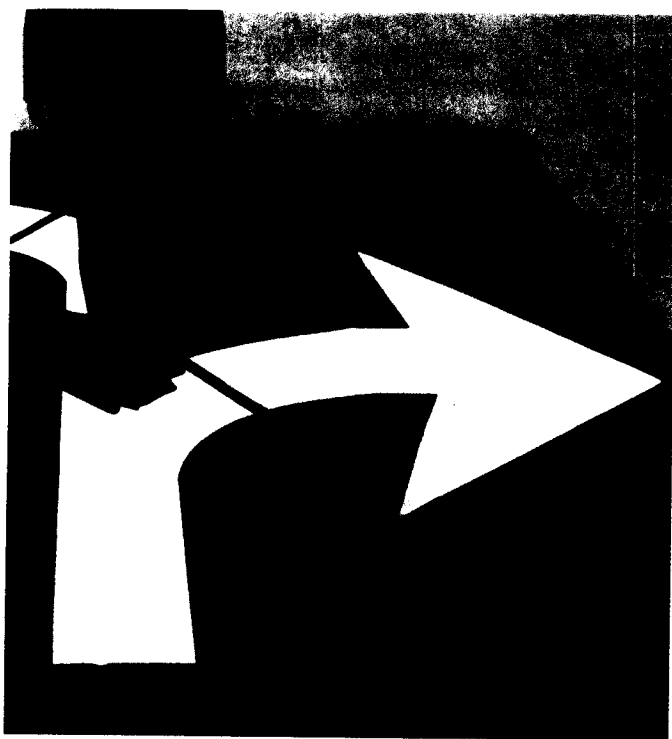


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Careers



For the Hottest Jobs, Go Regulatory

The most in-demand jobs in science, and how to get a piece of the action.

By Kelly Rae Chi

In June of 1999, and fresh from her bachelor's degree in chemical engineering, Joan Kwong started working on a rotavirus vaccine in the fermentation and cell culture department. She was working for Merck, in bioprocess research and development, growing mammalian cells and infecting them with genetically engineered viruses. About four years later, she was tapped to help draft a biologic license application (BLA, an application for commercial sales of a biologic) to submit to the Food and Drug Administration. As part of the team, she worked with her former colleagues in the lab to describe the detailed methods used to make the vaccine and measure its impurities.

"At that point I had no experience at all on the regulatory side," says Kwong, who now works as a regulatory affairs associate at Pfizer. "I didn't know what a BLA was." Thrown into a completely new aspect of drug development, Kwong began to realize that she enjoyed the challenges of her new work more

than the bench work. It was an "opportunity to use my technical knowledge of that vaccine but also to use some of my technical, writing, and editing skills."

David Serrano was developing biomedical diagnostics at Clinical Micro Sensors in Pasadena, Calif., a startup medical device company, and began to see that there were few areas for advancement in his lab. "The pay wasn't always that great. The company would always want me to work overtime. I didn't see a great future in it, and I wanted change." Serrano entered the Regulatory Science program at the University of Southern California and now works in regulatory affairs at a Los Angeles district office of the FDA.

Regulatory affairs offers an "interesting blend of opportunities," that involves learning new science, says Sherry Keramidas, executive director of the Regulatory Affairs Professionals Society (RAPS). With each new project, regulatory affairs professionals are expected to understand the science behind the products. The career path also combines law, policy, business, as well as soft skills such as project management, negotiation, and organization, she says.

For Kwong and Serrano, the move into regulatory affairs offered opportunities they wouldn't have had working at the bench. As demand for these kinds of jobs increases, and salaries go up to follow demand, other bench scientists may soon join them.

Life with Regulations

On a typical day, Kwong arrives in her office and prepares for a day of meetings. She sits with representatives from manufacturing, formulations, quality, and supply departments to discuss scaling up the manufacturing process for a biologic that's going into clinical trials. She gives the group guidance on the requirements they have to keep in mind as they scale up, and warns them if she thinks their procedures might run into trouble. Later, she will document each step of the process for an Investigational New Drug (IND) application.

In the afternoon, Kwong looks at a draft of guidelines on the manufacture, formulation and analysis of monoclonal antibodies from the European Medications Evaluations Agency (EMA), which is the European equivalent of the FDA. Companies need to comply with the guidelines of each country where they will market their product. Companies such as Pfizer have a chance to negotiate these guidelines, so Kwong assembles comments from other regulatory affairs professionals and scientists and discusses them with her supervisor.

