

Developing careers for regulatory affairs professionals



*Regulatory affairs plays the key role of ensuring that safe and effective medicines are brought to the market as quickly and efficiently as possible, for the benefit of patients. So how can the profession encourage talented scientists and healthcare professionals into this demanding, yet rewarding, role? **Janice Kirby-Smith** from NDA Regulatory Science considers the issues*

What does regulatory affairs encompass?

Regulatory Affairs is key to all stages of product development, so a broad understanding of the complete drug development process may be regarded as a prerequisite to consideration of regulatory strategy leading to successful product approval, in addition to a good understanding of the regulations governing medicinal products. Regulations and procedures are particularly complex in relation to Europe, with both national and EEA-wide requirements to consider. Expert scientific knowledge in the areas pertinent to development is needed, plus understanding of the clinical context in which the product will be used. The need for sound science to underpin regulatory affairs is crucial and a first degree in a relevant scientific discipline may be regarded as the basic starting point for developing a career in regulatory affairs.

How can we attract able scientists into regulatory affairs and ensure that their education and training are optimal?

There are many issues around the subject of recruitment of regulatory affairs professionals and the training they need. It seems that many scientists fall into regulatory affairs almost by accident. This was my route into the totally unknown and fledgling world of regulatory affairs. I was a hospital pharmacist, invited to

Medicines Division, Department of Health (forerunner of the Medicines and Healthcare products Regulatory Agency (MHRA)) on a three-month secondment to help set up the first computerised database of all medicines on the UK market. I did not expect to find the job interesting and accepted the invitation purely out of curiosity. However, this turned out to be the start of a long and enjoyable career in regulatory affairs.

Do today's science undergraduates and recent graduates have a greater awareness of the opportunities available within the pharmaceutical industry, and in regulatory affairs in particular?

Recent research in relation to pharmacy undergraduates has indicated that pharmacy students in the UK generally do not have enough information concerning the pharmaceutical industry to be able to make informed judgements concerning opportunities in this sector¹. Many students have a perception that work in the industry will be dull, difficult and laboratory-based, requiring a PhD. Results of a survey of careers advisers in UK schools of pharmacy confirmed that most schools devote little attention to industrial pharmacy compared with other careers.² Most careers advisers confirmed that they only received enquiries concerning industrial pharmacy occasionally, and several advisers commented that more work placements were needed to foster interest in the industrial sector.

Results of a focus group with final year pharmacy students in one school indicated that this group of students acknowledged that they knew very little about the industry, and felt that the industry should do more to encourage students (eg work placements). They felt that there were few opportunities, with high qualifications needed for entry (first class honours or PhD). Such views are probably true for other relevant disciplines too, particularly since other scientists may have less undergraduate teaching than pharmacists on the complete drug discovery and development process and/or less clinical experience of the use of medicines.

Figure 1 illustrates areas of interest to pharmacy students. Despite the relative lack of interest in industry-related topics, 83 (38%) of students were interested in learning

more about the industry and 43 (20%) were interested in learning more about regulatory affairs.

