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Review Article

PHARMACEUITICAL REGULATORY AFFAIRS: A REVIEW ON EDUCATIONAL SCENARIO

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Abstract: The present article discusses the regulatory education and its need, learning resources, courses available, syllabus contents, and job opportunities in regulatory affairs. The companies responsible for the discovery, testing, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals. The pharmaceutical biotechnology and medical device research and development industries are among the most highly regulated industries in the country. As India is growing very rapidly in pharmaceutical sector, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies.

Key words: Regulatory affairs, Public health, job opportunities

INTRODUCTION

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods).[1] The person indulging in the regulatory affairs must be familiar with all the guidelines, guidance and regulatory documents. He should have thorough understanding of a particular regulatory document which has been drafted. Such people are the primary communication link between the company and worldwide regulatory agencies such as USFDA1 (United States Food and Drug Administration) and European Union of Drug Regulatory Affairs (EUDRA). A number of organizations such as the Regulatory Affairs Professional Society (RAPS), the Drug Information Association (DIA), the Food and Drug Law Institute (FDLI) and international organizations such as the European Society of Regulatory Affairs play a vital role in providing relevant information. Commercial training companies such as Parexel- Barnett and the Pharmaceutical Education and Research Institute (PERI) conduct meetings on the regulatory affairs, which would be helpful to the professionals. Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals and those who don't, rely on the expert advice of independent regulatory consultants to meet their obligations. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents. The regulatory affairs professional is the only one who is completely responsible for holding products in compliance and maintaining all the records. One of the vital activities of the regulatory specialist is to ensure that the all the information regarding medicines has been correctly established to the patient covering labelling also. Even a small mistake in any of the activities related to regulatory can make the product to be recall in addition to loss of several millions of the money.

IMPORTANCE OF REGULATORY AFFAIR

In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company. Inadequate reporting of data may prevent a timely positive evaluation of a marketing application. A new drug may have cost many millions of pounds, Euros or dollars to develop and even a three-month delay in bringing it to the market has considerable financial considerations. Even worse, failures to fully report all the available data or the release of product bearing incorrect labeling, may easily result in the need for a product recall. Either occurrence may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients.

A good Regulatory Affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific Endeavour with regulatory demands throughout the life of the product, helping to maximize the cost-effective use of the company's resources.

The Regulatory Affairs department is very often the first point of contact between the government authorities and the company. The attitudes and actions of the Regulatory Affairs professionals will condition the perceptions of the government officials to the company –for better, or for worse! Officials respond much better to a company whose representatives are scientifically accurate and knowledgeable than to one in which these qualities are absent.

The importance of the Regulatory Affairs function is such that senior Regulatory Affairs professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies.[1]

Regulatory Affairs Education

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PHARMACEUTICAL DRUG REGULATORY AFFAIRS

This department is responsible for knowing the regulatory requirements for getting new products approved. They know what commitments the company has made to the regulatory agencies where the product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be notified.The Regulatory Affairs department will take part in the development of the product marketing concepts and is usually required to approve packaging and advertising before it is used commercially. Many companies operating in the high-technology health-care and related industries operate on a multinational basis and are very significant exporters.

REGULATORY BODIES

Regulatory bodies such as the Food and Drugs Administration (FDA) in the USA are responsible for approving whether a drug can proceed to clinical trials and whether it should be allowed on the market. The regulatory body has to evaluate the scientific and clinical data to ensure that the drug can be produced with consistently high purity, that it has the clinical effect claimed, and that it does not have unaccepted side effects. It must also approve the labeling of the drug and the directions for its use. In general, the regulatory body is interested in all aspects of a drug once it has been identified as a potential useful medicine.[1]

Functions and Responsibilities:

To develop a system to monitor and review the effectiveness of the College's quality assurance policies and procedures and consider the following:

1. The annual review of programs of study
2. .The validation and approval of new of programs of study through the academic board.
3. Student representation and feedback
4. Assessment procedures.
5. Staff development and training issues raised by review procedure and as appropriate to recommend to Academic Board the introduction of new quality assurance procedures and modifications to established systems.
6. To prepare an annual report and a quality Handbook.
7. To advise and assist academic and service units in carrying out self-assessm ent procedures;

8. To manage responses to the requirements of external quality agencies
9. To ensure the effective implementation of College systems for the comparability of the standards of programs of study - with reference to standards across and within disciplines.
10. To prepare forms and surveys for data entities.
11. To advise on any other matters this may from time to time be determined by the Academic Board. [2]

Responsibility of Regulatory Affairs Professional's

The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating. They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned. They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole.

It may take anything up to 15 years to develop and launch a new pharmaceutical product and many problems may arise in the process of scientific development and because of a changing regulatory environment. Regulatory Affairs professionals help the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labelling or in advertising.

Recent Advancements:

Recently, the Govt. of India has constituted a few autonomous bodies to gauge the standards of profession of Pharmacy & grade the colleges accordingly so that the students, parents, employers and funding agencies have a valid & reliable rating of the various Pharmacy colleges in the country.

These are:

(1)National Board of Accreditation (NBA) under the aegis of All India Council for Technical Education.

(2)National Assessment and Accreditation Council (NAAC) by the University Grants Commission.

