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Institute for Pharmaceutical Industry Fellowships

CAREER OPPORTUNITIES FOR PHARMACISTS AND THE PHARMACEUTICAL INDUSTRY

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PHARMACISTS AND THE PHARMACEUTICAL INDUSTRY

Today's pharmacy graduates have numerous career options. Traditionally, pharmacists have used their clinical knowledge in a variety of practice settings, including community pharmacies and hospitals. However, there are also many significant, alternative career opportunities within the pharmaceutical and biopharmaceutical industries. The extensive clinical training provided by the Pharm.D. degree program has helped to expand the pharmacist's roles and responsibilities within the industry.

The pharmaceutical industry now offers a wide variety of comprehensive experiences set in a dynamic corporate environment that allow pharmacists to apply clinical skills in innovative and exciting ways to improve patient healthcare. Employment in the pharmaceutical and biopharmaceutical industries setting provides opportunities for professional development and growth, lateral and upward mobility, and the opportunity to display and be recognized for one's unique professional expertise. Opportunities to collaborate with experts in multidisciplinary project teams further enhance the value and scope of the pharmacist's role. With advances in medical technology, the pharmaceutical and biopharmaceutical industries are constantly expanding efforts to discover, develop, and market new medicines, thereby creating more employment opportunities for pharmacists. This brochure provides information regarding some of today's popular industry career paths for pharmacists.

Early Phase Clinical Development

Early Phase Clinical Development encompasses research from pre-clinical studies through phase I-II trials of the drug development process. These trials are the first time an exploratory compound is studied in a human population and are commonly known as "first in human" trials. As a clinical research scientist, pharmacists assume lead roles in

- Implementing and managing clinical trials
- Authoring study protocols
- Selecting primary investigators and trial sites
- Ensuring proper data collection and interpretation
- Determining the best dose of the medication for later studies
- Reporting serious adverse events
- Publishing clinical study reports and manuscripts

As leaders of multidisciplinary teams, pharmacists in Early Phase Clinical Development liaise closely with various other departments, such as 1) Regulatory Affairs, 2) Data Management, 3) Drug Supply Management, 4) external contractors, and 5) Pre-clinical Safety Scientists.

With broad clinical backgrounds and knowledge of the drug development process, Pharm.D. graduates are well suited for Clinical Development. Opportunities in Early Phase Clinical Development exist in Clinical Pharmacology, Translational Medicine, Clinical Operations, and Contract Clinical Research Organizations.

Late Phase Clinical Development

Late Phase Clinical Development encompasses research from phase II and III human trials of the drug development process. A pharmacist acting as a clinical trial leader in Late Phase Development experiences many of the same challenges facing those in Early Phase Development, however, on a much broader and more global scale.

Pharm.D.s are well suited to assume a role in Late Phase Development as they have an extensive breadth of knowledge in

- Pharmaceutical product utilization
- Treatment modalities
- Pharmacokinetic/dynamic relationships
- Drug-drug interactions

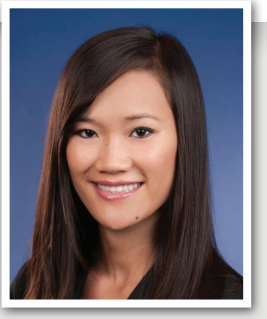
The aforementioned skills enable pharmacists to contribute to the development and implementation of complex study designs that are typically required at this stage of drug development.

Pharm.D.s in Late Phase Development have the opportunity to showcase their skills by

- Planning investigator meetings
- Chairing international clinical trial team meetings
- Overseeing deliverables from various external contractors

Combined with a strong scientific background, key skills necessary for a career in Late Phase Clinical Development include excellent organizational, writing, communication, and presentation abilities.

An Interview With: Tuong Vi Nguyen, Pharm.D. – Novartis Fellow 2013-2015



Q: What attracted you to Clinical Research for your fellowship and as a prospective career choice?

A motivation to be comprehensively involved in drug development is what drove me to pursue a career in the pharmaceutical industry. Clinical Development is a dynamic and fascinating functionality that interfaces with talented individuals in a variety of roles. I think clinical research experience provides a solid foundation for a great career in the pharmaceutical industry. It cultivates a fundamental and intricate understanding of clinical trials and fosters essential project management skills.

Q: How does having a Pharm.D. help you to excel in your current position?

The Pharm.D training provides you with the skills necessary for clinical research: a strong foundation in basic and clinical sciences tied with an emphasis on patient-centered care. The Clinical Development fellowship not only utilizes our clinical and analytical skills, but also offers a robust set of trainings to develop project coordinating skills essential to working within a highly matrixed pharmaceutical environment. I have the privilege of working in an intellectually stimulating environment where I am continually building on my clinical and technical knowledgebase.

Q: What advice can you give to someone seeking a fellowship or career in Clinical Research?

