

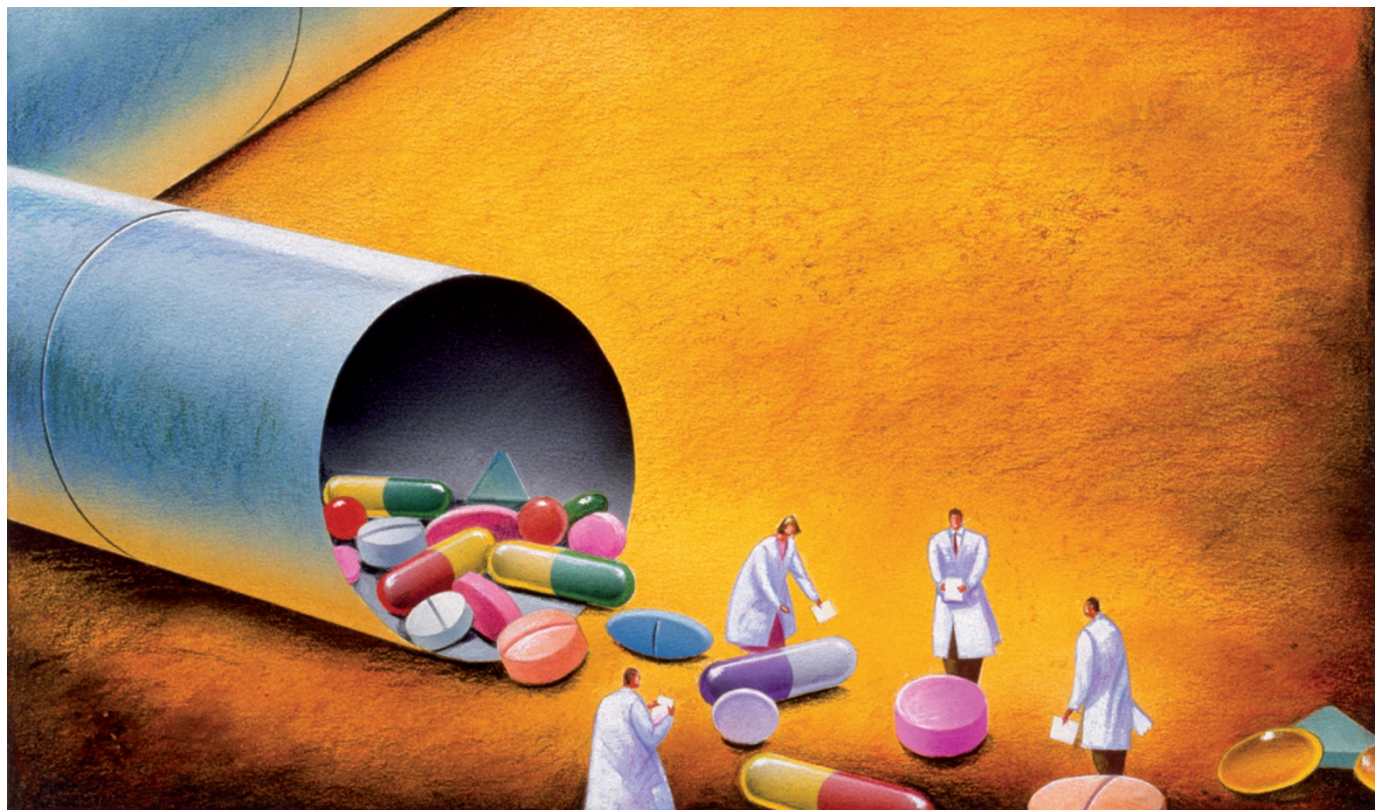
CAREERS

TURNING POINT Engineer takes up structural biology and cancer research **p.389**

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REGULATORY SCIENCE

Researchers in the pipeline

Prospects are starting to look bright in the growing field of science intended to aid regulation of food safety and drug development.

BY AMBER DANCE

When the Deepwater Horizon rig exploded in April 2010, releasing nearly 5 million barrels of oil into the Gulf of Mexico, fisheries were closed in more than one-third of US Gulf waters. Scientists had to test hundreds of samples of seafood for hydrocarbon contamination, but existing chemical tests took a week to yield results.

