

Options in regulatory affairs – specialties and skill sets

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Abstract

When one looks at the myriad career options open to professionals in regulatory affairs (RA) it can be somewhat overwhelming to understand what these jobs entail, from both a business standpoint as well as from a skills and competency perspective.

Results of two recent longitudinal surveys, conducted in 2007 and 2013, which assessed trends in hiring needs and training practices in US medical-product companies, will contribute to this discussion.¹ As these and other data suggest, there is a strong and relatively stable demand for professionals throughout regulatory and quality job categories.

Specialties

Performing a simple internet search for jobs in regulatory affairs (RA) in the medical products area yields hundreds of hits and a multitude of job titles. It is worth looking at and sorting these to understand what areas of expertise have emerged in RA over the years.

One of the most obvious characteristics deals with the distinctions within the term “medical products” – those that are related to drugs versus those dealing with medical devices. Typically, the drug arena also includes biologics and therapeutic biologics, but these are becoming specialty areas for development within many technical disciplines. Also within the drug sector there are RA professionals who focus on innovative products and those who deal with either generics or over-the-counter (OTC) products. Each of these will require different technical knowledge and experience and have geographical implications. And of course, there are also the combination products (drug/device) and companion diagnostics and biomarker development specialists within each of these groups.

One of the other areas of specialisation involves positions that are either labelled “global” or those that are region-specific. These roles may determine how much travel is required for the job as well as how much knowledge about local requirements is a prerequisite for the position. Often these roles will be determined by where in the product development’s lifecycle the responsibilities lie – either during development where both clinical (operations) and regulatory

knowledge is needed or in the post-approval phase where the regulatory requirements for pharmacovigilance may be needed. This speaks to the role of RA professionals in the contract research organisation (CRO) sector of the industry as well as within the R&D sector. With the amount of outsourcing that pharmaceutical and biotechnology companies are performing now, these are two very important areas of job growth.

Next we can look at careers that are strategic and those that are operational. Many individuals progress from operational roles into those that are more focused on regulatory liaison (with health authorities), policy and internal/industry innovation, but others can be quite content (and very successful) in remaining operational. Typically, this distinction can be found in the terms “regulatory affairs strategy” versus “regulatory operations”. Regulatory operations personnel are usually involved heavily with submissions support, and are technically very knowledgeable, but clearly there is a role and a need for RA staff to be knowledgeable and involved with all major filings and possess many of these same skills, as there is a great deal of strategy that goes into filings, especially those that are global.

Likewise, there are other specialties within specialties of RA, namely functions that are responsible for chemistry, manufacturing and control (CMC) information, or what are known as “CMC regulatory professionals”. This sub-specialty has long been established within pharmaceutical organisations, as have careers dealing with the regulatory aspects of advertising, labelling and promotional materials and those that are more clinical-focused. With increased regulatory guidelines and requirements within these disciplines, there continues to be a growing need for these specialists who have very specific backgrounds and come with highly honed technical skills.

One of the newer sub-specialties is in the area of regulatory intelligence (RI). There are varying definitions of what constitutes RI – everything from registration tracking (part of regulatory information management (RIM)) – to maintenance of databases and repositories of relevant guidances, to more skilled activities involving the analysis and interpretation of this mountain of information.

Another new area of expertise that previously may have resided solely with the business development functions of a company is in the area of health technology assessment (HTA). HTA is used to determine the cost-effectiveness of products and is becoming more focused “upstream” in a product’s development, as data need to be collected during the clinical phases as the basis for reimbursement decisions. Thus it is, like many aspects of RA, a very cross-functional activity. In addition, more regulatory agencies (eg, the European Medicines Agency (EMA)) are looking to incorporate these discussions into pre-submission and scientific advice meeting agendas which are usually organised and executed by RA professionals.

Finally, there is a continuing trend to include quality assurance (QA) under the umbrella of RA, and in fact many positions at higher levels are deemed RA/QA positions. While it is inherent that RA functions ensure compliance and overall quality of regulated products, it should be cautioned that this reporting structure has associated risk associated, as QA must function independently where auditing of regulatory functions is required.

