Talent shortage in regulatory affairs is cause for concern

The marked shortage in regulatory affairs professionals graduating from U.S. universities is worrying when compared to the projected needs of the pharmaceutical and medical device industries. Drs Frances Richmond and Terry Church at the University of Southern California interviewed staff at universities running MS or doctoral programmes, assessing their ability to produce graduates with suitable regulatory skillsets. They found that high tuition fees and visa restrictions for international students posed two of the biggest challenges in encouraging qualified participants to enrol in these graduate training programmes.

The field of regulatory affairs offers a wide range of potential careers, from strategy to operations to the relatively new field of regulatory intelligence. During the COVID-19 pandemic, both the pharmaceutical and medical device development industries have relied on regulatory experts more than ever to ensure that their products can be marketed to meet our healthcare needs. Regulatory professionals play a central role in the development of medical products. A strong regulatory team allows both faster progress towards commercialisation and fewer encounters with issues of non-compliance, giving companies a competitive advantage.

But despite the crucial role of these experts, the number of graduate programmes available to train them is small. As such, acquiring suitable candidates for the growing number of vacancies in this field is a continuing challenge.

Traditionally, regulatory professionals were recruited from competitors by offering them more enticing packages or from employees in other, similar areas of the company who could be retrained as substitutes. However, the narrowing pool of talent, combined with talent shortages in similar areas, such as Research & Development and Quality Assurance, is making it increasingly difficult to recruit replacements for retirees or promoted employees. Thus, companies are turning to universities to produce entry-level talent.

U.S. institutions educated over 50,000 PhD graduates in 2017 alone, with 76% of them pursuing careers in science and engineering. However, these programmes tend to produce a large number of specialised graduates competing for relatively few academic and research positions. Conversely, the U.S. produced 552 MS graduates and four doctoral graduates from regulatory affairs programmes in 2018, which falls far short of the increasing requirement to fill the jobs available.

Regulatory Science graduates at the University of Southern California (USC).

The current challenges in education and hiring within the regulatory profession were predicted as early as 2014, and worldwide organisations like the WHO and the Asia-Pacific Economic Cooperation (APEC) have identified the shortage of regulatory talent as an obstruction to the timely market access of essential medical products. So, with the problems facing the industry only growing, and attracting the attention of global institutions, what can be done to tackle them?

The Asia-Pacific Economic Cooperation (APEC) Center of Regulatory Excellence (CoRE) educates medical device regulators and industry professionals from APEC economies.

AN OVERVIEW OF THE LANDSCAPE

If we hope to produce enough suitable candidates to fill the rapidly increasing number of positions available and thus prevent delaying the market approval of medical products, we need to understand what the potential barriers are to recruiting students to graduate training programmes in regulatory science. That is the aim of a new study by Dr Frances Richmond and Dr Terry Church at the University of Southern California.

In their study, they identified 17 programmes across the U.S. that offered graduate degrees in regulatory science or affairs. Eight of these were distance programmes, four were exclusively given on-site and the final five were offered in hybrid configurations. The large majority of students, 77%, came from the existing workforce of food or medical-product companies, with only three programmes having more than 10 new entrants to the field. A large proportion of graduates, 70%, came from programmes in the Northeast, with schools in the Midwest and Southwest/Southeast producing 81 and 83 graduates respectively.

WHAT'S STOPPING STUDENTS?

The challenge most commonly identified by staff members was the high tuition fees of the programmes. While PhD programmes in basic science and research are supported by an extensive system of government grants, subsidies and student support to the tune of billions of dollars, programmes in regulatory science receive no public or private funding. Therefore, they rely entirely on tuition fees to continue running each year, making them expensive for students. These high fees are often not reimbursed by employers either, meaning that students are fully responsible for them.

It is crucial that young people are made more aware of the diversity of career options within regulatory science.

Another challenge has been the tightening visa restrictions, which affect an institution's ability to attract international students who previously provided a substantial source of new talent. These changes to visa rules have also led companies to shy away from hiring these candidates, as they anticipate difficulty securing a full-time visa for the longer term. Employment eligibility was viewed by the respondents in this study to be the main reason why the enrolment of international students was decreasing in U.S. graduate programmes.

The jobs that regulatory professionals do are often 'hidden' – their work is not visible to most. This can mean that both jobs and graduate training programmes are difficult to market to students who are unfamiliar with the possible career paths in regulatory affairs. In particular, regulatory programmes are not evaluated in the ways that MBA programmes often are by the popular press ratings or accreditation schemes, further obscuring the field of regulatory careers from the view of those who are initially unfamiliar with it.

