Science Careers From the journal *Science*

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(PhotoDisc)

CTSciNet Clinical and Translational Science Network

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All in the Details: Careers in Regulatory Science

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 (http://www.usphs.gov/)** , 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 (http://www.fda.gov/)** (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 (http://www.fda.gov/MedicalDevices/default.htm)** , for whom she reviewed dental products to ensure that they had met all regulations deeming them safe and effective.

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

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 (http://www.paxmed.com/)** , 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 (http://nursingandhealth.asu.edu/regulatory)** 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 (http://regulatory.usc.edu)** at the University of Southern California in Los Angeles. "You're doing science, but you're doing it in a legal framework."

(Courtesy, Sandra Shire)

Sandra Shire

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 (http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/default.htm)** 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.

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This is part of an article series for **CTSciNet (http://community.sciencecareers.org/ctscinet/)** , the Clinical and Translational Science Network, an online community. These articles are published on both Science Careers and **within CTSciNet (http://community.sciencecareers.org/ctscinet/articles/)** .

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.

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 (http://www.cmr.org/)** 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."

(Courtesy, Lawrence Liberti)

Lawrence Liberti

Regulatory scientists are well compensated. A **2006 survey (http://www.raps.org/PersonifyEbusiness/Portals/0/Documents/17_oct_06.pdf)** by the **Regulatory Affairs Professionals Society (http://www.raps.org)** looked at salaries and found the average salary for Ph.D. holders to be about $142,000. Those with bachelor's degrees earn about $95,000.

Formalizing training

(Courtesy, Frances Richmond)

Frances Richmond

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 (http://www.queensu.ca/)** 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 (http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/CommissionersFellow** 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 (http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/ucm187708.htm)** . Programs at the University of Florida **College of Pharmacy (http://www.cop.ufl.edu/departments/PHCA/Newsite/Graduatestudies/Prospectivestudents/popmasters.htm)** and ASU Phoenix's **College of Nursing and Health Innovation (http://nursingandhealth.asu.edu/programs/nursing/graduate/ms/rshs/collaboration.htm)** 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."

(Russ Bryant)

Jonas Santiago (*center*) is one of five students in the first class of the U.S. Food and Drug Administration/Center for Drug Evaluation and Research (FDA/CDER) Graduate Training Program at the University of Florida.

Getting into regulatory science

The push is on for more widespread formal education in regulatory science. Today, **fewer than 30 U.S. universities (http://www.raps.org/personifyebusiness/tabid/176/Default.aspx)** offer master's degrees, Ph.D.s, or certificates, as well as another handful in Canada and Europe.

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

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

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

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

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

The skills required for a regulatory science career go beyond a science background. Shire listed analytical skills, negotiating skills, and communication skills as being key.

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

Regulatory science resources

The U.S. Food and Drug Administration (FDA) **maintains an information page about regulatory science (http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/default.htm)** , which includes the recent announcement of the FDA/National Institutes of Health collaboration on regulatory and translational science.

Elsewhere on the FDA site, you can find information about the **CDER Academic Collaboration Program (http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/ucm187708.htm)** and **the Commissioner's Fellowship Program (http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/CommissionersFell**

The **Regulatory Affairs Professionals Society (http://www.raps.org/)** (RAPS) provides visitors with information on regulatory affairs, including its **Regulatory Career Advancement Guide (http://www.raps.org/personifyebusiness/CareerDevelopment/RegulatoryCareerAdvancementGuide/tabid/1114/Def** RAPS maintains a **list of degree programs (http://www.raps.org/personifyebusiness/tabid/176/Default.aspx)** related to regulatory science, including those in Europe, Canada, and Australia.

Nancy Volkers is a science writer in Vermont.

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New to the Profession

This section is for individuals who are new or relatively new to the profession with limited or no regulatory knowledge, and minimal experience in the healthcare product industry or the regulatory field. Many have education and/or experience in science, clinical studies or engineering and understand specific aspects of the healthcare product arena. Throughout Level I, these individuals develop basic knowledge and understanding of the regulatory and legal frameworks, regulatory requirements, legislation, processes and procedures and begin to develop the critical thinking skills essential to the profession.

At this level, you should possess skills such as project management, writing, coordination, and interpersonal and communication skills. A science background and basic statistical knowledge are advantages. At this level, individuals coordinate and support technical and scientific regulatory activities, research regulations and guidance and maintain and organize key information sources. *(Example job titles: coordinator and some associate positions)*

- **Who are regulatory professionals? What do they do?**
- **Overview by Typical Position Titles for the New Regulatory Profession (Level I)**
- **Knowledge and Skills of the New Regulatory Professional (Level I)**
- **Code of Ethics**
- **Recommended Reading**
  Articles and books to help you succeed and advance at this level in your career.
- **Professional Development**
  Continue your learning and plan your professional development. A wide variety of education and training opportunities are available.
- **Job Search Resources**
  Job search resources available from RAPS.
- **Networking**
  RAPS offers unprecedented opportunities for networking.

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Who are regulatory professionals?

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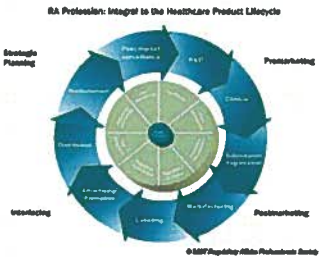
Regulatory professionals play critical roles throughout the healthcare product lifecycle, from concept through product obsolescence. They provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to people around the world. Continuous evolution in science and changes in the regulatory environment, healthcare sector and general economics shape the dynamic and expanding scope of the regulatory professional. Regulatory professionals must continually grow their knowledge and skills to be effective and to advance in their careers.



Scope of Practice
Regulatory professionals at all career and experience levels are involved in activities throughout the product lifecycle, and most are involved to some degree in bridging the gap between regulatory-related functions and organization and business activities. As expected, there are variations in time allocations among job levels, and there are differences in the type and level of involvement, including supervisory, direct involvement and support functions.

Compensation Overview
As in most professions, regulatory professionals' salary and overall compensation is affected by a number of related factors. Regulatory work is knowledge based, so experience, expertise and education all play a significant role in job performance and, ultimately, compensation. The RAPS Scope of Practice & Compensation Study examines the impact on salary and compensation of the following key variables: title; regulatory experience; professional experience; number of employees supervised; hours worked per week; highest degree earned and professional degrees (e.g. MD, PharmD, PhD, JD, MBA); years in current position; gender and organization type.

Professional/Regulatory Experience
Most individuals enter the regulatory profession with prior professional experience. Many have previous experience in scientific and clinical research, clinical laboratory work, clinical professions such as medicine or pharmacy, quality and manufacturing. Prior work experience tends to be closely related to education and training areas.

Product Type
The majority of regulatory professionals are involved with multiple product types. The most common product types are medical devices, combination products, pharmaceuticals, active pharmaceutical ingredient (APIs), biologics and biotechnology.

Multinational vs. National/Regional Focus
At all levels, regulatory professionals typically have a multinational, multiregional and/or worldwide focus. A good portion of individuals who have a national/regional scope of work will most likely devote at least some time to international submissions and compliance.

Employment Setting
Regulatory professionals work in diverse mix of employment settings and for employers of various sizes. The greatest number of regulatory-related professionals worldwide work in the industry sector. Other sectors employing regulatory professionals include government, academic institutions, clinical research organizations and other research organizations.

Education
The regulatory profession is a knowledge-based field, so it is not surprising to find that nearly all regulatory professionals have a higher education degree and the majority has some post baccalaureate education and/or graduate degrees.

Degree Trends/Areas
The majority of regulatory professionals have degrees in science—particularly in the life sciences or clinical sciences—and/or engineering. There is also a growing trend of individuals pursuing advanced education in business. For those holding a doctorate, the majority have a PhD in the life sciences or clinical sciences. In addition, a small percentage of the regulatory population holds a medical or veterinary degree or a professional pharmacy degree.

Regulatory Affairs Certification (RAC)
The RAC credential is the only professional certification available specifically for the regulatory profession. The RAC credential is attained by passing a knowledge-based examination. Currently, there are four RAC examinations (US, European Union, Canada and General Scope). This certification is very popular within the profession and strengthens the value and credibility one brings to an organization. The RAC credential may be particularly important for individuals at early and mid-career levels.

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Overview by Typical Position Titles

Coordinator Level Overview
The coordinator title typically reflects a newer regulatory professional and/or an individual whose responsibilities focus on administrative activities, information management, project/activity tracking and support.

