INTERNATIONAL JOURNAL OF ADVANCE RESEARCH, IDEAS AND INNOVATIONS IN TECHNOLOGY

ISSN: 2454-132X
Impact Factor: 6.078
(Volume 7, Issue 3 - V7I3-1823)
Available online at: https://www.ijariit.com

A review on regulatory affairs

Dr. J. Bhavani
tnbhavanisundaram@gmail.com
P.S.V. College of Pharmaceutical Science and Research, Orappam , Tamil Nadu

K. Kokila
kokilakumar898@gmail.com
P.S.V. College of Pharmaceutical Science and Research, Orappam, Tamil Nadu

M. Agil Kumar
agilkumar321@gmail.com
P.S.V. College of Pharmaceutical Science and Research, Orappam, Tamil Nadu

A. Tamil Selvan
mayuritamil97@gmail.com
P.S.V. College of Pharmaceutical Science and Research, Orappam, Tamil Nadu

R. Hariprakash
hariprakashhp00@gmail.com
P.S.V. College of Pharmaceutical Science and Research, Orappam, Tamil Nadu

ABSTRACT

Regulatory affairs professional play significant roles in the pharmaceutical industry as it concerns the lifecycle of the healthcare product, it offers operational direction, tactical and strategic, and assistance for working within the regulation to accelerate development as well as distribution of healthcare products safe and efficient to expedite the development role of regulatory affairs, a regulatory strategy is developed and implemented, to guarantee that the collective actions of the team of drug development lead to products which are approved by the Global Regulator but is also differentiated in certain ways from the competition and is also to assure promotion, are carried out in according to the guidelines and regulation founded by a regulatory authority. Regulatory affairs (RA) are an interesting career option for science graduate students who enjoy communication and teamwork, comfort with multi-task, and want to develop their knowledge in the broader area of the pharmaceutical sector. RA is a rewarding, intellectually stimulating, as well as highly respected profession in a pharmaceutical company.

Keywords: *Worldwide Regulatory Agencies, Regulatory Affairs Professionals, Regulatory Bodies, Regulatory Affairs, Pharmaceutical Industries, FDA, Ethical Considerations*

INTRODUCTION

Regulatory affairs are a profession commonly known as government affairs in regulated industries, including banking, energy, medical equipment, and pharmaceuticals. RA has a very particular significance in the healthcare industry (functional foods, Biologics, drugs and medical equipment,) many other firms have specialized departments of professionals in the field of RAif they are large multinational pharmaceutical industries or small, modern firms of biotechnology.

The present pharmaceutical industry is established properly and systematically following worldwide regulatory norms for the production of chemical as well as biological medicines for veterinary & human use and traditional herbal products, medical devices, as well as cosmetics. Stringent GMPs are followed, which were otherwise different a century earlier, for blood and its derivatives and regulated production of the conventional herbal medicines, cosmetics, dietary as well as food items.

There were some factors in each regulatory system, leading to the present well-specified regulatory framework. The systemic manufacture and marketing of safe, effective, and quality medicines have resulted. With the industry growing, the regulation in each area is becoming more complicated and established a requirement for regulatory professionals. We look at historical developments in the US, Europe as well as India in the pharmaceutical industry to comprehend the chronological evolution of the current pharmaceutical industry as well as the regulatory framework.[1]-[4]

DEFINITION

RA is a regulated industry profession. In the healthcare industry, RA also has very unique importance. The corporations are responsible for discovering, testing, manufacturing, and promoting these products also accountable for ensuring that they provide safe products that contribute to public health as well as welfare.[6]

OBJECTIVES OF REGULATORY AFFAIRS:

- How & why the pharmaceutical sectors, as well as drug rules, have established in the United States Main Regulations of United States
- European Union Regulations governing medicinal products
- The Pharmaceutical Industry Roles and Health Authorities for RA Professionals.
- EU Pharmaceutical Law
- EU Framework and its regulatory
- Forms of "Marketing Authorization Process" in EU Market
- India's major Rules and Act
- Development in various era of Indian Pharmaceutical Industry & Drug Regulations

