

## All in the Details: Careers in Regulatory Science

By Nancy Volkens April 09, 2010

*Regulatory science "is the art and science of taking new medical and food products to market and keeping them on the market, under the constraints of a variety of laws and requirements. You're doing science, but you're doing it in a legal framework." -- Frances Richmond*

Sandra Shire had spent more than a decade as a dentist in a federal prison when she decided she wanted something more. A commissioned officer in the [Public Health Service](#), she had long been interested in public health, and she had been thinking about pursuing a master's degree in the field. So, she decided to go back to school for a master's degree in public administration.

While working on her master's degree, the opportunity arose for Shire to interview at the [U.S. Food and Drug Administration](#) (FDA), and she felt like it was perfect timing -- the position would allow her to develop her career and expand her skills. Of her experience in graduate school, she says it "gave me the confidence and the skills to interview for a position in regulatory science." While she finished her degree, she worked at the FDA's [Center for Devices and Radiological Health](#), for whom she reviewed dental products to ensure that they had met all regulations deeming them safe and effective.

Since then, she has held jobs relating to a variety of different aspects of regulatory science. Shire spent 7 years in the FDA's Phoenix office reviewing and analyzing clinical trial data. "Every week was something different," she says. "One week I might review a heart drug study, then a study for an orthopedic device, then a test for blood diseases used by blood banks." After that, she spent some time in the private sector, working for [PaxMed International](#), a San Diego, California-based regulatory consulting company that specializes in medical devices. Today, Shire runs the new master's at Arizona State University (ASU), Phoenix.

As Shire's career path illustrates, regulatory science includes a broad range of responsibilities and a firm understanding of both the drug-development process and the continuum of research and regulations along that process. Regulatory science "is the art and science of taking new medical and food products to market and keeping them on the market, under the constraints of a variety of laws and requirements," says Frances Richmond, director of the [Regulatory Science program](#) at the University of Southern California in Los Angeles. "You're doing science, but you're doing it in a legal framework."

### Open opportunities

In February, declaring that it's time to "accelerate and illuminate the pathway from microscope to market," U.S. Department of Health and Human Services Secretary Kathleen Sebelius [announced a landmark collaboration](#) between FDA and the National Institutes of Health in regulatory science. The agencies will award \$6.75 million in research grants for projects that provide new methods, models, or technologies relevant to evaluating safety and efficacy during the development of medical products.

Regulatory science includes regulatory affairs, regulatory writing, risk management, compliance, and regulatory law. Every step in biomedical product development is regulated: research and development, preclinical studies, clinical studies, the manufacturing process, marketing, and post marketing surveillance. So, it follows that regulatory scientists work at each one of those steps, evaluating product candidates and trials, mediating among interested parties, finding compromise and gaining consensus.

These days, the field requires expertise from scientists in a variety of disciplines, including physicists, life scientists, chemists, and engineers. FDA, a natural home for regulatory scientists, offers employment in more than 30 distinct disciplines, including research science, pharmacy, statistics, veterinary medicine, nursing, and clinical medicine.

Besides job opportunities at agencies such as FDA, the companies developing biomedical products and devices employ regulatory-science experts to make sure the company follows all regulations and guidelines for every product, in every country in which a product will be marketed, even before the regulatory agencies gets involved. And independent companies, such as PaxMed, for whom Shire worked, have opportunities in regulatory consulting as well. "A lot of companies do the regulatory piece themselves -- unless it's really hard, and *then* they ask a consultant," Shire says. "It's kind of like general dentists doing all the easy root canals and sending the hard ones to an endodontist."

Regulatory science is an area that usually has more jobs than qualified candidates, Richmond says. And despite consolidation in the pharmaceutical industry, the market for regulatory scientists is generally stable, says Lawrence Liberti, executive director of the [CMR International Institute for Regulatory Science](#) in London.

Some areas are falling far short of filling jobs. Richmond points to global regulatory affairs (particularly positions that require Spanish or Japanese language skills), biomarkers, and diagnostic testing as areas that are especially strapped for applicants. Liberti agrees that the globalization of regulation is highlighting certain skills as being crucial. "There will likely be an increasing need for personnel who understand not only local regulatory requirements but also international and regional languages and cultural sensitivities," he says. "Well-rounded scientists who can interact in a global environment will be highly sought."

Regulatory scientists are well compensated. A [2006 survey](#) by the [Regulatory Affairs Professionals Society](#) looked at salaries and found the average salary for Ph.D. holders to be about \$142,000. Those with bachelor's degrees earn about \$95,000.

### Formalizing training

In the 1980s and 1990s, people working in regulatory science typically learned the ins and outs of regulatory work on the job -- but not necessarily at a regulatory agency. This was the case for USC's Richmond. After earning a Ph.D. in neurophysiology, Richmond worked on

studies of motor control at [Queen's University](#) in Kingston, Canada, where she began creating implantable devices to stimulate paralyzed muscles. "To get an implantable device on the market requires a lot of testing," Richmond says. "We had to read a lot and work with regulators, and gradually I became more responsible for that side of things.

