

Hiring and Training Needs in Drug/Device Industries: Focus on Regulatory, Quality and Clinical Professions



David M Locke, MS¹ and Frances J Richmond, PhD²

¹Doctoral Candidate, University of Southern California, Los Angeles, California

²Director, Regulatory Science Programs, School of Pharmacy, University of Southern California, Los Angeles, California

August, 2014

Executive Summary

A longitudinal survey was conducted in 2007 and 2013 to assess trends in hiring needs and training practices in US medical-product companies. A strong and relatively stable demand for professionals was suggested throughout regulatory, clinical and quality job categories when the two surveys were compared. Most respondents reported vacancies in Regulatory Affairs and Quality departments; fewer companies had openings in Clinical Affairs. Vacancies were distributed at all job levels, but those at associate and mid-manager levels were consistently reported by the largest number of firms. The most difficult job levels to fill appeared to be manager and director positions in all three sectors. The most important characteristics for entry level candidates were identified by respondents as writing, technical, and verbal skills. Attributes lacking in most candidates were sufficient experience for the job level, knowledge of product under development, leadership potential and knowledge of FDA requirements. From these results, we might predict significant educational and hiring challenges in the future, as experienced personnel in the demographic bulge between 55 and 70 retire in large numbers over the next decade.



Contents

Executive Summary	1
Contents	2
Introduction.....	3
Materials and Methods	4
Results	5
Discussion	11
To Conclude	15
Disclosures and Acknowledgements	15
References	16

Introduction

The development and commercialization of medical products is orchestrated by highly trained individuals in regulatory, quality and clinical roles. Over the last decade, it has been challenging to find and retain competent teams, in part because the activities for which they are responsible have become more demanding and more global in focus. This is reflected, for example, in the fact that 2500 – 4500 new final rules are published in the Code of Federal Regulation each year according to the Government Accountability Office (GAO).¹ As noted by Robinson (2006), the “mushrooming regulatory framework and associated regulatory burden has put significant strain on the existing population of regulatory affairs professionals worldwide.”² In the regulatory sector, governmental oversight and task complexity have increased. In the clinical sector, trials are under greater scrutiny and greater pressure to acquire a wider range of outcome data from different countries, in order to support both registration and reimbursement decisions globally. In the quality sector, the historical focus on inspection and quality control is evolving to a more holistic approach that includes, for example, systematic assessments of customer needs, design controls, quality by design, and human factors and risk assessments. All of these challenges have led to robust growth in the demand for individuals who are knowledgeable about current regulations and best practices related to these more demanding regulatory, clinical and quality functions.



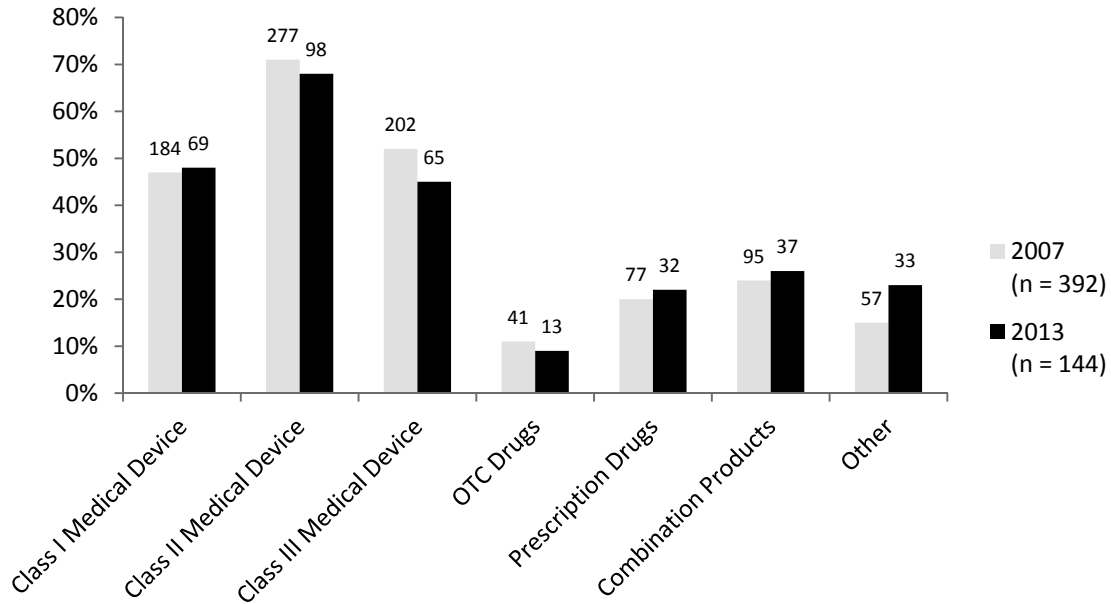
Do we have an appropriate workforce to satisfy these needs? Much anecdotal evidence suggests that positions have been hard to fill because the pool of qualified professionals is limited.^{3,4} Further, strong competition for qualified candidates is reflected by the steady growth in salaries over the last five years, an economic period of high unemployment and economic recession.⁵ However salary statistics alone do not provide much information on the availability of qualified professionals across different job categories. Further, we have relatively limited information about what constitutes a qualified applicant by companies that make and sell medical products. Educational institutions motivated to train an appropriately qualified workforce will need more specific information if they are to provide medical-products companies with appropriately prepared participants in this uniquely skilled job sector. Finally, little is known about the changes in hiring patterns over time. Thus, in this study, we have analyzed responses from medical-products firms surveyed at two different time points spaced 6 years apart, 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.

