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THE PHARMACEUTICAL INDUSTRY: A Pharmacy Student's Guide

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STUDENT AUTHOR BIO SKETCH

Christian Egly is a fourth-year (P4) pharmacy student in the Purdue University College of Pharmacy. During his years at Purdue, he worked in labs performing bench research in clinical pharmacology and biochemistry. He plans to work in the pharmaceutical industry after graduation. During his fourth year, he completed rotations in business development at Kashiv Pharma, LLC, and was hired there for an internship in 2017. In the article, Christian describes his personal experiences at Kashiv Pharma, LLC, and how industry can positively affect patient communities.

INTRODUCTION AND BACKGROUND WITH LITERATURE REVIEW

Pharmaceutical industry positions and job descriptions are largely unknown to pharmacy students. A recent article showed that pharmacy students are aware of postgraduate training programs, such as fellowships; however, evidence shows students do not receive enough information about industry career opportunities while in pharmacy school (Audette, McGann, Horton, & Silva, 2014; Shpilfogel, Tyrrell, & Alexander, 2015a; Yung, Johal, & Pan, 2004). Despite a lack of knowledge about career opportunities, the number of fellowship positions filled each year has grown significantly. The current number of fellowships occupied by pharmacists is approaching 450-an increase from 250 positions four years prior (Alexander, Dipsia, Wells, & Singh, 2018). Departments included under fellowships are medical affairs, regulatory affairs, clinical research and development, commercial, health outcomes research, and more.

The primary purpose of this article is to describe how a career in industry is beneficial to a variety of constituents, including patients, health care providers, and students. A secondary purpose is to highlight ten primary industry positions for pharmacists. By detailing a personal experience in industry, other pharmacy students can have a better glimpse of a unique career path and what this type of work involves.

METHODOLOGY

The Industry Pharmacist Organization (IPhO), the Rutgers Fellowship Brochure (Rutgers, 2017), and other sources were utilized to summarize ten pharmaceutical industry positions for pharmacists. Details of the different areas can be found in Table 1. In addition, depending on the company, some jobs may integrate multiple departments; for example, medical information and medical affairs positions have multiple similarities.

Departments with the most fellowship positions filled by pharmacists as of 2018 are medical affairs followed by regulatory affairs (Alexander et al., 2018). Opportunities, besides those mentioned, within early clinical development include clinical pharmacology and translational medicine. Students with an interest in pharmacokinetics/pharmacodynamics (PK/PD) should look into clinical pharmacology (Goh, Alrawi, & Lozito, 2006). Translational medicine would involve bench to bedside research integrating both basic science and clinical research aspects. Firsthand experience seems to be the ideal way for pharmacy students to understand industry positions. My own personal experience at Kashiv Pharma, LLC can be seen in the next section.

STUDENT EXPERIENCE

Kashiv Pharma is located in Bridgewater, New Jersey. The company specializes in 505(b)2 products, which is an accelerated approval pathway for reformulations of current drugs. For instance, a product approved, but dosed four times a day, has the potential to be reformulated. Reformulating the product could allow for once-daily dosing and would benefit patients in terms of compliance, better pharmacokinetics, level of effectiveness, or improved safety profile. I will explain my experience from working in the market research or business development sector as a rotation student and intern.

Daily responsibilities included reading clinical trials, utilizing Intercontinental Marketing Services (IMS) data for prescription volume and sales, scanning patents, searching for other drugs in development using a program called PharmaCircleTM, and utilizing various other sources. After compiling the information, I would make a document summarizing the data in order to explain the information to other people in the company. Final steps would be to determine whether the product concept was worth pursuing or if it should be abandoned.

Here is an example of how a typical product would be evaluated. Let's call the drug Product X. Product X is currently dosed three to four times per day and has adverse side effects. Using IMS data, the product had 12 million prescriptions written last year and \$360 million in sales, which tells us there is a good market for the drug. Next, looking at clinical trial information and the package insert can give us detailed clinical information about the product. Questions to answer include:

- 1. What does the PK/PD profile look like?
- 2. How effective is the medication?
- 3. Has there been an extended release product in clinical development before?
- 4. What does the safety profile look like?
- 5. Are side effects related to peak/trough concentrations of the drug?

