



A REVIEW ON CURRENT DEVELOPMENT OF REGULATORY AFFAIR IN PROFESSIONAL AND INDUSTRY

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ABSTRACT Regulatory affairs professional Play critical roles in a pharmaceutical industry because it is concern about the health care product life cycle, it provide strategic, tactical and operational.Pharmaceutical drug regulatory affairs covers different registration parameter of pharmaceutical product .As it is the new profession which was developed from the desired of all over the world to protect the public health by providing good quality of medicine including safety and efficacy in the area of not only pharmacy but also in the area of the veterinary medicine, medical device, insecticides , pesticides, agrochemical, cosmetic and complementary medicine .It also made the interface between the pharmaceutical company and the regulatory agencies. It is also responsible for maintaining the appropriateness and accuracy of the product information. And its main role to act as an liaison with regulatory agencies , providing expertise and regulatory intelligence in translating regulatory requirement into practical workable plan , advising the company on regulatory aspects and climate that would affect their proposed activities.

KEYWORDS : Regulatory affairs,world wide regulatory agencies, Regulatory affairs professional,regulatory bodies, pharmaceutical industries, FDA.clinical research affairs.

INTRODUCTION:

Regulatory affairs is a comparatively new profession which developed from the desire of governments to protect public health by controlling the safety and efficacy of product in areas including pharmaceutical,veterinary medicines,medical devices,pesticides ,agrochemicals,cosmetics and complementary medicine.

Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals. Regulatory Affairs is a rewarding, intellectually stimulating and highly regarded profession within pharmaceutical companies.The current Pharmaceutical Industry is well organized, systematic and compliant to international regulatory standards for manufacturing of Chemical and Biological drugs for human and veterinary consumption as well as medical devices, traditional herbal products and cosmetics. Stringent GMPs are being followed for blood and its derivative as well as controlled manufacturing for Traditional Herbal Medicines, Cosmetics, Food and Dietary products which was otherwise differently a century before. Each regulatory system had faced certain circumstances which led to current well-defined controlled regulatory framework. As a discipline, regulatory affairs covers a broad range of specific skills and occupations. Under the best of circumstances, it is composed of a group of people who act as a liaison between the potentially conflicting worlds of government, industry, and consumers to help make sure that marketed products are safe and effective when used as advertised. People who work in regulatory affairs negotiate the interaction between the regulators (the government), the regulated (industry), and the market (consumers) to get good products to the market and to keep them there while preventing bad products from being sold.

Regulatory Affairs in the pharma industry may be defined as "the interface between the pharmaceutical company and the regulatory agencies across the world."

REGULATION AND REGULATORY AFFAIRS:

India is home to about 10,500 manufacturing units and over 3,000 pharma companies, and exports all forms of pharmaceuticals from APIs to formulations, both in modern medicine and traditional Indian medicines. Everything from drug development and regulation to commercialization is highly regulated in the country. Every drug must undergo rigorous scrutiny and clinical trials before getting the market approval to ensure its quality, safety, and efficacy. In India, these standards are set by regulatory authorities or the Drug Control Authority (DCA). Regulation impacts all aspects of the pharmaceutical domain, from pharmaceutical companies and

independent innovators to regulatory or administrative bodies and patients.

The regulatory department holds a crucial link between drug products, companies, and regulatory authorities in determining the chances of drug development and the product to enter the market. Regulation involves a broad and extensive evaluation of a particular drug to ensure the protection of public health, drug registration, marketing authorization, pharmacovigilance, import, export, and distribution of the product. Regulatory Affairs is a blend of science and management that helps achieve the commercial goal of the drug-development organizations. RA takes care of everything from the development plan to supervising/reviewing of the submission guidelines in the drug development and authorization process.

QUALITIES OF A GOOD RA PROFESSIONAL:

- Authoritative
- Team Player
- Decisive
- resourceful
- Good Communication Skill
- Analytical Skill- Ability to evaluate the strengths and weakness of the technical and legal options open to a company.
- Good Informational Technology skills
- Negotiating Skills
- Able to reapply scientific and regulatory principles
- Ability to work with other disciplines
- Flexible- Always willing to learn.