The coordinator title is used more often by regulatory staff in industry and clinical practices sites than in other settings. The majority at this level have a degree in the clinical or life sciences or engineering. Some have a degree in liberal arts or humanities, and hold an RAC designation.

Associate Level Overview
The associate-level position often represents early regulatory career professionals, although this may not be a first or entry-level position in many settings. In some settings such as consultancies and law offices, the associate title is an advanced professional title. Associate-level professionals, on average, have more than four years of regulatory experience and 12 years of total professional experience. Previous career roles include nursing, pharmacy, laboratory and research roles, quality and manufacturing involvement.

Many at the associate level have graduate education and/or degrees. A small percentage hold an MBA degree, and the vast majority are trained in the clinical or life sciences or engineering. A good portion of associates hold the RAC credential.

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Knowledge and Skills

Professions are characterized by several factors, including an identifiable body of knowledge, a pathway for advancing knowledge and skills related to the profession and an emphasis on continued learning and development. The Regulatory Affairs Professionals Society (RAPS) developed the Professional Development Framework (PD Framework) for the healthcare product regulatory profession. The PD Framework offers a model for describing the basic body of knowledge and relevant skills for the regulatory profession across product lines, geographic locations and employer types at four major career stages. The PD Framework is based on two primary dimensions:

Level - referring to one of four professional/career levels

Domains - reflect scope of responsibilities throughout the product lifecycle

The levels and domains are organized within the framework by premarket and postmarket stages of product development, strategic planning and interfacing activities. For each level and domain, the PD Framework presents:

- Basic Professional Knowledge
- Institutional Knowledge
- Skills/Abilities
- Tasks/Responsibilities

Level I Framework
If you are new to the regulatory profession, you are a Level I professional. Many Level I professionals have education and/or experience in science, clinical studies or engineering and understand specific aspects of the healthcare product arena. Throughout Level I, these individuals develop basic knowledge and understanding of the regulatory and legal frameworks, regulatory requirements, legislation, processes and procedures. Level I professionals should possess skills such as project management, writing, coordination, and interpersonal and communication skills. A science background and basic statistical knowledge are advantages. At this level, individuals coordinate and support technical and scientific regulatory activities. There is less focus on technical skills and more focus on project coordination and support. *(Example job titles: coordinator and some associate positions)*

The PD Framework is an important tool in planning your professional development.

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Code of Ethics

Regulatory professionals play pivotal roles in the development, approval and surveillance of safe and effective healthcare products worldwide, ensuring compliance with applicable laws and regulations. The **Code of Ethics for Regulatory Professionals** is a living document that embodies the principles of professionalism and ethics to which regulatory professionals aspire and hold inviolable.

Duty
Have a primary duty to ensure our employers' activities are conducted in compliance with the laws and regulations of the authorities under which we operate, consistent with advancing, preserving and protecting public health.

Competence
Be competent to perform the services we have been hired or retained to perform. As regulatory professionals, we must commit ourselves to continual learning while being able to acknowledge areas that are outside our expertise.

Objectivity
Act in an objective manner. As regulatory professionals, we must base decisions on factual information. We must not be unduly influenced by competing or conflicting interests.

Integrity
Have integrity. As regulatory professionals, we must be principled and consistent in applying our views. We must live up to our commitments and be trustworthy and scrupulous at all times.

Honesty
Be honest in all dealings with our employers and others with whom we interact. As regulatory professionals, we must ensure that information and communications, whether oral or written, are accurate and complete. We acknowledge that personal and institutional credibility are crucial to our success.

Courage
Have the courage to make difficult decisions and present all relevant information to our organizations to promote wise decisions. As regulatory professionals, we must be able to withstand challenges to our views, while at the same time being accountable for our mistakes.

Fairness
Be fair in our dealings with all parties. As regulatory professionals, we must apply legal and regulatory standards equitably. We must be just and consider the interests of all parties in decision-making processes.

Respect
Be respectful of others, whether it is our peers, subordinates or external parties with whom we interact. We must treat all individuals with dignity and courtesy.

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Start Reading: Articles and Books

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Commonly Used Acronyms in the Regulatory Profession
For a more extensive list of acronyms and definitions RAPS has developed Regulatory Acronyms and Definitions Guides written separately for the US, Canada and the European Union (EU). These quick and easy reference books cover hundreds of terms and definitions most commonly used by regulatory professionals.

Regulatory Information Resources
In an effort to provide resources to enhance the professional knowledge base, RAPS is providing access to Chapter 36 of *Fundamentals of US Regulatory Affairs*, Sixth Edition, "Regulatory Information Resources." This chapter was written by Diane R. Whitworth, a member of the RAPS Board of Editors with extensive experience in gathering regulatory intelligence.

White Paper
RAPS has released a new white paper, *Regulatory Affairs Professional Development Framework: an Overview*, which describes the knowledge, skills and abilities of regulatory professionals. This is the first report of its kind to be published.

Articles in *Regulatory Focus*
Regulatory Focus magazine is the official monthly publication of the Regulatory Affairs Professionals Society, the foremost worldwide member organization creating and upholding standards of ethics, credentialing and education for the regulatory profession within the health product sector.

- Making the Right Moves---For You
- Many Career Paths Lead to Regulatory Affairs
- Tripping Into Regulatory Affairs...and Glad to Be Here
- Endless Opportunities for the Regulatory Affairs Professional
- Professional Development in Regulatory Affairs
- Regulatory Academic Programs: Deciding to Participate and Selecting a Quality Program
- Perspective: Have You Considered Consulting?
- Five Tips to Effectively Use a Recruiting Call
- Evaluating Job Opportunities With the Decision Matrix

2008/2009 Scope of Practice & Compensation Study
Every other year, RAPS conducts a Scope of Practice & Compensation Study that is designed to examine both the compensation and the range of duties and responsibilities—the "scope of practice"---of regulatory professionals working in the healthcare product arena. Data is collected from regulatory professionals around the world employed in industry, government, academia, research and clinical settings. Respondents are involved in a wide range of regulated healthcare products, including biotechnology, biologics, pharmaceuticals, medical devices, cosmetics and veterinary products.

Books
RAPS resources are essential to your career development. We offer a wide variety of industry specific publications that contain the information you need to succeed in your job and advance in your career. Visit the RAPS Bookstore »

Recommended Reading

Biologics

Biologics Development: 3rd Edition
Biopharmaceuticals: Biochemistry & Biotechnology
Development of Investigational Therapeutic Biological Products
Preclinical Safety Evaluation of Biopharmaceuticals

Canadian Regulations

2006 Fundamentals of CAN Regulatory Affairs

Clinical

Clinical Trials & Human Research
Good Clinical Practice: A Q&A Reference Guide
Protecting Study Volunteers in Research

Drugs

The Challenge of CMC Regulatory Compliance
Nanofabrication Towards Biomedical Applications
Preparation and Maintenance of the IND Application in an eCTD Format
Key Regulatory Topics: CTD
Key Regulatory Topics: eCTD
New Drug Approval Process: Accelerating Global Registration
The 'New' Part 11 and Drug Development
The US Drug Approval Trends and Yearbook
A Framework for Pharmaceutical Risk Management
New Drug Development: Eighth Edition
Guide to Drug Development
The Pharmaceutical Regulatory Process, Second Edition
Drug Truths: Disputing the Myths About Pharma R&D
Drugs From Discover to Approval

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Quality Systems and Control for Pharmaceuticals

Medical Devices

CE Conformity Marking
Medical Device Development
Design Controls for the Med Dev Industry
Medical Product Regulatory Affairs
Reliable Design of Medical Devices

EU Regulations

EU Pharmaceutical & Medical Device Regulations Fundamentals of EU Regulatory Affairs, 4th Edition
EU Acronyms and Definitions

Japanese Regulations

The Pharmaceutical Affairs Law
Drug Risk Management in Japan

Marketing and Promotion

Promotion of Biomedical Products
CE Conformity Marketing

Professional Development

Guidebook to Better Medical Writing
RAPS Scope of Practice & Compensation Study
True North: Discover Your Authentic Leadership
The CEO Within
Better: A Surgeon's Notes on Performance
The Best American Science Writing 2006

Standard Operating Procedures

Validation Standard Operating Procedures
Cracking the Case of ISO 9001: 2000 Manufacturing

US Regulations

Good Laboratory Practice Regulations
FDA Inspections & You (DVD)
US Regulatory Acronyms & Definitions Guide
Fundamentals of US Regulatory Affairs, Sixth Edition
How to Work With the FDA
FDA Regulatory Affairs
Title 21 CFR Pocket Guides (Various)
FDA: A History (DVD)

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Education and Training

ABOUT REGULATORY
NEW TO REGULATORY

New to the Profession
- Who are regulatory professionals?
- Overview by Typical Position Titles
- Knowledge and Skills
- Code of Ethics
- Recommended Reading
- Professional Development
- Job Search Resources
- Networking

Transitioning to Regulatory

MID-LEVEL
SENIOR / EXECUTIVE LEVEL
RAPS CAREER GUIDE HOME

RAPS educational opportunities are designed to help you build your knowledge improve your job skills and strengthen your abilities regardless of your geographic location or region(s) of responsibility. From earning your RAC to gaining access to quality information, research and a global network of peers, RAPS is the source for regulatory professional development and advancement.

