THE DRUG APPROVAL TACTICIAN

Regulatory affairs in the pharmaceutical industry is not just about stacking up reports. A good regulatory affairs professional uses their knowledge and skills in many points at the pipeline to help achieve approval in optimum time.

Regulatory affairs in the pharmaceutical industry is both a familiar and unfamiliar world. The industry is well known as being one of the most highly regulated, revolving around the approval of new compounds that emerge from the drug development pipeline by national or multi-national regulatory bodies. But telling someone that you work in regulatory affairs will usually elicit either an unknowing silence from early-stage employees or a cynical look from later-stage employees, no doubt mumbling about how you interfere with research and development.

Any possible lack of appreciation by other departments is due to the misconception that all regulatory affairs employees do is accumulate forms and reports and send them off to the relevant regulatory agency. True, regulatory affairs professionals are often compiling these documents. However, they are also involved in review of protocols, labelling, promotional materials, standard operating procedures and final study reports (both preclinical and clinical), licence maintenance and coordination of inspections by regulatory agencies.

But, as the key link between a company and the regulatory agencies, the job of a regulatory affairs professional can be thought of more as being one of science communication. They provide knowledge and interpretation of the endless laws and regulations to other project team members and to management, participating in problem solving at many levels, such as design and timing of clinical trials.

Most pharmaceutical companies have an individual or department for handling regulatory affairs; those that do not have this facility use external service providers, such as regulatory consultancies or contract research organizations that provide regulatory services. A recent survey¹ on clinical research employment carried out by CenterWatch, a Boston-based clinical trials listing and information service, shows how regulatory affairs is assuming increased importance. The survey found that people in regulatory affairs were most in demand, with around one in four pharmaceutical recruiters surveyed looking to fill positions in this area. The reasons cited were lack of candidates, heightened and ongoing regulatory scrutiny, increased spending, rising workloads and intensifying competition.

Most people working in this area have a science degree, such as biochemistry, toxicology, pharmacology, pharmacy or physiology, as this knowledge helps to build

up regulatory affairs knowledge on each new therapeutic compound (for example, the compound's pharmacology and toxicology). Traditionally, most regulatory affairs professionals entered the discipline from other areas, such as laboratory or clinical research. Often people were just thrown into the deep end by giving them a pile of regulations, and with luck they worked with a good mentor who was willing to share the skills that they had learned when once placed in the same nerve-racking position.

Now, thankfully, things have changed with the advent of degree programmes and courses that can provide such training. A small number of postgraduate degree programmes related to regulatory affairs have been set up worldwide, which outline the R&D process and how this is regulated (see <http://www.raps.org/careers/grad.cfm> and REF. 2). Some are also available as distance-learning courses, which is of benefit to staff in companies that are not located near these universities. Many organizations also provide educational meetings and courses (see BOX 1 and REF. 2).

Why choose a career in regulatory affairs? The variety of tasks provides an interesting challenge, and building regulatory affairs knowledge on each new therapeutic compound provides intellectual stimulation. The most sought-after qualities in a potential candidate are a strong science background with a knowledge of the industry and a strong grasp of regulatory affairs. The candidate should have excellent writing and oral communication skills and be someone who enjoys problem solving within teams. Good regulatory affairs staff are those who openly discuss the relevant rules and regulations among team members (who often will find such issues baffling) in order to prevent problems rather than simply cite them. And as the regulatory affairs field goes through many changes — for example, the introduction of the Common Technical Document, which aims to harmonize the application for approval in several countries — keeping up-to-date with these changes is vital. Rather than simply enforcing the law, being in regulatory affairs makes you the person with the drug approval game-plan, and your team needs to be aware of the tactics needed to reach the winning endpoint.

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1. Zisson, S. Clinical research jobs in the new economy. *CenterWatch* **8**, 1–6 (2001).
2. Gundersen, L. E. Training needs in regulatory science for the biopharmaceutical industry. *Nature Biotechnol.* **19**, 1187–1188 (2001).

Box 1 | Further information

Regulatory Affairs Professional Society (RAPS): ..... <http://www.raps.org/>
RAPS represents more than 8,000 professionals in regulatory affairs worldwide, and organizes educational programmes, professional certification and global information services, including a salary survey and an extensive online career centre.

European Society of Regulatory Affairs (ESRA): ..... <http://www.esra.org/>
ESRA represents regulatory affairs professionals both in Europe and worldwide. It provides a programme of training meetings and conferences, and has an online careers advice and coaching service.

The British Institute of Regulatory Affairs (BIRA): ..... <http://www.bira.org.uk/>
BIRA set up the first MSc and Postgraduate Diploma qualification. It carries out a salary survey every two years, has a career counselling service (in conjunction with the regulatory services provider Unicus) and has job opportunities online.

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