Answering these questions starts to delineate the product concept, which would give an impression whether Product X is capable of being improved or not.

Some surprising facts can come from a literature review. For instance, a few articles showed that extended release products previously existed for certain medications we were evaluating. The extended release product was even superior to the immediate release, but for unknown reasons, it was discontinued during development or in the post-market phase. If discontinuation occurs, it is important to determine the root cause. Was the profit from the drug not enough to sustain development? Did a company acquire a more important project? These are important questions to ask.

Once clinical trials, IMS data, and package insert data have been scoured, the competitive atmosphere must be

Molecule/API Name	contains	 clopidogrel 				0	
Clear							
₩ Column Manager 🚓 Fiter 🎒 Group Rows Pipeline & Products Intelligence Search Results - 203/203 records - 272 Product Programs							
						Product Name	Indications
Plavix Tablets - clopidogrel bisulfate Tablet(United States of America) - Iscover Zyllt(Europe) - Iscover(Japan) (<u>clopidogrel bisulfate</u>)	Myocardial Ir Stroke PAD Acute Coron: Atrial Fibrillat Thrombosis Acute Ischer Myocardial Ir Acute Coron: Acute Coron: PAD Acute Coron: PAD Atrial Fibrillat		United States of Ame Canada, United State Canada, United State Canada, United State Canada, United State Ganada, United States Japan Japan Japan Japan Japan Japan	(Sanofi-Aventis)	ORAL	· ORAL	Sanofi S.A. (Sanofi-Aventis) product owner Bristol-Myers Squibb Co. (BMS) co- development, co-marketing (United States o America, Argentina) - (Canada, Australia, China, Europe, New Ze Japan [*])
Clopidrel IV (clopidogrel bisulfate)	· Thrombosis	Pre Clinical Discontinued		Acusphere Inc. (Polymers for Medicine Inc.) (not active)	INJECTION	 NP injectable e 	m Acusphere Inc. (Polymers for Medicine Inc.) (not active) :product owner
CGT-2168 · clopidogrel bisulfate/omeprazole (clopidogrel bisulfate · omeprazole)	Acute Coron: Myocardial Ir Coronary Art			Cogentus Pharmaceutical Inc. (not active)	ORAL	- ORAL	Cogentus Pharmaceuticals, Inc. (not active) :product owner
DuoCover · Duoplavin Clopidogrel/Acetylsalicylic acid Zentva[Europe] · Plavix Protect[Brazil] · CoPlavix(Australia) · Compl: (acetylsalicylic acid · clopidogrel bisulfate)	 Acute Coron; Myocardial Ir Acute Coron; Cardiac Ische 	· Marketed	Europe, Brazil, Austra Europe Europe Japan	Bristol-Myers Squibb Co. (BMS)	ORAL	- ORAL	Bristol-Myers Squibb Co. (BMS) :product ow Sanofi S.A. (Sanofi-Aventis) :co-developmen (Europe [*] , Brazil, Australia, Japan)
Plavix Tablets, Generic Apotex clopidogrel bisulfate Tablets, Generic Apotev(Inited States of America)	Thrombosis Acute Coron: Stroke	Approved Approved Approved	United States of Ame United States of Ame		ORAL	· ORAL	Apotex Inc. :product owner (United States America)

Figure 1. A snapshot of typical Pharmacircle information for the drug clopidogrel. The site gives different phases of drug development and other information.