Online University

RAPS Online University provides an exciting opportunity to gain a comprehensive introduction to important regulatory knowledge areas 24 hours a day, 7 days a week.

This state-of-the-art, self-directed online learning system allows you to conveniently fit professional development into your schedule. Choose the topics you want to learn, and when and where you want to learn. The Introduction to Regulatory Affairs and the Healthcare Product Lifecycle course is a helpful introduction to the regulatory profession.

Introduction to Regulatory Affairs and the Healthcare Product Lifecycle
The regulation of healthcare products is dynamic and challenging, and the demand for qualified professionals is rising at an exceedingly swift pace. Whether you are a student considering pursuing a regulatory career, an individual transitioning into regulatory from a related career or someone already working in the field who wants to expand relevant skills, this is the course for you!

Introduction to Regulatory Affairs and the Healthcare Product Lifecycle will introduce you to essential areas of regulatory knowledge across a broad range of healthcare products, including medical devices, pharmaceuticals, biologics and combination products. You will also learn about key regulatory systems and major agencies in the US, European Union (EU), Canada, Japan and Australia, as well as typical tasks and roles regulatory professionals may assume within a company. This course will give you a strong sense of what a regulatory career encompasses, and if you are already working in or transitioning to the profession, it will quickly bring you up to speed on critical topics.

Additional Online University Courses

Effective Communication and Negotiation
Ethics
Global Regulatory Strategy
Good Clinical Practices (GCPs)
Good Laboratory Practices (GLPs)
Good Manufacturing Practice (GMPs)
Introduction to Regulatory Affairs
Regulation of Combination Products
Regulation of IVDs
The Role of the RA Professional
Medical Devices: Canada Regulations
Medical Devices: EU Regulations
Medical Devices: US Regulations

Webcasts

RAPS' unique Webcast series offers participants a convenient option for flexible, cost-effective learning. RAPS' Webcasts directly deliver the knowledge needed to keep pace with the dynamic regulatory environment. Topics range from regulatory updates and product specific issues to business skills.

Webcasts allow participants the opportunity to:

- Learn from industry experts and regulatory agency representatives
- Share the experience with colleagues for the cost of a single user fee
- Interact with speakers through live Q&A

Meetings and Conferences

Attend RAPS' worldwide meetings, conferences and workshops to network, gain insight on global issues and advancements, and play an active role in growing your profession.

The RAPS Annual Conference & Exhibition is a great opportunity for new regulatory professionals to learn about the profession and connect with colleagues. At this conference, top public and private sector regulatory professionals from around the world gather to discuss advancements in the profession as well as new healthcare product regulations and what they mean to you. Addressing multiple product lines and regulatory responsibilities throughout the product lifecycle, this one-of-a-kind event is not to be missed.

RAPS Certificate Programs

If you have recently entered the regulatory profession, RAPS' Online Medical Devices Certificate program is the perfect way to hit the ground running. The Online Medical Devices Certificate provides a complete set of professional tools and a solid foundation of regulatory knowledge. Students successfully complete four core courses and five elective courses that explore essential regulatory topics such as ethics, business skills and global and regional regulations. Students successfully completing all courses receive a certificate recognizing their achievement that can proudly be displayed for your colleagues to see!

Regulatory Affairs Certification (RAC)

Regulatory Affairs Certification, known as the RAC, is the only certification specifically for regulatory professionals in the healthcare product sector. The RAC credential is a professional distinction that denotes commitment to excellence and pursuit of knowledge and career advancement. RAC-credentialed professionals are among the current and rising leaders in the regulatory profession. They work in all parts of the world and in many settings, including industry, government and academic organizations. To date, more than 5,000 individuals have earned the RAC. It is recommended that candidates for the RAC have at least three to five years of regulatory experience.

Other Resources

Regulatory Degree and Certificate Programs – listings on this page will lead you to colleges and universities that offer graduate or certificate programs in regulatory.

Professional Development Portal
This portal is designed to support your development as a regulatory professional and give you access to a full realm of educational offerings from a variety of reputable institutions and organizations. Please select one of the listings below or view a provider's information and event listings by clicking on their logo.

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Title **Regulatory Affairs Associate III**

About the Organization

My company shares my passion for helping to improve human health around the world."

"This is My MedImmune."

Those who join MedImmune feel a sense of ownership about their future. They thrive with a recognized leader in the biotechnology industry and the wholly-owned subsidiary of AstraZeneca plc.

Here, you will join passionate professionals who advance science, technology and medicine to develop products designed to help people live better lives. You will excel in an environment characterized by respect, integrity and growth opportunities...that encourages both individual contribution and collaborative entrepreneurial thinking. Our products and/or product candidates are designed to address areas of need in infection, oncology, respiratory disease and inflammation, cardiovascular/gastrointestinal disease and neuroscience. Explore a MedImmune career as we strive to better more lives, more often, around the world.

Description

Title: Regulatory Affairs Associate III
Location: MD, Gaithersburg - Corporate Headquarters
Req: 02834

Position Summary:
- Responsible for collection, preparation and assembly of CMC documentation required for US and RoW regulatory submissions (INDs, CTAs, IMPDs, BLAs, etc.)
- Work closely with the Therapeutic Area RA Lead to coordinate with project teams in preparation for regulatory meetings, including development of briefing documents and pre-meeting rehearsals.
- Participates as the CMC Regulatory Affairs representative on various project teams as assigned.
- Proactively identifies potential issues, and potential resolutions, and brings them to the attention of management.

Major Duties and Responsibilities:
- CMC regulatory representative on assigned project teams within and outside of Regulatory Affairs. Participates on the cross-functional CMC project teams, as assigned.
- Performs functions in support of CMC sections of regulatory submissions including preparation and initial review, compilation of documents, coordination of review and approval of documents
- Interacts with Development and Quality team members to ensure the timely preparation and receipt of information required for regulatory submissions. Interacts with Therapeutic Area RA representatives to ensure timelines are met and CMC issues are communicated. Interacts with Regulatory Operations to ensure submission documents meet publishing requirements.
- Create and/or administer Regulatory CMC spreadsheets for tracking agency feedback, change control, CMC submissions, and others as needed
- Responsible for maintaining and tracking CMC submissions in accordance with the

established regulatory systems in coordination with Regulatory Operation staff
- Provides feedback on regulations and guidance documents to regulatory affairs and project teams
- Reviews analyses to validate the conclusions of studies
- Educates internal stakeholders on the intent and implications of regulations
- Assists in the planning, coordination, and preparation of CMC meetings with regulatory agencies

Position Requirements

Special Skills:
- Excellent oral and written communication skills;
- Strong interpersonal /group skills; capable of working collaboratively with colleagues in all functions;
- Self-motivated and action-oriented;
- High standard of professional ethics, integrity and trust;
- Excellent planning, organizational, and prioritizing skills with ability to multi-task;
- Consistently high professional image and demeanor;
- Proficiency in the use of MS Word„¥, Excel„¥ and other appropriate software programs.

Job complexity:
- Familiar with drug/biologic development process.
- Demonstrated ability to identify issues and initiative to recommend solutions.
- Ability to prioritize, multi-task, and schedule work to meet deadlines. Must be able to produce high-quality deliverables to meet tight deadlines and excel in a fast-paced team-oriented environment.
- Able to quickly assimilate information and be flexible with change.
- Able to successfully interact with all levels of the organization.

Supervision:
Requires minimal instruction to ensure satisfactory completion of routine work; with more specific instructions provided on new or unfamiliar assignments. Work independently to accomplish high quality submissions. Brings impediments/challenges to the attention of supervisor well in advance of due dates.

