

CHAPTER 1

Introduction

By Peggy Berry, MBA, RAC



The regulatory profession is not, in my opinion, one of those careers that kids dream about. In fact, most adults do not even know it exists or what regulatory professionals actually do. So, how do so many people end up in the regulatory profession? From my 20 years of experience in regulatory, I can report that the typical story about entering the profession begins: “It happened by accident...” or words to that effect. In this book, you will find similar stories from a variety of professionals.

Furthermore, regulatory can be entered from many different directions. Like spokes on a bicycle wheel that converge on a central point, many paths lead to the profession. Most professionals have a scientific background, but they may have worked in a research laboratory or a quality department, or as a university professor or a practicing physician before arriving in the regulatory arena. Educational credentials range from a bachelor’s degree to a doctorate. There are no hard and fast rules about requirements for a career in regulatory, resulting in maximum flexibility for applicants and hiring organizations. This book is structured to provide insights, considerations, tips and ideas for both new and seasoned regulatory professionals. You will find information about some of the more typical requirements for various levels and types of regulatory positions.

There are a number of different aspects of regulatory work that attract an individual to this profession. One is the variety of activities and areas available. At the macro level, one may work with branded or generic pharmaceuticals sold

by prescription or over the counter, with biologics or with medical devices that are new or substantially equivalent devices. One may perform regulatory duties at global or regional companies of any size. In addition, the company or the professional may focus on a specific therapeutic area. In this book, you will read about the experiences of regulatory professionals working in various types of organizations and different product areas. The authors also compare and contrast these work areas and organizational types with their own experiences, and share guidance and tips.

Another consideration for regulatory professionals is whether to specialize in areas such as chemistry, manufacturing and controls, advertising or labeling, or to remain a generalist. Several of the authors describe requirements for specialization and the benefits of doing so, as well as their own career choices. Each specialty area, type of company and product development sector has characteristics that are more or less appealing to each individual.

Personally, I have worked for the government, contract research organizations, biotechnology companies and small and large pharmaceutical firms. I have specialized in one area and otherwise been a generalist. In gaining all of these experiences, I learned that that I prefer working at small to medium-sized companies because I like performing a large variety of tasks and having a clear, visible impact on a given project or organization. I also am inclined toward change and continuous improvement and find fulfillment in changing jobs every four years or so. New roles allow me to learn from other professionals—within regulatory and other areas of the company—and gain new and diverse experiences that expand my overall regulatory knowledge.

There are three lessons that I have found most valuable throughout my career.

Listen and Learn

No matter what you are doing or how long you have been doing it, you will always get further ahead if you listen to those around you and adjust your response or reaction accordingly. I find that listening is one of the most effective tools that a regulatory professional can master. It helps in dealing with project teams, senior management, direct reports, contractors, consultants and FDA or other regulatory authorities. Every person comes into a situation with a certain set of biases and assumptions. It is important to intentionally minimize your own biases and challenge your own assumptions to be open to and fully aware of other people's perspective—whether you ultimately agree with it or not. Learning this skill will be helpful early in your career to fully understand what is expected of you, and it will be helpful later for many reasons, including fully understanding the regulatory agency's viewpoint and priorities.

There is a certain amount of passive learning that accompanies listening in the situations described above. But there is much more learning that can be done actively by the regulatory professional, including researching those you are doing business with, your direct competitors and so on. In addition, I would emphasize that to be the most successful regulatory professional possible, you should become a sponge for any and all information. Do not filter your learning because you think information is not relevant to your current job or company. Learn from every interaction and every situation. Over the years, I have found that I can learn something from every person whom I encounter. In some cases, it may be a technical skill such as creating an animation in PowerPoint or an xml file for a Common Technical Document (CTD), or a less-tangible skill such as how adults learn best. Everything you learn can eventually be used to help you advance your career, be a better person or build a better relationship in the future.

Ask Anyone Anything

My next piece of advice is to seize every opportunity to learn more. Just as children always ask “Why?”, so should you. Ask finance: “Why do you need this report? What do you do with it? Why does the SEC require it and does it apply to all companies or just ours?” Ask your boss: “What is the best way to present the accomplishments of the organization? Is there a specific way the CEO or the board wants to see the information? What is most important to the CEO or the board? How can I help you do your job better? Why did the company decide not to pursue that partnership or that deal?” I have found that virtually everyone wants to teach you about what they do and why they do it—you just have to be willing to ask, listen and learn. I have also found there is very little that is off limits. I would say that in 20 years of asking about 500 people more than a million questions, I can count on two hands the number of times that someone said, “I can’t tell you that information.”