The professional development framework described by the Regulatory Affairs Professionals Society (RAPS) in its 2013 publication¹ (with permission) provides an excellent visualisation of these many components (see Figure 1).

Levels and leadership

One other area for discussion that may be confusing for people both within and external to the world of regulatory involves the job titles that are used. Although there are basically only five terms used, they may vary widely on the skills that are needed for each.

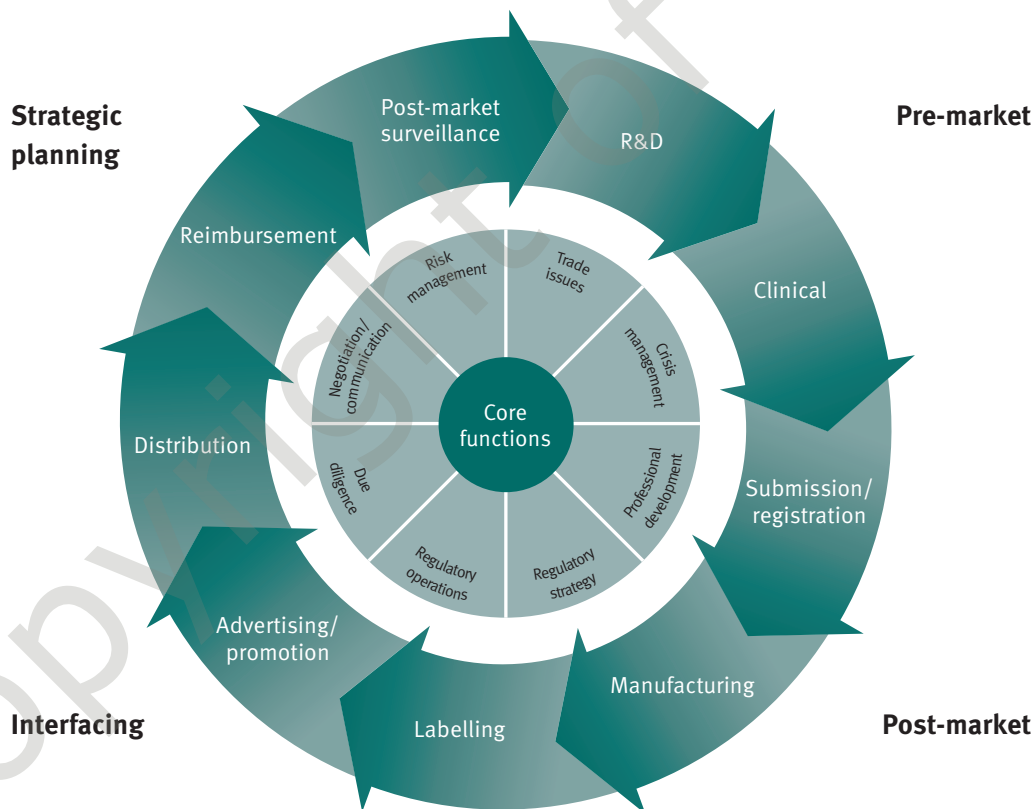
- **Regulatory Associate/Coordinator** – This is an entry-level position where staff will develop the basic knowledge needed to participate in the processes and procedures for regulated products.
- **Regulatory Specialist** – This is the next level in the progression of experience for a RA professional and may be when the employee begins to specialise. These positions often focus on specific technical skills and project management techniques.

- **Regulatory (Project) Manager** – Often this position does not involve the management of staff only projects (RPM), but when it does it is usually in a small team setting. Regulatory managers will typically have responsibility for time-sensitive activities and provide input for strategy decisions.
- **Associate/Director RA** – This leadership position is more strategic than the technical and tactical manager positions and will require experience and expertise that is either directly related to product development and lifecycle or specific activities within a company, such as advertising/promotion or pharmacovigilance reporting.
- **Vice President/Head of RA** – This represents the most senior and strategic level that RA professionals will attain within this discipline.

