

# IS IT TIME FOR ACADEMIC PREPARATION OF FUTURE REGULATORY AFFAIRS PROFESSIONALS?

**By Rosina Robinson**

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***Medical device industry is currently experiencing a shortage of regulatory affairs professionals***

The regulation of medical products has been expanding since early in the 20th century. Regulatory agencies are being established in an ever-increasing number of countries across the globe. Those that have established regulatory agencies are revamping their systems and attempting to harmonise with other selected jurisdictions. Agencies are also requiring more compliance activities and increasingly complex activities from the regulated industries that market products within their jurisdictions. This mushrooming regulatory framework and the associated increased regulatory burden have placed significant strains on the existing pool of experienced regulatory affairs professionals worldwide. In fact, there are those in the industry that have expressed this current shortage of regulatory affairs professionals as 'massive'<sup>1</sup>. This conclusion is further supported by a 1999 study<sup>2</sup> that suggested that the demand would continue to increase. All one needs do to personally validate these beliefs is to talk to the many employers who are struggling to find experienced regulatory affairs professionals and also to the regulatory affairs professionals who are barraged with regular telephone enquiries from placement agencies with numerous and lucrative new positions. As the regulatory affairs profession is practised in a variety of environments, it is logical to assume that this shortage of qualified personnel is shared not only by the regulated industry but also by regulatory agencies across the globe.

## **Challenges of achieving the required skills and knowledge**

***Individuals must also be knowledgeable in the technology of their products***

Adding to the complexity of finding the regulatory affairs professionals to fill the many and varied vacancies is the fact that these professionals must not only be skilled and knowledgeable about the regulations within their scope of practice, the interpretation of these regulations, and ultimately the application of these regulations, these same individuals must be knowledgeable, if not an expert, in the technology of their products. These products can range from the very simple to those that integrate the sometimes barely imaginable advancements in technology or may be one of those where previously discrete product characteristics have been blurred by its merging with another product type. Is the marketed product a drug, a biologic, a medical device, or a combination of two or all three product types? Will it be subject to premarket review and postmarket regulation as a single product or as two or more entities? If these conditions alone weren't sufficiently challenging, a product may be considered a medical device in one regulatory jurisdiction but something else in another jurisdiction. To add further to the

challenges, the speed of today's global communication requires regulatory affairs professionals to be prepared to address an agency's concerns at very short notice as well as to maintain a rapid pace of their own knowledge acquisition not only about the new requirements from the regulatory agencies but also about the technologies for their own products and their constituents. So the future regulatory affairs professional must be prepared to be a regulatory and technical expert, who is able to maintain and apply their knowledge on a global basis. This challenge sets the mind to spinning.

***Challenges faced by regulatory affairs professionals are ever-increasing***

## **Can suitable personnel be found in other areas?**

With the aforementioned mounting shortage of knowledgeable and skilled regulatory affairs professionals, perhaps this challenge can be addressed by transforming a professional with an appropriate background, be it a bench scientist, nurse, pharmacist, attorney, quality engineer, manufacturing engineer, physician, therapist or similar into a candidate for employment in the regulatory affairs department of the growing number of medical product producers. There lies the challenge and the opportunity.

Individuals currently in the regulatory affairs profession for any length of time generally entered their careers in regulatory affairs indirectly, learning the requirements from working with colleagues in the area, from government publications, and by trial and error. Companies with sufficient human resources to have a regulatory affairs department of more than one staff member would prepare others by mentoring and working along side them, gradually increasing their responsibilities and scope of involvement along the way, or what has long been considered 'on-the-job training'. However, this very successful and long exercised method of developing new regulatory affairs professionals may no longer be adequate to replace those who have taken advantage of the ever-increasing job mobility, to fill the slots left by retirees, and to augment the growing needs in regulatory departments. The luxury of time and additional human resources to execute internal development activities are no longer available to most companies, especially virtual companies who subcontract all work or start-up companies with limited and tightly controlled venture capital funding.