Materials and Methods

Surveys were used to query individuals employed in regulatory, clinical and quality roles by medical device, pharmaceutical, and contract-services companies across the US. The first survey was constructed and distributed by email using the software package, Survey Monkey (2007), whereas the second used the software package, Qualtrics (2012), the latter allowing a wider capability for statistical analysis. The initial survey contained 29 questions, and the subsequent survey added 4 additional questions. For some questions, contingency methods were used so that respondents were not forced to answer subsequent amplifying questions irrelevant to the respondent. To report results of the two surveys on comparable questions in the following text, brackets have been used to denote the results of the two surveys sequentially, separated by a semicolon. Both surveys were distributed to the same email panel of individuals whose names were collected by the educational-service company, Compliance Alliance. The first survey was disseminated over a three-month period in 2007 and the second over a six-month period from 2012-2013. A cover memo explained the purpose of the survey and provided assurance that individual responses would be kept confidential, but also identified that grouped data would be compiled and made public.

In the first survey, responses were obtained from 395 individuals. In the second, a somewhat smaller rate of responses was obtained from 152 individuals, as might be expected because many of the individuals on that list were no longer accessible. The career stages of the respondents, collected in an immediately precedent poll on a similar topic, ranged from associates to presidents; the most common title was manager. More than 67% of respondents reported more than 10 years of experience, and 19% had 5-10 years of experience. Most respondents had a bachelor's degree, 40% had a master's degree and 9% had a doctorate degree. A short series of questions to gather professional affiliation and background were posed to characterize the survey respondents further. 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 (Figure 1).