SCOPE OF REGULATORY AFFAIRS PROFESSIONAL IN INDUSTRIES

RA professionals are used in academics government regulatory bodies as well as industry. In these domains there are a broad variety of regulatory professionals:

- Biologics and Biotechnology
- Cosmetics
- In-vitro diagnostics
- Medical devices
- Nutritional Products
- Pharmaceuticals
- Veterinary Products

IMPORTANCE OF REGULATORY AFFAIRS:

The time to arrive at the market in today's computing environment is essential for a product and therefore the success of the company. Hence, it has substantial economic value for the company for its actions in the field of RA.

The importance of the RA function means that senior "RA professionals" are progressively being selected to positions of the board room, where they may advise & affect their companies' strategic decisions.

Regulation is a binding directive from an agency to explain how the law may be interpreted and complied. If the rules are not followed, the warning letter published may result in a portion of the FDA website that is not a positive idea for a pharmaceutical firm.

A new drug may involve a huge investment in its development and thus a few months delay in reaching it to the market may require enormous financial consideration. In worst cases, failure to completely provide all relevant data or to disclose the inaccurate labelling of the product might simply lead to the recall of the product. Either of these issues could result in the loss of several million sales units, and most importantly the decrease in confidence of the investor, patients as well as health professionals. RA is the initial point of connection between the government agency and the corporation.[8]-[10]

Historical Overview of Pharmaceutical Industry:

Several tragedies in the 1950s such as vaccine tragedy, sulfanilamide elixir as well as thalidomide tragedy have led to considerable improvements in the safety, quality along with the effectiveness of drug product laws. It also led to higher standards for GMPs: "Good Manufacturing Practices" and MA: "Marketing Authorization".

United States of America (USA):

During the Mexican-American War of 1846-1848, the USA has been the root of contemporary pharmaceutical industries. The US forces suffered from the import of spurious malaria, yellow fever, cholera, and dysentery medicine which led the federal government to set the Custom Laboratories. Importing Drugs Act of 1848 was the first legislation to govern imports of medicines. In accordance with this rule, the quality, as well as purity of import medicines upon port entrance, was required. The USP ("United States Pharmacopoeia") has been identified as an authorized compendium to determine drug quality and purity. Note that while USPC ("United States Pharmacopoeia Committee") was created in 1820, it was a non-Government organization until the "Import Drugs Act" of 1848.The aim was to establish a standard system, national formulary as well as quality control.

New laws on medication control began to come into force at the turn of the 19th century, owing to many tragedies throughout the world. It was the time when ancient conventions of drug production and distribution developed into the contemporary highly organized drug trade and regulated system of DRA ("drug regulatory Affairs"). During the last 5 decades following the import of Drugs Act 1848 in 1901, the tragedy of the vaccines occurred. In this period, the City & State Departments of Health used stables and vaccine processing plants in contrast to today's private sector.

Law demanding the exclusive vaccine production facility after two deaths caused by a failure of immunization. Tetanus-contaminating bacteria were found in the diphtheria anti-toxin manufactured by the St. Louis City Health Department. It concluded with the death in November 1901 of 14 children. Simultaneously, smallpox vaccination was discovered contaminated and nine further deaths occurred in Camden, New Jersey (Fig.1).

In the previous five decades, rules on drugs have grown quickly and several legislations have taken effect, leading to the organized regulatory framework of the FDA. The agency has grown to about 9,100 employees in various categories, including doctors, attorneys, veterinarians, pharmacists, microbiologists, chemists, and pharmacologists from a single chemist from the USAD:"United Stated Agriculture Department". At present, the Agency is accountable for public health protection via ensuring the safety, efficiency as well as safety of human & animal medicinal products. It covers more than one trillion dollars' worth in Animal Drugs, New Human drugs, Infant formulas, Complex Medical Devices, Biologics, Color Additives, and Food products (Table 1).