***Traditional methods for training new staff may no longer be sufficient***

While companies prefer to hire individuals with at least some minimum level of experience, the individuals who are interested in a career transition into regulatory affairs find themselves in the unenviable position of trying to find an employer who is willing to hire and train them. Is there a solution for these discordant needs?

## **Does academic preparation hold the answers?**

Professional regulatory affairs organisations such as the Regulatory Affairs Professionals Society, the Food and Drug Law Institute (US), The Organisation for Professionals in Regulatory Affairs (Europe), and product-specific trade organisations have been irreplaceable sources of continuing education opportunities for developing and

***One solution may be to educate new regulatory affairs professionals in academic institutions***

maintaining the knowledge of their members. Are these organisations, however, equipped to provide the depth and breadth of educational activities needed by individuals who have no on-the-job regulatory experience but who are interested in entry into a regulatory affairs position? Is now the time for the regulatory affairs profession to standardise the knowledge, skills and abilities required of an entry level regulatory affairs professional and delegate the preparation of future regulatory affairs professionals to academia for the sake of scale, efficiency and effectiveness? Is it time for academic institutions to take the on the role of educating regulatory affairs professionals in the same way that preparation of other professionals (e.g. nursing, respiratory therapy, physical therapy) has transitioned from experiential learning to academic preparation in the not-too-distant past? Will this shift from individual education (by the individual employer) or group education in an academic setting assure the regulated industry and regulatory agencies with potential employees with the knowledge and skill base on a scale and economy needed for the protection of the public health in the future? This is uncertain, but there appears to be movement in this direction.

***It is uncertain whether academic preparation will be able to fulfil the needs of the regulatory profession***

An ever-increasing number of academic institutions offer course work, both undergraduate and graduate, and structured post-graduate programmes (graduate certificates and Masters degree programmes) that are intended to fulfil the needs of both the individual who wishes to pursue a new career in regulatory affairs and the prospective employer. However, the ability of these strictly academically prepared students to fulfil the needs of the regulatory profession is relatively uncertain.

For those individuals who may be interested in learning more about the available resources, a list of academic institutions offering graduate degrees in regulatory affairs, as well as links to their programmes, is provided by type of post-graduate activity in alphabetical order by institution in Tables 1 and 2. Please note that the institutions routinely add and delete programmes or change their website addresses. Therefore this is only a starting point for the individual's search.

## **Experience is still preferred over academic qualifications**

While the number of academic programmes continues to grow, it is possible that many do not completely fulfil the needs of either the student or the industry. There continues to be a discontinuity between what happens after students have completed their required coursework and their ability to easily find employment as regulatory affairs professionals. Those who have hiring authority within the regulated industry still tend to value even minimal regulatory experience over an academic degree in regulatory affairs although they claim to value the commitment shown by adult students who have enrolled and completed academic programmes. Academic institutions and employers both bear some of the responsibility for addressing this discontinuity by creating partnering to fill the