"Back then, we had the great luxury of being able to learn the regulations and laws as they appeared, so you could gradually become an expert," she says. Today, however, there are far more laws in place, in addition to more and more complex science going into developing drugs. Although formal training isn't necessarily a requirement, there are a handful of programs around the country that aim to give applicants a firm grounding in regulatory science.

To that end, in October 2008 FDA accepted its first group of 50 fellows for [the Commissioner's Fellowship Program](#), selected from more than 1000 applicants. During the 2-year program, fellows train at an FDA facility, taking courses and completing a regulatory-science research project. Coursework covers regulations, science, and policy. The program is open to scientists who have a doctoral or professional degree or engineers who have a bachelor's degree.

In addition, FDA is partnering with universities for its [CDER Academic Collaboration Program](#). Programs at the University of Florida [College of Pharmacy](#) and ASU Phoenix's [College of Nursing and Health Innovation](#) offer coursework and practical experience in regulatory science. At Florida, students receive 2 years of funding toward a master of science degree or a Ph.D. in pharmaceutical outcomes and policy research. For Shire's program at ASU, which is slated to begin in fall 2010, the degree is a master's in regulatory science and health safety. Both programs require that students be commissioned in the U.S. Public Health Service and commit to work for FDA for a specified time period after graduation.

"In the past, a lot of training occurred within the FDA," says Greg Wood, director of the FDA's Academic Collaboration Program. But because science was advancing at such a rapid pace, he says that FDA administrators saw "that we needed to branch out and collaborate with academia to train people with more experience and hands-on knowledge so they could hit the road running."

Jonas Santiago is one of five students in the first class of the Florida program, which began in January 2009. When he graduated from college in 2002 with a geography degree, Santiago had career aspirations in the government sector, but he found that tightened federal purse strings had led to hiring freezes in many departments. Instead, he entered pharmacy school, earning his Pharm.D. from Howard University in 2009.

During his fourth-year clinical rotations with FDA, Santiago learned of the collaboration between FDA and the University of Florida. So he applied and was accepted. "There's a lot about research I didn't know -- when to use one study design versus another or how to scrutinize a study to look at its strengths and weaknesses," he says.

The education is meant to provide graduates with the skill set to evaluate medications, risk-management programs, and other initiatives in terms of safety, effectiveness, and cost. "Sometimes you need someone to understand the whole process in order to help with decision-making," he says. "This is giving me the tools to better succeed at FDA and promote innovation there."

## Getting into regulatory science

The push is on for more widespread formal education in regulatory science. Today, [fewer than 30 U.S. universities](#) offer master's degrees, Ph.D.'s, or certificates, as well as another handful in Canada and Europe.

The USC program offers a master's degree, a Ph.D., and several certificates. Graduates of the program find jobs easily, Richmond says, though 60% of enrollees are already employed and enter the program to enhance and sharpen their skills. They can complete the degree as full-time or part-time students; many hold full-time jobs and study part time.

One of those was Mary Ellen Cosenza, a 2008 master's program graduate. After an undergraduate degree in biology and chemistry, Cosenza worked at several biotech and pharmaceutical companies including a short stint in regulatory science in the mid-1980s. She eventually earned a master's degree and Ph.D. in toxicology, working at Lederle Labs in environmental toxicology. Recruited by Amgen, she spent another dozen years in toxicology before a colleague asked her to move back into regulatory science.

"By then, regulatory had undergone a tremendous change from when I'd been in it almost 20 years before," Cosenza said. The master's program "helped reorient me to the new world." She is now executive director of emerging markets in Amgen's Division of International Regulatory Affairs and Safety.

"I manage people around the world, as well as a core group that puts together filings, product renewals, and product labeling," she says. "We are looking at process improvements, better ways to do things." For example, when she started, the countries under her purview had no written process explaining how to file a new-drug application or a marketing application. Now they have manuals and processes to ensure that regulations are followed.

Cosenza's position in emerging markets -- countries that have recently begun to industrialize -- is a harbinger of the globalization of regulatory science. The 2006 survey by the Regulatory Affairs Professionals Society found that more than 75% of regulatory professionals in the United States and Canada had multinational or global responsibilities.

The skills required for a regulatory science career go beyond a science background. Shire listed analytical skills, negotiating skills, and communication skills as being key. "The people I've seen who've been the most successful are not only good scientists but also can gain consensus well," Liberti says. "There's a big personality component [to regulatory science] that often gets overlooked. Regulatory scientists need to be good listeners. They interact with sales and marketing, research, production...and all of those groups see a problem from a different point of view. It's the regulatory scientist that needs to bring consensus to that point of view."

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