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Position Title	Main Roles	Detailed Responsibilities		
Early Phase Clinical Phase I–Phase IIa Development clinical trials		 Manage trials Evaluate study protocols Summarize trial findings in reports Select and collaborate with trial site, Contract Research Organizations (CROs) Safety, tolerability, Pharmacokinetics/Pharmacodynamics (PK/ PD), drug-drug and drug-food interactions, dosing, and pilot efficacy 		
Late Phase Clinical Development	Phase IIb–Phase IV clinical trials	 Manage trials Evaluate study protocols Select and collaborate with trial site, Contract Research Organizations (CROs) Summarize trial findings in reports Efficacy studies with larger populations Long-term effects 		
Commercial Functions/Marketing	Sales and product advertising material production	 Oversee marketing materials by participating in medical and legal peer review committee Manage expenditures of marketing and determine return on investment (ROI) Collaborate with market research/business analytics department Work with sales training force 		
Medical Communications, Education, and Information	Education and information related to product	 Respond to information requests about a product from patients, families, physicians, etc. Formulate database with responses to medical inquiries Review promotional materials Plan educational materials through collaboration with Key Opinion Leaders (KOLs), managed care and academia 		
Regulatory Affairs	Communications with FDA and other regulatory agencies	 Regulatory communications throughout development of a product (discovery to post-marketing studies) Document production and analysis Investigational New Drug (IND) New Drug Application (NDA) Review/revise product labeling Review/revise advertising and promotional materials to ensure complies with regulations Consult with preclinical and clinical studies to ensure data required by regulatory agencies is generated 		
Medical Science Liaison (MSL)	Fieldwork; education to medical experts	 Maintain relationships with medical experts in specific therapeutic area within a geographic area Education for clinicians and sales force Communicate with internal stakeholders Relationships with managed market teams Involves 60–80% travel time Travel to hospitals or CRO sites for clinical trials (training and communication) Ensures compliance for credentialing of trial sites (background checks, medical testing (i.e., Tuberculosis test) and immunization verification, training on facility policies, HIPPA agreements, etc.) Development of educational materials 		

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Table 1. (Continued)

Medical and Scientific Affairs		
Drug Safety and Risk Management (Pharmacovigilance)	Drug safety evaluations and informational updates	 Monitor, assess, and evaluate safety profile of product throughout lifecycle Submit documents summarizing safety profile and concerns, including: Annual reports Investigational brochures Risk assessments Risk management plans (RMPs) Risk Evaluation Mitigation Safety (REMS) Anticipate regulatory problems with safety assessments and develop ways to deal with the concerns Participate in clinical development with focus on safety
Health Economics and Outcomes Research (HEOR)	Costs and consequences of products	 Provide proof of product's market value for medical intervention (device or medication), which can be used for: Market access Pricing Formulary decisions National/international clinical guidelines Support market and sales teams by utilizing publications, Quality of Life (QOL), Quality Adjusted Life Years (QALYs), health care models, etc. Publish and present health outcomes research Develop patient reported outcomes assessments
Business Development and Market Research	Assess unmet needs in medical community and financial incentives of developing certain products	 Evaluate market trends, utilize internal and external relationships, and analyze clinical data to identify opportunities to add to company's portfolio Determine whether to keep certain activities within the company or outsource to contract organizations Collaborate with medical affairs, intellectual property (legal), regulatory affairs, marketing, HEOR, and managed markets Ensure internal stakeholders' views align with external stakeholders to uphold appropriate return on investment and mutual benefits

evaluated. What other products for the disease state are already on the market or in clinical development? PharmacircleTM is a database that can show the current stage of development for a medication, which is particularly useful for evaluation of competitors. For example, PharmacircleTM shows whether a product is in preclinical, clinical trial phases (I–IV), on the market, or has been discontinued. The software also includes links to the websites of the companies that manufacture the drug. Important information from company websites includes news articles or annual reports highlighting the progress of the medication. In some instances, PharmaCircleTM may show that a drug is still in clinical development. However, the company website may have a recent press release showing negative results of the most recent trial. The assumption is that the drug would likely be discontinued. Patents help to understand if a certain technology or formulation has already been assessed. For instance, one of the products Kashiv evaluated was initially unstable. An outside researcher came to Kashiv for a partnership, claiming he had invented a technology that gave a stable formulation. He also claimed the formulation was completely novel. After searching patents, it was discovered that two to three other formulations existed and had patents for the same product. Not only were there patents for stable formulations of the drug, but a similar product was already marketed in Germany. The person who came to the company asking for a partnership did not have their own patent at the time.

After data has been gathered from IMS, clinical trials, package inserts, PharmaCircle[™], and elsewhere, the next steps could be taken, which involve external assessments of the product concept. These include talking with key opinion leaders (KOLs), submitting surveys to clinicians that use the current medication in practice, and contracting with other market research firms for discussions with pharmacy benefit managers (PBMs). Discussions with PBMs evaluate the likelihood that the new formulation of Product X will be covered by insurance. Talks with KOL's usually involve a phone call to experts in the field. Generally, these are medical doctors who extensively prescribe the medication and may have been involved in published articles covering the drug in question. The phone call is important to understand, from a primary source, how often the medication is used and how the drug compares to other medications for the same indication. Most often, the information the medical doctor gives coincides with the original research; however, if their opinion differs significantly, further evaluation of the literature is necessary. Feedback from multiple physicians is important. Interviewing multiple KOL's will generally give a good trend and help to see if there are outliers.



