REGULATORY FOCUS

First Years in a Regulatory Career

By Karen Kurt Teal, PhD

"The people who get on in this world are the people who get up and look for the circumstances they want, and, if they can't find them, make them."—George Bernard Shaw

Entering a new field is often a challenge, but knowing what to expect and how others have prepared for it can help. The best information comes from people who are right in the middle of the challenge. Therefore, as a professor in the University of Washington's Biomedical Regulatory Affairs Master's Program, I reached out to recent graduates from regulatory master's programs in the US to see how they are doing. I called the new careerists in December 2013. Expecting a wide range of experiences, I learned that the graduates' careers were varied, demanding and inspiring.

Read what these new careerists have to say about their "novice" period, what their backgrounds are, what their jobs are like and about their advice to others aspiring to enter the regulatory field. Their stories are meant to guide you in your journey.

How long does the novice period last?

About half the new regulatory professionals reported that their novice period lasted as long as they expected. The other half said it took longer than they expected to make decisions on their own.

Regulatory Strategist at Covidien, Plymouth, MN

Anna Eckerman has a background in quality assurance (QA). She said a combination of analytical and quality skills is very beneficial to regulatory. "The QA platform is a very helpful mindset." What else helps? "A good manager will help shape you, and guide you along the right path. Make sure you have a good relationship with the leadership at your

company." Eckerman thought the novice period would last between one and three years, but at one-and-a-half years in, she feels confident.

Regulatory Strategist at Booz Allen Hamilton, Atlanta, GA

Sheika Blount has a background in laboratory science. Blount began working in regulatory affairs in 2011 and thought her "novice period would last one to one-and-a-half years—but I was truly unaware of what was involved." It's still going on and it's late 2013. She had been working in biologics and drugs when her company went under, and she was out of a job. She was looking to continue in biologics, but a good opportunity opened up in devices and she took the position. Blount said the learning curve was steep and there was no training. Attending graduate school in regulatory has helped.

Regulatory Strategist at Vital Access Corporation, Salt Lake City, UT

Chris Phillips began handling regulatory submissions in 2011. He thought he would be a novice for two years, but he's still learning—"even just the vocabulary is overwhelming." This was why he decided to pursue a master's degree while working.

Reviewer and Program Manager, Division of International Compliance Operations, Center for Devices and Radiological Health, US Food and Drug Administration (FDA), Washington, DC

J. Girard Griggs said that during school at St. Cloud State University, he took his Regulatory Affairs Certification (RAC (US)) and spent two summers in Washington, DC, in the university's Medical Device Fellowship Program. Once he graduated from St. Cloud's Regulatory Affairs and Services Graduate Program in 2012, he "never felt like a newbie." He credits his graduate program for its thoroughness.

Interdisciplinary Scientist, Division of Nonprescription Regulatory Development, Office of New Drugs, Center for Drug Evaluation and Research (CDER), FDA, Silver Spring, MD

Benjamin Bishop, already a PharmD, graduated from the Arizona State University's (ASU) Master of Science in Regulatory Science and Health Safety Program in 2011. Bishop reported that his novice period got extended a bit: "I didn't think it would be that long—three to four months, six months max. It lasted six to nine months. It has depended on the type of supervisor I have. Some are less focused on training. This is a good thing for people to know: when you come into a new position, a lot depends on your supervisor."

Regulatory Health Project Manager, CDER, FDA, Silver Spring, MD

Kerri-Anne Jennings graduated from the ASU Master of Science in Regulatory Science and Health Safety Program in 2011. She has 15 years of experience in nursing, and during graduate school participated in a three-month internship with FDA. She has been a regulatory health project manager at the CDER for 18 months and feels "comfortable" doing her job, now. What was the key to her success? She imposed her own goal to learn everything she could in the first year. When people began asking her opinion after one year, she knew she had accomplished her goal.