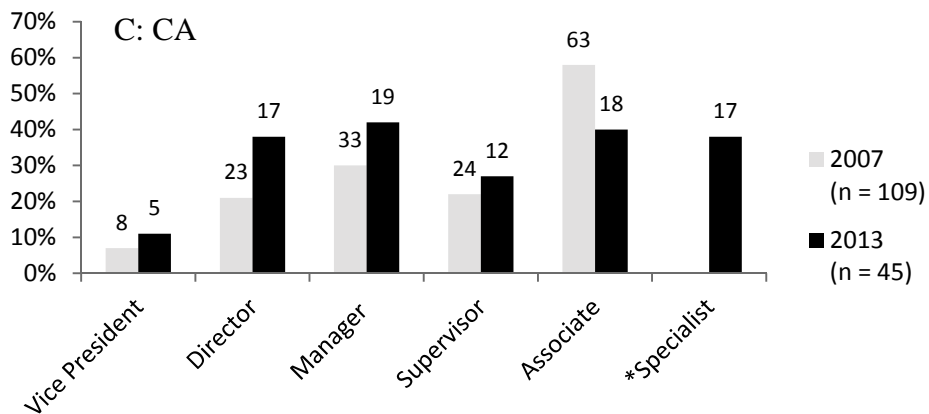
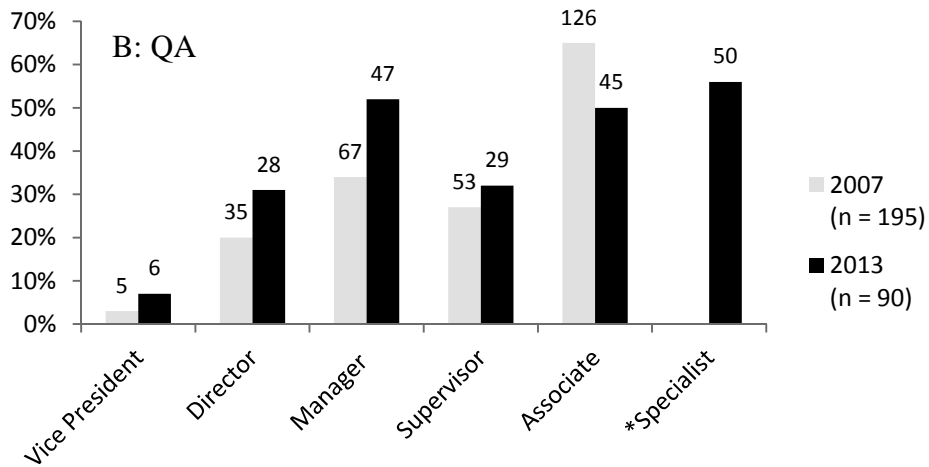
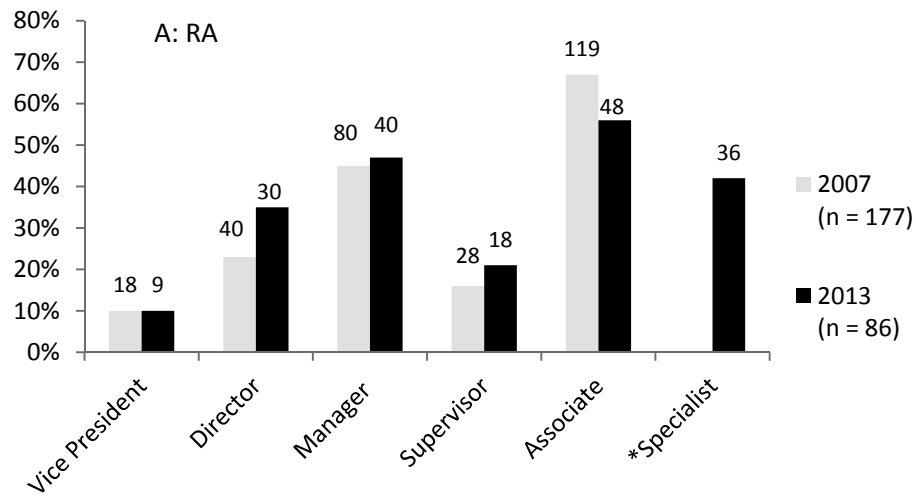
Figure 1. Which of these products does your firm manufacture (respondents were encouraged to identify all that apply)?



Results

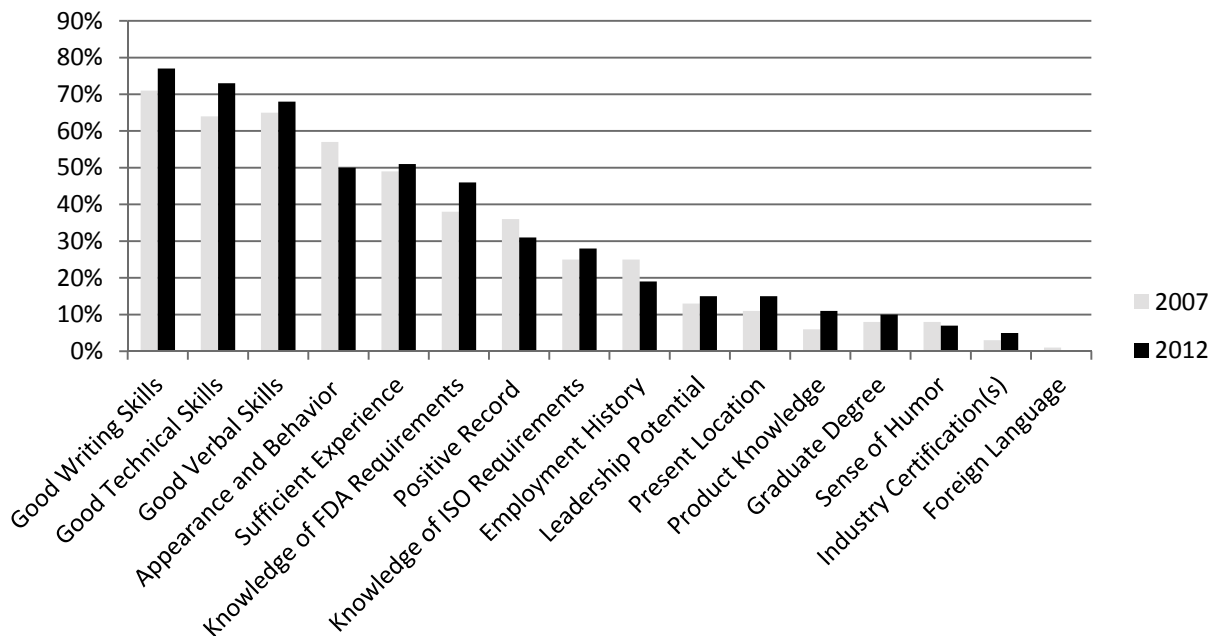
A strong continuing demand for professionals would appear to exist throughout regulatory, clinical and quality job categories from 2007 to 2013 (Figure 2). Most respondents from the two time points (i.e. 2007 & 2012-2013) reported vacancies in Regulatory Affairs (56%; 59%) and Quality (60%; 60%) departments; fewer (36%; 34%) identified openings in Clinical Affairs. When asked about the most difficult job levels to fill, manager followed closely by director positions were identified. Vacancies in various job categories were distributed at all levels of hierarchy, but most vacancies were reported at associate, specialist and manager levels. In Regulatory Affairs, over half (67%; 56%) of the companies in which vacancies were reported had openings at the associate level, and a slightly smaller number (45%; 47%) had vacancies at the manager level as well. In Quality Assurance, most companies with vacancies reported openings at the associate level (65%; 50%); vacancies at the specialist (specialist data was captured only in the 2013 survey) and manager levels were also common, with a shift toward vacancies at senior levels between 2007 and 2013 (director: 18%; 31%; vice president: 3%; 7%). Similarly, in Clinical Affairs, a higher proportion of openings was identified at the manager level (30%; 42%) in the later survey; openings at entry levels appeared to be shrinking (e.g., associates: 58%; 40%).