Figure 2. U.S. patent search results for amiodarone compositions. Notice not all results are directly related, but may only mention amiodarone formulations.

Table 2. Review of various tiers according to payer system, most ideal tier for approval would be tier 3. Preferred brands are mostly covered by insurance and take initial precedence in prescription utilization over tiers 4 and 5.

Tier	Drug Type	Cost (1, lowest– 5, highest)
1	Prefered Generics	Minimal (1)
2	Generics	Low (2)
3	Prefered Brands	Medium (3)
4	Non-preferred	High (4)
5	Specialty	Max (5)

Market research surveys are sent to physicians. Kashiv uses a contract organization to deliver the surveys to multiple physicians (example n = 25). These surveys generally use Likert scales (ratings of 1-10) to gather information. Criteria assessed for the medication generally include clinical effectiveness, side effects, and how the medication compares to others that treat the same disease state. Eventually, the product concept (Product X) is discussed with the physicians taking the survey. Finally, the physicians evaluate the need for improvement to the current formulation, how they believe reformulating will effect safety and efficacy, whether they think they would prescribe more of the drug after the reformulation, and so forth. Comparing survey data with data from existing clinical trials is important to ensure that the data matches. An example of conflicting evidence includes adverse event reporting in clinical trials differing from the amount of adverse events reported by physicians in the surveys or phone calls.

Another aspect of market research involves discussing the product concept with pharmacy benefit managers (PBMs). If Product X will not be covered by insurance, the likelihood of the product failing on the market increases. The same company that performs physician surveys is contracted by Kashiv for market research with PBMs. The contract company will usually make phone calls or visits with PBMs to discuss the current product, other medications on the market, and the concept of Product X. The PBM will provide information on which tier the current drug is covered, a forecast for the tier that developed Product X will be placed into, and their estimation for the cost of the product. The data gathered is generally a rough estimate, but it's important to determine w insurance companies will likely think about Product X when the drug is marketed. From personal observation, it seems difficult to get PBMs to see the benefit of once-a-day prescriptions without further evidence. For this reason, clinical trials of 505(b)2 products should aim to prove that Product X will be once a day and that it will improve the effectiveness and/or safety over the current formulation.

Generally, the steps above are the majority of the work done in business development. Next steps include meeting with members of the company to discuss market research data and to determine if Product X is a candidate for further development. If Product X is a good candidate, it will move on to the formulations team. Once a formulation is developed, the medication moves into clinical trials and to market, assuming success at each stage. Since the medication that Product X is based on is already on the market, the development process is generally much shorter than it is for a new chemical entity (NCE). The pathway for improved formulations is called the 505(b)2 pathway by the FDA. For NCEs the pathway follows a 505(b)1 route.

COMMUNITY IMPACT

Industry pharmacists' impact on pharmaceutical development could be largely beneficial to patients in the future. Products that pharmacists in industry develop could reduce pill burden, increase compliance, increase effectiveness, and reduce adverse effects associated with current therapies. By focusing on 505(b)2 products, the timeframe to bring these medications to market is greatly reduced compared to development of an NCE, allowing patients to access the medications sooner. Products evaluated at Kashiv Pharma cover patients in all age ranges so there is a large population that may be positively affected. Working with PBMs can allow for reduced prices of the medications to patients as well.

Improvement to medications not only impacts patients, but also the work of health care providers. Work in industry can profoundly impact health care systems, such as hospitals, long-term care facilities, and so forth. For instance, new medications could affect treatment guidelines for various disease states.

	505(b)(1)	505(b)(2)	505(J)
	NDA	NDA	ANDA
Scientific studies	Full	Partial	BE
New active moiety	Yes	Yes	No
New indication	Yes	Yes	No
New dosage form	Yes	Yes	Limited
New strength	Yes	Yes	No
Patent	Yes	Yes	No
Market exclusivity	Yes	Yes	No

Figure 4. 505(b)1 traditional NCE pathway vs 505(b)2 reformulation pathway. (Courtesy of Stegemann et al.)