There is an old saying that when choosing your career, you should think about what you would do if you didn't have to work! I had the opportunity to complete a research internship during pharmacy school – a great experience that led me to pursue a career in drug development. I would advise prospective candidates to proactively seek research experiences within their academic institution.

Q: How has the fellowship changed not only your professional but also your personal life?

I have met so many talented individuals in the fellowship as well as experts of medicine and science at Novartis who have challenged me to learn something new, to be bolder and to think outside of the box.

Q: What has been the "stand out" moment so far for you in your fellowship?

I had the opportunity to take the lead on the preparation and presentation of a novel study concept to our scientific board. It was nerve-wracking but fortunately I had a very supportive team that guided me through the process.

Commercial Functions, Including Marketing

The Marketing department is responsible for strategic and tactical implementation of the advertising and promotion supporting a company's products. The overall goal of marketing is to develop programs that drive healthcare providers' awareness of products and promote optimal medication utilization. Tactics include promotional activities, such as

- Creating sales materials and product advertising
- Organizing and creating strategies and tactics to support the life cycle of the product

The Marketing Research/Business Analytics department is also an important group within the commercial team. This department acquires information from various sources outside of the company to create an overall market "snapshot." With this information, Business Analytics supports Marketing in developing a clear and targeted message to appropriate physicians, patients, and third party payors. A Pharm.D. in Market Research/Business Analytics generally helps to:

- Analyze past and present market data to monitor current and future trends
- Forecast market trends
- Create patient population evaluation models
- Identify unmet medical needs

Pharmacists also make strong team members in the Managed Markets group. While working in Managed Markets, a Pharm.D. helps to develop strategies to evaluate the value of a product and to help optimize reimbursement from third-party payors or insurance companies. The Managed Markets group works to promote optimal medication use and enhance product market share versus competition. In addition, Managed Markets also works to improve overall resource management, the company's pipeline of products in development, and overall healthcare quality.

An Interview With: Keith Fairall, PharmD. – Janssen Fellow 2013-2015

Q: What attracted you to Business Analytics for your fellowship and as a prospective career choice?

I was intrigued by Business Analytics for a fellowship and career due to the strong integration of both clinical and business focus. Pharmacists are well equipped to offer the clinical expertise beneficial to this role, but also bring value through strategic planning and understanding of drivers in the marketplace.

Q: What advice can you give to someone seeking a fellowship or career in Business Analytics?

Individuals wishing to pursue a fellowship or career in Business Analytics should have interest beyond clinical understanding of the products. A passion for learning about how pharmaceutical businesses operate and remain profitable, while still placing patient needs as top priority will be important in this role. I advise anyone with interest to increase their knowledge on the role of 'analytics' in the work place and strive to identify common measures that companies use to indicate product success. If possible, seek an internship with a pharmaceutical company to gain better understanding of the analysis behind business operations.

Q: How has the fellowship changed not only your professional but also your personal life?

The fellowship has opened many doors within the pharmaceutical industry that I could never have expected. I have great exposure and leadership opportunity on company projects relating to my role, but also develop professionally through training offered by Rutgers. My experience has made me more confident in my skills and abilities to operate in the corporate world and improved my communication skills across the board. Offering an excellent opportunity for growth, the fellowship has provided a strong foundation for my future career in the pharmaceutical industry and helped me to identify both professional and personal goals.

Medical Communications/ Education/Information

Pharmacists in the Medical Communications/Education/ Information department utilize their clinical knowledge in the development of content for healthcare-related publications, meetings, and digital media for an array of audiences, including healthcare professionals and consumers. In this role, pharmacists

- Critically analyze and evaluate evidence-based medicine
- Plan and implement continuing education programs and materials
- Collaborate and network with key opinion leaders (KOLs) from industry, managed care, and academia to create promotional and educational programs
- Manage client expectations while effectively integrating key messages into programs for healthcare professionals
- Act as a key member in the development of publication plans
- Respond to external inquiries from patients and/or healthcare professionals
- Create and manage question-response databases for marketed products

In addition, a Pharm.D. in the field of Medical Communications can also be involved in confirming the accuracy and scientific quality of abstracts, posters and oral presentations of high level clinical data for presentation at various conferences and congresses both nationally and internationally.

In this role, a Pharm.D. works closely with 1) Brand Medical Directors, 2) Clinical Development teams, 3) Biostatistics, 4) Product Strategy teams, 5) Marketing, 6) Legal/Compliance, and 7) Field Medical teams.

