A REVIEW ON REGULATORY AFFAIRS

1ADITYA RAJU VISHWAKARMA, 2MAHESH KAKDE, 3SALONI NAGESH NAMPALLI, 4MEGHANA SOMNATH PATIL, 5SANDHYA RADHAKISAN DHOTRE
1STUDENT, 2STUDENT, 3STUDENT, 4STUDENT, 5STUDENT
1DBATU, 2DBATU, 3DBATU, 4DBATU, 5DBATU

Abstract:
Regulatory affairs (RA) professionals play critical roles in a pharmaceutical industry because it is concern about the healthcare product lifecycle, it provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. Regulatory Affairs is an attractive career choice for graduate students from a scientific background who enjoy communication and team work, are comfortable with multi-tasking and are eager to expand their knowledge in the wide realms of the Pharmaceutical world.

Regulatory affairs –
The profession arose out of the government's desire to protect public health by monitoring the safety and efficacy of products in areas such as pharmaceuticals, veterinary medicine, medical equipment, pesticide, pesticide. Food to fields such as cosmetics and additional pharmaceuticals.

Under the best of circumstances, it is composed of a group of people who act as a liaison between the government, industry, and consumers to make sure that marketed products are safe and effective when used as it advertised People who work in regulatory affairs negotiate the interaction between the regulators (the government), the regulated (industry).

Drug development for commercialization is strictly regulated.

All drugs must undergo rigorous and rigorous clinical trials before being approved on the market to ensure safety, efficacy and quality.

These standards are set by national regulatory authorities such as FDA in the US and COSCO in India. drug regulation covers the following areas: Imponization and pharmacovigilance for drug distribution (monitoring of adverse drug reactions)
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. A new drug may have cost many millions of Euros or dollars, pounds, 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 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. The Regulatory Affairs department is very often the first point of contact between the government authorities and the company.

Regulatory Authorities –
Regulators - Health care is my concern Medicines/pharmaceutical products for use by humans/veterinarians and medical devices must be safe as well as effective for their intended use. Various territorial regulators have arisen to ensure this. Major regulatory bodies include the World Health Organization American Food; 1st Medicines Administration (USFDA. United States), European Medicines Agency (EMA.Medicines and Health Products Regulatory Authority (MHRA. UK). Pharmaceuticals and Medical Devices Agency (PMDA Japan) and Central Medicines Agency for Standardization (COSCO, India). It was noted that the regulatory principles are different with respect to territorial requirements. The International Council on Harmonization or Technical Registration Requirements for Human Medicines (ICH) was established in 1990 as a joint US effort. Europe and Japan will unite various regulatory agencies around the world against the ICH has made incremental progress to improve coordination of urban development and drug registration with a higher level of safety. Although ICH has harmonized aspects of drug regulation globally, regional regulatory authorities continue to play a key role in drug approval throughout the region.

Role or Pharmacy Department:
A) In Developing
- Enforcement of legal requirements -

WHY NEED TO REGULATE
1. There is none which is not a poison. The right dose differentiates a poison and a remedy.
2. To ensure quality, safety and efficacy of drug products in order to assure the continued protection of Public Health.
3. No drug product is completely safe or efficacious in all circumstances, but there is a moral, as well as legal, expectation that appropriate steps are taken to assure safety and efficacy the Producers concerned. Benefit versus Risk.

PHARMACEUTICAL DRUG REGULATORY AFFAIRS

Regulatory Affairs is a comparatively new profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines [6]. The companies manufacture and marketing these products must ensure that they supply Quality products to public for their health and welfare. Now most of the companies have specialist departments of Regulatory Affairs professionals.

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. Changes to drug manufacturing and testing activities to determine if and when the FDA must be notified. 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. The Regulatory Affairs (RA) departments must be aware of the regulatory requirements in all the company's export markets[7].

REGULATORY AFFAIRS PROFESSION

The pharmaceutical research and development process of bringing a new drug to the market takes many years; it is therefore essential that the process be managed effectively from beginning to end in order to meet the regulatory requirements and permit a favorable evaluation of efficacy and safety in the shortest possible time [8]. The drug regulatory affairs (DRA) professional plays an important role in every phase of this process, from developing regulatory strategies following the discovery of a new chemical entity to planning post-marketing activities.