Skill sets

A number of papers have been published which have suggested that regulatory positions have been difficult to fill because the pool of qualified applicants is limited and because “the mushrooming regulatory framework and associated regulatory burden has put significant strain on the existing population of regulatory affairs professionals worldwide.”² Much of the work to date has focused on salary statistics and did not capture information about the skills that companies are looking for in their hiring. This has prompted a recent study to be conducted that analysed responses from medical products firms surveyed at two different time points spaced six

Figure 1: Professional Development Framework.



Source: RAPS

Figure 2: Which of these products does your firm manufacture? (Respondents were encouraged to identify all that apply.)

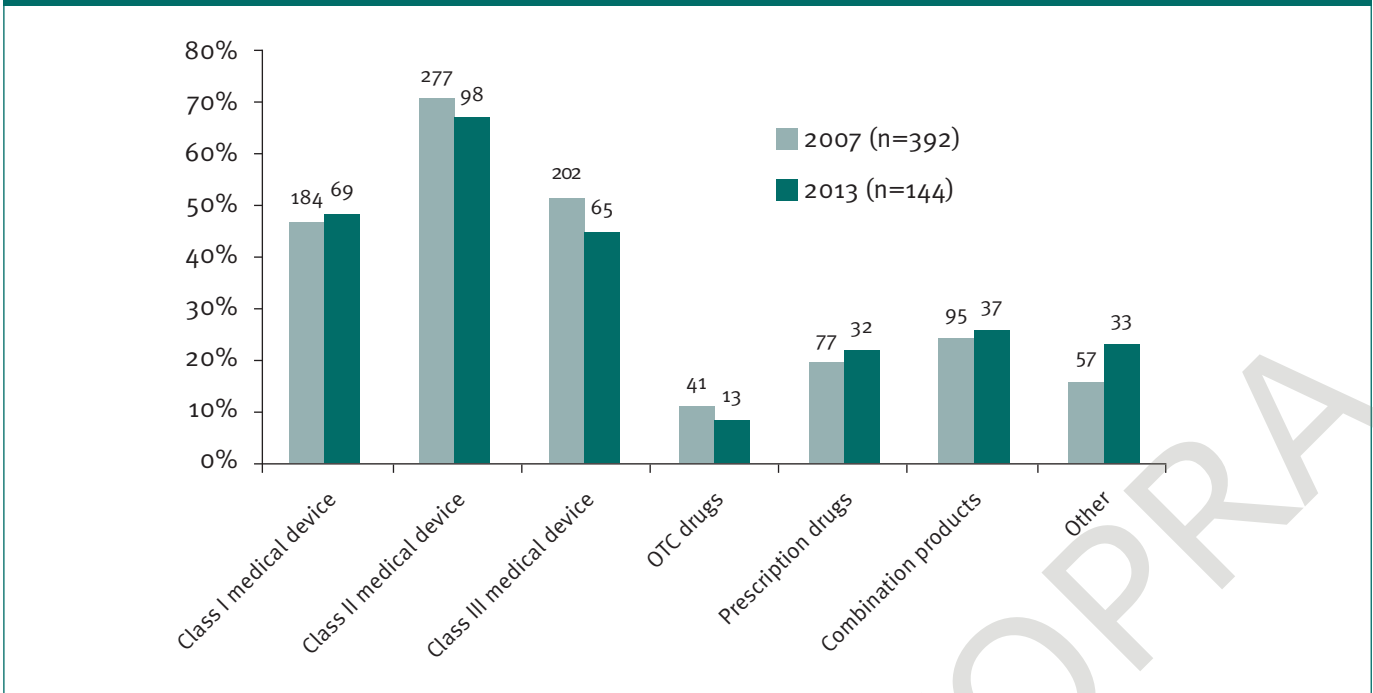
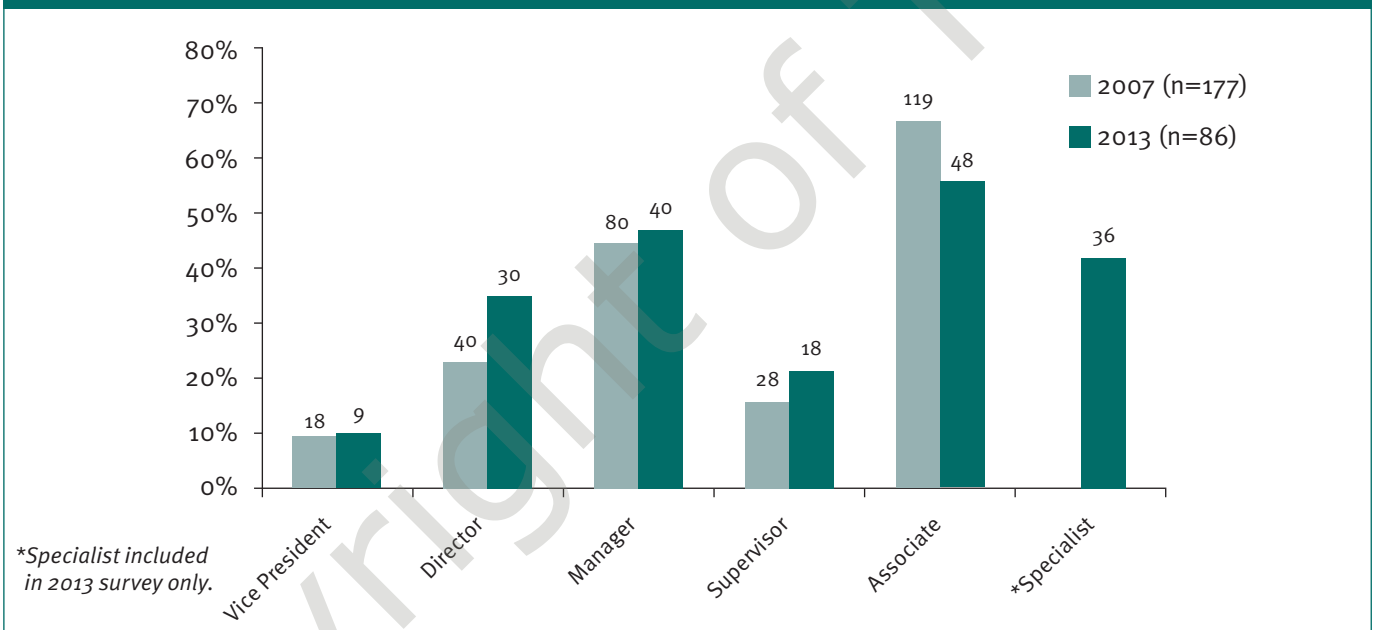


