World Patent Information 30 (2008) 233–237

Contents lists available at ScienceDirect

World Patent Information

journal homepage: www.elsevier.com/locate/worpatin

The ever-changing role of information professionals in pharmaceutical R&D

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ARTICLE INFO

Keywords:
Pharmaceutical
Career progression
Information professional role
Patent searcher
Management
Multi-disciplinary customers
Time management
Setting priorities
User training
Education
Resource allocation

ABSTRACT

The role of the information professionals in the pharmaceutical industry is explored with particular reference to the author's current role leading a team at a small pharmaceutical company. Particular emphasis is placed on the importance of establishing a good relationship with the customers for the searches, but topics such as time management, training and resource allocation for example are also covered.

1. Introduction

"What *exactly* do you do?"

I have been asked this question a lot, which does not really bother me, unless the person asking the question is a colleague from work. Even my children cannot articulate what I do as evidenced by one of their teachers asking me to take a leadership role in organizing their school's newly built library. Yes, I manage our corporate library, but my degree is in chemistry. I will be able to explain Derwent's fragmentation codes a lot better than the library of congress classification system. A medicinal chemist by training, I now work as an information analyst for a small pharmaceutical company.

1.1. Basic overview of the drug development process

The drug development process is long and expensive. Our industry is being challenged to meet business objectives set by senior management and stockholders, as well as the consumers' demand for safe, efficacious and inexpensive therapies [1]. Based on a number of published reports, it takes 10–15 years and about $800 millions to develop a drug. Only one out of five compounds entering clinical trials will be approved. The cost and time to develop a drug have steadily increased over the years, but based on the number of FDA approvals, these increases are not proportional to success. In 2007, preliminary reports indicated that the Food and Drug Administration (FDA) approved 19 new drugs (unconfirmed by FDA), the fewest since 1983. Why so few? As development costs increase, some companies are looking for new indications for their already approved drugs. In addition, unexpected changes in regulatory requirements delay submissions of new drugs. To stay competitive, we are continually looking for ways to decrease drug development time and cost and to increase our probability of success. If failure is inevitable, we aim to fail early and fail cheaply.

The biopharmaceutical industry is one of two industrial sectors that are R&D-intensive [2], the other being the semiconductors industry. As information professionals, we are in a position to influence and help our company to succeed. Here, are just some of the few areas, where information professionals can impact:

1.1.1. Decrease time to "NO"

Since drug development expenses are incurred sequentially, there are a lot of opportunities to challenge our scientific and business decisions as compounds move along the pipeline. We should exploit published literature to identify failures in the preclinical stage and learn from our competitors. Once we identify a development compound, we try to expose liabilities and flaws of that compound. Some companies have processes to 'crash test' their lead compounds *in silico* [3] and performing killer experiments early in development. We should leverage our collective knowledge and share R&D insights with our senior management as they make business critical decisions.

1.1.2. Reduce cycle time

Drug development process is repetitive. We need to recognize processes that can be automated or outsourced and workflows that

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doi:10.1016/j.wpi.2008.03.007

can be streamlined and improved. Redundancy should be minimized, if not eliminated. By optimizing our operations, we become efficient and more productive. Process improvement will free up time that is best used for critical and creative thinking and keeping current with scientific and technological innovations. Increasing productivity is one of the reasons GlaxoSmithKline created its R&D's Centres of Excellence for Drug Discovery. Wyeth adopted the "Learn and Confirm" [4] model to optimize their R&D strategies.

1.1.3. Increase the number of compounds that have a high probability of success

New target assessment is a critical process in our industry. We need to partner with R&D to increase scientific understanding by leveraging published information. There is a growing trend toward early R&D and business development collaborations. Although our ultimate goal is to bring a compound successfully through regulatory approval, drugs should also sell enough to recoup our R&D investments. Some drugs have been voluntarily withdrawn from the market by manufacturers due to lack of commercial viability. Another source of development candidates are in-licensed compounds. These compounds tend to have a higher probability of success [5,6]. We can support this activity by monitoring and tracking our competitors. In addition to commercial sources of information, we should include our internal data and public databases in our analysis.