GOALS OF REGULATORY AFFAIRS AS PROFESSIONAL:

- Protection of human health
- Ensuring safety, efficacy and quality of drugs
- Ensuring appropriateness and accuracy of product information

ROLES OF REGULATORY AFFAIRS PROFESSIONALS:

- Act as a liaison with regulatory agencies
- Preparation of organized and scientifically valid NDA, ANDA,INDA ,MAA,DMF submissions
- Ensure adherence and compliance with all the applicable cGMP, ICH, GCP, GLP guidelines, regulations and laws
- Providing expertise and regulatory intelligence in translating regulatory requirements into practical workable plans
- Advising the companies on regulatory aspects and climate that would affect their proposed activities
- Apart from the above main roles, there are various other roles which Regulatory Affairs professionals play.

Qualifications Required To Become A Regulatory Affairs Professional/ To Make Career in Regulatory Affairs:

- A Bachelor's degree in the field of science especially pharmacy, biology, pharmacology, microbiology, biochemistry is a must for getting into as RA.
- For junior positions, undergraduates or postgraduates is sufficient but for senior positions
- In the field of clinical research, it is mandatory for a person to have a doctorate degree.
- In order to get very good success in this field one must start his/her career with a related field like for example, laboratory testing, production, quality control, quality assurance, etc. with this he/she will get a good practical experience in drug development and its related process.
- However, professionals with essential skills in biology, clinical sciences, management, engineering, and writing are also highly desired candidates for this diverse field.

Regulatory affairs professionals earn:

Much like the setting and scope of a regulatory job, regulatory salaries vary, depending on job function, previous regulatory experience, seniority, geographic market, and highest earned degree.

And as market demand has increased, employers are willing to pay more for the right level of skill. Since 1995, salaries across all regulatory professions have maintained a general upward trend, increasing by an average of 3.3 percent per year. As of 2016, the average yearly salary for regulatory professionals at all levels was \$150,422.

According to the 'Regulatory Affairs Professional Societys (RAPS) 2018 report, the national average total compensation for U.S.-based regulatory professionals by job level is:

- Vice President: \$256,500
- Director: \$189,000
- Manager: \$139,000
- Project Manager: \$128,000
- Specialist: \$123,000
- Associate: \$93,000

Regulatory Affairs professionals interact with numerous functional areas which include:

Pre-clinical research : Pharmacology and toxicology testing to evaluate new drug candidates.

Clinical Research: Conduct of clinical studies, data collection, statistical analysis, report writing

Manufacturing: High levels of controls for the production of safe and efficacious products.

Quality control: Analytical testing of all products in terms of purity, safety, potency, and quality.

Quality assurance: Oversight of operations related to failure investigations, auditing, complaints and documentation management.

RESPONSIBILITY OF RA PROFESSIONAL:

- Keep up to date about international legislation, guide line and customer practices.
- Update with company's product range.
- Compliance of company product with current regulation.
- Impart training to R&D ,pilot plant, ADL, on current regulatory requirements.
- Formulate regulatory submission strategies.
- Prepare IMPD, DMF, ANDA, MAA, dossiers amendments and supplement etc.. as per regional guideline, submit them to regulatory authorities in a specified time frame.
- Monitor progress for all registration submission.
- Respond to queries as they arise and ensure that registration/approval are granted without delay.
- Handle regulatory and customer inspection, review audit report and compliance.
- Arranges consultations and meeting between the firm and government regulatory agencies.

NEED OF REGULATORY AFFAIRS IN THE PHARMACY CURRICULUM:

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. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory

agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries .

Recent development of regulatory affairs:

Starting in 1980 the European Union started to harmonize the regulation of healthcare products in the member states. The concept of regulating medicines was well established in most member countries along similar lines to the US model, but many countries did not have any significant medical device regulation. Concurrently the EU had been developing the concept of New Approach Directives where only broad concepts were written into the law and the bulk of the technological detail delegated to compliance with recognized standards (which are more readily update-able).

The Europeans took the radical approach of applying the New Approach Directive to Medical Devices and by doing so made the first significant conceptual advance in healthcare regulation for nearly 100 years.