Figure-1: RA Profession: Integral to the Healthcare Product Lifecycle[3]

Gathering Information

There should be no need to go over published sources of information, both commercial and governmental. The sources of gathering information are, any opportunity to see, hears, or talks with a regulator, a more experienced drug development expert, a colleague, or a sworn enemy is an opportunity to gather information. Never be afraid to ask a question, never be afraid to approach a new person who might have information need, and always be willing to listen. [1]

Communicating Information

The easiest information to share and communicate is non critical information. These are findings and data from public presentations and widely available sources that simply need to be put into a logical and relevant form and shared within the organization. The main issue with such information is getting to the right audience without boring them into forgetting that they're getting useful data. Most companies subscribe to news updates or have internal regulatory information updates via e-mail. However, these updates often have a hard time grabbing attention and actually being used as a resource. One suggestion is to make them playful and user-friendly, using popular Web pages as guides.

The difficult information to communicate is critical information. This could mean anything vital to the success or failure of a project, specific and important feedback from the FDA, subtle insight that weighs heavily on the future of the company, etc. While it would be simple to just shoot an e-mail off to the entire company, it is neither in the company's interest nor your interest to take that approach. The first thing to do is document the information carefully, so that we can fully understand it and its implications. Then think of those individuals who are that combination of "need to know" and "know who else needs to know." At small start-ups this might be the CEO or the president. At larger companies, the head of clinical,

a project manager, or a similar middle- to senior level manager fits the bill. Using these first points of contacts allows the information to pass through appropriate channels. It also allows for the dissemination of the information in the proper context. [1]

Documentation

One of the first things one learns in regulatory and compliance is "if it isn't documented, it wasn't done." Not following this basic principle leads to a large number of compliance failures and can also lead to the downfall of critical development projects. Projects in drug, device, and biologics development can take upward of years to complete and cost tremendous amounts of money. The time involved can be upward of five times longer than the average stay in a regulatory job, depending on location and industry. This means projects need to outlast the people who work on them, and the only way they can do this is to have solid documentation to support them. Document progress, document decisions, document information, document failures, and document successes. This need to document is important at large companies, where complex dynamics may move a project through the hands of multiple teams, and at small companies, where key decisions may be questioned by advisory boards, investors, potential investors, and potential partners. [1]

Submissions

Submissions to regulatory authorities are the ultimate "product" created by a regulatory department, and they also, in terms of content, format, and quality, represent the company and product. Often voluminous and spanning multiple technical areas, regulatory submissions are complex documents in every sense from an editorial, scientific, and paper-management perspective. At the same time, these documents represent the ideal opportunity for a regulatory professional to shine not just in the quality of the final product but in the way the document is brought together.[1]

Measurement of Quality

Certain indicators can utilize to measure the quality of Pharmacy education. Some of them are examination results, infrastructural facilities, R & D activities, Interaction with pharmaceutical industry, Job avenues, Students pursuing higher studies etc. [2]

Quality in Pharmacy Education

Quality is confirmation to specifications

Quality needs no definition; you recognize it when you see it:

Quality is a relative concept & can't be measured in absolute terms.

Quality has three important dimensions

(1) Quality for design

(2)Quality for Conformance

(3)Quality for Performance (5)

Quality in Pharmacy education means what students have learnt as a result of their interaction with teachers, departments and university. Good buildings with well furnished and well maintained classrooms, well equipped laboratories, a rich library with ample facilities for students, well qualified and committed faculty and an environment which facilitates the prevalence of an effective teaching – learning process.[2]

Goals:

1. To implement the Institution's approach to quality assurance and enhancement in an efficient and effective manner.
2. To ensure a commitment not only to quality assurance but also to the enhancement of the quality of the student experience.
3. To establish a comprehensive self-evaluation system in the field of quality control in the College.
4. To demonstrate that standards of programs/courses are appropriate and meet the requirement of the Oman's System of Quality Assurance and other external benchmarks.[2]

Future Developments

Many in the Regulatory Affairs Profession believe the New Approach to regulation will eventually be adopted for all healthcare products as it represents the best model for delivering new healthcare advances to market in a reasonable time with acceptable safety.

Regulatory Affairs departments are growing within companies. Due to the changing resources necessary to fulfill the regulatory requirements, some companies also choose to outsource or outtask regulatory affairs to external service providers. Regulatory Affairs department is constantly evolving and growing and is the one which is least impacted during the Acquisition and Merger, and also during recession. Global harmonization in standards has led to consistent approach in regulatory submissions and hence its review.[6]

Opportunities

_ International Opportunities
_Projects, secondments, relocation
_ Shaping the future within companies
_ Outside industry
_Trade bodies
_Become a regulator!
_ Sub-specialties
_Regulatory Operations
_Regulatory Intelligence
_ Other industry disciplines[4]

Major Regulatory Authorities

Country	Regulatory Authority
India	Central Drugs Standard Control Organization Drug controller general of India (DCGI)
US	Food and Drug Administration (US FDA)
UK	Medicines and Health care products regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
Japan	Japanese Ministry of health, Labour and Welfare (MHLW)
Canada	Health Canada
Brazil	Agency Nacional degradation Vigilancia Sanitaria (ANVISA)
South Africa	Medicines Contol Council (MCC)
Europe	European Directorate for Quality of Medicines (EDQM)
	European Medicines Evaluation agencies (EMEA)

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