Regulatory Affairs Specialist at Fujifilm SonoSite, Bothell, WA

Patricia Liau graduated from the University of Washington (UW) Biomedical Regulatory Affairs Master's Program in 2012. With an engineering background (BS computer engineering; MS biomedical engineering), she explained, "I was confident that my analytical skills would help me succeed in my new regulatory role quickly. Based on my skills and experience alone, I expected the novice period to last about six to eight months. However, it lasted only five."

So, why did the novice period pass so fast for Liau? Things in biotech are pretty changeable, and she had a surprise: "Within five months, three of my team members, including my manager, left the company for various reasons. I had no choice but to step up and take the lead in various regulatory compliance functions (audits, CAPAs, recalls,

metrics and complaints), which are typically owned across several people." Luckily, Liau succeeded. She felt that the length of the novice period really depends upon circumstances and initiative.

Regulatory and Compliance Specialist at Fujifilm SonoSite, Bothell, WA

Sudipta Chakrabarti also attended the UW Biomedical Regulatory Affairs Master's Program, graduating in 2012. She works with two different groups within regulatory—compliance engineering and regulatory compliance. She believes the novice period will last one-and-a-half years, and that she still has some work to do. She notes that Fujifilm SonoSite focuses on continuous training.

Conclusions

Based on this feedback, it appears a background in science or medicine helps a new careerist establish his or her authority. Patience is recommended for a beginner, who should learn to ask for opinions and advice. Success is tied to developing good relationships with managers. If necessary, the individual should consider enrolling in classes that can address immediate needs. After taking classes and gaining credentials, the early careerist still may find it will take a little longer than expected to feel confident.

What is work like?

Depending on their specific roles, some people in regulatory can anticipate what their days will be like, while others find that no two days are the same. What kind of workday do you like? Do you think, perhaps, as you grow in your career, you will welcome the lightning bolt of the unexpected? Reading these responses may help you decide whether any of these activities and daily work styles is right for you.

Lindsay Martin, a regulatory strategist at Edwards Life Sciences, noted there is a lot of writing and reading and not a lot of external stimulation or contact with coworkers: "You have to be extremely focused, have to multitask and have to endure everyone screaming for reports right now. It's very much a desk job. But it's more than a nine-to-five job. There are emergency submissions and recalls that demand a change in label. Sometimes you have to cancel your evening or weekend. The problems cannot be foreseen and there's always a super-tight deadline. You are the last part of the process, so you have to be able to work well under pressure."

Covidien regulatory strategist Eckerman said she is glad she has been well trained because "It's very stressful to have 30 people in a room asking you about the regulatory hurdles that a product faces." Eckerman also noted, "If you have to write about something, you better damn well know what you are writing about."

Vital Access Corp. regulatory strategist Phillips reports that once he got the job, he spent time learning how to craft submissions and responses and how to handle an audit. The company had only eight people and he was off site half the time, so he had to do a lot of legwork. "If I didn't get 100% there, they would fill in the gaps." Now they use an outside consultant to check their submissions.

For Fujifilm Sonosite regulatory affairs specialist Liau, no two days at work are alike. "I always start out with a plan on how I would like to tackle my tasks for the day, but I almost never follow through because there are always 'fires' that need to be put out immediately. The unpredictability in regulatory affairs keeps work very interesting." Liau works in regulatory submissions and product development, so she has to be current on global regulations. This involves significant reading and writing, and interaction with all key players at work. When there are regulatory submission deadlines, evening and weekend work is common.

Fujifilm's Chakrabarti divides her time between compliance engineering and complaint handling. In compliance engineering, she supports Canadian Standards Association (CSA) and Technischer Überwachungs-Verein (TUV) submissions and audits, and works on safety testing and datasheets. She currently works from nine to five, but says this could change soon.

Conclusions

From these comments, you know that regulatory specialists can anticipate long days, unexpected work on weekends and a varying amount of pressure. You must stay on the bleeding edge of regulatory news and trends. Sometimes others will help out and sometimes you are really on the hot seat. If you have the appetite for a significant amount of reading and writing and can handle having a lot of importance placed on your work, you will find satisfaction in regulatory.