Researchers at the US Food and Drug Administration (FDA) and other agencies joined forces to develop a speedier assay that would let them rate seafood as safe or unsafe within two days. By refining methods that already existed, the agencies were able to get a

new test up and running by July 2010. Fisheries reopened and seafood was back on menus weeks earlier than would have been possible with the original test. Such quick, collaborative problem-solving exemplifies the benefits of regulatory science done not only in government agencies, but also in industry and academia.

Regulatory science is “not a new thing, it’s just a new term”, says Erin Wilhelm, project director at the Center for Excellence in Regulatory Science and Innovation (CERSI) in Washington DC, launched in 2011 by the FDA and Georgetown University. “It’s really an umbrella term for all different kinds of science that impact drug development or device development or food science or tobacco regulation.”

People wanting to work in regulatory science mostly need expertise in a relevant branch of science, but focused regulatory training is also available (see ‘Learning the ropes’). Jobs may involve reviewing applications for product approval, as well as a variety of research topics, such as identifying biomarkers for drug activity, gauging risks to public health during the drug-approval process or tracking a drug’s effects after it has reached the market. Companies and industry groups that need to gain approval for their products are seeking team members who understand the regulatory world. Jobs are available in many countries, especially in the United States, where the field has garnered interest in government and other sectors. ▶

► Most people distinguish between regulatory science and regulatory affairs, which focuses on making sure that regulations are followed. “We’re talking real science,” says Hans-Georg Eichler, senior medical officer at the European Medicines Agency (EMA) in London. People who do regulatory science have diverse backgrounds, ranging from biochemistry to statistics. And they tend to think of themselves as statisticians or biochemists, not ‘regulatory scientists’, he says.

“It’s not been an area of high profile,” notes John Burris, president of the Burroughs Wellcome Fund in Research Triangle Park, North Carolina, which funds biomedical research. “People aren’t winning Nobel prizes in it.” Yet the results of regulatory science have the potential to make enormous impact, he says. For example, a job in basic research identifying biomarkers for disease could help scientists running clinical trials to identify who is responding well to treatment. And by testing drugs in model systems, researchers may be able to learn about the efficacy and side effects of a compound before taking on the cost and risk of human trials.

Model systems currently under development by regulatory scientists include the ‘human on a chip,’ which simulates ten different organs for drug-safety testing. Another is the virtual family — anatomically correct digital models of male and female adults and children, based on body scans of volunteers and used in computer simulations. The virtual family is already being applied to predict body-temperature changes in the tissues surrounding implanted devices when people are exposed to radio waves or microwaves.

OPPORTUNITIES ARISING

Governments and institutions have started to take note of the field. The Burroughs Wellcome Fund is evaluating applications for its first Innovation in Regulatory Science Awards — grants for academics addressing regulatory topics — which it initiated to kick-start investment in the area. It has received applications from about 60 faculty members in North America, and it plans to endow at least five projects with up to US\$500,000 each over five years. If the programme is successful, Burris hopes to make it an annual call for proposals.

The FDA does not offer many research grants, although it partnered with the US National Institutes of Health in 2010 to offer a total of US\$6.75 million for a few three-year projects in regulatory areas such as disease biomarkers. Last year, it also issued a call for external contractors to conduct regulatory research.

In Japan, the Pharmaceuticals and Medical Devices Agency established an Office of Regulatory Science in 2009. The Ministry of Health, Labour and Welfare offered ¥1.2 billion (US\$12 million) in grants in the regulatory field in 2012.

In Europe, the Innovative Medicines Initiative (IMI) in Brussels supports public-private

collaborations on topics such as biomarkers and disease models in the hope of improving the drug-development process.

The blooming interest in regulatory science has not necessarily translated into job opportunities at the FDA or EMA, however. Eichler says that the EMA’s job market was growing rapidly until 2009, when the economy began its downward spiral and hiring stalled. IMI executive director Michel Goldman, by contrast, sees opportunities worldwide, including in Europe, Japan and China. And a 2012 review by the non-profit Partnership for Public Service in Washington DC found that the FDA hired 2,221 people in 2010, up from 817 in 2007. However, many positions are temporary. And although FDA chief scientist Jesse Goodman anticipates hiring more people as the older generation of employees retires, this year’s federal budget cuts have the potential to hit the agency hard. The FDA spends the majority of its money on staff and related costs.