***Even minimal practical experience is still preferred over an academic qualification***

**Table 1. Colleges and universities offering graduate degrees in regulatory affairs**

<b>Institution</b>	<b>Degree</b>	<b>Website link</b>
Cranfield University, Silsoe, UK	Master of Science in Medical Technology Regulatory Affairs	<a href="http://www.cranfield.ac.uk/ibst/msc_ra/">www.cranfield.ac.uk/ibst/msc_ra/</a>
Johns Hopkins University, Baltimore, MD, USA	Master of Bioscience in Regulatory Affairs	<a href="http://advanced.jhu.edu/biotechnology/bioscience_regaffairs.cfm">advanced.jhu.edu/biotechnology/bioscience_regaffairs.cfm</a>
Long Island University, Arnold and Marie Schwartz College of Pharmacy, Brooklyn, NY, USA	Master of Science with a specialization in drug regulatory affairs	<a href="http://www.brooklyn.liu.edu/pharmacy/phbut07/grad03.html#4">www.brooklyn.liu.edu/pharmacy/phbut07/grad03.html#4</a>
Massachusetts College of Pharmacy, Boston, MA, USA	Master of Science in Drug Regulatory Affairs and Health Policy	<a href="http://www.mcphs.edu/academicPrograms/gradStudies/drugRegAffairs.html">www.mcphs.edu/academicPrograms/gradStudies/drugRegAffairs.html</a>
Northeastern University, Boston, MA, USA	Master of Science in Regulatory Affairs	<a href="http://www.ace.neu.edu/bouve/health/MRA">www.ace.neu.edu/bouve/health/MRA</a>
Regis College, Weston, MA, USA	Master of Science in Health Product Regulation	<a href="http://www.regiscollege.edu/acad/cen_grad_cs/grad_progs/ms_policy.htm">www.regiscollege.edu/acad/cen_grad_cs/grad_progs/ms_policy.htm</a>
San Diego State University, CA, USA	Master of Science in Regulatory Affairs	<a href="http://interwork.sdsu.edu/cbbd/regaffairs/regaffairs.htm">interwork.sdsu.edu/cbbd/regaffairs/regaffairs.htm</a>
School of Health Sciences, Humber College, Toronto, Ontario, Canada	Master for Science in Regulatory Affairs	<a href="http://healthsciences.humberc.on.ca/crra/home/programs/programs_ra.php">healthsciences.humberc.on.ca/crra/home/programs/programs_ra.php</a>
Temple University, Philadelphia, PA, USA	Master of Science in Quality Assurance/Regulatory Affairs	<a href="http://www.temple.edu/pharmacy_QARA/">www.temple.edu/pharmacy_QARA/</a>
University of Georgia, College of Pharmacy, Athens, GA, USA	Master of Science in Pharmacy with emphasis in Regulatory Affairs (under development)	<a href="http://www.rx.uga.edu/main/home/reg_affairs/index.htm">www.rx.uga.edu/main/home/reg_affairs/index.htm</a>
University of Rhode Island, Kingston, RI, USA	MS/PhD Program in Pharmaceutics and Pharmacokinetics	<a href="http://www.uri.edu/pharmacy/programs/graduate/ppk.shtml">www.uri.edu/pharmacy/programs/graduate/ppk.shtml</a>
University of St Thomas, St Paul, MN, USA	Medical device certificate	<a href="http://www.stthomas.edu/engineering/graduate/certmed.asp">www.stthomas.edu/engineering/graduate/certmed.asp</a>
University of Southern California, Los Angeles, CA, USA	Master of Science in Regulatory Science	<a href="http://regulatory.usc.edu">regulatory.usc.edu</a>