Figure 2. Percent of respondents whose employers have vacancies in regulatory affairs (A), quality assurance (B) and clinical affairs (C). *Specialist included in the 2012-2013 survey only



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%) (Figure 3); interestingly, hardly any 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 FDA requirements (54%; 53%), and writing skills (51%; 50%).

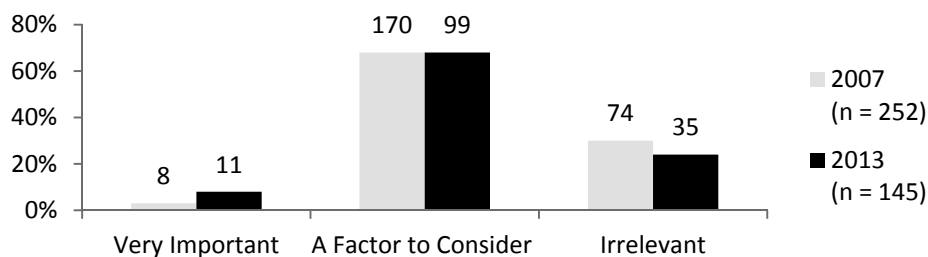
Figure 3 *When considering hiring an entry level candidate, which of the following skills are mandatory? Results are presented as percent of overall respondents; multiple choices were permitted.*



Respondents varied in what they considered to be a minimal standard for educational qualifications in different job categories. In both surveys, about half of the respondents felt that an associate degree was sufficient for an entry level position in quality assurance but only about one-third of the respondents felt that such a qualification was adequate for regulatory or clinical positions. Advanced professional preparation beyond the baccalaureate level was considered irrelevant for entry level positions by almost 25% of respondents in 2012-2013, only a small drop from the 30% who held the same view in 2007 (Figure 4). Substratification of the data suggested that this view was less prevalent amongst individuals working with prescription drugs than Class III medical devices (~30% versus 20%). For no product class was an advanced degree considered very important by more than 20% of respondents (Figure 5). However, most respondents (95%; 96%) considered advanced professional preparation beyond the baccalaureate level to be “very important” or “a factor to consider” at the managerial level (Figure 4).

Figure 4. Importance of advanced professional education beyond a bachelor’s degree?