Educational Requirements

Education: BS/MS in a scientific discipline.
Experience: A minimum of 2 years of increasing documented success relevant to Regulatory Affairs. Biopharmaceutical or pharmaceutical work experience is highly desirable. Experience working in a GMP environment is a plus. General knowledge of relevant regulations, guidance documents and policies (CFR, CDER/CBER, ICH, GMP) required.

MedImmune does not accept non-solicited resumes or candidate submittals from search/recruiting agencies not already on MedImmune¡¦s approved agency list. Unsolicited resumes or candidate information submitted to MedImmune by search/recruiting agencies not already on MedImmune¡¦s approved agency list shall become the property of MedImmune and if the candidate is subsequently hired by MedImmune, MedImmune shall not owe any fee to the submitting agency.

Company Info

MedImmune, LLC. is an Equal Opportunity/Affirmative Action Employer and does not discriminate on the basis of race, color, religion, gender, age, national origin, disability, veteran status, or any other characteristic protected by federal, state or local law.

This position is currently accepting applications.

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Job Summary

In Vitro Diagnostics - Regulatory Specialist POSTED: Nov 03

Job Code: 302

Salary:	Open	Location:	Atlanta, Georgia
Employer:	Battelle Memorial Institute	Type:	Full Time - Experienced
Segment:	Advocacy / Non-Profit	Required Education:	4 Year Degree

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Employer Information

About Battelle Memorial Institute

Battelle is the world s largest, independent research and development organization, working to advance scientific discovery and application.We re accelerating innovation by bringing people, science and technology together.From Education and Laboratory Management to National Security and Energy Technology to Health and Life Sciences, we provide innovative solutions to address the world s most pressing needs.We partner with government, industry, and communities to enhance quality of life for people everywhere.

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Job Description

As part of Battelle s Health and Life Sciences Global Business, you will touch every aspect of human health. We deliver far reaching solutions to some of the world s most pressing health challenges from developing medical products that change individual lives to pharmaceuticals that address potentially devastating health conditions on a global scale. Battelle supports your career by offering you the opportunity and resources to solve the most critical health problems, break through technology developments, mentorship opportunities, upward mobility, and company ethics and reputation.
Battelle s Atlanta Analytical Services (AAS) provides support to programs and activities within the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. Our mission is to provide high-quality technical support to CDC and its partners through technical staffing, program management, and reach-back capabilities through our advanced laboratory operations in Columbus, Ohio and other locations.

Our AAS Group is currently seeking an In Vitro Diagnostics - Regulatory Specialist. This position located in Atlanta, GA.

POSITION RESPONSIBILITIES:

·Coordination of process development and validation as applicable

·Work in conjunction with the CDC Regulatory Affairs Office, Battelle Program Managers, and Battelle Product Manager to develop regulatory strategies and written plans for several in vitro diagnostic products

·Coordinate, prepare input, and assemble submission packages (e.g. FDA premarket 510(k), or PMA) in coordination with the CDC Regulatory Affairs Office

·Assist in the decision-making process for reportable complaints. Completes adverse events documentation (MDR).

Contribute to risk assessments and development of mitigation strategies

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BENEFITS

Battelle s competitive benefits program includes comprehensive medical and dental care, matching 401K, employee pension, tuition reimbursement, work/life balance, paid time off, flexible spending accounts, disability coverage, and other benefits that help provide financial protection for you and your family.

Battelle is an Affirmative Action/Equal Opportunity Employer and supports diversity in the workplace. Applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, age, disability, veteran status, marital status, or sexual orientation. For more information about our other openings, please visit www.battelle.org/careers.

Requirements

THE FOLLOWING REQUIREMENTS MUST BE MET TO BE CONSIDERED FOR THIS POSITION:
·A minimum of a Bachelor s degree in a biological science or medical technology

·Minimum of 3 years experience in creating 510(k)/PMA s and technical files.

·Experience with the application and implementation of Quality System Regulations

·Excellent written and oral communication skills

·Practical experience in communications with regulatory agencies THE FOLLOWING IS DESIRED, BUT NOT REQUIRED TO BE CONSIDERED FOR THIS POSITION:

·Direct experience with regulatory submissions involving in vitro diagnostic devices employing real-time polymerase chain reaction (PCR) technology

·Experience working with government contracts and subcontractors

·Experience and understanding of diagnostic assay development and design control processes.

·Applicants with demonstrated experience working on multiple cleared device submissions will be preferentially considered.

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Battelle Memorial Institute
Atlanta GA
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Job Summary

Product Manager/Specialist POSTED: Nov 04
Job Code: RAPS2

Salary:	Open	Location:	Rockville, Maryland
Employer:	MSC, Inc. (NIH)	Type:	Full Time - Experienced
Segment:	Government	Preferred Education:	Doctorate

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Employer Information

About MSC, Inc. (NIH)

Medical Science & Computing, Inc. (MSC) is a small business focused on providing technical and scientific services to the Federal Government. Our staff has a long history of supporting the National Institutes of Health (NIH), as well as other Federal agencies such as the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Department of Defense (DoD).

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Job Description

Medical Science & Computing, Inc. (MSC) is searching for a Product Manager/Specialist to support the National Institutes of Health (NIH). This is a full-time opportunity with MSC, Inc., and it is on-site at NIH in Bethesda/Rockville, Maryland.
The Product Manager/Specialist (PM/S) is responsible for assisting with the management of malaria vaccine development initiatives, particularly virus-vectored and whole organism vaccines, which will include malaria vaccine candidates for Phase 1 and 2 trials as well as experimental malaria infection studies involving human subjects. The PM/S will have responsibilities for coordination and documentation of production, quality control, formulation and other components of the vaccine development process within the Lab, as part of regulatory documents to be submitted to FDA. The PM/S will also work with and help coordinate contractors and other external contributors to execute multiple, concurrent experimental infection studies and malaria vaccine initiatives. The PM/S will play a role in the coordination and oversight, from a QA perspective, of a series of steps performed by the various Lab experimental infection and vaccine associated units. These steps will typically not involve direct participation in generating data or other laboratory work, but will involve data analysis and GLP standard document review and preparation of essential elements of IND and other regulatory documents. These steps and other responsibilities of the PM/S in order of significance to the position include:
□Contribution to design and development of assays, trouble-shooting technical issues, and reviewing reports for product characterization □Identification of potential technical gaps in development pathway, initiation of action to fill the gaps □Logical division of projects into subtasks with detailed time lines; milestones for determining progression of these projects from one stage to another □Monitoring the progress of tasks and initiation of early remedial action when agreed timelines are not likely to be achieved □Review of the data from protocols, procedures and assays conducted by staff □Production of a series of laboratory protocols for each product □Facilitate development and implementation of QC procedures for assaying purity, integrity, stability and potency of the bulk antigen and formulated products □Supervision of immunogenicity studies to determine promising formulations and doses for vaccine trials □Participation in and where appropriate leading the publication of other documents for regulatory purposes (extra to IND applications), papers in scientific journals, presentation at scientific meetings, drafting patents, and reports for

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funding agencies Collection and organization of data generated by technology units, published literature, or other reports that are relevant to the projects Participation in planning in response to specific issues facing projects, such as the impact new discoveries made by the technology units (or elsewhere) might have on projects

Requirements

Masters Degree or PhD; biology, microbiology, chemistry or biochemistry Minimum 3 years experience in pharmaceutical or biotechnology industries or related research and development organizations on vaccine or drug development. Experience with virus vectored or whole organism vaccines is desirable. Knowledge of GLP, GMP and GCP, and FDA vaccine approval process Experience with project/program management in pharmaceutical or biotechnology industries or related research and development organizations Using tools such as MS Project Experience in preparing laboratory protocols, evaluating laboratory processes, analyzing research data for regulatory submissions. Experience with vector-based vaccine development preferred Demonstrated organizational skills are essential, as well as strong written and oral communication skills EOEM/F/D/V

Please submit cover letter which summarizes your relevant experience, resume and salary requirements to: careers@mscweb.com

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MSC, Inc. (NIH)
Rockville MD
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Job Title: Interdisciplinary Scientist
Department: Department Of Health And Human Services
Agency: Food and Drug Administration
Job Announcement Number: PH-CF-10-402757

Salary Range: $62,467.00 - $115,742.00 /year

Series & Grade: GS-0644-11/13

Promotion Potential: 13

Open Period: Monday, November 08, 2010 to Thursday, November 18, 2010

Position Information: Full Time Career/Career Conditional

Duty Locations: Many vacancies - Rockville and Silver Spring, MD

Who May Be Considered: United States Citizens

Job Summary:
Become a part of the Department that touches the lives of every American! At the Department of Health and Human Services you can give back to your community, state, and country by making a difference in the lives of Americans everywhere. Join HHS and help to make our world healthier, safer and better for all Americans.