Figure 3: Percentage of respondents whose employers have vacancies in regulatory affairs.



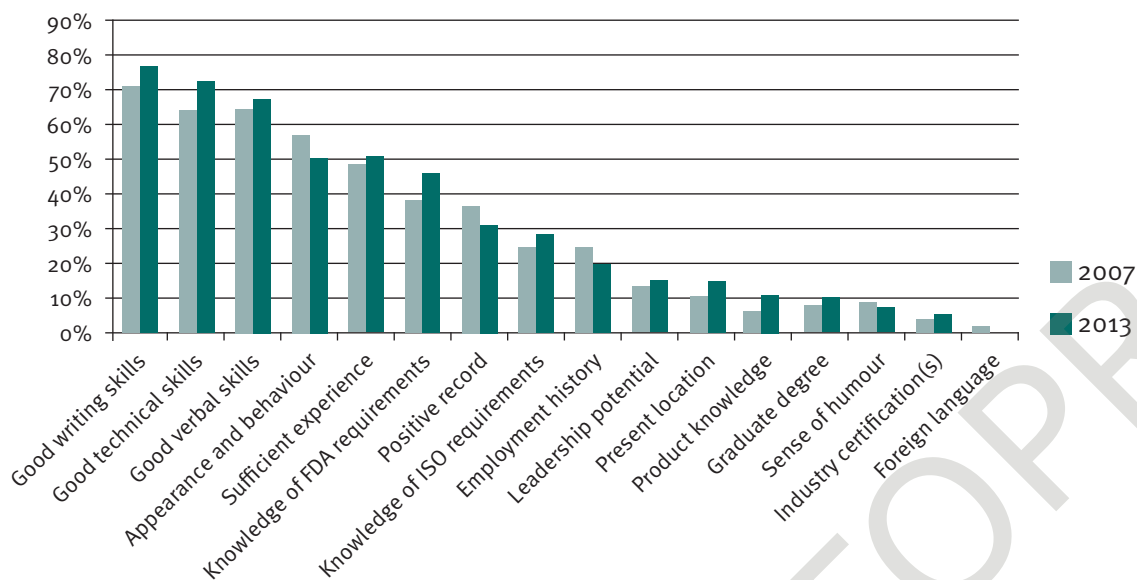
years apart.³ The survey included questions regarding the hiring challenges faced by regulatory, clinical and quality assurance departments. Results suggest a stubbornly large vacancy rate and a difficulty in identifying new entrants who have appropriate skills, with relatively few in-house solutions to ensure systematic training.