When considering entry level candidates



When considering candidates for a managerial position

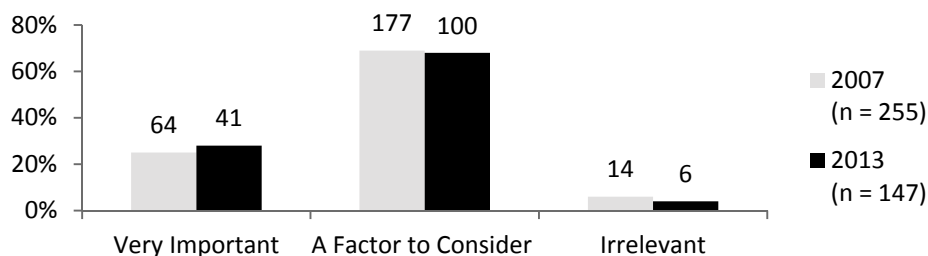
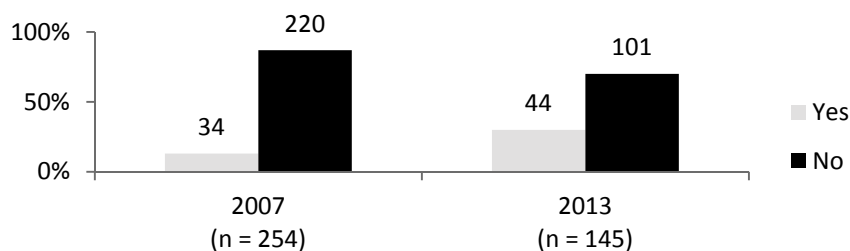


Figure 5. Cross-tabulation comparison of views of individuals in different product sectors with respect to the need for advanced professional education

		Which of these products does your firm manufacture (select all that apply)?							Total
		Class I medical devices	Class II medical devices	Class III medical devices	OTC drugs	Prescription drugs	Combination products	Other	
When considering entry level candidates, how important is advanced professional education beyond a bachelor's degree?	Very important	7	9	5	1	3	5	3	33
	A factor to consider	48	65	43	9	19	26	22	232
	Irrelevant	13	23	16	3	10	6	7	78
	Total	68	97	64	13	32	37	32	343
When considering candidates for managerial positions, how important is advanced professional education beyond a bachelor's degree?	Very important	19	29	18	2	9	16	8	101
	A factor to consider	49	66	43	10	19	20	25	232
	Irrelevant	1	2	4	1	4	1	0	13
	Total	69	97	65	13	32	37	33	346

About 70% of respondents in 2007 and about 65% in 2012-2013 identified that their employer would provide tuition reimbursement but only about a third (33%; 34%) gave time off for graduate education. Most companies (66%; 60%) reported in-house training programs for key skills such as FDA requirements. In the 2013 survey 25 percent predicted an increase in educational support by their firms over the coming years, while 16% predicted a decrease in educational support; nearly 60% suggested no change in their current support. A small but growing proportion of companies (13%; 30%) had formal internship programs in the job categories studied here (Figure 6).

Figure 6. Does your firm have a formal internship program in RA, QA or Clinical Affairs?



The results relating to the presence or absence of an internship program was cross-tabulated with the results relating to the presence or absence of tuition reimbursement. For all groups, the companies without internship programs were also less likely to have tuition reimbursement. A further cross-tabulation against the acceptability of an associate degree only for entry level positions showed an even stronger relationship. This relationship was statistically significant in both cases for respondents in Regulatory Affairs (Figure 7). Reimbursement for tuition and internship programs were reported in almost all companies with over 10,000 employees, and were less common in companies with fewer than 100 employees, but in middle sized companies, results were mixed.

Figure 7. Comparison of firms that offer tuition reimbursement for graduate education cross-tabulated with the presence or absence of an internship program (top) and the acceptability of an associate degree for entry level positions (bottom)

		Does your firm have a formal internship program in Regulatory, Quality and/or Clinical Affairs?		
		Yes	No	Total
Does your firm have a tuition reimbursement program for graduate education?	Yes	37	57	94
	No	7	44	51
	Total	44	101	145
	Chi-squared test, p-value < 0.01			

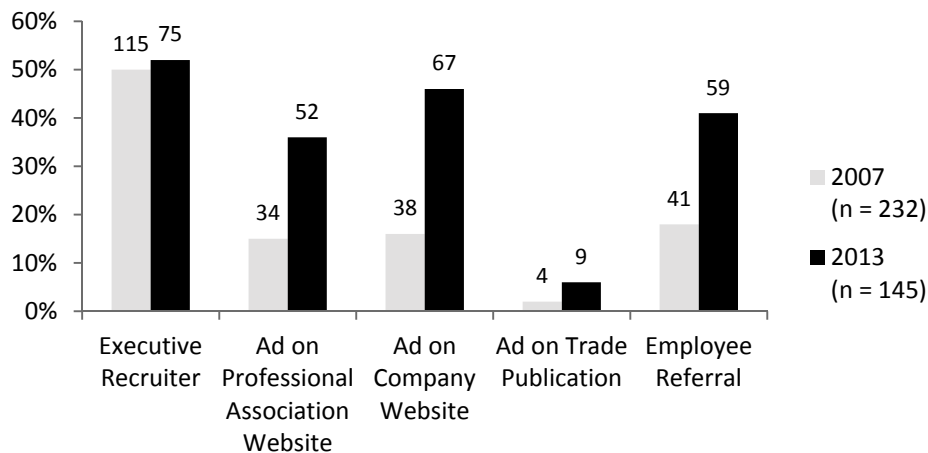
		Is an associate degree sufficient for an entry level position in Regulatory Affairs?		
		Yes	No	Total
Does your firm have a tuition reimbursement program for graduate education?	Yes	27	68	95
	No	25	25	50
	Total	52	93	145
	Chi-squared test, p-value = 0.01			