Other people potentially impacted by this article are pharmacy students. By sharing personal rotation and internship experiences, pharmacy students may benefit by having a glimpse into pharmaceutical industry work before having firsthand experiences.

STUDENT IMPACT

This article may give pharmacy students an opportunity to pursue further knowledge and understanding about the pharmaceutical industry. There is likely a lack of knowledge about what industry positions can be filled and the general work requirements of each. A better understanding exposes students to rewarding career options. Below are other pathways students can pursue to learn more about the pharmaceutical industry.

A couple of organizations specific to career paths in industry are the Industry Pharmacists Organization (IPhO) and the International Society for Pharmaceutical Engineering (ISPE). IPhO is specific to positions in industry that pharmacists usually take, which were summarized in the table earlier. The IPhO website provides information about professional development, fellowships, and careers, as well as published articles highlighting aspects of the pharmaceutical industry.

Advanced pharmacy practice experiences (APPEs) are another great way to obtain experience in the pharmaceutical industry. Many pharmacy students in my class have enjoyed rotations at Eli Lilly. Purdue University also provides track rotation opportunities, which can be two- to three-month experiences at one pharmaceutical company. A rotation at the Food and Drug Administration (FDA) in Washington, DC, is another experience that would be valuable to students considering industry. The department of regulatory affairs is currently the second-largest fellowship by the number of pharmacists, which requires extensive FDA communication. Having firsthand experience with the FDA might be viewed highly by companies when applying to Regulatory Affairs or other industry positions.

Internships are another pathway to obtain industry experience. My internship at Kashiv lasted two months, and I gained a considerable amount of knowledge during that time. An internship provides early experience in positions that can be acquired after pharmacy school. Networking is key in industry, and having an internship starts to develop a student's network.

Fellowships can also significantly help with networking. The Rutgers pharmaceutical industry fellowship

	DISCOVERY	NONCLINICAL Research	CLINICAL STUDIES
505(B)(1)	2-5 YEARS	1-5 YEARS	8-15 YEARS
505(B)(2)	<1-3 YEARS	< 1-2 YEARS	2-5 YEARS

Figure 5. Note the difference in time for production between each pathway. (Courtesy of Camargo Pharmaceutical Services.)

has approximately 200 current fellows. Each fellow has an opportunity to meet others through weekly activities at Rutgers College of Pharmacy and other partnerships. Pharmacists can pursue a wide variety of positions, as highlighted by the information earlier. However, a fellowship is not a requirement to break into the pharmaceutical industry. In fact, only 20% of current industrial pharmacists completed a fellowship (Alexander et al., 2018). Many started out as clinicians and transferred to industry or went straight into industry from pharmacy school. Oftentimes fellowships can provide an accelerated track to director roles.

Guest speakers and pharmacy school curriculum provide another avenue to learn about the pharmaceutical industry. Industry professionals occasionally come to speak about their work. One article evaluating 193 pharmacy students showed that 30% of students first learned about careers in the pharmaceutical industry from a guest speaker (Shpilfogel, Tyrrell, & Alexander, 2015a). Other times, pharmacy schools will have electives that students can take to learn more about industry. One ten-week course at the Massachusetts College of Pharmacy and Health Sciences (MCPHS) covering industry showed a significant improvement in first-year pharmacy (P1) students' knowledge across seven functional industry careers. The course improved student industry interest, from only 55% saying they were interested to 70% being interested in an industry career, and from 45% to 75% saying they had a specific area of interest by the end of the class (Audette et al., 2014).

CONCLUSION

Pharmacists are sought out for their broad clinical and scientific knowledge by pharmaceutical companies. This article touches on many of the different positions available to pharmacists through fellowships. There are several other industry positions besides those mentioned, such as manufacturing. Direct pharmaceutical experience through rotations, internships, or fellowships are important not only for training experiences, but also for building a professional network. In addition, joining pharmaceutical organizations such as IPhO and/or ISPE to meet peers interested in industry helps, as involvement provides multiple networking opportunities. I suggest taking pharmaceutical industry courses to understand more about the career opportunities. I hope my experiences provide a glimpse of responsibilities that a pharmacist may have in industry.

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