CAREER TRENDS

Exploring Careers Beyond the Bench

OUTREACH

BIOINFORMATICS

CLINICAL TRIALS

INTELLIGENCE ANALYSIS

ENTREPRENEURSHIP

SCIENCE WRITING

REGULATORY SCIENCE

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Beyond the Bench

Last month, the U.S. National Science Foundation (NSF) released a report* with some grim news that confirmed what is painfully obvious to recent Ph.D. graduates in science, technology, engineering, and mathematics (STEM) fields: Unemployment for this cohort is on the rise (at 2.4% in 2010, up nearly a percentage point since 2008). Although it remains below the U.S. national average for all workers (8.2%), for bright students who have invested many years in specialized education and training, the outlook is discouraging. Furthermore, according to an NSF survey, in 2008 only 16% of Ph.D.’s in science, engineering, and health fields held positions in academia within three years of earning a doctorate.† Prospects for employment can be improved, however, for STEM Ph.D.’s who make a concerted effort to learn about positions outside the lab and prepare themselves for alternative paths.

Recently, I participated in a Science Careers webinar that offered advice on nonresearch employment. The timeliness of this topic was reflected in the number of registrants signed up in advance for the webinar: 6,000, far above the average for other webinars hosted by this career resource. I was joined by Dr. Lori Conlan, director of Office of Postdoctoral Services at the U.S. National Institutes of Health, and Dr. Anish Goel, director of Geopolitical Affairs for Boeing Commercial Airplanes. We all agreed that our nonlab positions had allowed us the ability to follow our passions, forge our own paths, and provide us with flexibility to balance work and family life. Regardless of when we had made the move to a nonresearch career, no one expressed any regrets; but we agreed that the move can be challenging. It requires one to thoughtfully research career options and invest sufficient time in networking to build bridges to new communities.

Webinar participants asked about skills that are not sufficiently covered in most traditional science Ph.D. programs that are highly valued in many nonlab positions. Communications skills are near the top of our list, particularly the ability to explain complex scientific concepts to diverse audiences. Related to that is the ability to listen, which is the first step in understanding how the application of science can help meet the needs of others. Also high on the list is an understanding of people: how to recognize their strengths and shortcomings, to motivate them to achieve their best, and to assemble diverse teams that achieve what no individual could ever accomplish. Surprisingly, many Ph.D. scientists do not realize that much of their training and experience has imbued them with such skills and that they are better qualified for positions outside the lab than they think. Collaborating with interdisciplinary colleagues on projects over long distances, writing successful research proposals, planning the logistics for complex field experiments, analyzing large data sets, and contributing in meaningful ways to committee activities require skills that are relevant to the nonlab working world.

A Ph.D. in a STEM field opens doors, rather than closes them, but opening those doors is not easy. Before applying for any position, candidates should consider the breadth of their experience and make an honest assessment of themselves. Are they better suited to working alone, as part of a team, or as a team leader? What do they value most: that they solved the right problem, that they solved the problem correctly, that they got the job done, or how everyone felt about the job? A good place to start is with an Individual Development Plan (http://myidp.sciencecareers.org), an online resource to help scientists examine their skills, interests, and values; explore scientific career paths to find which ones are a best fit; and set strategic goals for the coming year.

If you are considering making the move from the lab, you are not alone. This transition is taking place at all career levels, spurred by different motivations. Whatever the reason, many have successfully taken this road, and so can you.

Marcia McNutt
Editor-in-Chief, Science

Shelley Bolderson was scraping mud from a trowel one day in an Anglo-Saxon midden in St. Neots, United Kingdom, when she realized she didn’t want to be an archaeologist any longer. “It was winter, and I’d spent ages on that particular site,” she recalls. “It was really kind of soul-destroying work.”

Until that point, Bolderson had worked as a freelance archaeologist around England, mostly in urban environments, where she assessed building sites before development. She had a bachelor’s degree in archaeology from the University of Southampton in the U.K. and wasn’t interested in doing a master’s or Ph.D. She sought temporary work while deciding what to do next.

One of her temporary jobs was at the University of Cambridge in the U.K. in the office that coordinates the Cambridge Science Festival, an annual, weeklong event that shares Cambridge-area science research with the public. “I saw a new career I had no idea existed beforehand and thought it looked really exciting,” she says. When a position coordinating the science festival opened up in the office, Bolderson applied for it.

It’s common for scientists do some outreach work alongside their research jobs—an occasional public lecture, say, or a talk at a local school. But a few scientists, including Bolderson, have turned outreach into a full-time job, connecting science and scientists with the public via their jobs at universities, associations, museums, or other organizations. Andrew Hickley, Bolderson’s former boss who’s now an independent consultant, says the mission and motivation of science outreach “is helping people understand science more effectively, helping them understand the role that science has got to play in society [and] in people’s lives.”

**What is outreach?**

For Bolderson, that has meant organizing the annual science festival and training graduate students, postdocs, and other researchers to host their own public-engagement activities during the year. She also helps manage the ongoing relationship between the university’s scientific community and the city government, with which she coordinates a summer science program for young people. Managing relationships with colleagues and community members is an important element of her work, she says.

**Transitioning from Researcher to Outreacher**

By Lucas Laursen—April 9, 2010

Science outreach careers bring science to the public in many settings, whether it’s by putting on special programs at the university, giving workshops in the community, or going into school classrooms. It’s a teaching gig, with the widest possible audience. Still, Hickley says, “there’s absolutely no substitute for standing up in front of a classroom full of kids.”

Chris Vanags of the Vanderbilt Center for Science Outreach (CSO) in Nashville, Tennessee, is a quintessential example. He coordinates a program that brings local high school students to the university once a week for science classes. He and his colleagues prepare lesson plans and teach just as if they were high school teachers but within a university setting. “Our goal is to teach kids to think like scientists though not necessarily to be [scientists],” he says.

Outreach coordinators at academic institutions also work with the scientists and departments within the university. Scientists with outreach components to their research funding may look to the university’s outreach specialists for assistance in designing outreach plans that complement their research, in writing the outreach portion of a grant application, or in executing the outreach plan once that funding comes in. Jennifer Ufnar, director of the Science Teacher Institute, also at the Vanderbilt CSO, often helps Vanderbilt scientists write broader-impact statements for their National Science Foundation (NSF) grant applications.