Regulatory affairs professionals are required to mediate the interactions between the FDA, EMA, and other regulatory agencies and the manufacturer. They are responsible for making sure their employers are meeting requirements set for all aspects of the development and approval of a product, from the manufacturing process to animal testing to clinical trials and marketing. ▶

CAREERS

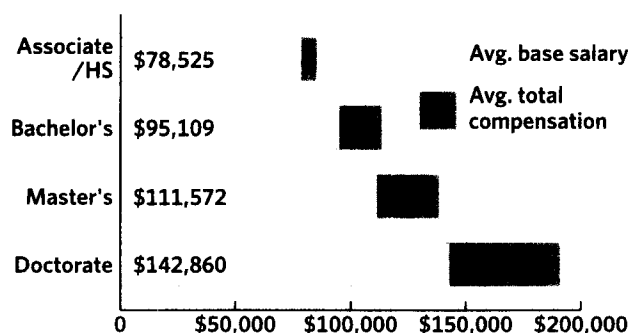
Without the help and expertise of people like Kwong and Serrano, companies can get into trouble. In 2000, Lifescan, a company owned by Johnson and Johnson, paid a \$60 million fine for selling defective blood glucose-monitoring equipment to diabetics and submitted false information about the problems to the FDA. Denise Dion, a senior regulatory consultant at Eduquest in Hyattstown, Md., who later did a follow-up inspection as part of her previous job at the FDA, says the fine was “just the tip of the iceberg” for Lifescan.

The company was also required to conduct additional validation testing of the monitors, hire an outside auditor to make sure

tions means that people like Kwong spend a good deal of time interpreting the requests of an oversight agency to apply them to the company’s specific application or project. In order to make the best guess of what an agency wants to see, Kwong will study how the agency has handled previous products and anticipate the agency’s questions about the product. Have we included enough details about the product’s purity? How much stability data will be required for Phase I development?

Serrano and Kwong still stay close to the science. They often interact with the scientists who are developing manufacturing protocols on a drug or testing its safety and effectiveness in clinical trials. As a regulatory professional, “you need to be able to understand the science,” so that you can ask the right questions about the product, Kwong says. “How you develop a product and conduct clinical trials is all science-based.”

Base and total compensation by highest degree earned



Average compensation and rate of increase of US regulatory professionals

Position	Average U.S. compensation	% increase between 2003 and 2005
CEO/President	\$252,000	34.2
Vice president	\$279,000	8.0
Director	\$166,000	8.4
Manager	\$107,000	4.7
Specialist	\$78,600	6.1
Associate	\$67,300	8.4
Coordinator	\$51,900	22.9
Consultant	\$130,000	21.0

Source: 2006 RAPS North American Compensation Study

manufacturing processes were in compliance with FDA regulations, and pay the FDA for all inspection and supervision costs. The expense of notifying customers about defective products, implementing corrective actions, and providing replacement products also added to the costs (the company would not disclose the exact additional costs of these measures). In general, “there’s no amount of things that can’t happen to you if don’t comply,” Dion adds.

The challenge is that regulations “don’t always drill down to the nitty gritty,” says Kwong. The generality of these regula-

Demand and compensation on the rise

“Right now the industry is starved for people,” says Frances Richmond, director of the Regulatory Science Program at the University of Southern California. “We just can’t get the word out enough,” she adds. “At the moment, I think most people don’t know that these opportunities exist. These are good jobs. They’re well compensated, especially after a few years.”

“It’s definitely a growing field,” says Rich Pennock, business unit leader at Kelly Scientific. “As the FDA continues to enforce the rules and, looking at regulatory affairs in the clinical trial process, and looking at the late phases of clinical trials, we see more and more validation and regulatory affairs type positions.” Pennock says that in the last 12 months, Kelly Scientific has seen a spike of about 20% in regulatory affairs positions in pharmaceutical, biotechnology, and medical device areas.

According to a 2005 RAPS survey of about 2,600 professionals, compensation in the health products regulatory affairs field is growing fast. The mean base salary for regulatory professionals based in the United States, across all levels and employment settings, was \$108,077 in 2005, reflecting an increase of 9.8% from \$98,355 in 2003. The average rate of salary growth in the United States during the same time period was about 7.6%.

Though it depends on background and level of experience, Pennock says someone with a bachelors or masters in the sciences can expect to make \$50,000 to \$70,000 as a starting base. Those who have a PhD can expect to make from \$60,000 to six figures as a base salary.

The future for these types of jobs is bright. The pharmaceutical industry is among the fastest growing, with much higher earnings than in other manufacturing industries, according to the US Department of Labor. David Jensen, founder of Career-Trax, a firm that identifies and recruits professionals in the biotechnology and pharmaceutical industries, estimates that jobs in the regulatory affairs and quality assurance areas will increase by about 15–20% per year for the next 10 years. This expansion will outpace other areas of growth, for example in research scientist positions, within the pharmaceutical industry, he says.