- Do you want to be involved with a variety of medical device actions?
- Are you interested in improving the safety and effectiveness of materials used in the manufacturing of medical devices?
- Are you interested in providing scientific information and consultation to industry, academia, and private laboratory scientists conducting research on medical devices?

WHO MAY APPLY: Applications will be accepted from all U.S. Citizens.

Applicants applying for a non-competitive appointment must provide appropriate documentation as proof of their eligibility.

Commissioned Corps Officers eligible candidates in the Public Health Service and "qualified" commissioned corps candidates may be considered for internal placement provided they submit a cover letter indicating commissioned corps status, a current resume or curriculum vitae, and provide all other required information specified in the vacancy announcement.

One or more positions may be filled using this vacancy announcement.

Key Requirements:
- You must be a U.S. Citizen or National.
- Resume and supporting documents (See How To Apply Section)

Major Duties:

This position is located in the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA). The Interdisciplinary Scientist serves as a reviewer of scientific data, applying an intensive and diversified knowledge to the regulation of medical devices. Specifically, the Interdisciplinary Scientist:

- Reviews scientific data which is submitted in support of a variety of medical device actions (including but not limited to, premarket approval applications, product development protocols, applications for investigational device exemptions, premarket notification of intent to market a device, and establishment inspection reports) for medical devices;
- Provides leadership and guidance to other supporting level scientists within the Division;
- Makes presentations to the medical and scientific committees which have the responsibility for the classification and premarket review of medical devices;
- Develops, modifies, and evaluates guidelines concerning data required in device actions submitted to the Agency for medical devices; and
- Presents reviews, conclusions, opinions, and recommendations to appropriate scientific review panels on PMAs, PDPS, petition for reclassification, etc.

Qualifications:

Basic Requirements for Biologist:

A. Successfully completed a 4-year degree in biological sciences, agriculture, natural resource management, chemistry, or related disciplines appropriate to the position. **OR**

B. Combination of education and experience with courses equivalent to a major as shown in A above, plus appropriate experience or additional education.

Basic Requirements for Microbiologist:

A. Successfully completed a full 4-year degree in microbiology, biology, chemistry, or basic medical science that included at least 20 semester hours in microbiology or other subjects related to the study of microorganisms, and 20 semester hours in the physical and mathematical sciences combining course work in organic chemistry or biochemistry, physics, and college algebra, or their equivalent **OR**

B. Combination of education and experience with courses equivalent to a major as shown in A above, plus appropriate experience or additional education.

Basic Requirements for Toxicologist:

A. Successfully completed a 4-year degree in that included a major field of study or specific course work in toxicology, or an appropriate discipline of the biological, medical, or veterinary sciences that included at least 30 semester hours in chemistry, biochemistry, or physiology, and 12 semester hours in toxicology. Courses in anatomy, chemistry, organic chemistry, biochemistry, biology, histology, and animal, human, microbial, or cellular physiology may be used to meet the 30-semester hour requirement in chemistry, biochemistry, and physiology. Courses in statistics, bioassay, and test design may also apply to this requirement. Courses in cytology, embryology, cellular or microbial genetics, and biophysics may also be used to meet this requirement in those instances where the course work provided additional insight into the biophysical, biochemical, and physiological relationships involved. Only toxicology courses may be used to meet the requirement for 12 semester hours in toxicology. This may include courses dealing intensively with toxicological search, methods in toxicology, essentials in toxicology, the study and review of toxicological literature, special reading courses, or other toxicologically-oriented subjects. (Transcripts must be provided). **OR**

B. Combination of education and experience with courses equivalent to a major as shown in A above, plus appropriate experience or additional education.

Basic Requirements for Medical Technologist:

A. Successfully completed a 4-year degree in medical technology, chemistry, or biology that included or was supplemented by at least 16 semester hours of biological science of which one course was in microbiology and one course was in immunology. (NOTE: If there is no mention of immunology or

immunobiology in the course title, the requirement for a course in immunology may be met by any course that covers the following topic areas: (1) definition and relationships of antigens and antibodies; (2) host-antigen interactions; (3) bursal and thymic influences on lymphoid cells; and (4) humoral and cellular response mechanisms.) The 4-year degree in medical technology, chemistry, or biology must have included or was supplemented by at least 16 semester hours of chemistry of which one course was in organic or biochemistry. The remaining chemistry courses must have been in general chemistry, qualitative analysis, qualitative chemistry, quantitative chemistry, physical chemistry, analytical chemistry. The 4-year degree in medical technology, chemistry, or biology must have included or was supplemented by at least 3 semester hours in college mathematics. (The remaining biology/chemistry courses must have been in general biology, zoology, or microbiology, clinical chemistry, hematology, and immunohematology (blood banking). Qualifying course work in these areas includes bacteriology, mycology, mycobacteriology, tissue culture, virology, parasitology, endocrinology, enzymology, toxicology, urinalysis, coagulation, hemostasis, cell morphology, immunology, serology, immunoserology, immuno-deficiency, hemolysis, histocompatibility, cyto-genetics, and similar disciplines or areas of laboratory practice. Related fields include physiology, anatomy, molecular biology, cell biology, embryology, pathology, genetics, pharmacology, histology, cytology, nuclear medicine, epidemiology, biostatistics, infection control, physics, statistics, and similar areas of science where the work is directly related to the position to be filled.) (Transcripts must be provided).**OR**

B. Successfully completed a 4-year course of study that included or was supplemented by at least 12 months in a college or hospital based medical technology program or medical technology school approved by a recognized accrediting organization. The professional medical technology curriculum may have consisted of a 1-year post-baccalaureate certificate program or the last 1 or 2 years of a 4-year program of study culminating in a bachelor's in medical technology.**OR**

C. Combination of (1) at least 35 semester hours of biological science, chemistry, and mathematics as described in paragraph A above and (2) additional appropriate education and/or experience totaling 4 years. This combination of education and experience must have provided knowledge of the theories, principles, and practices of medical technology equivalent to that provided by the full 4-year course of study described in A or B above. All science and mathematics courses must have been acceptable for credit toward meeting the requirements for a science major at an accredited college or university. Acceptable experience is responsible professional or technician experience in a hospital laboratory, health agency, industrial medical laboratory, or pharmaceutical house; or teaching, test development, or medical research program experience that provided an understanding of the methods and techniques applied in performing professional clinical laboratory work. Certification/licensure as a medical technologist (generalist) obtained through written examination by a nationally recognized credentialing agency or State licensing body is a good indication that the quality of experience is acceptable.

Basic Requirements for Chemist:

A. Possess a 4-year degree in physical sciences, life sciences, or engineering that included 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics.**OR**

B. Possess courses equivalent to a major as shown in "A" above, including 30 semester hours in chemistry, supplemented by course work in mathematics through differential and integral calculus, and at least 6 semester hours of physics, plus additional education or appropriate experience.

AND

Additional Requirements for Interdisciplinary Scientist - GS-11:

In addition to meeting the basic requirement for specialty field above, you must have the following:

A. Possess 3 years of progressively higher level graduate education leading to a Ph.D. degree or Ph.D., or equivalent doctoral degree in the biological sciences or related disciplines appropriate to the position.**OR**

B. Possess one year of specialized experience, equivalent to the GS-9 level in the Federal service, serving as a reviewer of a variety of medical device actions, such as pre-market notification of new medical devices (510(k) submissions), establishment inspection reports (EIRs), pre-market approval applications (PMAs), product development protocols (PDPs) investigational device exemptions (IDEs), and investigational new drug (IND) applications for transitional devices; evaluating the methods used in obtaining the results to determine the validity scientific significance and recommending strategies; developing, modifying, and evaluating guidelines concerning data required in device actions; developing or modifying existing guidelines and protocols for testing specific types of devices; presenting reviews, conclusions, opinions, and recommendations to appropriate scientific review panels on PMAs, PDPs, petitions for reclassification, etc.; providing scientific information and consultation to industry, academic and private laboratory scientists conducting research on the safety and effectiveness of materials used in the manufacture of medical devices; enhancing professional career development by collaborating with other scientists in order to obtain a greater understanding of problems associated with medical devices and keeps abreast of all industry changes to medical devices; serving as a witness in court cases involving an area of expertise; providing science expertise as a leader or participant on review cases where an interdisciplinary team of scientists and medical specialists are required; and serving as Executive Secretary of a medical device panel. **OR**

C. Possess a combination of specialized experience as described in B and graduate education as described in A that, when combined, equal 100% of the total requirement. (Only graduate education in excess of the first 2 years may be used in this calculation).