Outreach officers at scientific societies have some similar responsibilities, especially in interacting with the public. The British Science Association, for instance, organizes its own annual science festival, as well as a science and engineering week aimed at the general public. The rest of the year, the organization offers enrichment activities and material to schoolteachers and their students, coordinates student science project competitions, and helps organize local science and engineering clubs. Katherine Mathieson, the association’s director of education, supervises the managers of each of those outreach areas; she does little direct science outreach today, she says, but she enjoys having a hand in a variety of projects, established and new.

Mathieson notes that science-related businesses are another place to look for jobs with an outreach component, as those companies want to build good relationships with the community. However, “the major opportunities are going to be related to universities or similar institutions, such as museums,” Hickley says.
An outreach incubator at Vanderbilt

Ufnar’s career got a major boost when she connected with pathologist Virginia Shepherd, the director of the Vanderbilt CSO. Early in her career, Shepherd attended a session at a scientific meeting at which a speaker proclaimed that scientists have an obligation to the public, which funds their research, to devote 4 hours a week to teaching. Shepherd was attracted to the idea, and today she devotes far more of her time to outreach at the Vanderbilt CSO, where she coordinates the efforts of 15 postdocs and graduate students who handle more than half a dozen different science outreach initiatives. “It started off very modestly, and now we have funding of around $1.5 million a year,” she says. In addition to directing the Vanderbilt CSO, Shepherd still runs her pathology lab and publishes in biochemistry and microbiology journals.

“If I were going to hire somebody, I’d certainly look to see if they’d been involved in leading a program or if they were involved in a program for training.”

The work has given Shepherd and her protégés—including Vanags and Ufnar—an idea of the skills aspiring outreach workers need to communicate science to teachers and students. One key: laboratory experience. “Having worked in a lab really did help me because I was comfortable with the science,” Ufnar says, referring to her Ph.D. research in environmental toxicology at the University of Southern Mississippi in Hattiesburg. Another key, Shepherd says, is the ability to create partnerships. She points to NSF’s Graduate STEM Fellows in K-12 Education program, in which science graduate students commit to visiting a classroom on a weekly basis. “If I were going to hire somebody,” Shepherd says, “I’d certainly look to see if they’d been involved in leading a program or if they were involved in a program for training” during their scientific career.

Ufnar also teaches in Vanags’s high school program, brings schoolteachers into her water-contamination lab at Vanderbilt to teach them how to do research, and teaches at a nearby community college. A portion of her time is spent writing grant proposals, for her research in water contamination and to support her outreach efforts. “I do everything a traditional scientist would do, just in the outreach field,” Ufnar says. She hopes eventually to take the skills she is accumulating at Vanderbilt to another university, directing her own outreach center and forging closer links between the research community and the public.

Getting started

It’s possible to earn an advanced degree in science communication, but most scientists interested in outreach begin with small steps out of the laboratory. The ready availability of volunteer work makes it possible to try before you buy. For a one-time taste of outreach that doesn’t require a long-term commitment, Hickley suggests looking for a nearby science festival to see if they could use volunteers.

“With educational outreach, contacting the outreach center on campus is the perfect first step,” Ufnar says, adding that outreach officers would usually be delighted to utilize volunteer help from a grad student or postdoc. Even undergraduates can volunteer in outreach, as Ufnar did when she was still an undergrad.

Mathieson recommends volunteering at your institution before abandoning research to pursue a full-time outreach career. She got started in outreach as a volunteer answering calls from the public on Science Line, the now-defunct science-questions hotline. It was “anything-could-happen outreach,” she says. “It was really good fun getting a sense of the kind of questions people would ask and why they ask them.” When Science Line needed a full-time staffer, they hired her. “A lot of charities and small enterprises who do science outreach operate in that way. They’ll need volunteers for particular activities or events, and then when it comes to recruiting there’s an obvious pool to recruit from.”

Like many science-related jobs, outreach requires a combination of skills. “You need to be a good communicator first of all, … good at working with people, empathic; you need to understand what stage they’ve reached in their understanding,” Hickley says. Even if you decide not to pursue outreach as a career, the interpersonal skills you gain will help if you go into outreach full time—or even if you don’t. “You don’t have to be a scientist to do this stuff,” Hickley says, but if you are, there is absolutely nothing stopping you acquiring the skills for doing it.”
In my years as a scientific recruiter, I have worked in the clinical-drug research field only a few times. At the conclusion of each search, I marveled that this world is huge and so different from the culture I am used to. Then I promised myself to avoid it, because I just didn’t understand it. Before long I’d find myself back in it, thanks to a client company culture I am used to. Then I promised myself to avoid it, because I just didn’t understand it. Before long I’d find myself back in it, thanks to a client company with an urgent need.

I’ve finally read something that helps me understand the field and its major job categories. In this month’s Tooling Up column, I’ll review some of those categories, as laid out in the book Career Opportunities in Clinical Drug Research by Rebecca Anderson. Anderson’s book is a great introduction for anyone considering careers related to drug clinical trials, which is what this career area is all about.

Seven entry points
In this clear and well-written book, readers can read from front to back to understand how the clinical trials process works or dive into a section describing a career path that sounds appealing. The book has seven sections that describe seven career paths available to people seeking to break into the field, followed by four sections about careers that require clinical experience. I won’t discuss those here.

1/ The clinical research associate (CRA) A CRA represents the sponsor company and ensures that proper procedures are followed during the complex, long, expensive clinical trials process.

A CRA position is the most popular way to enter clinical careers, partly because such positions are relatively abundant. CRAs are employed both by sponsor companies and by contract research organizations (CROs), companies engaged by pharmaceutical and biotech companies to help chaperone a drug through clinical trials. Some CRAs enjoy the constant change and the variety of people and drugs they get to work with at a CRO, whereas others prefer to work for a drug company where they can follow a new therapy all the way through.