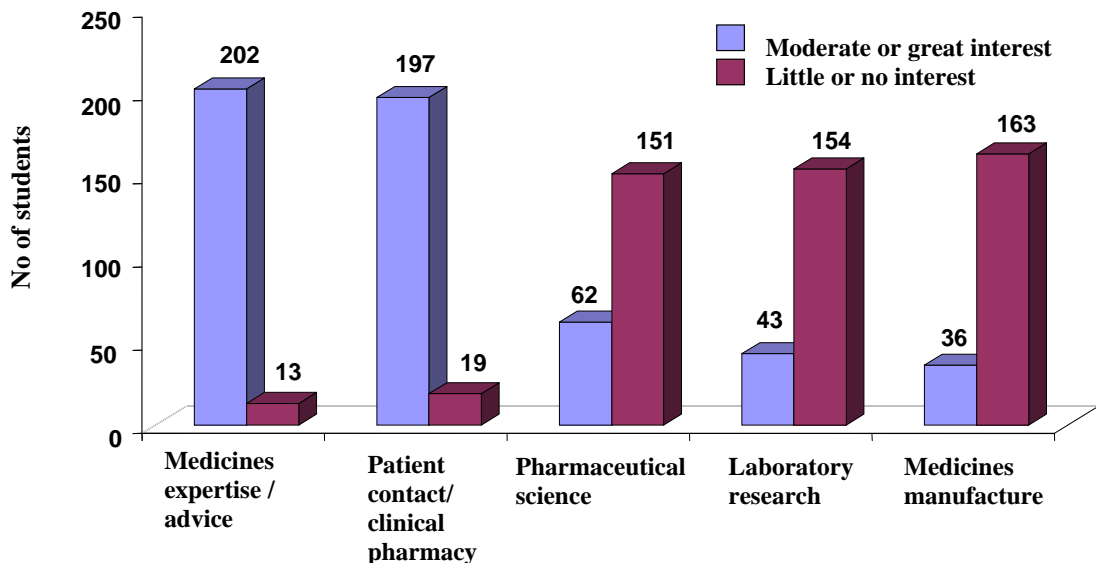


Figure 1: Expressions of interest in areas of a pharmacist's expertise [Note: Figures represent the number of students responding to these questions.]

Those with positive views gave reasons which included interest in research, range of career opportunities, good pay, or that they had enjoyed work experience.

Responses to certain questions in the survey are shown in Table 1.

Table 1: Student responses to questions relating to the pharmaceutical industry (n = 219)

Question	Yes	No	No response/ Not known
Have you ever considered possibly choosing a career in industrial pharmacy?	95	121	3
Do you think that industrial pharmacy might be a career choice worth exploring?	85	100	34

Do you think a career in industry would make good use of your expertise as a pharmacist?	65	93	61
For entry into the pharmaceutical industry, do you think a higher degree is needed?	74	110	35
Do you think a career in industry would provide good career development and promotion prospects?	132	29	58
Would you like to learn more about the role of pharmacists in the industry as part of your degree course?	83	103	33
Would you like to learn more about drug regulation and regulatory affairs as part of your degree course?	43	137	39
Might you be interested in a career in the pharmaceutical industry?	71	106	42

Other research has shown that students' experience in the workplace can have a great influence on career choice³. In the UK, the Industrial Pharmacists' Group of the Royal Pharmaceutical Society is trying to encourage pharmaceutical companies to offer more vacation work placements and pre-registration places to pharmacy students. However, there is no common centralised application procedure, with companies having different recruitment strategies and competing with each other. There is a view that highly motivated applicants will in any case find a way into the industry.

In some countries, undergraduates are prepared for careers in the pharmaceutical industry and drug regulation, but it appears that in the UK we are not capitalising on opportunities to promote and develop regulatory affairs roles.

Another group of recruits who require particular consideration are those who may wish to change the direction of their careers later in life. There are perceptions that transferring into regulatory affairs is difficult and that existing skills may not be appropriate. However, in relation to pharmacists, some of the best regulators have come from other sectors including community, hospital and academia and have built

very successful regulatory affairs careers, enhanced by their wealth of specialist knowledge of both clinical and scientific aspects of drugs. In view of the ever increasing demands on community pharmacists, some of this group consider leaving the profession altogether. This represents a waste of valuable medicines expertise which could well be channelled into alternative fields such as regulatory affairs, a role for which pharmacists may be considered to be particularly well equipped, in view of their education and experience.

Views of industrial pharmacists on their careers

In contrast to student expectations concerning pharmaceutical industry jobs, research in the UK has shown that industrial pharmacists consider that there is a wide range of job opportunities in the industry, with regulatory affairs featuring prominently⁴. Whilst 107 (70%) of industrial pharmacists surveyed worked in research and development, 54 (35%) worked in regulatory affairs and 92 (60%) in other non-laboratory based roles (they may be employed in several concurrent roles). Most industrial pharmacists surveyed were very enthusiastic about their roles and particularly highlighted regulatory affairs as being rewarding, with its contribution to the nation's health by obtaining marketing authorisations for new products, good use of scientific and clinical skills and good career prospects; confirming that regulatory affairs can indeed be a fulfilling career.