Drug Regulatory Affairs

Drug Regulatory Affairs is "the professional discipline consisting of the knowledge of the regulations, guidelines, policies, and precedents governing the discovery, development, manufacturing, governmental approval, commercial distribution, advertising and promotion of medicinal products." Pharm.D.s working in Drug Regulatory Affairs (DRA) have the opportunity to participate in large US and global cross-functional project teams in nearly all aspects of the drug development process. DRA associates are able to track the progress of a product and gather key learnings from Health Authority interactions to guide the project team on how to file and conduct trials for a drug program, register a product and gain approval. A pharmacist in Regulatory Affairs may

- Develop and provide Regulatory strategy
- Create and compile submissions to Health Authorities including Investigational New Drug (IND) Applications and New Drug Applications (NDA)
- Interact with FDA (Food & Drug Administration) and Global Health Authorities such as the EMA (Europe) and MHW (Japan)
- Lead Health Authority Communications related to FDA Meetings and Advisory Committee Meetings
- Develop and revise labeling
- Review and approve advertising and promotional material
- Maintain approved products through IND and NDA Annual Reports, DDMAC submissions, labeling and line extensions

A position in Regulatory Affairs provides exposure to drug development activities and a unique opportunity to utilize one's clinical pharmacy skills.

An Interview With: Meena Ramachandra, Pharm.D. – Bayer Fellow 2013-2015

Q: What attracted you to Regulatory Affairs for your fellowship and as a prospective career choice?

Choosing my fellowship position was not something that I determined arbitrarily or dreamt of overnight, rather it was a culmination of my rotational and work experiences that solidified the focus of the position I wanted to pursue. I was in search of an outlet for which I could apply my clinical knowledge to a bigger picture and contribute to the process of developing an unnamed molecule in a lab to a medication or drug that would reach the hands of those who truly need it. What attracted me most to this functional area is the fact that regulatory professionals are involved in all phases of drug development and are constantly working cross-functionally. Whether it is offering input on clinical trial design, reviewing advertising and promotional material, or corresponding with health authorities, Regulatory Affairs professionals can bring value to an organization in a diverse number of ways.

Q: What advice can you give to someone seeking a fellowship or career in Regulatory Affairs?

No matter how much research you do online or how many brochures you read, the best way to learn about a career in Regulatory Affairs is to talk to those who live and breathe it day in and day out. By hearing people's experiences, you can determine it is the right fit for you. In Regulatory Affairs, priorities and business needs can change in an instant. You may never experience a "typical day" or may have a workload that is constantly fluctuating. Flexibility, interpersonal skills, and attention to detail are all traits that will help you succeed in Regulatory Affairs.

Q: What has been the "stand out" moment so far for you in your fellowship?

The opportunities and projects that I have been involved with during my fellowship have been amazing each in a unique way. However, a "stand out" moment that I experienced very early on during my fellowship was when I was sitting at home eating dinner and watching TV. While I usually jump for the remote and try to fast forward through commercials, this time, a huge smile erupted on my face as I watched a commercial that I had been reviewing from concept/design to implementation. Watching that commercial and remembering all the discussions and work that went into this piece reminded me of how the work you do in the industry has to potential to reach millions of people.

Medical Science Liaison

Medical Science Liaisons (MSLs) are therapeutic specialists who coordinate the communication of clinical information between pharmaceutical companies and medical experts in the field. An advanced degree (eg, MD, PhD, or Pharm.D.) is usually required to obtain a position as an MSL. The majority of MSLs hold a Pharm.D. degree. Depending on the company, the MSL can have many different titles (e.g., medical science managers, medical information scientists, regional scientific managers).

The MSL is a field-based associate who collaborates with and communicates information to

- The sales force
- Practitioners in the field
- Clinical trial investigators
- Internal stakeholders
- Managed Markets teams

Generally, the MSL reports to the medical department. Specific functions of the MSL include developing and cultivating relationships with experts, training speakers and the sales force, providing medical information support, and developing educational programs.

Overall a pharmacist is well suited for a career as an MSL, as it requires one to be able to clearly and effectively communicate an extensive amount of clinical knowledge to other healthcare professionals. MSLs are also expected to build relationships with many individuals in the healthcare field, as they are often seen as the "face" of the company out in the field. Pharm.D.s bring an extensive range of scientific knowledge to the MSL position, including their ability to learn and understand aspects of various therapeutic areas.

Medical and Scientific Affairs

Pharmacists in the Medical and Scientific Affairs department develop and coordinate the implementation of medically accurate and credible medical education programs and serve as scientific resources to communicate product information to external customers via various promotional and educational programs. A Pharm.D. in Medical and Scientific Affairs

- Provides expertise on global life cycle management
- Collaborates with Global Brand Medical Directors and their teams
- Integrates data from internal and external sources into actionable information for clients
- Reviews and approves promotion and advertising from a medical perspective in compliance with FDA regulations

At certain companies, Pharm.D.s in Medical Affairs also have the opportunity to develop and manage Phase IV trials, know as "post-marketing studies." These trials include

- Post-marketing safety or "pharmacovigilance" studies
- Investigator Sponsored Studies (ISS)
- Expanded label studies
- Alternate dosing or scheduling studies
- Unique patient population studies

Pharmacists' extensive understanding of drug products prepares them to identify and understand a product's potential impact in the "real world" as opposed to what was seen previously in controlled trials.