Either way, a CRA job is heavy in paperwork and requires good organizational and people skills. There’s always a lot of travel, as the CRA moves from trial site to trial site, monitoring the trials activities, coordinating documentation, and meeting with clinical investigators.

2/ The data manager The data manager and his or her team are the architects of systems that produce data. And because the product of clinical trials is data—lots of data—this job is an important one. Before a trial begins, the data manager and her team review draft protocols for the study to ensure that the trial is designed from the beginning with accurate and precise instructions for those responsible for implementing the protocol. The team writes a trial’s data-management plan and confirms that all the reporting forms and data-transfer procedures make sense. Once a trial is under way, the group reviews incoming data and maintains its database, ensuring that everyone is following the rules, then hands off the data to the biostatisticians for review.

3/ The biostatistician The product of a trial—the data—has to be analyzed and interpreted when it starts coming back from the study sites. This is where the biostatistician comes in. The U.S. Food and Drug Administration (FDA) will approve a product only if the data meets certain statistical criteria, so position is very important in a trial’s success. Sponsor drug companies use biostatisticians before a trial begins to help set the parameters for data collection and review. But their main work is analyzing the trial data and extracting results.

Because statistics are known to be massaged from time to time to suit the needs of a pharmaceutical company, this area of work is highly regulated. Biostatisticians (and other clinical staff members) are expected to be honest and ethical in their work; the field has its own codes of ethics. Company-employed biostatisticians may be tempted or urged to overemphasize the positive, but they cannot hide the negative.

4/ The clinical quality assurance auditor Clinical quality assurance (CQA) auditors inspect all documents and processes for a study to ensure that they all comply with good clinical practice (GCP) guidelines and standard operating procedures (SOPs). This book includes a handy list of the most common acronyms. There are many.

Today, studies are done all over the world, and there is increasing pressure to harmonize standards and procedures. The CQA auditor is in the thick of things in the regulated world of clinical studies, ensuring compliance with ever-changing rules and regulations.

5/ The regulatory affairs specialist I’ve written before on this topic, and there are several other articles in our archives at Science Careers about regulatory affairs careers. In the book, Anderson describes in detail the work that regulatory affairs specialists do in collaboration with the clinical study team and their involvement with regulatory agencies.

6/ clinical safety The clinical safety professional is responsible for monitoring, coding, organizing, and tracking adverse events that occur during a trial. The clinical safety person is really a patient advocate. He or she must track negative
results that occur in a trial and ensure that each patient is given the appropriate medical care. The clinical safety specialist is responsible for reporting adverse events to FDA. Nurses dominate the field, although it’s possible for other degree holders to enter if they’ve had 2 to 4 years of clinical experience.

**7/ The medical writer** One of the most frequent questions we get on the Career Discussion Forum is “how do I get a job as a medical writer?” Given the volumes of information that come out of a clinical trial, there’s a lot to write about. Pharmaceutical companies, hospitals, and other clinical trial sites, government agencies, and marketing companies (also known as medical communications companies) employ medical writers. Here are some previous links for material already published on Science Careers about the medical writing career.

- **Tooling Up: The Medical Writing and Corporate Intelligence Career Tracks** – bit.ly/aiop8Y
- **Working as a Medical Writer** – bit.ly/1vSbsPL
- **Careers in Medical Writing: Opening Doors** – bit.ly/1wamzAR
- While most medical writing gigs involve useful work, there is a moral hazard in the field that’s best avoided: ghostwriting. The following resources will help you steer clear:
  - **Hunting Ghosts** – bit.ly/hesn5w
  - **Ghostwriters in the Medical Literature** – bit.ly/Z8l1fG
  - **The Ethical Conflicts of a Medical Writing Career** – bit.ly/oMoQuX

**Final thoughts about clinical jobs**

Although my impressions of this book are very positive, I’d guess that the author started writing it before the job-market downturn of the past few years, which has dramatically impacted the pharmaceuticals industry. It’s just too optimistic about prospects for finding jobs.

Today, jobs are hard to find in just about every field, including clinical trials. So I asked Anderson to opine about the qualities most useful for people who want to enter this field, whichever track they enter on. “First, the clinical process is managed by a team,” she replied. “While it’s easy to say, ‘We hire team players,’ that doesn’t quite cut it. You need to be the kind of person who really pulls their own weight independently and who can be counted on by her fellow team members. Secondly, you need to be good with meeting deadlines, which certainly isn’t taught in grad school. Thirdly, you need to be able to follow the rules, as this is a highly regulated career. People’s lives are at stake.”

“And lastly, you need to be open-minded, willing to try new things, open for fresh learning. After all, you’re seeing the benefits of new therapeutics in people for the first time. That’s incredibly rewarding.”

In a highly competitive economy, companies need to stay ahead of their competition if they are to stay afloat. To this end, companies routinely scan all the public information they can find about competitors, including annual reports, scientific papers, regulatory filings, and social media. They talk with key opinion leaders and utilize other primary sources of information. Placed in perspective, this information is a sort of early warning system for companies in competitive markets, helping them to navigate the waters of the business world. The field is called competitive intelligence (CI).

The people performing CI are commonly called “CI analysts.” Some companies have CI departments. Specialist CI-consultancies also exist, but many people perform CI without bearing the title. Within companies, program managers, business-development managers, and senior vice-presidents for strategic planning—and others—often undertake CI roles. CI skills are also required to perform a big part of what venture capital firms call “due diligence.” Stock analyst firms do similar work to decide which companies to invest in. National agencies that support economic development and international trade employ CI skills, too.

**Scientists as Competitive- Intelligence Analysts**

By Sabine Louët — October 7, 2011

Whatever their official title, CI analysts find out where a company’s competitors are heading.

**Competitive intelligence with a technical flavor**

Whatever their official title, CI analysts find out where a company’s competitors are heading. They make head-to-head comparisons between their (or their client’s) company and competing companies for every aspect of a company’s operations, then place this information in the broader context within which the company operates.

To analyze competitors’ sales strategies, for example, they compare the number of people employed in sales, how the sales force is organized, and other means those competing companies have deployed to sell, taking into account the regulatory and economic context in which they operate.