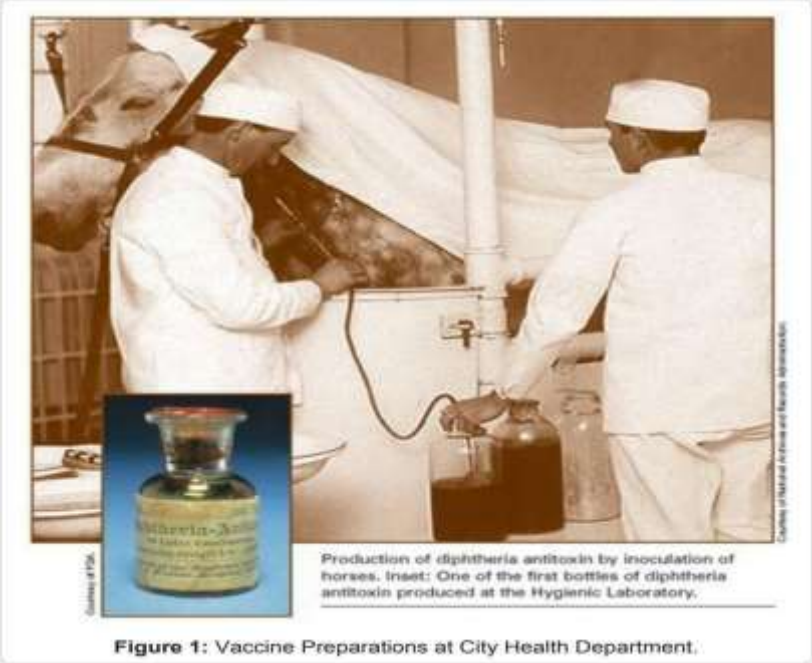

Figure 1: Vaccine Preparations at City Health Department.

European Union (EU):
With the primary purpose of keeping harmful items off the market, healthcare regulation has emerged in European countries. In terms of Efficacy, Safety, and Quality, few other reasons were accountable for well-defined regulation and the highly sophisticated pharmaceutical industry. Ethical considerations: In 1964, the declaration of Helsinki was laid down to prevent unsafe and unethical clinical experiments and to ensure the safe and appropriate treatment of people. Economic problems:

In the second part of the 20th century, the first health insurance scheme was established. Pricing transparency came from the shift of costs for medicinal products from the consumer to the commercial and public health systems. Unsafe usage of products: The main drug regulatory revolution in European countries began after the thalidomide tragedy. A German manufacturer sold new sedatives medicines throughout Europe towards the end of the 1950s.

The European Economic Commission's first Directive laid down "65/65/EEC" requires no drugs may be sold in "European Communities" unless at least one competent agency inside Europe has authorized them. The purpose of this act was to get the European Economic Commission's single standard marketing approvals for the drug procedure. At the same time, several additional guidelines were implemented for a product category such as homeopathic, immunological, and radio pharmaceuticals medicines, and labelling, classification as well as promotion directives were coming into effect.

India:
The Indian medicine industry was quite early till the 20th century. Most of the medicines have been imported from outside. The demand for pharmaceuticals expanded greatly after the First World War and led to the introduction of cheap and standard medications, same as in the United States post "Mexican American war".[3]

a) 1900-1960: Government approved the Poisons Act of 1919 in order to manage cheap medications on the market. This Act governs the sale or possession of poison-specified substances. It also stipulates safe care of the poisons, poison packaging & labelling, maximum quantities to be sold, inspection, and poison tests sold throughout the year by the seller. The Dangerous Drugs Act of 1930 followed the Poisons Act.
This Act governs the cultivation, manufacturing, and possession, import, export, transship, and sale of opium-by-opium plants.
The 1985 Act on Narcotics and Psychotropic Substances was enacted and revoking the Dangerous Drugs Act of 1930 and Opium Act of 1878. During this era, the following acts and regulations were adopted:

- **Drugs and Cosmetics Act, 1940:** Produce, distribute, Import, and sell pharmaceuticals are regulated. This act includes Siddha, Unani, Homeopathic and Allopathic medicines.
- **Drugs & Cosmetics Rules, 1945:** The laws of the "Drugs and Cosmetics Act" govern only the manufacturing and not consumption, usage, or possession of Ayurvedic medications for sale.
- **Pharmacy Act, 1948:** This legislation was last modified in 1986 and controls the Indian pharmacy profession.
- **Drugs Prices Control Order,1955 (DPCO) (under the essential commodities Act):** In 1995, the DPCO was changed further. According to this law, the government could examine as well as set the highest selling price for formulation and bulk drugs.

- **Drugs & Magic Remedies (Objectionable Advertisements) Rules, 1955:** These regulations manage India's drug advertising.

b) 1960-1970: Multinational corporations controlled the market share and only a few Indian producers were present. The pharmaceutical industry of India has grown early. There was relatively little focus on pure research and development because of the absence of patent protection. The cost of drugs and the market availability was quite high because of the very heavy dependence on imports on drugs.

c) 1970-1980: The government has taken charge and enacted a few acts and regulations over the Medicines Regulation.

- **Indian Patent Act 1970**: It is the foundation for the protection of a patent in India. It allowed the patent only to be obtained by technique and methodology for the manufacturing of the drug substance. Under this Act, product patents were not allowed. From 20 April 1972, the 1970 Indian Patent came into force. The Indian Patents and Design Act of 1911 was replaced by this new act.
- **Drug prices capped:** DPCO was implemented to manage the high price to users.
- **Local firms start to make an effect:** The Indian Patent Act 1970 allowable the product patent; local enterprises started the manufacture of products/drugs by reverse engineering utilizing various production processes. As a result of this new medicine, numerous more substitutes against costly imported new pharmaceuticals became accessible at low cost and also on the market. That has led to,

1) Export of Bulk drug post-patent expiry
2) Export increases to nations such as South America, China, Africa, and Russia.

d) 1980-1990: Investment in API development and manufacturing facilities was initiated by the industry. Export incentives were also granted by the government. The Act on "Narcotic Drugs and Psychotropic Substances" of 1985 regulating the use of narcotic drugs as well as substances was issued.

e) 1990-2000: In the pharmaceutical sector, domestic markets expanded rapidly and globalization occurred in that era. The corporations have started research activity. India joined the PCT ("Paris Cooperation Treaty") in 1999 and introduced a product patent useful from 1 January 2005.

f) 2000-2010: The age of innovation and research is regarded during this time. Innovative research activities, medication formula patenting, methodology, indications, and the merging of firms have been launched over these years.

- **Patent Amendment Act 2005:** It makes provision for "Black Box application", in accordance with which the manufacturer may market that product after 2005 with no "infringing product patent", whether it has made a considerable investment in product manufacture, created as well as trademarks, if the patent application is filed before the 1 January 2005, and then according to the transit provision of TRIPS:"Trade-Related Aspects of Intellectual Property Rights".
- **Compulsory Licenses:** These licenses may be given for the production and export of medicinal products to any nation with or without production capability, to solve public health problems for the product concerned.[11]

REGULATORY BODY

Definition:

A regulatory body is a public or governmental organization set up to perform a regulatory role. This includes imposing requirements, criteria, or limits, The standard set for activities specified and complied within those areas. Regulatory authorities cover a broad range of occupations; however, not all occupations are self-regulating and controlled. A regulatory body could also be called a regulatory authority, regulatory agency, or regulator.[12].

The Regulatory Affairs professional and its responsibilities:

It is thus vital to ensure the process of pharmaceutical research and development of the marketing of a new medicine is efficiently handled from start to finish in order to fulfill regulatory standards and to allow a positive assessment of effectiveness and safety as early as feasible.