In the first survey, done in 2007, responses were obtained from 395 individuals. In the second, 2013 survey, a somewhat smaller rate of responses was obtained from 152 individuals, as might be expected because many of the individuals from the original survey could not be reached. The career stages of the respondents ranged from associates to presidents; the most common title was manager. Respondents

were found to be employed in companies of a full range of sizes; most responses (30%) originated from companies employing between 1,000–10,000 individuals over the two surveys. Survey participants often had experience in more than one product type but the respondent group appeared to include more individuals from medical device than pharmaceutical backgrounds (see Figure 2).

When respondents were asked about openings in their respective companies and departments, the results showed vacancies in various job categories which were distributed at all levels of the hierarchy, but most vacancies were reported at associate, specialist and manager levels. In RA, more than half (67%; 56%) of the companies

Figure 4: When considering hiring an entry-level candidate, which of the following skills are mandatory? (Results are presented as a percentage of overall respondents; multiple choices were permitted.)



in which vacancies were reported had openings at the associate level, and a slightly smaller number (45%; 47%) also had vacancies at the manager level (see Figure 3).

Survey questions also explored the expectations of companies with respect to applicant qualifications. The mandatory characteristics most frequently identified for entry-level candidates were good writing skills (71%; 77%), good technical skills (64%; 73%), good verbal skills (65%; 68%), professional appearance and behavior (57%; 50%) and previous job experience (49%; 51%) (see Figure 4). Interestingly, almost no respondents identified that knowledge of a foreign language was mandatory in either survey. When asked to identify which attributes were lacking in the majority of candidates from a list of 16 options, more than half of the respondents identified limitations related to job experience (65%; 60%), knowledge of the products under development (70%; 60%), leadership potential (63%; 58%), knowledge of US FDA requirements (54%; 53%), and writing skills (51%; 50%). It should be noted that these skills were across all three areas surveyed – RA, QA and Clinical Affairs (CA) and included a question that was region-specific (US), specifically around FDA regulations.

Conclusions

Regulatory professionals, as well as those with clinical and quality training, continue to be in high demand. The demand is intensified by the limited number of new entrants with appropriate job-related skills, and by an apparent shortfall of qualified individuals available to take mid-level management positions. Hiring can be challenging because certain key skills, including leadership and

writing skills, product knowledge and overall industry experience seem to be lacking in a high percentage of candidates.

Companies have identified that key skills for entry-level positions include not only good technical skills and product knowledge, but also soft skills such as good writing skills, and professional appearance and behaviour. Luckily these soft skills can be taught, either formally or informally.

Despite these challenges, and because there are non-traditional ways to enter RA and so many niche specialties within this sphere, the career path of a regulatory professional continues to be one with longevity and variety.

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- For more information on RA levels and careers, you can consult any number of texts produced by RA professional societies, namely TOPRA's "Careers in Regulatory Affairs" (2010) and the RAPS Professional Development Framework: An Overview (2013) and "Choosing the Right Regulatory Career" (2010).