Although no forced unpaid leave or lay-offs are expected, the budget cuts could lead to delayed hiring and reduced travel and overtime.

PETRI DISHES AND PAPERWORK

A regulatory agency is the obvious — although not the only — place to start a career in regulatory science. Some FDA employees have left experimentation behind, whereas others split their time between research projects and reviewing applications for product approvals.

In some ways, working in regulation is like being a principal investigator, says Candice Jongsma, a regulatory-science fellow at the FDA Center for Tobacco Products in Rockville, Maryland. She may not do the experiments herself, but she reviews data, asks questions and makes recommendations. One of her projects is to compare the lists of ingredients in new and existing tobacco products and determine whether the new recipe raises health questions that will need to be addressed before approval.

TRAINING PROGRAMMES

Learning the ropes

Training in regulatory science has tended to be an on-the-job apprenticeship, with the major requirement a solid background in science, but targeted education is also available.

Fellowships can help researchers to explore the regulatory side of science before applying for a permanent position. Candice Jongsma is among the first Tobacco Regulatory Science Fellows at the US Food and Drug Administration (FDA) Center for Tobacco Products in Rockville, Maryland; her one-year programme is co-sponsored by the US Institute of Medicine. Jongsma applies her chemistry knowledge to look for safety concerns in the ingredients of new products, and her fellowship includes training courses and personal meetings with the secretary of Health and Human Services and the commissioner of the FDA. The FDA also sponsors a two-year Commissioner’s Fellowship, which may open the door to further work at the agency after they have completed the programme.

Meanwhile, educational programmes focused on regulation are on the rise. They are often geared towards working professionals, and involve weekend or evening classes and online learning. Some curricula concentrate on science and drug development; others focus more on laws and regulations, or pricing and business decision-making, says Frances Richmond, director of the International Center for Regulatory Science at the University of Southern California in Los Angeles, which offers master’s and doctoral degrees.

Master’s programmes are in development, and are expected to open this year, at Georgetown University in Washington DC; the University of Maryland in Baltimore, as an online course; and the University of Pennsylvania in Philadelphia. In the Maryland programme, for example, students will get a grounding in regulatory affairs, drug discovery and development, clinical research and surveillance to track the safety of a drug after it has been approved.

In Europe, students can enrol in short courses lasting a few days, or year-long master’s programmes. Many focus on regulatory affairs and some on regulatory science. The Innovative Medicines Initiative (IMI) in Brussels runs the postgraduate PharmaTrain programme, which includes short classes and master’s-level training in drug development. Its classes are available in several locations across the continent. The IMI’s European programme in Pharmacovigilance and Pharmacoepidemiology, called Eu2P, offers online training at the certificate, master’s and PhD level.

The Japanese Pharmaceuticals and Medical Devices Agency has united with a dozen universities to allow its employees to earn graduate degrees and to let university graduate students conduct their thesis research at the agency.

“Talent is hard to find,” says Richmond. “A person with good science skills and a degree in regulatory science generally has no problems getting a good job.” **A.D.**

Ernest Kwegyir-Afful was a neuroscience postdoc when he applied for a two-year fellowship at the FDA in the hope of getting to conduct research that would have an immediate impact. At the FDA's Center for Food Safety and Applied Nutrition in College Park, Maryland, Kwegyir-Afful worked on estimating the risk that small quantities of food allergens might endanger sensi-

"It's a field that you would enjoy if you don't want to think one-dimensionally."

He came up with a computational method for risk analysis that was closely tailored to allergens. After finishing his fellowship last September, Kwegyir-Afful accepted a permanent position at the centre, doing similar work. Regulatory science is "a field that you would enjoy if you don't want to think one-dimensionally," he says, noting that he works with experts in topics such as toxicology or law. Communication skills and a team-oriented approach are essential, says Frances Richmond, director of the International Center for Regulatory Science at the University of Southern California in Los Angeles.

