JYP

# Emerging Opportunities in Pharma Industry

**Jha D, Jasubhai K[1], Tomar MS**

*Clinical Pharmacology, Pharmacokinetics and [1]Drug Regulatory Affairs, Ranbaxy Laboratories Ltd, Gurgaon, Haryana-122015, India*

***Address for correspondence:*** *Diwakar.Jha@ranbaxy.com*

**ABSTRACT**

Almost every pharmaceutical graduate, during the tenure of his/her study, is in a dilemma when it comes to choosing the professional field. Conventional jobs related to formulation, synthetic chemistry, analytical research, microbiology, marketing and sales are evergreen and well known, but there are some newer opportunities with tremendous potential which need to be talked about. There are upcoming jobs in the fields of clinical research, regulatory affairs and intellectual property rights. These are prospering at a very high rate and can give rise to a sea of opportunities in the coming years. The demands of these fields are continuously growing because of stringent regulatory requirements and a big pool of talented scientists to address these issues. The word 'outsourcing' also has a significant impact on the pharmaceutical industry. The lower economic costs, a vast pool of skilled workers and a large demographic variation of patient population favor the winds of change. Big pharmaceutical houses in the developed countries are keen on outsourcing their production and research to developing countries like China, India and Malaysia to increase the margin of their profits by lowering their research and filing costs. This in turn is a boon for the Indian pharmaceutical industry and is giving rise to the concept of contract manufacturing and contract research among the Indian counterparts. The outcome: strategic alliances between both Indian firms and foreign based companies and Indian companies entering the domain of contract research.

**Key words:** Opportunities, Clinical research, Regulatory affairs, Intellectual property rights, Contract research

**DOI:** 10.4103/0975-1483.51867

## CLINICAL RESEARCH

Clinical research involves two aspects of drug development. The first involves characterizing the pharmacokinetic and pharmacodynamic development of both generic drugs and investigational new drugs. The second involves the demonstration of strong clinical evidence of the product's efficacy and safety through well designed and controlled clinical trials involving human patients. A proper study design is very important to ensure the bioequivalence of the test drug with the reference drug. Apart from physico-chemical awareness, it requires knowledge of pharmacokinetics, chemistry and the best possible analytical methodologies for the test molecule. Designing a clinical study, development and validation of a suitable analytical method to determine the concentration of the analyte in matrix as per the requirements of different regulatory guidelines, is quite challenging. This is where pharmacy professionals can play a key role with their basic understanding of clinical pharmacology, pharmacokinetics and pharmaceutical analysis. A clinical study also includes the study of interaction with other drugs. It is not just clinical research that is driving the employment brigade, work force is also needed for data management, documentation, quality control and quality assurance which are the mandatory requirements demanded by various regulatory agencies worldwide. A reputed consultancy firm, Mckinsey, reports that Global

Pharma majors are going to spend to the tune of $ 1-1.5 billion for clinical trials in the next two to three years, from the current $ 300 million. Indian companies are willing to share the financial risk for the financial rewards from the discovery of new drugs. This has already led to collaborative work between global major Merck and Advinus, GlaxoSmithKline and Indian giant Ranbaxy and many other big deals. Indian companies like TCS, Quintiles, iGates, Cognizant, Accenture, Piramal Life Sciences, Wockhardt, Sun Pharma and many CROs are looking for a work brigade which to meet this demand.

## REGULATORY AFFAIRS

Regulatory Affairs (RA) is a vital unit in a pharmaceutical company that successfully drives the Research & Development (R&D) efforts of the company to the market. The regulatory department works with a focus to get products to the market with a commercially viable label, in the least possible time and expense. In view of the increasing global competitiveness among pharmaceutical companies, the key to success lies in obtaining timely marketing approval from the Regulatory Affairs of the region where the drug is to be sold. Various government agencies are involved in regulating drugs within their market. Some of them include USFDA-US, EDQM-Europe, TGA-Australia, MHRA-UK & TPD-Canada.

