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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.

The Pharmaceutical Industry CAREER OPPORTUNITIES FOR PHARMACISTS



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: Justin Dennie Pharm.D. — Merck Fellow 2009-11

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

A: Throughout my pharmacy school curriculum, the two classes that represented the core of pharmacy to me were pharmacokinetics and pharmacology, areas which I found the most intriguing and where my passion lay. Clinical pharmacology was a natural fit for my interests, in that determining the true pharmacologic and pharmacokinetic profile of a drug in humans are the major objectives in clinical pharmacology studies. These studies include first in human studies, QTc studies, renal studies, hepatic studies, microdosing studies, just to name a few, but all contain fundamental principles in pharmacology and pharmacokinetics.

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

A: Pharmacists are very well poised for a rewarding and impactful career in clinical pharmacology, and throughout R&D for that matter. Pharmacists are trained in most of the fundamental principles in drug development (pharmacology, pharmacokinetics, medicinal chemistry etc.). We possess the communication and interpersonal skill set necessary to effectively and efficiently lead project teams. We help steer candidate compounds through Phase I studies to eventual product launch. Pharmacists are trained as generalists and our skills can truly be applied to all aspects of R&D, not just to Phase I drug development.

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

A: To excel in clinical pharmacology, it is important to rely on one's clinical pharmacy training and be open to new ideas and principles. I reflect upon my first departmental meeting where we were presented with the current company pipeline. I had recently taken the NAPLEX and thought I was an expert on anything drug or pharmacology related. I came to the harsh realization that this was not the case as I could only recognize a handful of candidate drug targets or mechanisms of action in the company's entire preclinical/ Phase I pipeline. This confirmed the notion that the pharmaceutical industry is at the cutting edge of medicine and drug development, and in order to be successful, I would have to be in a state of continuous learning and self improvement.

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 continuing medical education or consultant panels

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 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: Hiliary Johnson, Pharm.D. — Sanofi Fellow 2009-11

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

A: I selected a Marketing Fellowship because I wanted an experience where I could utilize my strong clinical background, while gaining insights into the business side of the industry. I enjoy being challenged, and getting to use my creativity to solve problems and generate innovative ideas. It's rewarding to know that by working in pharmaceutical marketing I am benefitting patients around the world by enhancing awareness and helping to find solutions to the expanding problem of diabetes and the treatment and management options that are available to help control it.

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

A: The Strategic Marketing Fellowship has provided me with a unique opportunity to apply my clinical knowledge within the commercial functions of the pharmaceutical industry. My pharmacy background and rotational experiences give me an advantage in that I understand not only the drugs, but the target customer and their needs, whether they be healthcare providers, hospitals, pharmacies or patients.

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

A: I recently witnessed the successful outcome of two live speaker training meetings I put together for 250 key thought leaders in a diabetes speaker's bureau. This was the culmination of months of hard work and interaction with multi-disciplinary teams

including medical, legal, and regulatory, as well as with outside vendors, key thought leaders, and the sales force. I was able to implement an exciting, new facilitators training workshop into the meeting that resonated very well with attendees. This was a unique opportunity for a fellow, and one that strengthened my teamwork and leadership skills. It was also very important to the business as we work to re-engage key thought leaders and increase our share of voice in the diabetes market.



Medical Communications/Education/Information | Drug Regulatory Affairs

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 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: Jerald Grace, Pharm.D. — Roche 2nd Year Fellow

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

A: Drug development has always been an interest of mine. During my last year of pharmacy school, I had the opportunity to do an industry rotation in Regulatory Affairs, where I developed labeling assessments, sat in on cross-functional team meetings and delivered presentations on current FDA hot-topic issues. I enjoyed working with other disciplines and staying abreast of the ever-changing regulatory environment. This experience is what interested me to pursue Regulatory Affairs as a career post-graduation.

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

A: My standout moment in my fellowship was when I helped my team file a New Drug Application (NDA) with the FDA. During the process, I was able to sit in on team discussions where final decisions were made for the drug's trade name, proposed labeling language and specific submission timelines. I even assisted with developing some of the documents that would go into our submission. I was able to witness firsthand the amount of time, dedication, and teamwork it takes to actually get a new drug on the market. The experience was phenomenal.

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

A: Take full advantage of all opportunities you may be presented with. Regulatory affairs offers you the potential for a vast array of assignments that will develop your overall expertise within the department. Try everything. You never know where your professional experiences will take you.

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.

Elaine Alexander, Pharm.D. — Bayer 2nd Year Fellow

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

A: I selected a Medical Affairs Fellowship because I knew it would allow me to apply my clinical knowledge and strengthen my communication skills, while developing business acumen to be successful in the pharmaceutical industry. Medical Affairs is such a large “umbrella” which has allowed me to work cross-functionally with many departments (including medical communications, drug safety, health economics, and the medical science liaison team) and truly identify my professional interests.

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

A: Having a PharmD sets the initial foundation of clinical knowledge, professionalism, and strong work ethic that are necessary to excel in the pharmaceutical industry. I interact with a team of professionals who value my ability to critically evaluate scientific data and medical literature, as well as to speak on a clinical level. These are skills that are transferrable from the classroom to the corporate environment of the pharmacy world.

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

A: Now more than ever, I believe in the power of professional networking. The Fellowship program has brought me together with so many incredible and inspiring individuals, many of whom I may never have crossed paths with otherwise. I’ve established a professional network with colleagues and have identified

several mentors who will continue to support me throughout my career. I’ve applied the same networking skills to my personal life and have made life-long friends and memories with many fellows.

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

A: Seek opportunities and don’t be afraid to try new things. There is no limit to your growth potential! Volunteer to get involved in an interesting project or take the time to rotate with another department. You may discover talents and passions that you never knew you had.



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, known 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.

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