Additional Requirements for Interdisciplinary Scientist - GS-12:

In addition to meeting the basic requirement above, you must have at least 1 year of specialized experience equivalent to the GS-11 in the Federal service, reviewing scientific specialty data which is submitted in support of a variety of medical device actions (including but not limited to, premarket approval applications, product development protocols, applications for investigational device exemptions, premarket notification of intent to market a device, and establishment of inspection reports) for medical devices; skillfully apply, adapt, and modify technical methods, procedures, and techniques in performing the review; summarizing and making recommendations concerning scientific specialty data; providing leadership and guidance in scientific specialty area to other supporting level scientists; making presentations to the medical and scientific experts who have the responsibility for the classification and premarket review of medical devices; developing, modifying, and evaluating guidelines concerning data required in device actions applicable to regulation of medical devices; developing or modifying existing guidelines and protocols for testing specific types of devices; presenting reviews, conclusions, opinions, and recommendations to appropriate scientific review panels on PMAs, PDPs, petition for reclassification, etc.; providing scientific information and consultations to industry, academic, and private laboratory scientists conducting research on the safety and effectiveness of materials used in the manufacture of medical devices; enhancing professional career development by collaborating with other scientists in order to obtain a greater understanding of problems associated with medical devices and keeps abreasts of changes to the medical device industry; coordinating programs dealing with a scientific specialty field relative to medical devices; serving as an expert witness in scientific specialty field in court cases dealing with medical devices; providing science expertise as a leader or participant on review cases where an interdisciplinary team of scientists and medical specialists are required; and serving as Executive Secretary of a medical device panel.

Additional Requirements for Interdisciplinary Scientist - GS-13:

In addition to meeting the basic requirement above, you must have at least 1 year of specialized experience equivalent to the GS-12 in the Federal service, reviewing scientific data submitted in support of a variety of medical device submissions such as pre-market applications (PMAs), product development protocols (PDPs), applications for investigational device exemptions (IDEs) premarket notification of intent to market a device, and reports such as establishment inspection reports (EIRs), to determine if a

regulatory decision on the safety and effectiveness of the device can be made; providing immediate supervisor reports of his/her scientific evaluation of medical device submissions; reviewing technical data submitted in support of the medical device submissions with respect to accuracy, precision, and reliability and making judgment on whether the supporting data provided are sufficient to substantiate labeled claims; serving as a technical authority regarding a variety of medical devices and making comparative evaluations for medical devices; reviewing research protocols to evaluate medical devices; writing and evaluating guidelines concerning the data required in submissions for medical devices and their marketing; making presentations to the medical and scientific expert who serve as panel members which have the responsibility for the classification and pre-market review of medical devices; serving as an expert witness in area of scientific specialty in court cases dealing with medical devices; evaluating and making recommendations for necessary regulatory action required for medical device complaints and product problem reports; advancing expert knowledge and keeping abreast of medical device industry; providing scientific expertise as a leader or participant on review cases where an interdisciplinary team of scientists and medical specialists are required; and serving as Executive Secretary of a medical device panel.

ARE YOU USING YOUR EDUCATION TO QUALIFY? You MUST provide transcripts or other documentation to support your educational claims. Unless otherwise stated: (1) unofficial transcripts are acceptable, or (2) you may submit a list with all of your courses, grades, semester, year, and credit for the course. All materials must be submitted by the closing date of the announcement. **(MUST ATTACH ALL TRANSCRIPTS)**

SPECIAL INSTRUCTIONS FOR FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. For further information, visit:
http://www.ed.gov/about/offices/list/ous/international/usnei/us/edlite-visitus-forrecog.html

Only experience obtained by the closing date of this announcement will be considered.

Status candidates must meet time in grade requirements (52 weeks at the next lower grade level).

Non-competitive appointments must provide documentation.

How You Will Be Evaluated:

Once the application process is complete, a review of your resume and supporting documentation will be made and compared against your responses to the assessment questionnaire to determine if you are qualified for this job. If, after reviewing your resume and or supporting documentation, a determination is made that you have inflated your qualifications and or experience, you may lose consideration for this position. Please follow all instructions carefully. Errors or omissions may affect your eligibility.

Category rating procedures will be used to rate and rank candidates. The category assignment is a measure of the degree in which your background matches the competencies required for this position. Candidates will be ranked into 3 categories: Best-Qualified; Well-Qualified; and Qualified.

The Category Rating Process does not add veterans' preference points or apply the "rule of three", but protects the rights of veterans by placing them ahead of non-preference eligibles within each category. Preference eligibles who meet the minimum qualification requirement and who have a compensable service-connected disability of at least 10 per cent must be listed in the highest quality category (except in the case of scientific or professional positions at the GS-9 level or higher).

Qualified candidates will be assigned to a quality category. The category assignment is a measure of the

Imm Thee Wan, Ph.D.

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
301.xyz.abcd
WanIT@fda.hhs.gov

20123 Rite Way
Germantown, Maryland 20874
240.qvc.idta
WanIT@gmail.com

SUMMARY

Chemist serving in functional capacity as a **Regulatory Health Project Manager for Quality** with ~5 years Food and Drug Administration experience. Augmented skills obtained as **Ph.D. Analytical Chemist and Measurement Scientist** with 8 years experience in basic and applied research in academic, governmental, and pharmaceutical/cGMP laboratories to solve complex problems in specialty areas. Applies knowledge, skills, and abilities to projects to meet goals and milestones in a Chemistry, Manufacturing and Controls (CMC) technical environment. Enthusiastic, results-oriented self-starter that can be relied upon to leverage diversity of experience to meet project goals in a timely and efficient manner. Known and respected as a hands-on technical lead and mentor, serving as a resource to less experienced colleagues regarding complex issues; leads by example to ensure a cohesive high-performance team. Flexible; adaptable; able to work independently or as a team member. Strengths include analysis of information and identification of trends and patterns to devise innovative solutions and recommend optimal course of action and improvement.

PROFESSIONAL EXPERIENCE

Chemist, Office of New Drug Quality Assessment **2010 – present**
Regulatory Health Project Manager, Office of New Drug Quality Assessment **2005 – 2010**

Food and Drug Administration, Silver Spring, MD

- Performs fact finding analysis to identify scope, breadth, effect, and implications of drug shortage and drug product safety issues associated with transdermal drug delivery system labeling, drug carton and container labeling standardization, genotoxic impurity detection and control in drug substances and drug products. Consolidates facts and responses to pending issues to formulate the issues into a framework suitable for analysis by senior management and staff.
- Centralizes responses to Authorized Generics Congressional mandate through monitoring and reporting. Updates and standardizes existing records and generates quarterly report to Congress. Monitors internet activity and reviews annual reports and industry press releases to identify and record new Authorized Generics. Responds to and interacts with CDER's Division of Drug Information to answer public requests and inquiries in a timely manner.
- Facilitated the review of the Chemistry, Manufacturing and Control (CMC) portions of INDs, NDAs, and DMFs to achieve timely resolution of scientific and regulatory conflicts or problems and avoid delays in achieving goals. Served as the primary point of contact for communication with pharmaceutical industry representatives. Provided regulatory guidance to internal and external stakeholders.
- Developed and implemented standard operating procedures to satisfy information requests from CDER's Office of Generic Drugs. Trained personnel, analyzed data and evaluated quality control procedures to increase accuracy and efficiency of responses to 100 yearly requests from outside stakeholders. Compiled and analyzed performance in written semi-annual report to facilitate training and resource allocation.
- Advanced knowledge of new project managers through the development of technical training modules and coaching of new project managers regarding day-to-day issues. Presented personal perspectives to Rockford College, Saginaw Valley State University, University of Maryland students to educate them as to FDA's public health mission and role.
- Facilitated 85+ industry meetings focusing on CMC content of Investigation New Drug Applications (INDs), New Drug Applications (NDAs) and Drug Master Files (DMFs). Developed and implemented teaching techniques for Successful Meetings and Minutes course for CDER Learning Network to increase quality level of meeting facilitation and record keeping for new hires. Adopted changes to materials based on updates to Center policies and guidance. Awarded special letter of recommendation from industry agent for professional facilitation of industry meeting with international client.