Additional information was gathered about perceived educational needs using open-ended questions. In both sets of surveys more than 70 comments were received in response to the question, “What programs would you like to see educational institutions offer?” The range of suggestions did not differ greatly between the two time points. Many identified a need for coursework focusing on quality or regulatory aspects of product development and manufacturing, and courses that complement formal training with real world issues and practical problems (e.g. drug and device submissions, negotiating). In response to the question, “What skills do you think are particularly important to improve the competitiveness of an entry level employee in RA, QA and CA?”, a recurring comment of the many responses (n=114; 86) was the need for strong writing skills as well as strong interpersonal skills with the capability to

negotiate, deal well with people and show initiative. In addition, several comments highlighted critical and logical thinking and a strong formal knowledge and practical experience relevant to the job category.

Asked about the ways by which they recruit regulatory, clinical and quality professionals, about half of the respondents reported the use of executive recruiters (50%; 52%), but a variety of other methods appeared also to be employed, including advertising on professional association and company websites, employee referrals, contacts at universities with regulatory degree and/or certificate programs and social networking (e.g. LinkedIn) (Figure 8). It is notable that an increase was seen in all recruiting modalities between the 2007 survey and the 2013 survey, with “Ad on Company Website” and “Employee Referral” seeing the largest percentage increases.

Figure 8. *How do you locate most of your employees in RA, QA and Clinical Affairs?*



Discussion

It is perhaps surprising that the specialized workforce employed in regulatory, clinical and quality job functions has received so little attention with regard to employment trends and educational development. Even the most basic employment statistics, tracked in considerable granularity for hundreds of occupations by the US Department of Labor (USDOL), fail to provide specific data regarding personnel in regulatory, quality and clinical positions. Instead, such positions are hidden in the overall statistics for job functions defined by educational background or job level (e.g. chemists, biochemists, natural science managers, and “managers, all other”), in ways that cannot be deconstructed.⁶ The exploratory study presented here provides new information about the nature of employment and talent management in US medical-products industries that has not been available from other datasets.

The data in this study must be considered with a full appreciation that external validity can be hard to assure when using survey methodologies. The study population, composed of busy professionals often suffering from survey-fatigue, is difficult to characterize comprehensively or sample uniformly. Nevertheless, the consistency of results across the two time points at which the surveys were conducted does help to add confidence in the validity of the results.

Two observations seem particularly compelling from this work. First is the finding that many companies have multiple open positions in Quality Assurance, Regulatory and Clinical Affairs despite the economic recession and slow recovery between 2008 and 2013. These results are consistent with previous salary surveys in the regulatory, quality and clinical sectors that have shown steady increases in compensation and a generally positive outlook of current professionals with respect to future employment opportunities.^{5,7} Regional analyses of workforce needs, such as that by the Healthcare Institute of New Jersey, have also predicted high levels of growth in the past, and particularly call out “clinical scientists, public relations managers, regulatory affairs managers, lawyers and product managers/marketing managers.”⁸ However, such analyses are often outdated and focus necessarily on a geographic or discipline-related subsector.⁹

Second, the employment opportunities suggested by this study appear not to be related specifically to the size of the company or nature of its product lines. Individuals associated with devices, drugs and combination products all reported significant hiring needs overall. In this study, more respondents self-identified with medical devices than pharmaceuticals, although their representation may appear overrepresented because the respondents in the medical device field will often self-identify with device experience related to more than one device class. The lack of change in these trends is interesting in light of the substantial economic challenges experienced by the medical-products industry over the past five years. Further, the finding that both medical device and pharmaceutical companies have similar hiring needs is interesting in light of the differences in economic challenges that they have faced. Medical device companies have experienced robust recent growth¹⁰, whereas pharmaceutical companies have seen highly publicized layoffs associated with patent expirations for a number of blockbuster drugs.^{11,12} Not surprisingly the strongest signal for employment shortfalls was identified in companies marketing combination products, where the required skillsets are broader and training and experience can be more difficult to obtain.