What did you get from your master's degree in regulatory?

All of the people I interviewed completed a master's degree in regulatory, which required determination. As one specialist remarked, "Your family sacrifices with you." A person enrolled in a graduate program must be ready to take fewer breaks and have less time for fun—it is just part of what you have to do to gain valuable knowledge. Everyone with whom I spoke had a very high regard for their regulatory program. They were quick to credit professors with realism and honesty and felt they got what they wanted out of school.

What value did you get from school?

Both Phillips at Vital Access Corp. and Blount from Booz Allen found that graduate school made them better at research: Blount said studying regulatory affairs taught her where to find things. She said she spends a lot less time Googling for answers. At school, she had help with the FDA website; one class assigned the students to read and discuss FDA subject pages. She is very thankful to know about how to search for 510(k) information. Blount also found value in doing group projects because "it helped with the on-the-ground relationships. Group projects in school are also good practice for professional work when the teams are spread out." She says she is better with client and internal company meetings. School honed a valuable skill that the profession recognizes.

Both FDA's Bishop and Fujifilm Sonosite's Liau gained an unexpected benefit from their graduate programs: networking opportunities. By learning about and joining the American Pharmacists Association while at ASU, Bishop came to understand how networking can build connections in industry and with FDA. Networking was something he would not have done on his own, and it really helped. Liau asserted that interacting with class guest speakers "ultimately got me my first regulatory job."

FDA's Griggs credited both his master's program at St. Cloud State University and the Regulatory Affairs Professionals Society RAC exam for his preparation: "The RAPS programs enabled me to achieve a more well-rounded education in the various disciplines of regulatory affairs. St. Cloud focuses on medical devices, so the RAPS programs exposed me to drugs and biologics. Earning the degree and preparing for the certification exam were an excellent combination for my career."

Pashmi Vaney, who is currently looking at positions in Seattle, said she learned more about herself. "I learned about my skill set—which was a surprise. I learned about writing. The technical writing course was very eye opening, especially for an international degree candidate. When a professor invited someone to come to speak on how we worked in groups, it was very, very helpful."

Edwards' Martin highly valued professors' input on issues that directly affect her work: trending issues, codes and the gray area in emergency subjects.

Conclusions

The graduates reported satisfaction with the new knowledge they had gained, which included experiential learning from group work and professional networking. They were offered invaluable insight into the mistakes their professors made before them. They also learned how to conduct research so they could find something they desperately needed, right away. In summary, they gained a systematic introduction to the tools of the trade.

Is it hard to get a job in regulatory?

When you enter a graduate program, you always have an eye on the job market. After all, this is why you are canceling weekend getaways and ignoring your laundry in order to read assignments. You want to get a great job. Teachers hope that graduates will find their knowledge and credentials make them enticing to companies. I was particularly concerned with the job hunting experiences of recent graduates.

Some of the interviewees admitted that regulatory is a difficult field to break into—hiring has slowed in Seattle, for example, but even hot markets like Boston are showing signs of cooling for the time being. How has the hiring market affected people?

Zachary Sagawa, senior regulatory affairs specialist at the Infectious Disease Research Institute (IDRI) in Seattle, reported things are difficult but not impossible. He was lucky about his practicum placement; it led to his current job. He advised aspirants to the field of nonprofit life sciences to "just put yourself out there. Do some cold calling yourself. People are volunteering for projects."

Edwards' Martin had to fight to get in. She said when she was in biomedical R&D and was transferring methods to a European group, she started to understand the bigger picture of developing a product. After eight years in R&D, she really wanted that regulatory viewpoint: "Through regulatory I would have a lot more vision about where the company was going." She made a strong case for moving from R&D to regulatory within the company. But how did she do that? She applied for the position four or five times. After that, she went to see the Human Resources director and asked what she had to do to convince him she was right for a regulatory position. The HR director said he was assessing her by using a list of key terms for the job. He thought she did not fit. But Martin took a stand: she told him through her experience in R&D she knew what a protocol should include, and had strong statistical review skills. "If I had not been tenacious, I would not have broken in." She took a demotion in title to get into regulatory, but did not take a cut in pay. She regained her higher level title within a year.

