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TREND OF REGULATORY AFFAIRS IN PHARMACY EDUCATION

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ABSTRACT

The emerging need of regulatory affairs professionals so as to meet the competition at a global level has given the Indian pharmaceutical sector a reason for rapid progression. Public health is an area of major concern for government agencies across the globe ,they keep a strict scrutiny on the safety and efficacy of products ranging from pharmaceuticals ,medical devices, veterinary medicine, cosmetics and Agrochemicals. Pharmaceutical companies have an objective of supplying safe and effective products to the market so as to contribute towards constant improvisation in the healthcare sector. This is where regulatory affairs professionals come into the picture and plays a major role by serving as a linkage between these pharmaceutical industries and regulatory agencies globally. A thorough understanding and command over the guidances by regulatory agencies, laws and regulations can give an edge to the regulatory professionals worldwide. the current requirements of pharma industries need to be implemented by the standard pharmacy curriculum so as to contribute towards industrial growth. The article thereby highlights the regulatory education its needs and requirements for example the resources available, courses and content of curriculum and finally the scope and opportunities for job in regulatory sector.

Keywords: *Pharmaceutical Regulatory Affairs, Pharma education*

INTRODUCTION

The cut throat competition amongst the pharmaceutical industries has given rise to a concept that understanding guidelines and applying it to activities that comes under regulation are key to exist in the industry. Being a highly regulated industry the demand for people handling regulatory issues are on a very large scale. There are existing specialized RA department in multinational pharma companies and small biotechnology companies with a concept that the success of a regulatory strategy lies on factors like interpretation ,communication and application of the existing regulations to companies and the constituency. the pharmaceutical regulatory affairs sector comprises of people working in all stages that is right from the application phase of new or generic drug to the marketing stage. Industries like pharmaceutical, chemicals and biotechnology and cosmetics provides job opportunities in regulatory affairs. A biotech regulatory sector is an upcoming and booming field because of its contribution towards drug development and pharma industry [1, 2].

PHARMACEUTICAL DRUG REGULATORY AFFAIRS

The basic system on which the drug regulatory affairs sector works comprise of an individual acting as a link between the company and the regulatory agencies which requires a thorough understanding of the guidelines as the individual is responsible for the drug approval in respective countries. Submission of supplements and annual reports to the agencies is an important aspect of pharma drug regulatory affairs along with communication to the centre of drug evaluation and research at FDA headquarters. Changes related to the manufacturing site and testing must be evaluated and notified to the FDA. The regulatory affairs department is generally involved in marketing strategies of products with special emphasis on packaging and approval. The countries where the company's products are exported have different regulatory requirements and regulatory department is expected to be aware of all the current regulations [3].

REGULATORY AFFAIRS EDUCATION AND INSTITUTES OFFERING REGULATORY AFFAIRS IN INDIA

The individual serving as a coordinator between the agencies for example USFDA, EUDRA, and the company must be well knowledges with all the guidelines, guidance and drafted documents while organizations like regulatory affairs professional society (RAPS) , Drug information association (DIA), Food and drug law institute etc. provides the necessary information. Health care product research development process and regulatory oversight as a foundation course are included in the curriculum. A full time and a part time course in regulatory affairs are available where a full time course is meant for a person who wants to pursue career in regulatory sector and a part time course is to be familiar with the terms and concepts . there are full fleged courses available in colleges and universities that offer regulatory affairs along with it distance, e –learning, etc. but it is a vast area and theoretical knowledge is not enough until a person has a field experience as the issues on the field are regularly updated so it is important to keep up with latest regulations and amendments. The critical step is the reduction in time for a product to reach a market so regulatory procedures when followed correctly plays an important role in the economical growth of a company. A new drug when marketed costs millions of dollars and any delay in getting it marketed due to inappropriate documentation leads to the financial burden on the company [4, 5].

In certain instances there can be product recall due to incorrect labelling or inability to report data that can cause a huge blow to the sales sector with mental pressure on investors, health care professionals and patients. A regulated professional with an approach of one time task completion and coordinating skills can help in maintaining resources. Since regulatory affairs professional is the link between government authorities and company so through their strategy development skills and advice on critical issues [6].