At companies whose products are technology or research-based—in the pharmaceutical, chemical, energy, telecom, and information technology (IT) sectors,
among others—the intelligence gathered by CI analysts must cover technical information relevant to a company’s competitive mission and environment. This field—the technical/scientific version of CI—is dubbed “competitive technical intelligence” or CTI. CTI analysts may, for example, track the results of a competitor’s clinical trials, and determine whether trials are on schedule, based on direct interviews with clinicians involved in the trials. This helps a company anticipate whether their competitor will be first to bring their drug to market and allows them to adapt their commercial strategy.

They may not realize it, but by the time they graduate, most Ph.D. scientists have developed a skillset that not only is directly relevant to CI but is also transferable across industries. Some key skills …

They may not realize it, but by the time they graduate, most Ph.D. scientists have developed a skillset that not only is directly relevant to CI but is also transferable across industries. “You don’t need a lot of training to do CI when you have a Ph.D.,” says Jay Paap, president of management consultancy firm Paap Associates in Waban, Massachusetts, which is involved in CTI. Ph.D.s are accustomed to trawling through peer-reviewed literature, perusing databases, and sourcing information on the Internet. “They don’t call it CI, but they have developed the basic training to do CI.

Ph.D.s have a range of analytical skills, which CI analysts need to squeeze valuable information out of a broad range of sources. Ph.D.s are also able to learn quickly; CI analysts often have little time to familiarize themselves with a new field. Conveying findings to non-experts, such as a company’s senior management team, is also part of a CI job, so the written and verbal communication skills scientists have developed during their Ph.D. will prove helpful, too.

But what really gives Ph.D.s an advantage is that they come in with “an understanding of the technology studied,” thanks to their backgrounds in relevant science, says Ken Garrison, CEO of the professional organization for Strategic and Competitive Intelligence Professionals (SCIP), based in Alexandria, Virginia. Another advantage to a Ph.D. is the credibility that comes with it. Most of the technical people in large organizations “don’t trust someone that does not have a Ph.D.,” Paap says.

In a new environment

But Ph.D.-trained scientists need to make some adjustments before they can use their skills effectively in the CI world. According to Garrison, the difficulty for scientists “is to go from a Ph.D. program with a narrow focus to [analyzing] an industry with a broad focus.” Also, companies use CI to complement market research to help senior management decide on research and development and sales strategies, so CI analysts need to watch closely not only the technology and the market but also the broader political and economic context, Garrison adds. The job requires “somebody who can take a look at the bigger picture and be critical” of what they observe, agrees Eric Garland, founder and managing partner of CI consultancy Competitive Futures Inc. in St. Louis, Missouri.

As they enter the CI field, Ph.D.s need to learn how to use standard IT tools to tackle the huge amounts of information hidden in databases, newsletters, and event reports, as well as in social media such as blogs, tweets, discussion forums, and RSS feeds. Increasingly, CI professionals need foreign-language skills, partly because the exponential growth of online information is driven by social media sites of all languages, and partly because many companies requiring CI work are multinationals with diverse markets worldwide.

Finding a way in

Scientists are most often hired in CI straight after their Ph.D. as subject-matter experts in a CI consultancy. They contribute their scientific knowledge and mind-sets as they hone their skills alongside seasoned CI professionals. Because CI is a discipline and not a profession, “entering the field would require self-teaching at the beginning,” Garland says.

Some other Ph.D.s take an industry route, typically gaining a few years’ experience as industry scientists or in other technical positions before moving into a job with a CI component within the same company. Prior industry experience helps scientists understand how R&D relates to business issues and the broader context in which a company operates.

The cultures of some large multinational organizations are such that it’s necessary to prove yourself in a different role before being awarded a strategically sensitive position such as CI. For many people entering the field, “it is a second stage in their career,” says SCIP’s Garrison. In the pharmaceutical industry in
Bridging the gap
Scientists who want to increase their chances of CI employment can learn the typical tools used by CI analysts through formal training. Two main non-academic institutions provide CI certification programs: the Fuld Gilad Herring Academy of Competitive Intelligence in Cambridge, Massachusetts, and the Institute for Competitive Intelligence in Butzbach, Germany. Alternatively, scientists may take CI modules offered as part of librarian training, business and information degrees, studies in marketing, and continuing education at academic institutions including Manchester Metropolitan University in the United Kingdom and the University of Toronto in Canada.

Regardless of the amount of self-teaching and training received, Garland emphasizes the importance of approaching experienced members of the CI community to get further advice. Prominent CI practitioners can be approached at SCIP events or through community discussion forums such as the 8000-strong SCIP LinkedIn Group or the CI2020 Web site. If you haven’t got one already, finding a mentor can be particularly helpful.

It is difficult to anticipate the need for the CI workforce in the coming years. On one hand, the growing number of CI software tools, which automate retrieving and archiving of information, is likely to drive the number of external CI consultants down, warns Chris Hote, CEO of on-demand CI software Digimind, based in Cambridge, Massachusetts. On the other hand, some experts believe that an increasingly unpredictable and faster-moving business environment will drive the need for CI up. “The number of firms with [CI] programs will increase as the value of performing CI becomes apparent. So I expect always a demand” overall, Paap says. “If you are interested in being broad and are able to synthesize information, there are a lot of good opportunities.”

Whereas some budding entrepreneurs start a company so that they can be their own boss or get rich quick, scientists usually have a different motivation: to transform their research findings into products or services that help people. This is what motivated three academic researchers who talked with Science Careers about how they started their own businesses, and how other scientists can do the same.

Starting a new business is not for everyone. The move involves financial risks, for you, for others, or for both. Budding entrepreneurs need to learn the language of finance, marketing, and business strategy. And it can be challenging to balance entrepreneurial activities—which can often be time-consuming—with continued academic responsibilities.

But the three entrepreneurs we interviewed didn’t face these challenges alone, nor will most other researchers considering a business start-up. Many academic institutions encourage researchers to commercialize their findings while maintaining their academic posts. And if the experience of these three scientist-businesspeople is any guide, academic researchers can find support (including financing) in their own communities.