- Increased efficiency by 66% from initial submission to FDA response through the development and implementation of procedures to facilitate and coordinate the review of multi-organizational regulatory policy and procedure inquiries from industry. Tracked and completed the review of 35+ requests for guidance and policy determination.
- Attained Federal Acquisition Certification for Contracting Officer Technical Representative (FAC-COTR) certification (31 Jul 2009- 31 July 2011).
- Completed Project Manager training courses through the Center for Drug Evaluation and Research, Office of Training and Communication:
  - Basic Drug Law
  - Basic Statistical Methods
  - Biologics Law
  - Facilitation Skills
  - Good Manufacturing Practices
  - How to Handle Difficult People
  - IND Regulations and Policies
  - Introduction to Generic Drug Regulation and Reviews
  - Medical Terminology
  - NDA Regulations and Policies
  - Presentations Skills for Informative Scientific Presentations (Foundational Skills)
  - Successful Meetings and Minutes
  - Successful Negotiations
  - Technical Writing Skills for Non-Reviewers
  - Time Management
  - Topics in Clinical Trials

Senior Scientist, Pharmaceutical Analysis
Shire Laboratories, Inc. (now Supernus Pharmaceuticals, Inc.), Rockville, MD 2003 - 2005

- Analyzed (dissolution and assay) bulk, finished pharmaceutical, and excipient samples according to written cGMP/FDA/ICH protocols for performance of material characterization studies in a solid dosage environment.
- Reduced analysis turnaround time by 66% in 3-month period through implementation of automated analysis hardware and resource management techniques while understaffed by 33%.
- Conserved resources and increased efficiency by revising maintenance programs for laboratory instrumentation. Minimized instrument downtime and ensured high efficiency levels by coordinating instrument maintenance plan with calibration staff and project timelines.
- Received award for oral presentations of safety policies and procedures to 15 colleagues and contributions to the development of safety instructional programs under reduced staffing levels. Increased compliance level and reduced potential for accidents and violations of standard operating procedures.
- Received award for providing leadership and support to 5 junior level chemists and 12 colleagues during the successful transition to an automated information management system (LIMS).
- Training Courses Completed
  - Communication and Interpersonal Skills for IT and Technical Professionals
  - Comprehensive Overview of FDA Regulatory Compliance for Drugs and Biotech Products
  - Eastern Analytical Symposium, Somerset, NJ

Research Chemist; National Academy of Sciences/National Research Council Postdoctoral Fellow
National Institute of Standards and Technology, Gaithersburg, MD 2001 - 2003

Research Advisor: Dr. Nu Mee Whale

Focus: Near-field Scanning Optical Microscopy and Single Molecule Spectroscopy

- Characterized local organization and environment during the crystallization processes of isotactic polystyrene to develop a better understanding of these processes.
- Developed techniques to elucidate local environment characteristics and phenomena in sodium dodecyl sulfate/polyacrylamide gels used in electrophoretic separations of proteins. Increased level of understanding and optimization of widely-used technique.
- Developed a UV laser-scanning confocal microscope to explore photophysics, photochemistry, and dynamical behavior of single molecules in various materials and local environments through the use of fluorescence spectroscopy and polarization anisotropy measurements.
- Published 5 papers in refereed journals and conference proceedings and made or contributed to 4 oral and poster presentations.

TEACHING EXPERIENCE

Faculty Research Associate, University of Maryland, College Park, MD **2007 - Present**

- Laboratory Instructor for General Bioanalytical Chemistry Laboratory (~12 students), including separate discussion class in the Science in the Evening post-baccalaureate program designed to prepare students for medical, dental, veterinary, biotech/biosciences graduate programs and professional advancement.
- Topics include an introduction to the physical aspects of chemistry; chemical kinetics, thermodynamics, electrochemistry, and analytical chemistry with an emphasis on bio-analytical instrumentation and techniques.
- Leverage use of Blackboard and Web based interaction technologies as instructional tools in and out of the classroom to increase student involvement and efficiency of quality communication.

Adjunct Lecturer, Montgomery College, Germantown, MD **2003 - 2004**

- Primary Instructor for Basic Chemistry Lecture and Introduction to Chemistry Lecture and Laboratory (~35 students each) at an urban community college with diverse student demographics, backgrounds, and abilities.
- Topics included fundamental chemical mathematics, computational methods, metric system, matter, energy, chemical and physical properties, laws of conservation of mass-energy, foundations of atomic theories, elements, compounds, formulas, and stoichiometry. Laboratory work dealt with practical skills and techniques such as weighing, using units of metric system, and performing experiments that illustrated and reinforced the principles discussed in Lecture.

Visiting Lecturer, Michigan State University, East Lansing, MI **2000 - 2001**

- Taught multiple sections (1410 total students) of an Introductory Chemistry class in a 432-student lecture setting at a Carnegie Research Level I Institution, including separate recitation classes.
- Topics included atoms, molecules, ions; chemical calculations; reactions, energy changes; gases; periodic properties of elements; chemical bonds; states of matter, solutions; acids and bases; aqueous reactions and ionic equations.
- Completed several Michigan State University Teaching Assistant Program workshops and Michigan State University/Lilly Teaching Seminars to improve teaching skills.

Adjunct Lecturer, Saginaw Valley State University, University Center, MI **2000 - 2001**

- Primary Instructor for two Basic Chemistry classes (~40 students each) at a regional four-year university with students from a wide range of backgrounds and abilities.
- Topics included an introduction to general chemical principles: periodic properties, fundamental chemical calculations, formulas, equations, bonding, and nomenclature.

Adjunct Lecturer, Lansing Community College, Lansing, MI **2001**

- Primary Instructor for a General Chemistry class (~30 students) at an urban community college.
- Topics included measurement, aqueous reactions, stoichiometry, thermochemistry, atomic structure, bonding, and acids and bases. Provided an in-depth introduction to general chemistry for students who planned careers in the health professions, physical sciences, biological sciences, or engineering.
- Implemented email and other internet/computer technologies as instructional tools in the classroom through the participation in several Lansing Community College Center for Teaching Excellence workshops.

Graduate Teaching Assistant, Michigan State University, East Lansing, MI **1995 - 2000**

- Taught in the University curriculum including recitations in General Chemistry I and II. Major curriculum classes included recitations and laboratories in Introductory Analytical Chemistry, Introductory Analytical Instrumentation, Advanced Analytical/Physical Chemistry I and II. Supervised undergraduate level students.
- Awarded merit level teaching assistant rating as one of the top 10% of graduate assistants in the Department of Chemistry.

EDUCATION

Certificate, Public Health, Georgetown University, Washington, DC **2008**

Selected as part of charter cohort to complete Certificate in Public Health through Georgetown University and the Food and Drug Administration, Center for Drug Evaluation and Research.

- Course work included:
  - Health Services Administration & Policy
  - Basic Statistical Methods
  - Epidemiology
  - Human Behavior & Science
  - Environmental Health

Ph. D., Analytical Chemistry, Michigan State University, East Lansing, MI **2001**

- Awarded Meritorious Teaching Assistant and College of Natural Science Fellowship.
- Published 6 papers in refereed journals and conference proceedings. Made 9 oral and poster presentations, including 2 invited talks.

B.S., Chemistry, Wayne State University, Detroit, MI **1995**

- Awarded Herman & Perry Feigenson Scholarship in Chemistry, Henry M. Selden Scholarship in Chemistry, Albert Feigenson Award in Chemistry and Wayne State University Merit Scholarship.
- Published 3 papers in refereed journals. Made or contributed to 2 poster presentations.