Education is good but experience is better

In this industry, Richmond says, experienced regulatory professionals are more important than ever. About half of regulatory affairs professionals hold a graduate degree, according to the RAPS survey, and most hold degrees in sciences, engineering, or clinical professions. Richmond, who had several PhDs in her program about seven years ago, says that at the time, it was unclear whether having a PhD was necessary. "Now we have a lot of companies who really value the talent because working with the FDA is not trivial, and you have to represent the product and all aspects of that product," she says. "You can only really do that if you know the science."

A degree in regulatory affairs can help accelerate change. Denise Fairman in Philadelphia had some industry experience and had completed half her degree in regulatory affairs at Temple University when she was hired for her first regulatory affairs job. Temple and other schools, such as University of Southern California, offer master's degrees and certificate programs in regulatory affairs and cater

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to working professionals by offering night and weekend classes. Both programs offer core courses in food and drug law and study designs in drug development and testing. The students can choose to focus on different aspects of regulatory affairs from manufacturing drugs to clinical trials. Students often work in teams to present case studies about the enforcement actions of oversight agencies and write submissions to those agencies, Richmond says.

Most companies are willing to invest in continuing education from the entry level all the way up, Keramidas says. Pfizer reimbursed Kwong's master's degree in regulatory affairs, and though she learned much of the basics there, the learning never stops. In a constantly changing industry, Kwong is challenged daily to fulfill the ever-fluctuating requirements. "I really enjoy getting to see the broader picture of a project," she says. ■

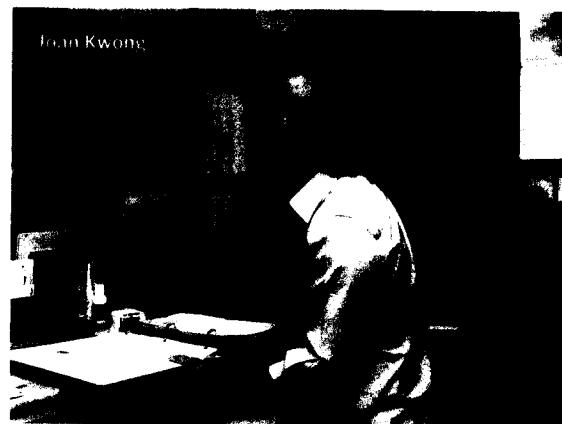
So you want to be a regulatory affairs professional - here's how to get started:

The academic two-step. For a PhD coming straight out of academia, the switch to regulatory affairs can be tough, but not impossible. "It's very doable," but it takes two transitions, David Jensen says. You'll have to start by moving from the academic bench to the industry bench, keeping in mind that the company is interested in hiring you for the research experience you have right now. Once you get your foot in the door, start letting people know right away that you're interested in regulatory affairs down the road, he says. Network within your company and take training courses. A transition could take less than two years. "Take those transitions one at a time and be patient," Jensen says.

You'll be fighting against the bottom line, so have thick skin. As a regulatory professional, you'll be dealing with high-level executives who don't have science backgrounds, and who might not understand the need for detailed safety testing and documentation. When Eduquest's Denise Dion first started working as an FDA investigator, she expected companies to

be more controlled and concerned about detail. "People can't see how doing it right can help the bottom line," she says, "It costs at least 10 times more to fix quality problems that it would to prevent those problems." She often spends time convincing companies that getting it right the first time will save them money in the end.

Acronyms abound, so learn as you go or take classes. Before Joan Kwong obtained a master's in regulatory affairs, she moved from bench science to more of a regulatory role within the pharmaceutical industry. At first she says she was bombarded with "so many acronyms and specific descriptions of how things work." She'd encounter boggling sentences such as the following: "The critical upcoming tasks for this team include preparing for the FDA EOP2 meeting with CBER and the SAWP meeting with CHMP, updating the DMF, and authoring CMC sections of the IND and IMPD to support Ph3 studies." Kwong learned a lot of on the job, but taking a couple of classes helped polish her fluency in regulatory acronyms.



Start small. Working as a regulatory associate within a smaller company gave Denise Fairman a broader range of responsibilities. "It was an excellent opportunity," she recalls, and one that could help her if she decides to move to a larger company. At Lannett Company in Philadelphia, a manufacturer of generic drugs, Fairman prepares submissions for the regulatory aspects of manufacturing and marketing of several different drugs. She regularly calls up the FDA to answer questions about the submissions. Her friends who work in larger companies have more repetitive roles, she says, such as writing reports for the clinical phase of drug development. "With a small company you wear a lot of hats, which I found very interesting."