Additionally, research has suggested that the job titles used in regulatory careers can often be confusing to

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USC's Regulatory Science Bootcamp on clinical trials features speakers from industry, academia and government.

Access to medical products will be impeded if we do not have enough trained people to move new products from discovery to market.

new entrants. Job levels and areas of specialisation are described differently between companies. A Director of Regulatory Affairs can variously describe work in areas as diverse as labelling, operations, strategy or intelligence. This is particularly confusing to potential new entrants to the field who may be unaware of the importance or variety of the roles in regulatory science.

THE PROBLEM OF SENIOR ROLES

Often, vacant roles are those at either the associate or mid-management levels. This poses a problem to new entrants in the field, who lack the job experience to take on management roles but who may appear overqualified for junior or entry-level positions if they hold MS or even PhD degrees in basic science. Manager or director positions require extensive technical and product knowledge of medical product development as well as knowledge of FDA regulations that cannot be gained without specific training and job experience.

This difficulty in finding suitable external candidates for available vacancies is often exacerbated by a lack of in-house training opportunities for existing employees. Many companies appear reluctant to offer educational programmes or internships that could widen the field of sufficiently experienced individuals.

It is crucial that young people interested in medical sciences are made aware of the diverse career options within regulatory science.

If the ongoing scarcity of new entrants continues, companies run the risk of large numbers of experienced professionals retiring in a short space of time. This would leave many senior jobs open with few experts qualified to replace them, resulting in a shortage of both new entrants into the field and of experienced professionals. This is of particular concern as over the next decade it is projected that more than 70,000 regulatory job openings must be filled. Interestingly, this problem is not one solely faced by industry. Several staff members at universities noted the difficultly in attracting faculty members to teach in their regulatory graduate programmes, with many of the current staff approaching retirement; regulatory agencies find it difficult to recruit qualified individuals as well.

AN UNCERTAIN FUTURE

The combination of these challenges resulting in an all-round shortage of talent is a cause for major concern. It is crucial that young people with an interest in medical sciences are made more aware of the diversity of career options within regulatory science and that steps are taken to ensure that graduate programmes to equip them for such roles are more accessible.

If these issues are not addressed, access to medical products will be impeded. The short supply of individuals will retard the development of medical products from new discovery to marketable product. These shortages are likely to be felt most strongly by smaller companies that are unable to compete for the experienced professionals that they need to guide their teams. Overall, many companies will lose their ability to compete successfully in this highly regulated industry, if they have problems to navigate the complex steps required to secure marketing approvals for their products in a timely way.

The burden falls to employers, universities and policymakers to work together to find ways to ensure that there is both steady and abundant flow of talent into regulatory careers in order to prevent damaging delays.

Behind the Research

Dr Frances Richmond

Dr Terry Church

E: fjr@usc.edu **T:** +1 323 982 9850 **T:** +1 323 442 3531 **W:** https://regulatory.usc.edu/

Research Objectives

Drs Richmond and Church study the challenges to talent acquisition in regulatory science.

Detail

University of Southern California
CHP 140, I540 Alcazar St
Los Angeles, CA 90089
USA

Bio

Dr Frances Richmond is Director of the D.K. Kim International Center for Regulatory Science at the University of Southern California. She was the founding Chair of the Department of Regulatory and Quality Sciences at USC, offering certificate, MS and doctoral training in regulatory and quality management or medical products.

Dr Terry Church is Assistant Professor in Regulatory and Quality Sciences at the University of Southern California, School of Pharmacy. He is Associate Director of Undergraduate Education and teaches in the undergraduate degree programme, Pharmacology and Drug Development (PDD). Prof Church's academic focus is on the application of pharmaceutical regulations, patterns of addiction, disaster management, and education and training.

Collaborators

- Susan Bain
- AGRE organisation

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Personal Response

What do you think would be the most effective first step in attracting more prospective students to graduate programmes in regulatory science?

"We need to establish an affordable path for highly talented students at graduate levels. Our competitiveness depends on having well-trained young scientists and engineers with additional regulatory capabilities. The governments of some countries now recognise that medical product companies will be more competitive globally if their regulatory staffing is higher in quality. They have invested heavily to put graduate-level programmes and regulatory institutes in their best universities. Such programmes are also needed in countries that have become complacent in their historical economic leadership of pharma and medical device sectors if they are to maintain their leadership."