Asking questions also builds relationships. When you ask people about their work and they share with you and teach you, you are adding people with a variety of skills and a vast amount of knowledge to your own personal network. Having a large group of “go-to” people can help you later when you need resources they possess.

Never Say No

Not only do I suggest you never say no, in fact, I think you should seek out opportunities to volunteer or take on additional responsibilities. This does not mean that you should work 20 hours a day and have no life outside work in order to advance. However, it does mean you should volunteer to help anyone

who needs assistance with his or her job, even if it means staying late or coming in early. For example, if you notice that regulatory operations is preparing a big submission, ask whether there is anything you can do to help, even if operations is not your job or you have never done it before. Often, you can check links and bookmarks or perform a quality check on documents and, in the process, learn about putting together a submission and how FDA might navigate that submission. You might also volunteer for special projects you have the skills or ability to complete so you can gain additional experience or build better relationships.

For example, about 15 years ago, I volunteered to build a major database that would be used by the entire company to track a certain type of document, actions required, responsibilities, responses and other key items. It took about three weeks to build the comprehensive database and teach several users how to input information into the system. The database was in use for about 10 years and the heads of the impacted units never forgot I had stepped in and volunteered to give them a tool to make their jobs easier and made them more efficient. To this day, I can call those individuals for information or advice and they occasionally still refer to how that database helped them.

Another aspect of this advice is to always try to do the work of the next position you want. When an opportunity arises that will allow you to take on more responsibility within your own department, even if it is only temporary, take it—every small step will lead you closer to the position you want. During my own career, I often boldly requested more responsibility and opportunity and was frequently rewarded for taking the chance, including getting more responsibility, gaining additional learning and experience outside my specific job function and, ultimately, receiving promotions or being sought after for highly visible projects. The worst that could happen is for someone to say you are not quite ready or they have chosen someone else this time.

For example, I worked for a company whose projects were led by PhD professionals. When there were too many projects for the available PhD project leaders, the company had to decide whether to postpone a project, give too many projects to a single leader or hire another project leader who would then have too few projects. Recognizing this dilemma, I went to the president of the company and said that I wanted the opportunity to lead the project. I told him why this would be a good choice; what experience, skills and abilities I brought to the table; what I was willing to do to get the job done; and what I would do to get mentoring in the areas where I did not have enough information or needed some guidance. In view of my self-confidence and the plan I presented, I became the first non-PhD project leader for the company. I still had to fulfill all my

regulatory functions and did not receive a promotion or more money. However, it was one of the best choices I ever made because I learned a lot about leadership, management, overall drug development, providing relevant information to senior management, and guiding a project team to get a job done.

So, seek out opportunities, ask for what you want or what you think would be beneficial, show how you can contribute and never say no in the face of an opportunity—and you will expand your possibilities and find new choices.

There are at least 100 other pieces of advice or wisdom or learning I could share, but most of them would all circle back to the three I have mentioned. I strongly believe you are in control of your own career; you can shape it and, with some creative thought and consideration, you can shape your world to achieve what you want.

This book can be a step in your journey. Read what others have been through, learn from their experiences, consider their advice and ponder their thoughts. Discuss these things with your colleagues or your supervisor to gain additional insights. If you have more questions, take my advice and ask anyone anything—reach out to the authors, ask them for more information about what they do, extend your network to include them, meet up with them at a RAPS conference or connect through LinkedIn. Do not manufacture constraints for yourself—others will do that. Instead, remember that you can talk to anyone, learn anything, and break any boundaries. This confidence will open a new world of ideas and opportunities you could never have planned.

Good luck in your career!

Support Groups and Organizations for Regulatory Professionals

By Amy Grant



Support groups and organizations offer many benefits to regulatory professionals. People find great value in networking and sharing nonproprietary information and experience. There are many opportunities to specialize and deepen one's knowledge of regulatory and to learn and improve in general. Collaborations in groups and organizations have produced benefits such as standards for technology, revisions and clarification of regulations and guidelines and critical path initiatives ultimately resulting in innovative medicines for patients. Support groups and organizations offer opportunities for leadership, development and mentoring; all of which enhance a regulatory professional's skills and practices.

Support groups are informal networks of people that may or may not be part of a formal professional organization. Support groups may be formed within or outside the workplace and may involve people with common interests who meet informally on a regular basis to discuss their challenges and experiences.

Professional organizations are formalized bodies with a common interest or purpose. Some professional organizations may also have support groups and activities such as special interest groups, workshops and local chapters, and activities that offer benefits to smaller subgroups of the membership.

Working in regulatory requires innovative thinking; interpretation of laws, regulations and guidelines; and experience-based decision making. Support groups and organizations provide educational forums for discussion