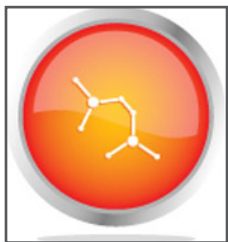




Regulatory Affairs Jobs

This article examines the growing number of regulatory affairs jobs in biotech. It describes both associate-level and entry-level positions as well as their requirements, training, and average salaries. It also outlines specific steps that permit a prospective regulatory affairs specialist to break into this increasingly competitive industry. It posits that there will be higher growth of regulatory affairs jobs as more biotechnological products demand their specialized oversight.



Biotechnology is a vastly expanding field due to its use of technology to manufacture effective health products. It is poised to steadily grow as more consumers purchase its assorted products: pharmaceuticals, vaccines, medical devices, and even cosmetic products. Yet, these products' complexity demands compliance

with safety and quality standards. Regulatory affairs (RA) specialists ensure these standards are met throughout a product's development and ultimately issue its safety clearance for public consumption. Regulatory affairs jobs are maturing into a dynamic livelihood as biotechnology changes the face of American healthcare.

Well-qualified RA specialists maintain a working knowledge of both safety and quality-control regulations pertaining to a product under their inspection. Their knowledge, as befits a more globalized society, includes not only US regulations but those of other countries. RA specialists also oversee the product's research procedures, clinical trials, and manufacturing processes. Many RA specialists work for large agencies such as the US Food and Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA). Others work for biotech companies, government agencies, clinical organizations, and private inspection firms.

Regulatory Affairs in the Biotech Industry

Regulatory affairs jobs in biotech largely demand oversight specific to each product under inspection. Basically, RA specialists oversee the safety and quality of a product (whether a pharmaceutical product or a surgical procedure) starting from its research and development stage to well after its market release. Throughout this entire process, they ensure that the product complies with governmental laws and safety regulations relevant to its nature. These specialists also liaise between the company and federal, state, and

local regulatory agencies, such as the FDA or OSHA. They regularly counsel the company's manufacturing department about safety and quality guidelines, keeping them informed on new information pertaining to both. These specialists also independently research new business, marketing, and economic trends that may further that product's success.

Ongoing regulatory education also functions as a core part of regulatory affairs jobs in biotech. Many RA specialists attend courses and seminars offered both by their own companies and by outside educational companies. These courses fulfill these specialists' urgent need to keep abreast of new domestic and international regulations and trends.

Types of RA Jobs

The types of RA jobs run a fairly small range because the job duties tend to reproduce from one RA job to another. The most common professional-level RA job is "Regulatory Affairs Director" or "Regulatory Affairs Associate." This job requires overseeing the entire regulatory department of a company or firm, with an emphasis on managing the company's compliance efforts toward its product(s). They spend a great deal of time preparing regulatory files and reports. This person may also train new RA employees, communicate with the FDA, monitor the department budget, and regularly attend RA seminars. The average RA director earns about \$143,000 per year.

More entry-level RA jobs include "Regulatory Writer" or "Regulatory Submission Specialist." They may also be known as "Documentation Coordinator" or "Documentation Specialist." These jobs involve preparing and submitting documents, such as drug licensing applications, to regulatory agencies like the FDA. They comprise much review and revision of procedures, files, and other documentation. Moreover, they often involve drafting product labeling and researching Adverse Reaction Reports. Their yearly salaries range from \$65,000 to \$74,000.



Biotech Career Feature

Another RA job that demands an associate's degree or technical training is "Regulatory Compliance & Inventory Technician." This job involves registering products, monitoring the allotment and maintenance of the product's supplies and materials, and performing auditing duties such as inventory. This job's average salary is \$42,000 per year.

Regulatory Affairs as a Career Path

A significant number of people are choosing regulatory jobs in biotech as transitional careers. These people are not limited to scientists, though they often share a scientific background. In fact, these jobs attract many people formerly employed in law, administration, project management, and social work. Many current RA specialists stress to job-seekers that recruiters seek regulatory-affairs experience before a deep educational background. Recruiters also seek transferable skills such as the ability to memorize copious regulation-related information, attention to detail, written and oral communication skills, and a continual drive to learn.

Nonetheless, many RA specialists hold science-related degrees, especially in life sciences, technical sciences/ engineering, and clinical sciences. A 2002 North American survey additionally determined that 60% of RA specialists hold master's degrees while 20% hold doctorate degrees. Currently employed RA specialists believe that the most lucrative RA positions demand either a master's degree with 2-3 years of RA experience or a Ph.D. degree. Other

educational opportunities abound, with graduate programs in RA, RA certification (RAC), and distance learning. There is also a professional society called Regulatory Affairs Professionals Society (RAPS) that offers members an "online university" and a career development center.

RA recruiters particularly advise those wanting to enter regulatory affairs to start by working for a biotech company, perhaps as a research assistant. Conversing with the company's RA specialists and volunteering time in regulatory projects will help prospective RA specialists gain experience with RA work. This experience along with their familiarity with the company will boost their employability when a new RA job opens in the company. Experienced RA specialists also advise candidates that whenever a product is nearing its clinical-trial stage, RA job openings tend to increase.

Conclusion

Regulatory affairs jobs in biotech represent a consistently growing field as interest mounts in more technologically advanced health and cosmetic products. These jobs' salaries have grown in step with this demand throughout the last few decades. The average RA specialist's salary increased by 13% throughout the last nine years, and the average RA specialist now earns over \$93,000 per year. Those with the most RA-specific training and education are predicted to fill the majority of these proliferating jobs.

EmploymentCrossing is the largest collection of active jobs in the world.

We continuously monitor the hiring needs of more than 250,000 employers, including virtually every corporation and organization in the United States. We do not charge employers to post their jobs and we aggressively contact and investigate thousands of employers each day to learn of new positions. No one works harder than EmploymentCrossing.

Let EmploymentCrossing go to work for you.