An Interview With: Will Jackson, Pharm.D. – Bristol Myers Squibb Fellow 2013-2015

Q: What attracted you to Medical Affairs for your fellowship and as a prospective career choice?

Medical affairs represented a unique opportunity to apply the clinical knowledge I gained from pharmacy school. In Medical Affairs, I've supported brands by being the medical information expert creating medical letters to health care professionals. In addition, I've been out speaking and educating doctors on new drug therapies. The best part about Medical Affairs is the ability to have different opportunities to work in various roles throughout one's career. I've always been energized by being a part of innovative medicine, and Medical Affairs allows me to do that in many different ways.

Q: How has the fellowship changed not only your professional but also your personal life?

The fellowship has given me confidence to pursue things I did not think I could accomplish. I've always enjoyed research, but I never moved forward into publishing anything. The fellowship has a large emphasis on scholarly activity, and they provide the resources to succeed. I met with Dr. Toscani and Dean Barone on multiple occasions to discuss research and publication potential. With their support, I've finished the first draft of a manuscript that I will be submitting to a journal. It has been a huge personal success to pursue this project.

Q: What has been the "stand out" moment so far for you in your fellowship?

My stand out moment has to be when I was meeting a doctor in San Diego to discuss clinical trials. Part of my fellowship as a Medical Scientist Liaison requires me to travel and meet with various health care professionals and scientists. At this point in my fellowship, my mentors in the program began to push me to take the lead in a lot of these interactions. I was speaking with major thought leaders in their respective therapeutic areas. It was in San Diego that I realized how much I've grown in knowledge and confidence to be able to speak with such major thought leaders. It was also the point I realized how far I've come in my professional development since the beginning of the fellowship.

Drug Safety and Risk Management

Throughout the development lifecycle of a pharmaceutical product, the Drug Safety Department assumes responsibility for ensuring that a product will be marketed and used in a safe and effective manner. Pharm.D. graduates have found a niche in this department by

- Evaluating a product's safety profile throughout its development and into its post-marketing stage
- Participating in clinical development team discussions relating to adverse events
- Integrating information from pre-clinical safety trials to ongoing trials
- Contributing to ongoing safety documents submitted to health authorities
  - Periodic Safety Reports (post-marketing)
  - Annual Safety Report (submitted to the EMA)
  - IND Annual Report (FDA equivalent to the above report)
  - REMS (Risk Evalution and Mitigation Strategy) and RMP (Risk Management Plan)

In this role, pharmacists have the ability to project their broad knowledge of pharmaceutical products onto study findings and to help guide compound development. With the keen eye of a pharmacist, vital decisions, such as determining a drug's maximally tolerated dose or appropriate populations to be studied, can be made in a safe and objective manner.

Health Economics and Outcomes Research

The Health Economics and Outcomes Research (HEOR) group helps to identify, measure, and compare the costs and consequences of health-related courses of action to assign a "perceived" value to a pharmaceutical intervention. The value proposition is integral to determining the price of pharmaceutical products. A lengthy analysis is performed before any conclusions are reached, and it is during this data analysis that a Pharm.D. can make a significant contribution. Pharmacists are no stranger to clinical and economic data, and can assist in the analysis of a drug product's

- Prospective and retrospective clinical data
- Competitive pricing (Red Book-USA, Drug Tariff-UK)
- Quality of life (QOL) and quality-adjusted life-years (QALYs) data

Once these important data are reviewed, a Pharm.D. in HEOR can create tools to help guide a product's pricing. This analysis can be used by many agencies to

- Compare the economic effect of two or more drug products
- Assist in the development of drug formularies
- Develop national or international clinical practice guidelines

For more information, scan this QR code.

Conclusion

The career paths described are representative of the many exciting possibilities that await pharmacists entering today's pharmaceutical and biopharmaceutical industries. Additional areas of concentration include Business Intelligence, Consumer Health, Promotion Compliance, Policy & Advocacy, R&D Strategy and Analysis, and many others.

With a career in the pharmaceutical industry, a pharmacist has an unparalleled opportunity to make a significant contribution to the development and delivery of medicines to patients around the world. The pharmacist's role in industry has evolved from traditional areas of sales and manufacturing, and currently encompasses a wide array of clinical, medical, and marketing functions. Frequently, positions sought by pharmacists in the pharmaceutical industry require additional postgraduate training, which can be obtained through participation in a fellowship or residency program. Individuals interested in a career in industry are encouraged to research and consider carefully the available postgraduate training program options to help them make informed career choices with respect to the pharmaceutical industry.

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