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: Vani Kumaran, Pharm.D. — Pfizer Consumer Fellow 2014-2016

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

A: Throughout my time at Rutgers, I took advantage of research opportunities. Once I was in my P3 year, I started to carefully evaluate the options available to me for a career and where I wanted to begin. I was fortunate and had colleagues who were already in the fellowship program who told me about FIND (Fellowship Information Networking Day) and spoke to a few individuals in Clinical Research, Clinical Development, and Medical Affairs while I was there. From there, I did my research and that launched my career in Clinical Development.

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

A: My role essentially designs, executes, and interprets the results of several types of clinical trials for new formulations, claims, and brings products from the Rx side to OTC in the US. The Pharm.D. degree is tremendously important in my field as we must design studies for products across all different therapeutic areas and consider drugs that must be excluded, the pharmacology, pharmacokinetic profile, and metabolism of these drugs with respect to our innovation product. Clinicians are also responsible for communicating such data to several different audiences which include leadership within the company, investigators, and reviewing documents that will ultimately be read by the patient. The Pharm.D. helps with communication skills as engagement among healthcare professionals and patients is practiced during pharmacy school and applied daily in the field and with key players in clinical studies.

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

A: I think it is very important to ask as many questions about the role, challenges, development, and culture throughout the experience of a candidate. Specifically for Clinical Research, read about the role through job descriptions online and in our company brochures. Listen to the webinar provided by RPIF, which is a resource I wish I had when I was applying to fellowships. Continuously evaluate what you want out of your postdoctoral experience when meeting with fellows and colleagues. After FIND, I made a list of 6 companies that I wanted to apply to and wrote down who I had met and what resonated with me.

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

A: Currently I serve as the clinician on one of our global clinical programs and it has been a spectacular and unique professional experience. My “stand out” moment so far has been the opportunity to present and discuss these studies with the head of our group and receive positive feedback on the work that I have put into this program.
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.


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

A: I pursued the business analytics fellowship because it offered opportunities that directly related to my career goals. My interest in the commercial space came from an internship opportunity in the pharmaceutical marketing sector. This opportunity gave me an initial understanding and appreciation for core skills that I am now robustly refining and further developing as a business analytics fellow. Performing competitive analyses and insight gathering for strategic decision-making are among some of the skills I hope to leverage to continue to seek innovative opportunities in the commercial space.

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

A: The core of the fellowship and a career in business analytics-related functions lies in the ability to be a strategic and quick thinker. Although the daily functional aspects can be learned, an individual who will truly shine in this field is one who is innately inclined to think outside-the-box. Being able to look at data or pieces of information from numerous angles and generate concise yet powerful insights that are truly actionable is a powerful talent in this field. Individuals seeking this position should have a passion and interest in learning about business intelligence, market research, and other business analytics functions.

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

A: It would probably take several pages for me to describe every single way that the fellowship has impacted my life thus far. However, one of the major benefits is the incomparable amount of networking opportunities it has provided. Not only have I been given a consistent opportunity to interact with a multitude of business partners and fellows (who will ultimately become my professional colleagues), but I have also been able to network with a variety of professionals across the industry, with many outside my immediate partner company. Furthermore, the fellowship has allowed me to learn and understand myself better in terms of my career plans and personal goals. Broadly, I would say that through the experiences in the Rutgers fellowship program, I have come to better understand what my interests are and where I see myself in the future, both professionally as well as personally.
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, FDA 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: Daphne Torre, Pharm.D. – Genentech Fellow 2014–2016

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

A: Healthcare has immensely evolved in the past decade, especially with the new technologies that this generation brings. Because of all the changes in healthcare, the regulations and processes for drug approvals have advanced as well. For me in particular, I wanted to see and experience how drugs go through the development and approval process in the United States. Additionally, I wanted to get perspective on how this same process is handled in countries outside of the US. The cross-functional collaboration and teamwork that happens across many departments was another aspect that attracted me to this role.

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

A: First and foremost, do your research. I have realized throughout my fellowship that there are many different sub-sections within Regulatory, so it is important to know the different types and where your interests lie. Second, know why you want to do a Regulatory Affairs fellowship—some can say that this field is a bit of a niche for pharmacists but there is great value for us in this department allowing us to showcase our clinical expertise. Third, know what type of fellowship you are seeking and be mindful of what experience you are looking to get. Lastly, reflect upon what skills you possess that would make you a good candidate for a Regulatory Affairs fellowship, as this will be key during interviews.

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

A: On the work side of things, I would say the “stand out” moment has to be experiencing and attending a meeting with one of the divisions at the FDA a few months ago. It was a great learning experience and went far beyond my expectations. But on the fellowship side of things, I have met some amazing people throughout my fellowship, even despite being on the West Coast, and am truly grateful for all the connections and memories.
Medical Science Liaison

Medical Science Liaisons (MSLs) are therapeutic specialists who coordinate the communication 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: Nik Borodin, Pharm.D. - Bristol-Myers Squibb Fellow 2014-2016

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

A: The Virology Medical fellowship provides a unique opportunity in the fast-paced, expanding Therapeutic Areas of HIV and Hepatitis C. The first year in medical information allows you to optimize the skills learned in pharmacy school by writing standard response letters, responding to HCP questions about your drug, and reviewing promotional pieces for medical accuracy. Building off the core skills acquired during your first year, the second year in medical strategy allows you to become a medical expert in the challenging field of HIV. This fellowship also provides a very unique clinical rotation opportunity in an HIV clinic where the fellow is allowed to round with the doctors, make clinical interventions and counsel patients on their medications. Altogether this fellowship sets you up for a wide variety of potential career choices including medical information, MSL, medical strategy/affairs and many more.

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

A: In addition to thoroughly training me to become a highly effective pharmacist and full-time employee in the pharmaceutical industry, the fellowship has also given me 100 new friends. Everyone in the program is fun, outgoing and super friendly. As soon as the fellowship started we all hit it off instantly and after just a month of knowing everyone, I felt like these had been my friends for years. Whether it is canoeing on the Delaware River, exploring the big apple, or going down the shore for the weekend, there is always a fun activity going on amongst the fellows!

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

A: Although I have been presented with numerous “stand out” moments during the fellowship, whether it be leading the planning of medical conferences, running advisory boards or presenting valuable research at a major conference; one moment I would call specifically would be the CE presentation I gave at Bristol-Myers Squibb. This unique opportunity allowed me to give a CE credit presentation to not only my co-fellows but also many pharmacists at Bristol-Myers Squibb. By both increasing my presentation skills and also expanding my network immensely at the same time, this event is one of many opportunities that this prestigious program has provided me that will most definitely help to jump start my career in the pharmaceutical industry.
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 Evaluation 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
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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