Although we focus our efforts to predict which compound will succeed, we need to be better at identifying compounds that are not good drug candidates before investing resources. Our companies should provide an environment conducive to knowledge sharing and reuse of information. There are a number of enabling technologies that are gaining traction such as identifying biomarkers, using surrogate endpoints, implementing dose-response adaptive clinical trials design and utilizing new techniques to predict a drug's efficacy, toxicology and metabolism profiles.

The main reason drug candidates fail is due to lack of efficacy. Some companies are allocating resources to take another look at these compounds for other indications, especially those that failed late phase clinical trials due to lack of efficacy. Repositioning a failed drug is an attractive route to new drugs since lack of acute toxicity has already been demonstrated in phase 1 trials. Repositioning a drug also has some attractive patent implications. Novel method-of-use patent applications can be filed which may result in longer patent life [7].

2. Challenges and opportunities

2.1. Multi-disciplinary customers

Information professionals supporting R&D need to be comfortable and confident interacting with their customers. We take pride in hiring only the best- the best chemists, pharmacologists, clinicians, etc. and we need to encourage these "experts in their field" to articulate their needs when asking us for help. Sometimes they themselves are not clear on the correct question to ask. This is where the interviewing aspect of our job plays an important role in helping our customers ask the correct question. For our part, we need to continually keep on top of scientific innovations. This may be easier for those who have scientific background, but can be quite challenging for those who do not.

2.2. Time management and setting priorities

I have yet to find a job where I have enough hours in the day to do what I planned to do for that day. Our job becomes a juggling act, especially on days when an unplanned urgent request comes in. Some people like working on more challenging requests first. Personally, I was trained to do 'quick wins' first. Whatever your time management style, remember it doesn't hurt to stop and take a moment to regroup, especially when things are getting daunting. Aligning your priorities with the corporate objectives is a good place to start. You will do yourself a big favor by paying close attention to the changing company objectives and challenges. Ask yourself, "Is what I'm doing adding value to the company?" Allocating time to establish a good relationship with your customer is a good investment and a valuable step if you want to be proactive. Be firm when setting delivery dates for search results. Is the request really urgent? I tell my clients that the quality of my work is directly proportional to the time I have to design my search strategies, execute queries and analyze the data.

2.3. User training and education

As I mentioned earlier, we hire the "experts in their field", and as a consequence, they are extremely busy. To stay competitive, we provide for-fee high quality resources to our clients. It pains me to see how some of my users use these quality resources that we went out of our way to provide to them. I keep telling them, "I am giving you a Porsche sports car, please do not drive it like a Hyundai!" We are responsible for making sure that our users know how to use these tools effectively. Finding a convenient time for a training session can be quite challenging. We offer flexible training opportunities to accommodate our users' schedules and travel plans, such as linking to our vendors' webcasts and customizing sessions tailored to functional groups and project teams. In addition to comprehensive documentations posted on our intranet, we are exploring ways to make training videos available on demand. I find that I'm more successful educating my clients when I show them how to answer a question using our tools, instead of merely showing them technical functionalities. We work closely with them when they are setting up alerts profiles and routine searches.

2.4. Service function/supporting roles

We are a support driven team. Although our names do not appear in the inventors and authors index fields, we might get an acknowledgement at the end of the paper. This is a considerable change for those of us who came from another career where we were the author or the inventor. Even though we play a supporting role, our function is critical to the success of research projects. We partner with our customers and we become the "Go-To" people. Support from our line management is crucial in elevating our needs and challenges. Sometimes our activities are so far removed from theirs that they may only hear about us if there is a problem. We need to be vigilant in educating our senior management of our successes and celebrate them. I have been asked how I am able to consistently get feedback from clients. Easy, I just ask.

2.5. Resource allocation

I am fortunate to work in an industry where information is classified as an asset. We leverage all available information and value – added analysis to give us a competitive edge. Patents are a huge source of information in drug discovery, however patent analysis can be a challenging exercise due to limitations of available analysis tools and the quality of patent publications [8]. I have been asked time and time again, why we need to pay for for-fee information resources where there seem to be plenty of free information available on the web. If the information will be used to support a decision that has legal and financial implications to our company,