The European Model for medical device has largely been adopted by the Global Harmonization Task Force as the international template.

Future development of regulatory affairs:

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.

Career Opportunities in the Life Sciences Industry:

Regulatory affairs liaisons manage the process of working with project teams and interacting with the regulatory health agencies, such as the Food and Drug Administration (FDA) or the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In addition to regulatory affairs liaisons positions, there are a vast array of other career opportunities, such as managing and submitting regulatory information, document management, and publishing.

Positions within regulatory affairs offer excellent job security. The reason is simply supply and demand: not enough people today have experience in regulatory affairs and at the same time, the FDA has increased its standards, requiring more supporting studies and paperwork before products can be approved for human use. To be successful in this position, it helps to be very detail- and process-oriented, and to possess excellent writing, communication, and interpersonal skills.

Regulatory Affairs Specialists assist in obtaining and maintaining government approval for drugs, medical devices, nutritional products, and related materials. They are often employed by pharmaceutical, biotechnology, and medical device companies. They may also work in government or law. The duties and responsibilities of Regulatory Affairs Specialists have expanded in recent years as a result of company acquisitions and restructuring, worldwide globalization of markets, and constantly evolving regulations. Typically, individuals in these positions work within an office of regulatory affairs where they work on document preparation, information management, file maintenance, and coordination of tasks across multiple departments. Part of their strategic directive is to achieve a balance between regulatory concerns, technology, marketing objectives, compliance, time to market, and costs. The office of regulatory affairs is a dynamic work environment where communication with employees at all levels within the organization is extremely important.

Regulatory Affairs organization:

Regulatory Affairs Specialists must understand all aspects of product development, including research, clinical trials, manufacturing practices, regulations, and approval processes. They help review product promotional materials, labeling, batch records, specification

sheets, or test methods for compliance with applicable regulations and policies. They often advise project teams on subjects such as premarket regulatory requirements, export and labeling requirements, or clinical study compliance issues. In addition, they determine the types of regulatory submissions or internal documentation that are required in situations such as proposed device changes or labeling changes.

A variety of job titles may be used in this profession, including Clinical Quality Assurance Associate or Specialist, Drug Regulatory Affairs Specialist, Product Safety Specialist, Quality Assurance Documentation Coordinator or Specialist, Quality Assurance/Regulatory Affairs Specialist (QA/RA Specialist), Regulatory Affairs Analyst, and Regulatory Affairs Associate. Some typical job tasks include:

- Explain regulations, policies, or procedures
- Maintain data in information systems or databases
- Ensure compliance with regulations
- Advise others on regulatory and compliance matters
- Evaluate applicable laws and regulations to determine impact on company activities
- Provide technical review of data or reports
- Coordinate regulatory documentation activities
- Identify and interpret relevant regulatory guidelines

Regulatory affairs positions have increasing levels of responsibility and more senior individuals typically assume titles of manager or director. Jobs in this field are likely to increase due to expanding government regulation within the health and pharma industries.

Healthcare RA:

The regulatory function in healthcare industries is vital in making safe and effective healthcare products available worldwide. Individuals who ensure regulatory compliance and prepare submissions, as well as those whose main job function is clinical affairs or quality assurance are all considered regulatory professionals. The most significant responsibility of a Regulatory professional in an export company is to get a product successfully registered and approved by the Health Agency of the country like FDA for USA or EMA for Europe.

Regulatory professionals are employed in industry, government and academia and are involved with a wide range of products, including:

- pharmaceuticals
- medical devices
- in vitro diagnostics
- biologics and biotechnology
- nutritional products
- cosmetics
- veterinary products

The regulatory professional's roles and responsibilities often begin in the research and development phases, moving into clinical trials and extending through premarket approvals, manufacturing, labeling and advertising and postmarket surveillance.

CONCLUSION:

Many in the regulatory affairs profession believe the new approach to regulation will eventually be adopted to for all healthcare products as it represents the best model for delivering new healthcare products advances to market in a reasonable time with acceptable safety 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 regulatory affairs department growing within companies.

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