmental protection, and laboratory operation and practices – to mention only a few that are of interest to the Journal of Regulatory Science – has made it necessary, and sometimes critical, for organizations and businesses to have a regulatory affairs position. Some large companies and organizations also have a regulatory compliance control program or system.

Regulatory compliance means adherence to laws and regulations; non-compliance may result in fines and even more serious legal consequences, in addition to an organization’s possible loss of public image. The Regulatory Affairs Officer is the person in charge of regulatory compliance in many public agencies and private businesses.

Given that the regulatory affairs personnel are entrusted with the task of ensuring compliance with laws and regulations, they must be intimately familiar with the applicable laws and regulations and with the tools – internal and external to the enterprise – used to ascertain compliance. In the past, regulatory affairs knowledge was acquired mainly through experience. Nowadays, several universities have addressed the need for regulatory affairs training by establishing courses – and in some cases full majors and graduate degrees – in Regulatory Science or Regulatory Affairs.

ⁱ U.S. Food and Drug Administration. (2017). “Advancing Regulatory Science”. Retrieved from <https://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/default.htm>

ⁱⁱ Punia, P. (2013). “Regulatory Affairs Vs Regulatory Sciences”. Retrieved from <http://www.epmmagazine.com/blogs/regulatory-affairs-column/regulatory-affairs-vs-regulatory-sciences/>

ⁱⁱⁱ Volgers, N. (2010). “All in the Details: Careers in Regulatory Science”. Retrieved from <http://www.sciencemag.org/careers/2010/04/all-details-careers-regulatory-science>

^{iv} Moghissi, A. A., Straja, S. R., Love, B. R., McBride, D. K., Stough, R. R. (2014). Innovation in Regulatory Science: Evolution of a New Scientific Discipline. *Technology and Innovation*, 16(2), 155-165.

^v U.S. Food and Drug Administration. (2017). “Global Summit on Regulatory Science”. Retrieved from <http://www.sciencemag.org/careers/2010/04/all-details-careers-regulatory-science>