In this position, the DRA professional must possess a proficient scientific background (B.Sc, M.Sc., Ph.D., M.D. B. Pharm, M.Pharm or Pharm.D.) and have acquired a thorough understanding of the regulatory process. The DRA professional is responsible for ensuring that the legislative requirements are met, recruiting scientific advice, setting regulatory strategy, ensuring application guidelines for clinical trials, submission of application to conduct clinical trials, managing the regulatory submission, minimizing time to market (every day counts), advice on a global development plan, optimizing submission strategies, interaction with commercial side of business such as pricing, reimbursement, check progress of evaluation and anticipate questions, clarifying raised questions, plan response and strategies with other departments, planning and managing agency meetings/hearings, negotiating approval and product information with agencies.
C) In post approval phase -

- Compliance
- Submission of variations/amendments
- Renewals
- Pharmacovigilance
- • Product information review
- • New indications/new formulations
- • Regulatory input to development plan/Regulatory Intelligence.

- Figure 2 - Various Role or Drug Regulatory Affairs Departments

- Responsibility or the Regulatory Affairs Professionals •

- Ensuring that their companies comply with all of the regulations and laws pertaining to their business.
- Working with federal, state, and local regulatory agencies and personnel on specific issues related to their business.
- Advising companies on the regulatory aspects and climate that would affect their proposed activities.
- Keep in line with international guidelines and current practices.
- Keep up to the date with a company's product range.
- Collect, collate, and evaluate the scientific data that their research and development colleagues are generating.
- Formulate regulatory strategies for all appropriate regulatory submissions such as domestic, international and/or contract projects.
- Coordinate, prepare and review all appropriate documents for example dossier and submit them to regulatory authorities within a specified timeframe in conjunction with the organization.
- Prepare and review of SOPs related to RA Review of BM R/MF R, c. change, umf R and other relevant documents.
- Monitor the progress of all registration submission.
- Maintain approved applications and the record of registration fees paid against submission of DMFs and

Respond to queries and ensure that registration approval are granted without delay.

Panic in R&D training. Pick plant Scale Up and Post Marketing Surveillance (ADR).

Manage and review audit reports and compliance, regulatory and customer inspections.
Provide accurate and complete information about the quality, safety and effectiveness of the product to the physicians and other healthcare professionals.

Development of ICH

Most pharmaceutical and biotechnology firms employ drug development project teams to guide the processes involved in early drug discovery phase through the various drug development stages and finally making the drug candidate into a therapeutic product.
The drug development team includes a diverse group of individuals with different philosophies and approaches to the development process. All team members must work closely together to ensure that the drug is both safe and efficacious.

The responsibilities of these project teams include:

1. Reviewing records on clinical trial results conducted by scientific disciplines.
2. Integretating new research results with previously generated data.
3. Planning research studies to further characterize a drug candidate.
4. Preparing a timeline for drug development, including the definition of key milestones.
5. Monitoring the status of research studies to ensure that they are being conducted according to the timeline and critical path in the development plan, and, if appropriate, modifying the plan as new information becomes available.
6. Comparing research results and development status and timelines with drug candidates under development by competitor.
7. Conducting appropriate market surveys to ensure that the development of a drug candidate is economically justified and continues to meet a medical need.
8. Revising the status of the drug development program to management and making recommendations on the continued development or the drug candidate.

Drug development teams consist of the following groups of teams:

1. Nonclinical pharmacology and toxicology (NPTA) teams

These groups study a drug product in animal models of efficacy and safety in order to identify potential efficacy and safety issues in humans. It is critical for the clinical and development groups to work closely with the toxicologists in the design of animal studies to ensure their relevance to the clinical environment.

3. Clinical research

Clinical research is the ultimate responsibility for the design and execution of drug safety and efficacy studies on the shoulders of clinical research. Clinical trials must be science-based, with proper statistical methodologies and clinical relevance. Clinical research interacts directly with the FDA and is responsible for the identification and execution of study documents. Clinical research, in collaboration with biotechnology and regulatory affairs, prepares publications necessary for the marketing of drug products.
CONCLUSION

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 Due to the changing resources necessary to fulfill the regulatory requirements, some companies also choose to outsource or out task regulatory affairs to external service providers. 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.

REFERENCES

6. “Careers in Regulatory Affairs from Practitioner to professional,” Naturejobs Biotechnology, 2002;20(4): 409-41:
11. Available online: www.centrewatch.com
12. Training needs in regulatory sciences for the biopharmaceutical industry. 2001;19(12),1187-1189
16. The Fourth Quadrant: A Map Of The Limits Of Statistics