“Trust your partners.”
Cory Berkland’s interest in business developed during his graduate engineering studies and blossomed into two companies, within which he still plays an active role. While Berkland was working on his Ph.D. in chemical and biological engineering at the University of Illinois, Urbana-Champaign, faculty members there started a company that incorporated Berkland’s research on fabricating micro- and nanostructures from biodegradable polymers. That venture didn’t succeed, but it “opened up my eyes to the possibility of starting a business,” says Berkland, now an assistant professor of chemical and petroleum engineering at the University of Kansas, Lawrence.

In March 2007, 4 years after earning his Ph.D., Berkland and biotech veteran George Laurence started Savara Pharmaceuticals, now headquartered in Austin, Texas.

The company applies Berkland’s work making nanoscale particles to pharmaceuticals. Some drugs are better administered as a dry-powder inhalant than as a water-soluble compound, but controlling the size of the dry-powder particles has been difficult. Savara’s technology, based on Berkland’s research, provides
control over the particles' size and prevents them from clumping together, making delivery of the drug more effective.

Last year, Berkland applied his micro-encapsulation technology to another enterprise, co-founded with entrepreneur Bo Fishback. That company, Orbis Biosciences in Kansas City, Kansas, is based on Berkland's research from the University of Illinois on processes to create microscale spheres and capsules with uniform properties. Orbis Biosciences applies these processes to a variety of manufacturing industries, such as cosmetics, food, and drugs.

Berkland relies on his business partners to run the day-to-day operations. He serves as scientific adviser to both Savara and Orbis. So far, Berkland says, his role with the companies has not conflicted with his academic duties. “The companies have been very complementary to my responsibilities as a professor,” Berkland says, “and that's partially because the companies are both interested in publishing and bringing in grant money.”

Berkland’s experience with a business in graduate school exposed him early to the steps and effort needed to start a company, which include finding financial backing for the enterprise. He tells Science Careers in an e-mail that by the time he started Savara and Orbis, “I managed to find excellent partners,” referring to the investors and entrepreneurs from the surrounding area who provided the companies' financial backing or became co-founders. “Trust your partners,” Berkland adds, “they create opportunity that will shape the company and your research.”

The Wallace H. Coulter Foundation was another source of support for Berkland: The foundation awarded him a 2-year Early Career Translational Research Award in Biomedical Engineering, which is offered to academic research with commercial potential. Berkland was one of 13 awardees in 2008.

Berkland urges researchers thinking about starting a business to get to know people in industry. “They're the ones who know the market; they're the ones exposed to the problems that the work is facing. And if we know those two things, as inventors, we can do our job.”

“**You have to believe in your technology.**”

Like Berkland, Guillermo Ameer has entrepreneurial interests and an academic position—in Ameer’s case, in bioengineering. An associate professor in Northwestern University's medical school in Chicago and its engineering school in Evanston, Illinois, Ameer studies properties of materials that can mimic human tissue, particularly materials that prevent rejection or scarring when implanted into humans. (Science Careers profiled Ameer in January 2004, highlighting the journey from his native Panama to Texas and eventually to his position at Northwestern.)

Ameer’s company, Vesseltek BioMedical, started last year. It will produce medical devices for cardiac and circulatory patients who have a high risk of blood-vessel blockage. The first product is expected to be a synthetic blood-vessel graft with a coating that reduces clots and scarring.

Starting the company was a way for Ameer to ensure that his research wouldn't just go stale in journal articles. “I decided to do this because if I did not do it, it was likely the technology would go nowhere,” he says. Ameer's sense of urgency stemmed from his desire to see his research lead to tangible products, but it was also motivated by the time limits on his patents. Ameer holds (with others) three U.S. patents issued between 2000 and 2006 and more in Europe. Several other patents are applied for or pending. “The technology was compelling, but at the same time, patents have a lifetime,” he says. Developing products, taking them to market, and generating sales often require long lead times, so Ameer realized the clock was ticking on his 20-year patents.

There was a lot to do, Ameer notes. “I had to learn a lot about the business side of things.” He called on associates from Northwestern to get Vesseltek BioMedical off the ground. In this enterprise, Ameer partners with a Northwestern colleague, Melina Kibbe, who has medical expertise, and a former student, Antonio Webb, who handles research and development. Ameer also founded and is still actively involved with another medical technology company, ProSorp BioTech.

His entrepreneurial activity “does take time” from his academic duties, Ameer says, but so far he has managed to balance the two. The university allows him one day each week for professional and business activities unrelated to his faculty post.

Starting a business comes down to the degree of confidence you have in your research, Ameer says. But you still need a support structure to make it happen. Funding, of course, is vital. “You need to get a quick sense of whether or not this is the kind of project that will be able to attract funding from investors.” Ameer had confidence enough his project met that threshold that he launched VesselTek before he had financing lined up.

“You have to have faith,” Ameer says. “You have to believe in your technology and what you're trying to do.”

“**My goal: to have a job where I'm excited to do what I do every day.**”

Christopher Rogers decided to make a clean break and leave the academic world behind when he co-founded Exemplar Genetics. The company provides porcine models of particular diseases, models that are used to develop gene-based treatments and drugs. As a postdoc at the University of Iowa Carver College of Medicine in Iowa City, Rogers used the pig model to better under-
stand the genetic underpinnings of cystic fibrosis—research that earned him a first-author publication in *Science* in the 26 September 2008 issue (p. 1837).

Rogers designed a new set of processes and techniques to develop the porcine model of cystic fibrosis, but he soon realized those processes could have a much wider impact. “What we had done for the cystic fibrosis pigs was applicable to other diseases” for which the previous animal models were not sufficient, Rogers says. He saw both a research and a business opportunity. “Most university researchers are interested in a particular disease or a particular function,” Rogers says. “We felt that since we would be targeting multiple diseases, it’s best done outside the university.”

That set of processes and techniques became the platform on which Rogers and his partners built Exemplar Genetics. They took full advantage of the services offered by the Iowa Centers for Enterprise on the University of Iowa campus, as well as those provided by the community and state.