Conclusions

You add to your chances of getting hired fast if you get out there and begin networking. As I gathered comments, it also became clear the regulatory job seeker must be willing to interview for out-of-state jobs. Candidates have to contemplate changing locations. Business may bring you back, eventually. But to be employed, you must be prepared to discover new parts of the US and the world.

If you could go back, what would you add to your master's experience?

Having been through graduate school myself, I remembered how often I thought of things I wished I had studied during graduate school. I asked this question to find out what it is new regulatory careerists wished they had studied or done before leaving school.

Covidien's Eckerman would have loved more exposure to the clinical side. "I was more familiar with the postapproval space, the regulatory understanding of validation requirements for manufacturing. I would have liked to know more about analytic test methods during a pivotal or Phase 3 drug trial."

CDER's Jennings said, "Even though I went through the ASU regulatory program, I would still pick up more classes." Jennings adds, "I wish I had a photographic memory for the 21 CFRs."

Vital Access Corp.'s Phillips noted when he began working, "I would have liked to have been given a way to internalize the codes, and more time to apply my studies."

Conclusions

It was surprising to hear so many people mention they wished they had had more time to memorize the Code of Federal Regulations. It suggests a certain defined course of action that may yield satisfaction for anyone—and it does not cost a thing except time.

Final Thoughts

Each interviewee was asked for a piece of advice or closing remark applicable to anyone with a similar background who wanted to follow in their footsteps. They were asked this because specific advice is invaluable—especially to people at the beginning of their path to a specialty. And some advice was good for everyone.

FDA's Bishop recommended interviewing people from the regulatory side and the industry side before deciding on a path.

Covidien's Eckerman exhorted aspirants to "be as well-rounded in regulatory as you can be, and have a general thirst for knowledge—ask questions about everything."

Vital Access's Phillips felt that "Regulatory is a good place to be. You can be at the forefront of delivering valuable patient care." He advised regulatory applicants to be ready to commit.

FDA's Jennings advised nurses going into regulatory to "keep an open mind—you are serving the public at FDA, just as you were in nursing."

FDA's Griggs advised people who started out as engineers to do a regulatory master's program, internships and the RAC, and figure out the perfect environment. Also, "know there is room for a person who does not want to write hundreds of pages."

In these hard times, Vaney suggested aspirants should know the market and plan ahead. Edwards' Martin said hopefuls should know statistics and be able to critically analyze a lot of information quickly.

Fujifilm's Chakrabarti seemed ready to continue studying to stay up-to-date. "In some sense this is the nature of regulatory jobs—they require continuous improvement."

Conclusion

After reading about these experiences, you should have a firmer idea of what is involved in the first years of a regulatory career. If you aspire to enter regulatory, you must be hungry to keep on learning and be completely ready to anticipate change. Eventually, you must master a large body of knowledge because people will come to you for help. Also, you need to accept that this mastery is gradual and that great strategists ask lots of questions and never stop learning about their field. In addition, almost everyone interviewed admitted to making sacrifices and working very hard to get where they are today. Finally, Eckerman's heroic struggle to get the HR manager to acknowledge her skills demonstrates your value is not always visible to other people. You must analyze your situation, make sure you are doing everything you can to sell yourself and, as George Bernard Shaw so sagely advised, make the circumstances for your own success.

About the Author

Karen Kurt Teal, PhD, has taught technical writing for the University of Washington's Biomedical Regulatory Affairs Program for five years. She is on the board of directors for the Organization for Regulatory and Clinical Associates and serves as secretary of the Association of Graduate Regulatory Educators. She can be reached at karenkurt.teal@gmail.com.

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