Regulatory-strategy units at pharmaceutical companies are good places to explore the regulatory side of industry, says Robert Meyer, who directed the FDA Office of Drug Evaluation before becoming vice-president of global regulatory strategy for Merck at its campus in Upper Gwynedd, Pennsylvania. Company regulatory scientists would do well to understand the relevant laws for FDA reviewers, which can help company scientists to do the right experiments and to offer the FDA the data it needs to make decisions, says Meyer. That is especially true for people working at small companies, because they participate in many aspects of product development, says James Polli, co-principal investigator of an FDA CERSI at the University of Maryland in Baltimore.

Academic scientists, too, can address regulatory questions or advise the FDA. Subha Madhavan, a bioinformatician at Georgetown University, is building databases that will be used by FDA scientists looking to understand why people respond to drugs in different ways, and how vaccines might be linked to autoimmune disease. She regularly meets FDA staff to explore their needs, and expects to publish the work.

"Regulatory science is the field of the future, if you will, in terms of drug development and device development," says Wilhelm. "At some point, it will mean something to say, 'I am a regulatory scientist.'" ■

Amber Dance is a freelance writer in Los Angeles, California.

TURNING POINT

Adam de la Zerda

Adam de la Zerda was on track to become an electrical engineer when a personal loss prompted him to switch to cancer biology. Now a structural biologist at Stanford University in California, de la Zerda has developed a technique for imaging tumour cells.

Why did you take up cancer biology?

In my undergraduate programme at the Technion Israel Institute of Technology in Haifa, I focused on computer science, engineering and physics. When I started my PhD at Stanford, I was working on experimental quantum physics. But during winter break in my first year, a good friend passed away from cancer. That was a true turning point for me. I started examining how to apply my background to cancer research.

Was it a difficult leap?

No. Stanford has a flexible structure that can accommodate such transitions. I could have an adviser from anywhere in the university; I found an amazing one in Sanjiv Gambhir, who was working on molecular imaging. I knew that early detection of cancerous tissue could have prevented many cancer deaths, including my friend's. Gambhir agreed to let me join his lab without a biology background.

How did you persuade him?

I think my motivation convinced him, but I had also read a lot about his imaging work. I was able to explain why I was so excited about the prospects for direct applications. I launched a project to convert light into sound so we could look into tissue and find out whether cells are cancerous. My programming skills helped me to create our first real imaging unit using lasers and ultrasound systems.

Why did you pursue a postdoc in chemistry?

As my PhD ended, I realized that much of what we do as biologists relies on chemistry. I had never taken a chemistry class, and wanted to study it. My dad has a PhD in chemistry, which also helped me to appreciate the subject. Luckily, Carolyn Bertozzi, a chemist at the University of California, Berkeley, accepted me as the first engineer in her lab. My knowledge of chemistry was at a first-year-undergraduate level, but I learned a lot, often from undergraduates.

Did you plan to do a one-year postdoc?

No — I had a three-year fellowship. Some people want to stay in their field and crank out papers; I wanted to expand my toolkit with organic chemistry. After a year, I saw an opportunity to apply for a faculty position in



structural biology at Stanford. I was in no rush to leave the postdoc, but I felt ready. I got the position and started last autumn.

How did you approach the interview?

It is important to have an interesting story to tell when you apply. Given the tough job market, hiring committees are risk-averse. They don't want to hear, "I want to solve X problem." They want to hear, "This is exactly how I'm going to solve X problem." I feel fortunate that the search committee was willing to accept me, whereas others may have said I was at too early a stage.

Last year, you won the Dale F. Frey Award for Breakthrough Scientists. How will it help you?

It is awarded by the Damon Runyon Cancer Research Foundation in New York, which contributes 100% of the donations it receives to research that will affect patients. Through the foundation, I have met venture capitalists whom I am trying to bring to research brainstorming sessions. I want to work out how best to translate my group's research and patents into commercial medical devices. I want the harsh feedback at the start of a project to help us to make sure that our technologies will help patients. We are willing to take big risks, but we want to make sure that there are big benefits.

Should engineers explore life sciences?

Yes. In the past year I have been teaching a class that exposes engineering students to biology; 300 students have taken it. I show them how engineering tools can solve problems in biology and medicine, especially in cancer and cardiovascular disease. Several engineering students have joined immunology and cardiology labs. That makes me extremely proud. ■

INTERVIEW BY VIRGINIA GEWIN