The Centers for Enterprise helped get patents on Rogers’s processes and “biological material” (the actual herd of pigs); the company licensed the gene-model technology from the university. In addition, the Centers for Enterprise put Rogers and his partners in touch with the Iowa Department of Economic Development, a state agency that helped find additional funding for the company. Exemplar Genetics found lab and office space in the university’s BioVentures Center, a business incubator in nearby Coralville, that is part of the Centers for Enterprise.

Rogers decided to devote his full energies to Exemplar Genetics rather than dividing his time between an academic position and the company. He has few regrets. “It’s very different from the academic track that I was on from graduate school to postdoc, but it’s certainly been exciting and it’s fun,” says Rogers. “That’s my goal: to have a job where I’m excited to do what I do every day.”

Although Rogers's title is director of research and development, there are still plenty of business decisions and functions he needs to fulfill. “It’s funny how my business vocabulary has increased, and that was completely unexpected,” he says.

Rogers encourages academic researchers to consider the entrepreneurial option and to be honest about their motivations. “You need to want to do this because it is different from an academic environment, from a purely basic research environment,” he says.

At the same time, Rogers says, academic researchers should be ready to recognize their own limitations and partner with colleagues who can bring other crucial expertise to the enterprise, adding, “People should do what they know and find other people to do the things they don’t know.”

Someone recently asked me how I choose the careers highlighted in my regular Career Tracks columns for Tooling Up. Usually I watch the discussions on the *Science* Careers Forum (for which I serve as moderator) and see what career paths the participants are interested in. I choose what seem to be the most popular career tracks for further exploration.

This month’s Career Track column combines one of the most-asked-about careers on the forum—medical writing—with one of the least-known career tracks for scientists: corporate-intelligence sleuth. The combination comes in the career path of Jim Gardner, one of our regular posters on the forum, who has been providing advice there on careers in medical writing for at least a decade. He worked for 6 years as a medical writer with two pharmaceutical companies before moving into a new category of job: Jim is currently the senior manager for global business intelligence at a major pharmaceutical company.

**A career away from the bench**

In 1996, Jim had just graduated with his Ph.D. in neuroscience from Princeton University, where he studied sleep physiology. But in the months before graduation, he developed terrible allergies to the animals he had been using in his studies, which forced an abrupt shift in his career path. Suddenly those prestigious labs he had been speaking to about postdocs weren’t as attractive as they had been.

Jim’s options were to work at the bench in physiology studies, or to start an M.D., which would allow him to work with humans. The bench work didn’t appeal to him as he felt burned out with basic research, and starting an M.D. wasn’t in the cards; he and his wife had two young children by the time he was leaving graduate school. He needed to make money, not spend it on tuition and fees.

Jim attended one of my science-career workshops the year he graduated, and from there he began talking to industry employers, even though everyone in the lab told him, “You’ve got to do a postdoc.” He applied to a temporary staffing firm, indicating his interest in medical writing, and the firm immediately put him in touch with Wyeth (now part of Pfizer), which was developing a new type of sleep drug.
“They were hungry for people who knew the field and who could write,” Jim says. “They were so short of medical writers at the time that they didn’t let me leave the building on my interview day. I signed up on the spot.” One lesson he learned in this process was that it pays to know the field you’ll be writing about. “That’s one of the keys to looking for a medical writing job. You go where you have experience,” he says. So it pays to do the research on what companies have in the pipeline.

The number of medical writers a firm employs can vary dramatically. In a small to midsize biotech company, there may be two or three people whose job is exclusively to write. But in a larger company, employers need dedicated staff members for every molecule in clinical development and for marketed products, where they’re needed to keep current the technical literature doctors need to prescribe those products.

It pays to know the field you’ll be writing about. “You go where you have experience.”

**Moving up the ladder**

Jim had been at Wyeth just 5 months when a recruiter called, seeking to introduce him to the large company where he still works today. His job in the new firm was also as a medical writer, and he absolutely loved the work, especially its variety.

“I was assigned writing projects for many different departments, although much of it came in the form of regulatory documentation,” Jim says. “But, even there, the work can be quite varied. For example, there is no end to the number of clinical-study reports that cross the desk of the medical writer. Also, another interesting type of project is what are called Investigator’s Brochures, which are basically extensive reports detailing all the research on a prospective drug to date. These are provided to the doctors who elect to work on clinical trials that advance these drugs through the regulatory pipeline.” These brochures must be updated regularly as data come in from new studies, keeping medical writers busy.

Because I know that a regulatory submission for a new drug can literally fill up a moving van with files, I knew Jim wasn’t kidding when he said that there was no shortage of work. But I also sensed that this fellow, a competent and able manager, wouldn’t have been happy sitting in a corner somewhere pecking away at his keyboard. But that’s not what he was doing.

“A lot of people make the mistake of thinking that medical writing is a job for a loner. In reality, it’s a leadership position in a company, one that requires a great deal of people skills.”

“During the first 5 years of his career as a medical writer, Jim worked on many projects that didn’t move forward, including a COX-2 inhibitor that the firm chose not to advance to the market. His big break came when he got to work on a new-product application for the U.S. Food and Drug Administration. One of his employer’s big biotech investments had paid off, and the product was going to market. Jim was the head writer who took it through the regulatory-approval process.

**The corporate sleuth**

By early 2002, Jim had written every kind of document a medical writer could be asked to write. He was itching to broaden his writing and research skills into some other area. It was then that he spotted an internal posting for a position called “corporate intelligence.”

All major companies have a department like this, a small squad of writers and researchers with scientific backgrounds—they must also be capable of writing and speaking well—who are tasked with making educated guesses about what’s in the pipeline at competing companies.

Jim considered himself a big reader, and he had always kept up with his field in journals and business magazines. The job requires keeping tabs on the company’s competition by reading everything about their current and future product development: journal articles, business-magazine reports, and regulatory filings—while also maintaining a very busy travel schedule. “I go to conferences and listen to all the key people in our fields of interest, just to hear what they are saying about who’s doing what and about what the next steps are likely to be.” The job was a perfect fit. He was very happy when he was given the internal transfer.
Jim and his colleagues produce reports, which they present to management, showing exactly where their own company’s development efforts stand and drawing comparisons to where competitors likely are. Jim and his colleagues are the “eyes and ears” of his employer in the outside world, in a tough, competitive market. “I consider my work to be the early warning system for our corporation,” Jim says.