PROFESSIONAL MEMBERSHIPS AND SERVICE

American Association of Pharmaceutical Scientists (AAPS), Member
Sigma Xi Scientific Research Honor Society, Member
American Chemical Society (ACS), Member
Mortar Board Senior Honor Society, Member and Trustee

ADDENDUM – PRESENTATIONS

1. *Invited* - Me. "Presentation Title." Rockford College, Rockford, IL, February, **2010**.
2. *Invited* - Me. "Presentation Title." Rockford College, Rockford, IL, February, **2010**.
3. *Invited* - Me. "Presentation Title." University of Maryland, College Park, MD, May, **2009**.
4. *Invited* - Me. "Presentation Title." Saginaw Valley State University, University Center, MI, October, **2008**.
5. These people, Me, and those people. "Presentation Title." Exploring the Proteome II Symposium, Bethesda, MD, May **2003**. Poster #X.
6. These people, Me, and those people. "Presentation Title." Experimental Biology 2003 –Translating the Genome, San Diego, CA, April **2003**.
7. Me and those people. "Presentation Title." 225th American Chemical Society National Meeting, New Orleans, LA, March **2003**. PMSE-XXX
8. These people, Me, and those people. "Presentation Title." Biophysical Society 47th Annual Meeting, San Antonio, TX, March **2003**.
9. *Invited* - Me. "Presentation Title." National Institute of Standards and Technology, Gaithersburg, MD, April **2001**.
10. Me and some other person. "Presentation Title" 220th American Chemical Society National Meeting, Washington, DC, August **2000**. PHYS-XXX.
11. *Invited* - Me. "Presentation Title." Advanced Micro Devices, Sunnyvale, CA, March **2000**.
12. These people, Me, and those people. "Presentation Title."219th American Chemical Society National Meeting, San Francisco, CA, March **2000**. PMSE-XXX.
13. Me and some other person. "Presentation Title" 219th American Chemical Society National Meeting, San Francisco, CA, March **2000**, ANYL-XXX.
14. These people, Me, and those people. "Presentation Title." SPIE – International Society of Optical Engineering International Microlithography Conference, San Jose, CA, February **2000**.
15. These people, Me, and those people. "Presentation Title." American Institute of Chemical Engineers Annual Meeting, Dallas, TX, November **1999**.
16. These people, Me, and those people. "Presentation Title." SPIE – International Society of Optical Engineering International Microlithography Conference, Anaheim, CA, February **1999**.
17. Me and some other person. "Presentation Title" 49th Pittsburgh Conference and Exposition, New Orleans, LA, March **1998**. XXX.
18. Me and some other person. "Presentation Title" 213th American Chemical Society National Meeting, San Francisco, CA, April **1997.** ANYL-XXX.

ADDENDUM – PUBLICATIONS

1. These people, Me, and those people. "Title." In Applications of Scanned Probe Microscopy to Polymers ACS Symposium Series #897; James D. Batteas, Chris A. Michaels and Gilbert C. Walker, Eds.; American Chemical Society: Washington, DC, **2005**; XX.
2. These people, Me, and those people. "Title." *Appl. Phys. Lett.*, **2004**, *85* (8), XXXX
3. Me and those people. "Title." *Polym. Mater. Sci. Eng.*, **2003**, *88*, XXX.
4. These people, Me, and those people. "Title." *AIP Conf. Proc.* **2003**, *680* (1), XXX.
5. These people, Me, and those people. "Title." *J. Vac. Sci. Tech. B.*, **2002**, *20* (1), XXX.
6. Me and those people. "Title." *J. Phys. Chem. A.*, **2001**, *105* (28), XXXX.
7. These people, Me, and those people. "Title." *Inorg. Chem.*, **2000**, *39* (7), XXXX.
8. These people, Me, and those people. "Title." *Polym. Mater. Sci. Eng.*, **2000**, 82, XX.

9. These people, Me, and those people. "Title." *Proceedings of SPIE – International Society of Optical Engineering Advances in Resist Technology and Processing XVII*, **2000**, *3999*, XXX.
10. These people, Me, and those people. "Title." *Proceedings of SPIE – International Society of Optical Engineering Advances in Resist Technology and Processing XVI*, **1999**, *3678*, XXX.
11. These people, Me, and those people. "Title." *Inorg. Chem.*, **1999**, *38* (25), XXXX.
12. Me and those people. "Title." *J. Phys. Chem. A.*, **1999**, *103* (8), XXX.
13. These people, Me, and those people. "Title." *Inorg. Chem.*, **1995**, *34* (1), XXX.

Uwont Rgrt, Ph.D.

1234 Beautiful Terrace
Silver Spring, MD 20906

336-abc-defg (mobile)
iamthebest@live.com

SUMMARY OF QUALIFICATIONS

- Effective at achieving individual and team goals
- Frequent presenter at journal clubs and scientific meetings
- Wrote and edited a research grant ad manuscripts for peer-reviewed journals
- Research skills include microbiological techniques, cell culture, microscopy, endotoxin assays, and biochemical and molecular biological approaches

EDUCATION

Ph.D., Microbiology and Immunology, 2007
Wake Forest University Graduate School of Arts and Sciences, Winston-Salem, NC
Dissertation: "Roles of Nontypeable *Haemophilus influenzae* Lipooligosaccharide Composition in Endotoxic Potency and Bacterial Biofilm Phenotypes"
Dissertation Advisor: Work Ismilif, Ph.D.

B.S., Biology, *magna cum laude*, 2002
Bennett College, Greensboro, NC

LEADERSHIP EXPERIENCE

Member, Fellows Retreat Planning Committee, National Institute of Dental and Craniofacial Research/NIH, Bethesda, MD, September 2007-April 2008

- Planned professional development activities for retreat attendees
- Aided in organizing event agenda
- Arranged, compiled, and edited abstract booklet materials

Basic Science Representative, NIH Fellows Committee, January 2008-Present

- Discuss issues of interest to NIH fellows
- Promote upcoming seminars and workshops to the postdoctoral community
- Planned and moderated a career development workshop
- Leading and coordinating a judging panel for a scientific abstract competition

RESEARCH EXPERIENCE

Postdoctoral Research Fellow, NIH/National Institute of Dental and Craniofacial Research, Bethesda, MD, August 2007-present

- Determine how formation of multispecies bacterial communities affects gene regulation of individual participants

Graduate Student, Wake Forest University Health Sciences, Winston-Salem, NC, 2002-2007

- Defined the impact of *Haemophilus influenzae* endotoxin alterations on endotoxic potency, and on biofilm formation and maturation

Summer Research Fellow, Howard University Graduate School, Washington, D.C., Summer 2001
- Studied the effects of propylthiouracil on mouse olfactory bulb protein expression

Summer Research Fellow, Purdue University, West Lafayette, IN, Summer 2000
- Tested the effects of a genetic mutation in *Arabidopsis thaliana*

FELLOWSHIPS AND AWARDS
4th American Society for Microbiology Conference on Biofilms Student Travel Grant, 2007
Biofilms Summer Workshop Student Travel Grant, Center for Biofilm Engineering, 2006
Ruth Kirschstein Predoctoral Fellowship (F31), NIH, 2005-2007

PROFESSIONAL TRAINING
Real Time and Quantitative PCR Course Participant, Foundation for Advanced Education in the Sciences, Bethesda, MD, 2008
Biotechnology Techniques Course Participant, Foundation for Advanced Education in the Sciences, Bethesda, MD, 2007
Biofilms Summer Workshop Participant, Center for Biofilm Engineering, Montana State University, Bozeman, MT, 2006
American Physiology Society Short Course on Writing and Reviewing for Scientific Journals Participant, Orlando, FL, 2005

PRESENTATIONS
Selected Conference Abstracts
Me and Some Other Person. Abstract Title. 4th ASM Conference on Biofilms. Quebec City, Quebec, 2007.

Me and Some Other Person. Abstract Title. 1st Annual NIH National Graduate Student Research Festival. Bethesda, MD, 2006.

Me and Some Other Person. Abstract Title. 105th ASM General Meeting. Atlanta, GA, 2005.

Me and Some Other Person. Abstract Title. 104th ASM General Meeting. New Orleans, LA, 2004.

Invited Talks
Presentation Title. Mid-Atlantic Microbial Pathogenesis Meeting. Wintergreen, VA, 2007.

Presentation Title. North Carolina Branch ASM Meeting. Raleigh, NC, 2004.

PROFESSIONAL AFFILIATIONS

- American Society for Microbiology, 2003-Present

COMMUNITY SERVICE

Biology Textbook Reader for Recording for the Blind and Dyslexic, NIH Chapter, Fall 2007

PUBLICATIONS

These People, **Me**, and Those People. Title. *Infection and Immunity.* 2008 (76): XX-XX.

These People, **Me**, and Some Other Person. Title *Journal of Bacteriology*. 2007 (189): XX-XX.

Me and Those People. Title. *Infection and Immunity*. 2006 (74): XX-XX.

Manuscripts in Preparation

Me and Those People. Title. To be submitted to *Infection and Immunity*.

Some Other Person, **Me,** and Those People. Title. To be submitted to *Infection and Immunity*.