IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

A REVIEW ON REGULATORY AFFAIRS

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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 bet ween the government, industry, and consu mers to make sure that marketed prod ucts arc safe and effective when used as it advertised People who work in regulatory affairs negotiate the interaction bet ween the regulat ors (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. Umitcd Stales), 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 Hamtonization 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) Jn Developing

- Enforcement of legal requirements -

WHY NEEDTO REGULATE

1there 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 assuresafety 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 tho

Role orDrug Rq:ul ntory Affairs Department:

A) Jn Development phase -

•Ensuring that the legislative requirement s are met –

Recruit Scientiric Adviceauthorit ies

-AdNice on development studiestodemonstrate sa fety. qua l i t y a.nd cfficncy parameters.

•Setuprcgulat01y -.rategy.
•Ensure application or guideli nes for clinica l trials.

•Submission of application to conduct clinica l trials.

•Managi1ngthe regulatorysubmission -

-M ini mize time t o m:irket (every day counts)

-Ad vice on a globa l dc,clopmcnt plan

•Opcimize submission s1rntcgics -

-Dosicr preparation

-Form:it. document re-uses

-Eltttronic submission.

-R e, ew high-level docu mcnts/rcpons

•Interact with conunercial sideof business such as pricini:311drei mbursement.

• Check progress of evaluation ond anticipuc questions.

• Clarify raised questions. plan response and strategics with ocher deputmcn ts.
• Plan and m:imge agency meetings/hearings.

• Ncgoci atc appro,'lll and Product Information wit h agencies.

C) lnpost approval phase -

- Compl iance
- Submission of \'llriations/amcndmcnts
- Renewals
- Pharm:iieovigilancc
- •Product infonn1tion review
- •New indicat ions *I* new formulations
- •Regulatory input to development planv Regulatory Intelligence.

- Figure 2 -Va rious Role orDrug Regulatory A!Tnirs Department
- Responsibilit y or the Regulatory Affairs Professionnls •
- Ensuring that their companies comply with all of the regulations and laws pertaining to their business.
- Vorking with federal, state and local regulatory agencies and personnel on specific issues related to their business.
- Advising companies on the reguluory aspects and climate that would affect their proposed activities.
- Keep in 1m1ch wi1h in1crn. 1ion:il lcgisln1inn. guideline.< nnd cu<lomcr prn clicc<.
- Keep up to the date with a company's product range.
- Collect, collate, and evaluate the scientific data that their research and development colleagues arc generating.
- Formu late regulatory strategies for all appropriate 1egulatory submissions such as domestic, interrutional andfor contract projects.
- Coordinate, prepare and review all appropriate documents for ei1ample dossier and submit them to regulatory authorities within a specified time frame in conjugation with the organization.
- Prepare andreview of SOPsrcla1cd to RA. Review of BM R .MFR .c.:hangcc.:untrul und other relevant
- docu ments.
- Monitor the progres s of all registration submission.
- Maintain approved applicat ions and the record of registration fees paid against submission of DMF's and

Respond to q ueries nnd ensure that rcgi!llrationl approval arc granted without delay.

Panicip!tc in R&D tru ining.Piloc plant Scale Up. nnd Post Mar kt-ting Surveillance (ADR).

Manage und review audit repons and compl iance, regul:ltory and customer inspections.

Provide accu rate anti complete inform:ition about the quality, safety and effectiveness of the produ ct to the physicians and other healthcare professionals.

Development of ICH

Mosl pharmaceutical und biotechno logy firin employ dnig development project team to gu ide the processes involved in early drug discovery phase. through the various drug development stages and finally m:iking the drug cand idate into a therapeutic produ ct.

Thedrugdevelopmentteam includesndiversegroupofindividualswithdifferentphil05ophiesu.nd upproochcs tothe1le\'clopment process.Allteam membersmust wcwkclosely togethertocrturethatudrugis boihsafeand efficacious.

Thercsponsibili1ie1 ofthesepr0jectteamsinclude-

I. Reviewing rccard1rc:suhs from Cll pl'Timcnls cunduelcd by scicmilic discipli nc:s.

2. lntegcnti ng new research resultswith previously generated datn.

3. Planning research studies to fu nher char;ictcrizc;i drug cnndidatc.

4. Prcpnri ng a tlct11ilctl drug development plan, including desigmuion of key poi nts or development

milestones, gencrmins n timeline for comp let ion. anti defin ing the critical path.

5. Monitori ng the stutus ofresearch studies to ensurethnt they orebeing conducted according to the timel inc 5

uod critical path in the dcvclopnlCnl plan und, if appropriate, mooifying lhc plan ns new information becomes

nvnilablc .

6. Compari ng research results anti development statusn.nd timelines with drug candidates under development by complitor .

7. Conducting oppropri nte market surveys to ert urc thJt the development of a drug candidate is economica lly justified and continues to meet a medical need.

8. Reponing the statusofthe dnig devel opment program to man.igemcnt and m:iking recommentl ttion. on the conti nued development or 1hc drug canditbte.

Drug tlcvelopment tcatn'I consist of following gcoup ofteams-

1.Nonclinical pharmacology and toxicol()jl)• Tenm

nm group studies 1hcdrug produel in anim::it models forefficacy and safety in order to identify pocentiD.1 efficacy and safoty issues in hum:ins.It is criticnl for lhc clinical and development groups to work closely wi1h lhe ICJticologists in the design of anim::il s1udics to ensure their rclcvncc lo the clinical environment

3. Clinical resarch

Clinicol rcscorch h:ls the ultimate rcspon1bility for tcstini: drui: products in hu man_ :the moni1ori ng of dru& safely rests squarely on the shou lders of cli nical reseuch.Cli nical trials musl be science-based 'ilh proper slali\tical mc1hodologics and h:l\'C clinically relevant end point,.Clinical c:irch inleracts dircc:1ly with t he FDA and i responsible for the &encr:ition of study rcporl 'i1h i nput from biO'l t:llis1ici:ins and rci;u latory affairs.Cli nical research c:in also i:encr.ue 1hc publicat ions necessary for the marketing ofmy drug product.

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.

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