Corporate intelligence staff members also work closely with the business development and scientific licensing departments, helping these teams understand what kinds of molecules or technology they should be looking for each year. The pharmaceutical industry now favors getting their new product leads from either academia or smaller companies, and Jim says that the intelligence staff members rate these before they are acquired. They even give them a score so that all the players know how important each is to their employer.

Paving a career path
Corporate intelligence is not a career track you can enter easily from the outside world. Because of the small number of staff members employed in this category in each company—a big company might have a dozen people—and because of the specialized knowledge required for the job, these positions generally go to people who already work for the company.

That’s why medical writing is a good starting place in the industry, because, besides the fact that it’s a solid, integral career track by itself, it can also be a gateway into corporate intelligence—or business development, or licensing. Once you’ve got a foot in the door, you may find that a wide variety of internal transfer opportunities available to you.

Medical writing is a good starting place in industry, because, besides the fact that it’s a solid, integral career track by itself, it can also be a gateway into other positions within pharma and biotech.

“...It’s a fun place to be and an exciting time to be in big data,”

Today’s bioinformaticists are in for a real treat. With a seemingly endless stream of biological data being generated across sectors, there is high demand for talented, experienced professionals at the crossroads of biology, statistics, and computer science. Scientists who can analyze large amounts of information and present it in a clear manner to decision makers are finding the sky is the limit in terms of jobs and career pathways, especially in the big pharma and biotech sectors.

“It’s a fun place to be and an exciting time to be in big data,” remarks Sriram Mohan, professor of computer and software engineering at Rose-Hulman Institute of Technology, who is spending his sabbatical developing bioinformatics software for Avalon Consulting, a data management firm.

And what an immense amount of data it is, due in part to a paradigm shift in the field, from data generation to data analysis, says W. Jim Zheng, associate professor in the School of Biomedical Informatics at The University of Texas Health Science Center at Houston. Now, with so much data being produced because of easier and more cost-effective tools, there is an even greater need for specialists who can make sense of the mountains of information in such a way that is meaningful for scientists and clinicians, and ultimately beneficial to customers and patients.

The increase in job opportunities is also being driven by a change in how bioinformatics is perceived in industry and academia. Previously, “scientists and companies used to look at bioinformatics as a tool,” says Wim Van Criekinge, a professor of bioinformatics at Ghent University in Belgium and chief scientific officer at MDxHealth, a company developing epigenetics-based cancer diagnostics. Bioinformaticists would be called upon to answer a question about data; their role was to run an algorithm on a database that provided that answer. “But the subject has evolved from a service, like histology, to its own research arena.... Bioinformaticists are now the motor of the innovation,” he adds. They not only answer the data inquiries, but also, more importantly, determine what questions need to be asked in the first place.

As a result, “there are many opportunities for scientists to pursue a bioinformatics/big data career in the biotech/big pharma industry at the moment,” notes
Jared Kaleck, senior director of computational chemistry/biology and formulation development at executive search firm Klein Hersh International.

**Discovering where the careers are**

To begin to recognize where the jobs are and how the career tracks are accessed, it helps to understand how bioinformaticist positions are organized within different firms. In pharmaceutical and larger biotech companies, big data scientists may find themselves working in one of three different types of organizational structures. In one, all of the big data scientists and bioinformaticists work out of a central core. This large team could be concentrated in research and development (R&D) or information technology (IT) departments, and the scientists work almost like consultants on projects throughout the company, and are lent out as needed.

In a second model, bioinformaticist positions are decentralized, and located within different therapeutic areas. For example, at Johnson & Johnson (J&J), Patrick Ryan leads the epidemiology analytics group. As a clinical informaticist, he develops statistical methods to analyze “observational databases,” such as electronic health records, to map disease patterns in order to better understand “the real-world effect of our medicines, and to develop safety protocols and mitigate risk for the patients,” he explains. His team is part of an overall epidemiology department which reports to the chief medical officer of J&J. But he notes that the company also has a robust informatics and IT division, whose mission is to “provide technical perspective on how to manage and analyze data.”

The third kind of organizational structure found in big pharma is a hybrid of the other two. Christian Reich, global head of discovery informatics at AstraZeneca, shares that his company currently follows this model, although he notes that the trend sees enterprises restructuring themselves to follow one of the other paradigms every few years. His job entails overseeing a principal group of 25 specialists, but other informaticists are sprinkled throughout the company. Similarly at Pfizer, bioinformaticists are embedded in therapeutic units as well as core centers of excellence, says Susan Stephens, senior director of research and development business technology at Pfizer.

Genentech follows a similar mixed model, explains senior director of bioinformatics, Robert Gentleman (who is also a co-developer of the statistical computing and graphics programming language known as R). Bioinformaticists are organized in a core center, but they “integrate with different functional areas,” he says. “They are in one department, but day-to-day they work directly with disease area specialists.”

Depending upon where they are housed in their company, big data scientists can expect to have varying tasks. In R&D, bioinformaticists conduct research on new approaches to analyzing data and help design and possibly even build the analysis tools utilized by scientists throughout the company, says Reich. Here, the idea is to examine existing open-source algorithms to apply them in novel ways, or to create entirely new algorithms that rely heavily on mathematical and statistical expertise. “The goal is to put together a platform so the data analysis can be done easily, and return high-quality results,” he adds.

Bryn Roberts, global head of operations, which includes informatics for Pharma Research and Early Development at Roche, notes that in his company’s hybrid structure, informaticists and data scientists are involved in a wide range of activities. They develop and support software systems; they procure and make external scientific content available and actionable by scientists throughout the company; they implement and maintain workflow systems, such as e-lab notebooks, for both drug discovery and regulated functions; and they support and perform data, image, and text mining and analysis to support scientific decision making.

“I have to fight Google, Amazon, LinkedIn, and hedge funds to hire the top people. They are valuable in any industry.”

