

A photograph of a male scientist in a white lab coat and glasses, focused on his work at a laboratory bench. He is using a pipette to transfer liquid into a multi-well plate. The lab bench is equipped with various pieces of equipment, including a pipette and a multi-well plate. The background features large windows with a green frame, allowing natural light to illuminate the scene. The floor is a light-colored, reflective material. The overall atmosphere is professional and scientific.

Beyond the Laboratory

*The road from
the academic research lab
to regulatory*

By Patricia Costa-Giomi, PhD



Young adults who love science typically follow an academic pathway. They enjoy basic research and laboratory work, and therefore pursue advanced degrees in a science field and continue on to do postdoctoral training in an area that interests them. When at the end of this long path they consider the next step in their careers, some of them decide to investigate opportunities outside the academic environment and beyond the laboratory. A position as a regulatory professional in the pharmaceutical industry is one of these options. This article elaborates on factors to be considered and steps to be followed when making a career change to regulatory.

Career Choices

Individuals who have spent a good part of their 20's in a lab working on a PhD in a basic field and focusing on publications and a thesis might not know where to begin when looking for alternatives to an academic career. They might be aware of opportunities in the pharmaceutical industry sector offering the prospect of higher income, more stability and a wider range of careers. Although these advantages are real, they should be evaluated against the major benefit of academic work: the scientist's ability to pursue his own ideas and interests. This will not be the case in the pharmaceutical industry where support for research projects is dependent upon a complex list of factors, and funding can be withdrawn based upon reasons beyond the scientist's control. Therefore, the scientist should use caution when evaluating a move to the industrial sector.

Once the scientist has decided to seek a position in the pharmaceutical industry, the most likely way to be recruited for a first job, at least in my experience, is to apply for positions in the laboratory. In the current job market, companies are unlikely to hire an outside individual without experience. Even if the scientist is planning to stop working in a laboratory setting eventually, the chances of obtaining a first job in industry are higher within her own area of expertise. The most likely scenario is that the individual will apply for an entry-level discovery research scientist position in a familiar field or one that uses a technology in which she is an expert.

If finding a scientist position in the pharmaceutical industry proves to be too difficult, the individual might consider additional postdoctoral training at a company in an area closely related to drug development, such as toxicology or pharmacology. This training will help the person acquire useful expertise, and although more training on top of years of schooling may not be appealing, it might be worthwhile in the long run.

Once the scientist obtains a discovery research position in a pharmaceutical company she can begin learning about career opportunities outside her field. Ideally, she will advance to become the discovery research leader in a compound development team. If this opportunity is not available, the scientist should make an effort to identify the compound development teams related to the therapeutic area in which she is working. By joining this kind of team, the scientist will become acquainted with drug development and the various roles played by individuals in this process. Functions such as clinical research, project management and regulatory affairs represent possible career paths for an individual with science training.

In order to make a decision about the next career change, the scientist needs to invest some effort in learning about the potential career paths represented in the compound development teams. To discover whether a particular line of work suits her personality, interests and intellectual ability, it is

worthwhile to proactively meet with professionals representing the line functions within the organization before an actual opening becomes available.

A Regulatory Career

Regulatory affairs is the function within drug development that some of us have chosen when we decided that it was time for a change. As most readers know, the regulatory affairs department within a company is responsible for all interactions with boards of health. It is involved throughout the entire lifecycle of the product from the time it is first tested in humans until it is marketed worldwide for a particular indication and beyond. In this process, the regulatory representative interacts with all the line functions responsible for generating the data included in the regulatory filings to boards of health. I find that my training and skills as a scientist are being utilized at my job as a regulatory professional, and in addition, I have the opportunity to develop new skills.

While the regulatory professional does not have ownership of information as a scientist would, she has access to the data related to a product and her knowledge and understanding of

the documentation is important when answering queries from the health authorities. As a scientist, I generated my own data, analyzed and interpreted results, and wrote papers that underwent peer review before publication. As a regulatory professional, I am involved in a similar process since I am ultimately responsible for the submission to boards of health of scientific information related to a drug, and I am in charge of ensuring that questions and comments from the health agencies are adequately addressed by the company's scientific experts. As a scientist, I wrote a thesis plan and as a regulatory professional, I write regulatory strategies. As a scientist, I had to stay current with the literature in my field of expertise, while as a regulatory professional, I have to keep up with the regulations and outcomes of advisory committees related to the therapeutic area I am working in. In addition, I am accountable for negotiating with health authorities, and this is one of the new skills I have developed in my regulatory role.

After exploring the new possible pathways within industry, the scientist might decide, as I did, that regulatory is the career opportunity she



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would like to pursue.

There are various activities that the candidate can explore in preparation for a possible opening in regulatory affairs within the company. For example, some companies have formal or informal internship programs, which allow individuals from one department to work on a part-time or project basis in another. There is a dual benefit to this type of program: the scientist gets firsthand experience in the job and also interacts with people in the department to create a network of contacts in the new area. If an internship program does not exist, the candidate might want to propose a well-thought-out initiative to management.

Another activity involves becoming familiar with the regulatory filings related to the compounds of the therapeutic area with which the scientist is involved in the lab. The scientist might already be contributing to these filings through writing discovery study reports. The scientist might also want to attend some basic regulatory training courses taught by several reputable organizations, including RAPS. Finally, perhaps the most effective approach would be to pursue an academic degree in regulatory affairs from a recog-

nized institution or a regulatory affairs certification (RAC) from RAPS. The degree or the certification will go a long way toward compensating for a lack of previous experience. The better the candidate understands the scope and complexity of the job, the more persuasive she will be in explaining how she can be effective as a regulatory professional after a reasonable transition period.

Conclusion

Career changes are both intimidating and exciting experiences. As we develop as individuals our interests and needs might change, and it is our choice to adjust our careers to continue to learn and be productive contributors. ■

Author

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