By Daniela Drago, PhD, Sandra Shire, DMD, MPA, Charles H. Swanson, PhD, and Jean E. Feagin, PhD

The regulatory landscape has evolved dramatically in the last few decades.¹ Today's regulatory professionals perform key functions in their organizations, including ensuring compliance with regulations and facilitating the development and commercialization of new products. These professionals must be equipped to address the increased complexity of the modern regulatory landscape. One important way to prepare is through graduate studies. Graduate education in regulatory plays a pivotal role in the healthcare field and has experienced significant growth in recent years. To promote consistency in the body of knowledge offered by graduate regulatory programs, leaders of these academic programs formed the Association of Graduate Regulatory Educators (AGRE). This article focuses on the development of graduate regulatory education and the role AGRE can play in advancing the regulatory field by promoting excellence and fostering partnerships among stakeholders.

Building the Regulatory Profession

Historically, lawyers analyzed and explained the laws and regulatory requirements to those working in regulated industry. Over time, companies established regulatory departments that are responsible for knowing the regulations, guidance documents and standards that influence their businesses. Using their expertise in science, clinical research, engineering and regulatory requirements, regulatory personnel developed policies and standard operating procedures to ensure compliance with requirements and facilitate product development and commercialization.

Several key professional societies, trade associations and standard-setting organizations have emerged over time to support those who work in the regulatory field. The Regulatory Affairs Professional Society (RAPS) was founded in 1976 and aims to support and lead professionals involved with regulation of healthcare products.² The Organisation
for Professionals in Regulatory Affairs (TOPRA), founded in 2004, has similar aims with a European focus. Together with other organizations, such as the Food and Drug Law Institute (FDLI), the Drug Information Association (DIA), and the Advanced Medical Technology Association (AdvaMed), they contribute to a body of knowledge and provide a forum where professionals can exchange ideas. These organizations offer seminars and publish articles and books on pertinent topics for those in the regulatory profession. Moreover, certification programs are available through professional associations and confer a professional, rather than an educational, achievement. In 1990, RAPS introduced a professional certification: the Regulatory Affairs Certification (RAC). Those in the regulatory profession who wish to become certified must pass a comprehensive exam. The RAC is the only globally recognized professional credential for those involved with the regulation of healthcare products.

Recently, DIA launched certificate programs in four key areas related to the discovery, development, and lifecycle management of safe and efficacious medical products.

The Rising Demand for Broader Skills and Competencies

Over time, the US Food and Drug Administration (FDA) and other regulatory agencies have increased their oversight of medical products. As regulations have increased, so have the demands on regulatory professionals, who must develop both strategic and operational skills. Today’s regulatory professional has a significant breadth and depth of responsibility. The result is a unique field that combines expertise in the areas of science, law and business.

The scope of regulatory work spans the entire spectrum of the product lifecycle:

- preclinical and clinical research
- regulatory strategy
- product development
- quality
- manufacturing
- labeling
- product approval
- registration
- reimbursement
- advertising and promotion
- distribution
- postmarket surveillance

In addition to subject matter expertise, the successful regulatory professional must have strong interpersonal skills and excellent verbal and written communication abilities. Helping to bring new, safe and efficacious products to market in a timely manner requires productive collaboration with other stakeholders. It also demands the ability to write and review quality submissions, negotiate skillfully and work effectively with regulatory agencies. Formal graduate education programs provide greater breadth and depth of regulatory knowledge than is possible through on-the-job training, and fosters the development of critical thinking skills.

Developing Regulatory Professionals Through Graduate Education

How did regulatory professionals develop these critical skills in the past? The early model primarily involved on-the-job training, augmented by occasional regulatory conferences and seminars. Because there were no formal training programs in regulatory, individuals with backgrounds in R&D, manufacturing, quality, clinical research or law were recruited as candidates for regulatory jobs. They often began in entry-level positions and developed their regulatory strategic and operational skills under the supervision of senior regulatory staff. As their skills developed, they were given additional responsibilities and promotions. Even the development of senior professionals involved on-the-job training. Occasionally, experienced regulatory professionals were hired from other companies or regulatory agencies.

As the regulation of medical products expanded worldwide, the need for regulatory professionals grew. The on-the-job-training model was strained by both the number of individuals who needed training and the ever-increasing body of regulatory knowledge. Many companies found it more cost-effective to hire experienced regulatory professionals
from other organizations. This was not a viable long-term strategy, as it did not adequately increase the existing pool of regulatory professionals.

Colleges and universities responded to this need by developing graduate regulatory programs. The first master of science (MS) program in regulatory studies was started in 1968, but it was not until the late 1990s that others appeared. The number of MS programs continues to grow with current estimates at about 20 in the US. Other common educational options are individual regulatory courses and graduate certificate programs.

MS programs in regulatory affairs or regulatory science provide the most extensive education (doctoral programs are rare). Developed with guidance from regulatory professionals in the healthcare products industry and government agencies, MS programs offer courses taught by industry experts, former regulators and academics. Educational programs vary in scope and format. Some cover the entire spectrum of FDA-regulated products; others focus on one specific product type (e.g., medical devices). Courses are offered on site, online or using a hybrid approach.