At Genentech, bioinformatics scientists participate in all levels of the investigative process, from helping to design experiments that will find genetic markers for disease, to leveraging their bioinformatics skills to help find biomarkers that will aid in patient selection.

Elsewhere in big pharma, big data scientists may be tasked to investigate trends in diseases and drug development and discovery, which can involve collaboration with the marketing team. They may also provide quantitative support for business decisions, such as in which therapies firms should invest, says George Telthorst, director of the Center for the Business of Life Sciences at Indiana University.

Contract Research Organizations (CROs) also offer much for those interested in the big data profession. As Dimitris Agrafiotis, vice president of informatics and chief data scientist of Covance, one of the world’s largest CROs, attests, “CROs are becoming the R&D engine of the pharmaceutical industry.” Covance data scientists can expect to be involved in myriad projects across the entire drug development continuum, from biomarker discovery to preclinical development, clinical trials, health economics and outcomes research, and even marketing.

Beyond working in big pharma or biotech, there are also opportunities for data scientists in industry support companies, such as those that produce bioinformatics software and other data analysis tools. Furthermore, bioinformaticists are recruited by health insurance corporations and hospital management organizations.
Beyond the Bench

Even academia has seen an uptick in bioinformatics career opportunities, as the discipline itself is expanding. Zheng recalls a time in the early days of genomics when doing big data research meant scientists had to leave the university lab and head to industry, but the tide has changed. Now, programs like the National Institutes of Health’s Big Data to Knowledge funds academic research in bioinformatics.

Pursuing big data skills

Experts agree that the most successful bioinformaticists (and the ones who land the jobs) are those who have a multitude of skills. But the starting point is always knowledge of life sciences, also referred to as “domain expertise” in the industry. In fact, “the deeper you understand the biology, the better you do your job in this area,” says Zheng. Hiring managers specifically seek out scientists who have doctorates in various areas of life sciences, including molecular and cellular biology, chemistry, genetics, immunology, and epidemiology. At Genentech, Gentleman looks for candidates who possess expertise in the biology of a particular disease.

Additional critical skills are required for big data careers in industry, such as text mining, ontology, data integration, machine learning, and information architecture. A superior “quantitative ability,” as Gentleman calls it, which covers a range of statistical capabilities, is a must, as are overarching computing skills. These include core programming abilities, such as coding in C++ or Java, or scripting in PERL or Python, says Van Criekinge. It is vital to be able to navigate operating systems like UNIX and Linux as well as have knowledge of common tools such as Hadoop and NoSQL databases, adds Mohan. Experience in data visualization and building effective user interfaces, as well as familiarity with hardware, buttresses your marketability.

In addition to scientific problem-solving skills, bioinformaticists must have business proficiency. “Bioinformatics is a team sport,” says Stephen Ruberg, distinguished research fellow, advanced analytics of Eli Lilly and Company, and thus project management, teambuilding, and communications experience is a requirement. In fact, “being able to communicate with the other scientists is really the most important skill we look for,” says Gentleman.

Nimbleness and the ability to adapt quickly are also fundamental. “It’s a fast-paced environment,” says Van Criekinge. “You have to have a mindset of constantly using new tools, or you will become obsolete in two years.”

Landing big data jobs

It would be ideal if companies could find candidates who have all of the above skill sets, but sources indicate that that is wishful thinking. More often than not, hiring decisions are made based on the immediate needs of the team, especially given their interdisciplinary nature. “We look for people whose expertise

complements the existing group’s skills,” says Roberts. However, just because you lack a specified talent or interest area as noted in a recruitment ad, doesn’t mean you shouldn’t apply anyway. “We share CVs internally all the time,” says Stephens. So even if she can’t bring you in to her group at Pfizer, she may be able to find another team at the company for which you would be a good fit.

In some cases, companies are growing their own talent, as a result of the lack of large numbers of qualified, multi-skilled candidates. At Roche, “we offer continuous training in various areas and encourage our staff to attend conferences, publish, or pursue higher degrees,” says Roberts. Pfizer data scientists have myriad chances to pursue professional development, and are also granted time to try out new techniques, says Stephens, something she refers to as “sandbox opportunities.”

“...being able to communicate with the other scientists is really the most important skill we look for.”

Experience plays a major role in gaining access to jobs. Kaleck highly recommends doing an industrial postdoc or internship, but in absence of these, scientists might consider “bridge” programs, like the Insight Data Science Fellows Program. This fully supported, six-week training opportunity offers postdoctoral fellows the chance to work on real-world problems for the likes of Facebook and Microsoft. This appealed to Vincent Fusaro, whose Ph.D. is in bioinformatics. As a fellow, he gained expertise in databases, Python, machine learning, and data visualization, which helped him land a position as a self-described “data ninja” for Invitae, a genetic information company. Today he is responsible for software engineering, data analysis, and pipeline and product development, among other tasks.

The expanding big data universe

Data scientists can expect the field to change and evolve in novel ways in the near future. But the bottom line is that “companies are growing their bioinformatics,” says Kaleck. “There are 100% more job opportunities opening up in bioinformatics than ever before,” much of which is driven by an increase in venture capital investment.

Given that big data “is the hottest field on the planet,” says Agrafiotis, those who have the requisite skills and expertise often have their pick of opportunities. “I have to fight Google, Amazon, LinkedIn, and hedge funds to hire the top people. They are valuable in any industry.”

In particular, the future of big data in big pharma and biotech sectors is bright and exciting. “Bring your expertise to health care,” says Telthorst, “and you’ll know you’re going to make a difference, at the patient level and at the societal level.”
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 degree program in regulatory science and health safety 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 postmarketing 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.

Regulatory science includes regulatory affairs, regulatory writing, risk management, compliance, and regulatory law.

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.

“Regulatory science is an area that usually has more jobs than qualified candidates.”

**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 skills required for a regulatory science career go beyond a science background. Analytical skills, negotiating skills, and communication skills are key.

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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Paul D. Tieger and Barbara Barron-Tieger

Career Inventories
Myers-Briggs Type Indicators
Strong Interest Inventory
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Other Resources
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