The majority of pharmacists felt that their education and training were key factors in enabling them to perform well in industry and regulatory affairs roles. Only eight of 153 considered that appropriate industrial experience was more important than their basic pharmaceutical education. Sixty eight (44%) considered that pharmacy provided the ideal basic training for regulatory affairs, with its combination of science, medicines use and pre-registration practical training (in the UK, five years education and training entirely focused on medicines). Responses to certain questions in the survey are shown in Table 2.

Table 2: Responses to questions concerning pharmacists' careers and their views (n = 153)

Question	Yes	No/No response/ Not known
Did you undertake part of your pre-registration training in the industry?	59	94
After qualifying as a pharmacist was your first job in the industry?	66	87
Have you worked in other occupations as your main employment?	141	12
Do you feel that being a pharmacist enables you to do your job better than if you had studied a different discipline?	133	20
Do you think that more pharmacists should be encouraged to choose a career in industrial pharmacy?	131	22

Preparing for a career in regulatory affairs

The pharmaceutical industry is an important part of the UK economy and it is clear that science undergraduates should be given an understanding of drug development and be made aware of the wide range of opportunities for employment in the pharmaceutical industry, so that they can make informed decisions concerning their career paths, and so that able scientists are not lost through their lack of awareness of the opportunities for development of a worthwhile career in regulatory affairs. This raises the question of whether modules concerning product development and drug regulation should be offered at undergraduate level, or whether the excellent postgraduate opportunities offered by TOPRA to those who are already in regulatory affairs posts are adequate. Such topics are not generally included in the undergraduate curriculum in the UK, but the situation is somewhat different in universities in other countries, some of which offer industrial or regulatory affairs options at first degree level. Would this provide a good model for preparation for regulatory affairs careers in the UK and elsewhere? How far can regulatory affairs be taught in an academic environment, rather than being based on practical

experience in the workplace? For many regulatory affairs posts advertised, industrial experience is a prerequisite, and many employers expect recruits to have gained experience behind the laboratory bench or in manufacturing before switching to regulatory affairs. Is this the preferred route into regulatory affairs?

It may be concluded that the education and training needs of recruits into regulatory affairs differ substantially depending on many factors, including discipline and prior work experience. Recruits may be new graduates from a variety of scientific backgrounds, with varying levels of basic knowledge of the spectrum of scientific disciplines underpinning regulatory affairs, little idea of product development and no experience of project management and other necessary skills which need to be developed. In contrast, other new recruits into regulatory affairs may already have built successful careers in other fora such as research and development, academia or clinical practice, making the transition into regulatory affairs at senior management level. Hence, it is clear that regulatory affairs recruitment embraces a very wide range of prior knowledge, skills, expertise, experience and seniority, and it follows that training needs across the spectrum are equally diverse.

How can the education and training needs of such a diverse group of recruits to the regulatory profession be met?

This is a question which is open to debate, and which the education group at TOPRA is examining. The group would greatly value contributions to this debate. If you want to be part of the debate, please contact Lynda Wight, TOPRA Executive Director at lynda@topra.org

References

¹ Kirby-Smith J, Portlock J, Brown D. Investigation of student views on industrial pharmacy. Pharm Ed 2008;8:7-11.

² Kirby-Smith J. Investigation of the role of the pharmacist in product development and drug regulation. D Pharm thesis. University of Portsmouth; 2006.

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- ³ Joshua A, Fleming G. A learning opportunity for pharmacy students. *Pharm J* 2002;269:106-8.
- ⁴ Kirby-Smith J, Portlock J, Brown D. Investigation of industrial pharmacists' views on careers in the pharmaceutical industry. *Pharm J* 2008;281:270-7.