MS programs in regulatory studies typically require 33-39 credit hours, and include coursework and practical experiences that prepare graduates to contribute strategically and operationally to the profession. They provide education in a variety of key regulatory topics, including domestic and international requirements, regulatory strategy, submission preparation and pre- and postmarket compliance. Many programs also offer courses in related fields, such as quality, clinical research and reimbursement. Students develop an understanding of regulatory’s role in business operations and cultivate critical communication skills. MS programs prepare students to enter the profession, and accelerate the career of those already working in the field. Target employers for graduates include regulated industry, regulatory agencies, hospitals, Institutional Review Boards (IRBs) and consulting firms.

A recent survey of MS programs in regulatory studies reveals an upward trend in the number of graduates. With 15 programs reporting data, the total number of graduates grew from 227 in 2009 to 312 in 2013 (see Figure 1). This growth also reflects the addition of new programs during that timeframe. Because not all programs responded to the survey, these numbers should be considered underestimates.

This infusion of university-educated professionals serves the profession well. Graduates of university-based programs also will be an excellent source of faculty for these programs in the future. The broad healthcare enterprise also benefits from structured, high-quality MS degree programs. Graduates achieve a concrete skill set that instills confidence as they collaborate with professionals in other disciplines in the healthcare industry.

Often in response to local needs, educational programs developed across the country and are housed in a variety of university departments (some are in colleges of pharmacy, others in nursing colleges, medical schools, engineering departments or schools of public health). As the number of graduate programs increased, program leaders recognized the opportunity to work together to improve the consistency and quality of regulatory education.

**Graduate Programs and AGRE**

In 2010, Frances Richmond, PhD, director of the regulatory science program at the University of Southern California, invited leaders of graduate regulatory programs to meet and discuss

![Figure 1. Growth in the Number of MS Graduates in Regulatory Studies](image-url)
issues of mutual interest. Representatives from 16 programs, including leaders of programs in the UK and South Korea, attended the initial meeting, the objective of which was to foster better communication among the programs. Participants agreed to develop and share best practices to further advance graduate regulatory education. The initial network established through this 2010 meeting has now been formalized with the founding of AGRE.

AGRE members meet twice a year to share ideas, experiences and opportunities for improvement. Several working committees have been established to advance educational expertise in specific topics. One of the first projects was the development of core competencies for graduates of MS programs in regulatory studies. They describe what graduates of these programs should know and be able to do. The members of AGRE defined five critical areas for their curricula: regulations, clinical trials, quality, communication and strategy. Defining core competencies in these five areas was the first step in promoting quality and consistency in regulatory higher education. Individual programs may use the competencies to assess and improve their course offerings. Core competencies also provide potential employers with a deeper understanding of the skills they can expect from graduates. A comprehensive description of the AGRE core competencies is forthcoming.

AGRE provides an ongoing forum for educators to identify and work on projects to improve higher education in regulatory. As regulatory systems and requirements evolve, graduate programs will need to keep pace. AGRE members expect to work with other stakeholders in regulatory education (i.e., professionals working in industry, regulatory agencies and professional societies) to ensure graduates develop the knowledge and skills necessary to succeed.

Regulatory is a critical function in the medical products industry. Regulatory professionals facilitate the development and timely submission of applications for market authorization of new medical products, and work to ensure marketed products comply with expectations for quality, safety and effectiveness. Colleges and universities that offer graduate regulatory education programs are expected to take an increasingly important role in preparing these professionals in the years to come. AGRE is uniquely positioned to support this growth and ensure excellence in regulatory education.

References

About the Authors
Daniela Drago, PhD, is an assistant professor and director of the regulatory affairs program at George Washington University (GW). She has more than 10 years of experience in global regulatory affairs encompassing Europe, the US, Asia-Pacific and Latin America. Prior to joining GW, she worked in the pharmaceutical and medical device industries for companies ranging in size from start-ups to Fortune 500. She can be reached at drago@gwu.edu. Sandra Shire, DMD, MPA, is associate director of inter-professional programs and a clinical associate professor at Arizona State University. She has more than 20 years of regulatory experience, including 15 years at the US Food and Drug Administration as a reviewer of new medical products in the Center for Devices and Radiological Health and as an investigator for FDA’s Biosearch Monitoring program. She inspected high-profile and complex domestic and international clinical trials for a wide range of products. She can be reached at Sandra.Shire@asu.edu.

Charles H. Swanson, PhD, is director of the regulatory affairs and services graduate program at St. Cloud State University, St. Cloud, MN. He has more than 30 years of regulatory experience, including 29 years at Medtronic. He held several leadership positions at Medtronic, including chief quality and regulatory officer, and actively worked through Advamed to influence FDA policy for medical devices. He can be reached at chswanson@stcloudstate.edu. Jean E. Feagin, PhD, is practicum director of the biomedical regulatory affairs master of science program at the University of Washington (UW). She has six years of experience in regulatory affairs, including certificates in clinical trials and biomedical regulatory affairs from UW. She can be reached at feagin@uw.edu.

Cite as: Drago D, Shire S, Swanson C, Feagin J. “Answering the Call for Excellence in Regulatory Education.” Regulatory Focus. May 2014. Regulatory Affairs Professionals Society.

© 2014 by the Regulatory Affairs Professionals Society. All rights reserved.