To obtain timely marketing approval, companies can either strengthen their own regulatory department or outsource the same to some regulatory affairs consulting firm. Outsourcing of regulatory affairs work seems a more beneficial option, both in terms of time and money, with changing global regulatory norms. Maintaining a large regulatory affairs department can be very expensive and scope of knowledge can be limited to certain aspects. On the other hand, a regulatory affairs consultant keeps updating himself with the current regulation and has vital experience in the field to expedite the approval process. Pharmaceutical Regulatory Affairs involves both Investigational New Drugs (IND) & Generics. Well established regulatory firms can provide service in the following ways:

Compiling and formulation of large regulatory application for submission for both APIs in different countries, commonly called, as dossiers.

- Expertise Knowledge regulatory and scientific knowledge.
- Expertise knowledge and support in terms of local regulatory authority.
- Expert solutions to FDA and other regulatory agencies' queries.
- Access to Scientific and technical resources.
- Formulation and implementation of regulatory strategies at a global level.

Job opportunities for professionals are excellent in the areas of Regulatory Affairs and Quality Operations. Career options include the pharmaceutical, biotechnological, veterinary, cosmetic, food and medical devices industries, Contract Research Organizations, government. These professionals will find employment as Regulatory Affairs Associates, Regulatory Affairs Assistants, Quality Assurance Associates, Quality Assurance Investigators, Documentation Administrators and Medical Information Associates, Drug Inspectors, Drug Controllers, Regulatory Affairs Consultants for Pharma/Biotechnology Industry, Regulatory Food Safety Scientist, Pharmacovigilance Manager, Drug Safety Specialist etc.

## INTELLECTUAL PROPERTY RIGHTS

Patents are exclusive property rights in intangible creations of the human mind. The new product, article of manufacture or process described in the patent application must be something that has never been previously disclosed anywhere in the world and something that would not be obvious to a person ordinarily skilled in the field involved. The owner of a patent has the right to exclude others from making, using, offering for sale, or selling his or her invention for a period of 20 years from the filing of the patent application. Patent protection for chemical and pharmaceutical products is especially important compared with other industries because the actual manufacturing process is often easy to replicate and can be copied with a fraction of the investment required for research and clinical testing. Every country with a patent system has a national patent office where claims of inventors may be made a matter of public record. As mentioned above, in many countries, there is an examination before an inventor is given any substantive rights. All IPR professionals should have well-structured information related to patentable inventions, copyright violations against any original research, papers, articles etc. Today, IPR is progressing as a muscle of law and protection against one's ability and creativity with the following job prospects:

(a) Writers: They draft applications and intellectual property licensing agreements as well as various kinds of legal documents such as drafts, appeals, etc.
(b) Counselors: Give opinions to clients on protecting their intellectual property in the form of trade marks,

copyrights, patents, industrial designs etc. and render advice pertaining to infringement thereof.

(c) Scientists: Patent lawyers with a technical background, to understand the specifications on innovation in the patent applied for.

(d) Good advocates: They protect the intellectual property of their clients before the Intellectual Property Tribunals, Courts, and before the Customs organizations.

We hope that this article will provide a new insight to our budding pharmacy professionals and help them opt for new career options. It is also a high time for teachers and educational institutions to revise their study curriculum based on the needs of the industry so as to create a talented pool of professionals for the same.

## REFERENCES


1. http://en.wikipedia.org/wiki/Regulatory_Affairs
2. http://www.livemint.com/2008/12/23232645/Creating-8216informal8217.html
3. Hunshyal R.D., Biradar S.S. (2005) Intellectual Property Rights (IPRS) In Pharmaceutical Sector Health Administrator Vol: XIX Number 1: 48-50
4. http://www.prlog.org/10079931-regulatory-affairs-outsouricng-in-pharmaceutical-industry.html
5. http://www.earthinstitute.columbia.edu/cgsd/documents/lehman.pdf