Results presented here also seem to suggest that the medical products companies are not well prepared for the changes that are occurring and will continue to occur in the next few decades. Over the past 20 years the volume and depth of administrative law and regulation have grown significantly, so that the level of preparation needed for these job functions is now much higher. Not surprisingly, advanced education was identified to be important for middle and senior job functions, and more educational opportunities in regulatory, clinical and quality areas were identified by respondents as needs for the current workforce. However, it can be challenging to assure an adequate stream of qualified executives and managers in today’s environment. Many companies still appear to regard an associate degree as adequate preparation for entry-level

positions, yet these new entrants will not have the requisite background to qualify for senior positions even after they gain company experience. At the same time individuals with strong academic qualifications are often considered to be overqualified for entry-level positions, and underqualified for managerial job functions that require specific previous industry experience. In such a situation, we might predict that appropriately prepared managers and directors will be difficult to hire. Ironically, companies that see an associate degree as an adequate qualification also seem less likely to support tuition reimbursement for their employees across all sectors. This result appears to devalue education as a responsibility for some companies. It may be important in the future to characterize the creative approaches and best practices that forward-thinking companies are considering to address their longer-term talent management. For example, a few companies, including Johnson & Johnson, Medtronic and Allergan, have instituted leadership-development tracks or fellowship programs into which they can recruit talented young people who will eventually be capable of moving to managerial and executive levels.^{13,14,15}

The need to construct sophisticated regulatory, clinical and quality teams in a global environment will become particularly challenging because a large exodus from senior job functions is predicted as numbers of "baby boomers" retire. Organizations should understand their own internal demographics so that they can plan for this exodus, but almost no information is available on the age profiles and retirement intentions of senior professionals in pharmaceutical and device firms. Further, retention of key senior individuals will be more difficult in situations of talent shortage. If firms currently find that they are having difficulties in recruiting competent personnel, as seems clear from the data collected here, they will find this difficulty to be magnified greatly in future, when the number of individuals over age 65 is projected to grow at a faster rate than the number of individuals between 20 and 64.¹⁶

What do the data collected here say to educational institutions? A principal concern of respondents is the need for stronger job-related skills, both in domain-specific knowledge and in soft skills related to communication, writing and critical thinking. These competencies can be difficult to teach efficiently, but must be part of curriculum developed by the growing number of university programs offering post baccalaureate training in regulatory, quality and clinical affairs.¹⁷ Rather than teaching "the rules", curricula should include problem-based learning and case studies to ensure that students develop verbal and writing skills as well as improvements in critical and logical thinking. Teaching these "soft skills" will become increasingly important as US-based training programs attract large numbers of foreign students who have fine minds and promising capabilities to work in emerging markets, but face challenges with communication in English as a second language. Internships and cooperative programs are useful mechanisms by which students can acquire experience and job-related communication skills, but this survey suggests a paucity of such programs.

Leadership potential, product knowledge, and overall experience are identified as the most important skills that are often missing in applicants. Such skills take time to develop, and are not well addressed in early-stage programs or certifications that use multiple choice questions

to assess competencies. These skillsets may instead be best developed in promising individuals by a combination of experience and advanced educational preparation at the doctoral level, though only a few universities now offer such programs (e.g., University of Southern California, University of Wales).

What do the data say to biomedical companies? Results suggest the possibility that many companies are not developing their employees adequately for the challenges ahead. Although the data show that a slowly growing number of companies provide some degree of tuition reimbursement for job-related coursework, they typically rely on their personnel to undertake this training on their own time. Considering that many individuals in entry-level and middle management positions are in an age group that typically has significant personal and family obligations in addition to demanding jobs, this *ad hoc* approach may not provide adequate incentive to ensure the type of professional growth needed to serve the company well.

The relatively large number of vacant positions at entry levels is striking. It is surprising that relatively few companies are addressing this challenge with targeted internship programs. The results suggest considerable scope to improve the match between hiring needs and available personnel. Such attention to personnel development may be critical to gaining efficiencies in the lengthening globalized product development path that is currently constraining the commercial success of medical products.