**Table 2. Colleges and universities with certificates of graduate studies in regulatory affairs**

<b>Institution</b>	<b>Certificate</b>	<b>Website link</b>
California State University, East Bay, Hayward, CA, USA (in partnership with San Diego State University)	Regulatory affairs Online Certificate Program	<a href="http://www.extension.csu Hayward.edu/html/reg.htm">www.extension.csu Hayward.edu/html/reg.htm</a>
Hood College, Frederick, MD, USA	Certificate in Regulatory Compliance	<a href="http://www.hood.edu/admissions/graduate/index.cfm?pid=/admissions/graduate/certificate/_certificate_main.htm">www.hood.edu/admissions/graduate/index.cfm?pid=/admissions/graduate/certificate/_certificate_main.htm</a>
Lehigh University, Bethlehem, PA, USA	Certificate in Regulatory Affairs	<a href="http://online.lesn.lehigh.edu/reg_affairs_overview.htm">online.lesn.lehigh.edu/reg_affairs_overview.htm</a>
Northeastern University, Boston, MA, USA	Multiple (both on-line and on-ground programmes)	<a href="http://www.ace.neu.edu/grad/certificates">www.ace.neu.edu/grad/certificates</a>
Purdue University, West Lafayette, IN, USA	Regulatory and Quality Compliance Graduate Certificate Program	<a href="http://www.ipph.purdue.edu/RQC.pdf">www.ipph.purdue.edu/RQC.pdf</a>
San Diego State University, San Diego, CA, USA (Center for Bio/Pharmaceutical and Biodevice Development)	Advanced Certificate in Regulatory Affairs	<a href="http://interwork.sdsu.edu/cbbd/regaffairs/adv_cert.htm">interwork.sdsu.edu/cbbd/regaffairs/adv_cert.htm</a>
Temple University, Philadelphia, PA, USA	Post-Master's certificate in Advanced Quality Assurance or Regulatory Affairs	<a href="http://www.temple.edu/pharmacy_QARA/qara-postmasters-cert.htm">www.temple.edu/pharmacy_QARA/qara-postmasters-cert.htm</a>
University of California San Diego Extension, San Diego, CA, USA	Certificate in Regulatory Affairs Essentials	<a href="http://www.extension.ucsd.edu/Programs/index.cfm?vAction=certDetail&amp;vCertificateID=79">www.extension.ucsd.edu/Programs/index.cfm?vAction=certDetail&amp;vCertificateID=79</a>
University of California San Diego Extension, San Diego, CA, USA	Certificate in Regulatory Affairs for the Biomedical Industry	<a href="http://www.extension.ucsd.edu/Programs/index.cfm?vAction=certDetail&amp;vCertificateID=77">www.extension.ucsd.edu/Programs/index.cfm?vAction=certDetail&amp;vCertificateID=77</a>
University of Georgia, College of Pharmacy, Athens, GA, USA	Certificate: An FDA Regulatory Overview of Medical Products: Drugs, Biologics and Medical Devices	<a href="http://www.rx.uga.edu/main/home/reg_affairs/index.htm">www.rx.uga.edu/main/home/reg_affairs/index.htm</a>
University of Maryland, Baltimore County, Baltimore, MD, USA	Post-Baccalaureate Certificate in Biochemical Regulatory Engineering	<a href="http://www.umbc.edu/gradschool/gradcatalog/chemeng_05.html">www.umbc.edu/gradschool/gradcatalog/chemeng_05.html</a>
University of Washington Extension, Washington, DC, USA	Certificate Program in Biomedical Regulatory Affairs	<a href="http://www.edoutreach.washington.edu/ext/certificates/bio/bio_gen.asp">www.edoutreach.washington.edu/ext/certificates/bio/bio_gen.asp</a>

experience gaps, thereby providing students and their prospective employers (the regulated industry and the regulatory agencies) with what they are looking for, the regulatory knowledge and an environment to exercise their knowledge, experiences that an employer can further develop with targeted educational opportunities. Current regulatory affairs professionals also bear some of the responsibility for ensuring regulatory affairs professionals for the future by becoming involved in highlighting the challenges and opportunities of regulatory affairs for their scientific colleagues within their own organisations and by becoming involved in educating the next generation of regulatory affairs professionals within their own organisations and in the academic environments.

**Regulatory affairs professionals must help to educate their successors**

Who will take up this challenge? The future of the regulatory affairs profession is at stake.

## References

1. Marsh A, Strouts P, Harvard J: *Recruiting in Regulatory Affairs*. *Pharmafocus*, 16 September 2005.
2. Temple L: *Supply and Demand in the RA Profession*. *Regulatory Affairs Focus*, January 2006.

**Rosina Robinson**, RN, MEd, RAC is a Principal Consultant, Regulatory Services, Medical Device Consultants, Inc and Adjunct Faculty in Regulatory Affairs at Northeastern University, Boston, Massachusetts, USA. She can be reached at [robinson@mdci.com](mailto:robinson@mdci.com).

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