RECENT CHANGES

National Board of Accreditation (NBA) under all India council for technical education (AICTE) and National assessment

and accreditation council (NAAC) BY University grants commission, are the two autonomous bodies framed by the government of India to mark the standards of pharmacy profession and to put grades to colleges so as to analyze and rate them overall [7].

DRUG REGULATORY AFFAIR PROFESSIONALS AND THEIR RESPONSIBILITIES

A drug regulatory affairs professional acts significantly during the entire process of drug product being marketed, right from the research and development phase . Each phase has to meet the required regulatory requirement so as to launch a product with good safety and efficacy. A very important role of DRA professional is to get approval from the health therapeutics products program (TPP) for submission of a drug meanwhile checking whether the investigational drugs and marketed drugs meet the regulatory compliance with food and drug act and regulations and TPP guidelines. A DRA professional should have a scientific background with a degree in either BSc, MSc, PhD, M. Pharm, B. Pharm, Pharm D should have a thorough knowledge of all the regulations and regulatory bodies on a global level. There is a mutual relation and negotiations amongst different regulatory bodies and health authorities so the regulations are constantly being updated and reviewed thus putting up a challenge to DRA professionals to be aware of all the updated changes and its implementation of the approval process. The system is multidisciplinary and they work together as a team so a DRA professional needs have organizational and leadership skills so that he can play an active role in team building activities. Co ordinating in the team leads to relevant and useful information required for framing documents as per current TPP policy further analyzing it for accuracy. The responsibilities of a DRA professional may vary right from managing pharmacovigilance activities to electronic submission, but the role is a sole one and that is to act as a link between the sponsor and TPP.

An important aspect of being a DRA professional is that they should have an effective negotiation skills which includes writing and communication skills as a skilled negotiator can answer the queries during the submission process and also satisfactorily fulfill the business objective of the sponsor [8, 9].

A DRA professional job begins right from the development of a product till the product is launched into the market, thus contributing at an economic and scientific level. They are required to be well updated on all the current regulations across the countries in which the product is to be distributed. They deal with the problems that may arise at a scientific level and regulatory level of maintenance of record, scientific approach and data review and presentation [9].

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GROWTH OF REGUALTORY SECTOR IN INDIA

India , a choice of the global companies for conducting clinical trials and research and development has led to a phenomenal increase in the pharma research industry with the introduction of a new product patent system contributing towards the growth. This led to an increase in pharma regulatory jobs as well , figures and market research suggested that there was a growth of $ 630 million by the end of the year in 2012 in a clinical trial sector in India. Along with India, UAE is another country looking for expansion in pharmaceutical and regulatory sector.

The growth of regulatory sector also depends on enhancing the professional skills in the regulatory affairs sector, implementing regulatory affairs as a course in the pharmacy curriculum.

India with its booming and regulated pharmaceutical, biotechnology and medical research industry needs regulatory affairs professionals to come up into the competition at a global level. The professionals need to be thorough with the legislations and guidelines of the regulatory bodies so the pharmacy colleges need to implement and frame the syllabus as per the current requirements of pharma industries so that they can provide a valuable contribution to the country's economy and growth.

CONCLUSION

The survival strategy to stay in the regulatory market should be to execute work as per the current legislation and guidelines. DRA professionals are the key factors in getting the quality products marketed in a specified period of time along with safety assurance. Regulatory department and DRA professionals are well established in major pharmaceutical corporations and biotechnology companies providing an ample amount of job opportunities for youth. The fact that it is unaffected during recession, takeover, merger and acquisition further makes it a desirable profession. The critical factor remains the same for a drug to be marketed and it is a reduction in time for quality products to reach the market along with its safety assurance and it is only possible by the constant efforts put up by the DRA professionals. The efforts and proper conductance assured by regulatory professionals, thus serve the country and the company in the best possible way by adding to their success and growth.

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