To Conclude

Regulatory, clinical and quality professionals appear to be in high demand. The demand is made worse 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 is made difficult 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 identify 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 behavior. Results suggest a wide range of views on the importance of educational preparation but advanced degrees are generally seen as much more important for senior than junior positions. Because the primary way to gain experience needed for senior positions has been to enter companies at a junior level, companies risk hiring individuals who cannot be groomed for senior roles unless they are willing to hire new entrants who appear initially overqualified. Further, many companies appear reluctant to invest in educational benefits for employees or internships that might expand the field of talented individuals. These results suggest significant educational and hiring challenges to create appropriate skillsets in professionals of the future. This challenge is likely to be magnified as experienced personnel in the demographic bulge retire in large numbers in the coming years to leave open senior positions for which fewer appropriately trained and experienced individuals may be available.

Disclosures and Acknowledgements

The authors have no potential conflict of interest with respect to the research, authorship, and/or publication of this article. They received no financial support for the research, authorship and/or publication of this article. We thank Compliance Alliance, Arlington, for assistance with identifying survey participants and Dr. Michael Jamieson for helpful comments on the manuscript.

References

1. Carey, MP. Counting Regulations: An Overview of Rulemaking, Types of Federal Regulations, and Pages in the Federal Register. Washington, DC: Congressional Research Service; May 1, 2013. <http://www.fas.org/sgp/crs/misc/R43056.pdf>. Accessed 1 January, 2014.
2. Robinson, R. Is it time for academic preparation of future regulatory affairs professionals? *Journal of Medical Device Regulation*. 2006; May:18-23.
3. Henry, K. Using creative staffing to combat RA staffing shortages in the US. *Regulatory Affairs Focus*. 2006; 11:34-36.
4. LeClaire, J. Pharma cos. facing talent shortage in specialty areas. *Boston Business Journal*. 2007; <http://boston.bizjournals.com/boston/stories/2007/10/22/story6.html>. Accessed January 1, 2014.
5. Regulatory Affairs Professionals Society. *2012 Scope of Practice and Compensation Report for the Regulatory Profession*. Regulatory Affairs Professionals Society Web site. <http://www.raps.org/2012-scope-of-practice-compensation-report/what-they-earn.aspx> Published 2012. Accessed January 1, 2014.
6. Bureau of Labor Statistics. *Occupational Outlook Handbook, 2012-13 Edition.*, U.S. Department of Labor Website. <http://www.bls.gov/ooh/> Published March 29, 2012. Accessed January 1, 2014.
7. Regulatory Affairs Professionals Society. *2006 North American Scope of Practice/Compensation Study*. Rockville, Maryland: RAPS; 2006.
8. Healthcare Institute of New Jersey. *The Workforce Needs of New Jersey's Pharmaceutical and Medical Technology Industry*. <http://www.heldrich.rutgers.edu/sites/default/files/content/HINJ.pdf>. Published May 2007. Accessed 24 January 2014.
9. Horn CV, Cleary J, Fichtner A. The Workforce needs of Pharmaceutical Companies in New Jersey That Use Nanotechnology: Preliminary Findings. The Center for Nanotechnology in Society, Arizona State University; 2009.
10. Wiltz, C. American medtech market to grow 6.4% annually through 2017. *MDDI on-line*, at <http://www.mddionline.com/article/american-medtech-market-grow-64-annually-through-2017-infographic>. Published 2007. Accessed January, 2014.
11. *Patented Medicine Prices Review Board, Annual Report*, www.pmprb-cepmb.gc-ca Published 2012. Accessed, January 1, 2014.
12. Wiecek, AS. Pharma layoffs 2013. *Drug Discovery and Development*, <http://www.dddmag.com/2013/12/infographic-pharma-layoffs-2013>. Accessed December 2013.
13. Leadership Development Programs. Johnson and Johnson Website. <http://careers.jnj.com/leadership-development-programs>. Accessed January 1, 2014.
14. Leadership Development Rotation Programs. Medtronic Website. <http://www.medtronic.com/careers/student-opportunities/mba/ldrp/>. Accessed January 1, 2014.
15. USC-Allergan Pharmaceutical Industry Fellowship Program. University of Southern California Web site. <http://pharmacyschool.usc.edu/files/2010/10/71661-USC-Fellows-Booklet-2013-LR.pdf>. Accessed Jan 1, 2014.
16. L'Allier, JJ and Kolosh, K. Preparing for baby boomer retirement. *Groco CPAs and Advisors*. June 2005.

http://www.groco.com/readingroom/babyboomer_retirement.aspx. Accessed January 1, 2014.

17. Worzalla, JF and Tarwater, OR. Teaching regulatory affairs. *Regulatory Focus*. 2007; 12:10-14.