Responsibility:

It is responsible for the submission to the regulatory bodies of the registration documents and all the following negotiations required for maintaining the marketing permission for the items involved. From the start of product development, they provide technical and strategic assistance at the highest standard in their organization, providing an essential commercial and scientific contribution to the development program's success and of the corporation as a whole.[30]

List of responsibilities of Regulatory Affairs Department:

1. The task of regulatory affairs professionals in all the areas where the corporation desires to sell its products is to monitor the continuously changing law. They also advise and compile, gather and assess scientific data generated by research and development colleagues on the legal and scientific limitations and needs.[31]
2. Submission of DMF's and other documents.
3. Track the status of all registration applications.
4. Keep accepted requests and record the registration fees received against
5. Maintain the product selection of a company up to date.
6. Maintain contact with international law, guidelines as well as customer practices
7. Ensure that the products of a corporation comply with existing rules.

ROLE OF REGULATORY BODIES

It is generally a not-for-profit organization, which develops the interest of a person who is involved in this specific profession. Its fundamental duty as a legal document is the development and supervision of professional education, the establishment of a code of ethics as well as the maintenance of professional standards.

Main Roles of Regulatory Bodies:

- Licensing of nurses.
- Monitor and enforce standards of nursing education.
- Monitor standards of nursing practice
- Set and enforce nursing practice standards.
- Set the requirement for nursing professionals to be registered.
- To assist and support professional members.
- To guarantee the rights of the public to quality health care services.

MAJOR REGULATORY BODIES:

1. International Council for Nursing(ICN)
2. State Nurses Registration Council (SNRC)
3. Indian Nursing Council(INC)

REGULATORY BODIES

INDIAN NURSING COUNCIL (INC):

Indian Nursing Council is India's national health and nursing educational regulatory authority. INC is an independent agency of the "Ministry of Health &Family Welfare", India's Government, establishing a standardized level of training for nurses, visitors, and midwives to the healthcare sector as per section 3(1) of the Act 1947 of Parliament on Central Government. In 1949, the INC was established.

OBJECTIVES:

1. Recognition for the purpose of the registration as well as employment in India & abroad of credentials as per Section 10(2)(4) of the "Indian Nursing Council Act" of 1947.
2. To prescribe the curriculum & nursing program regulations.
3. Authorizing Indian and Foreign Nurses with foreign qualifications to register in accordance with Section 11(2)(a), 1947 of "Indian Nursing Council Act".
4. A standard for nursing training for nurses, health visitors, and auxiliary nurses' midwives is established and monitored by inspecting the institutions.
5. To advise on several critical issues relating to nursing education in the country on Examining Boards, State Nursing Councils, Central Government, and State Governments.
6. Power to revoke recognition as per section 14 of the Act, if the Institution does not uphold its norms in accordance with Section 14(1)(b), where the institution of training of nurses, midwives, auxiliary nursing midwives, or healthcare visitors does not meet the Council guidelines.

REGULATORY AFFAIRS IN THE PHARMACEUTICAL INDUSTRY

Professionals from regulatory affairs provide technical as well as strategic guidance to R&D, production, departmental QC, etc., providing an essential scientific and commercial contribution to the success of a product development program as well as the corporation as an entirety. A new pharmaceutical product takes up to fifteen years to develop and commercialize, and there might be various obstacles in the scientific development process as well as a varying regulatory environment. Regulatory professionals assist the firm to prevent difficulties arising from irrelevant data, inadequate research, or bad data presentation.[25]-[26]

Importance of Open access and special features of OMICS Group:

The dissemination of information plays a key role in openaccess. It's user-friendly and doesn't make it difficult for anybody to access it. It has a translational capability covering 50 prominent global languages and its audio version is upgraded.

Digital papers encourage everyone to share new frontiers and discover new opportunities. It could respond to the expectations and aspirations of young people since it is social networking enabled. The fact that editors, authors, and reviewers get scientific credits is a noteworthy dimension.

REGULATORY AFFAIRS IN RESEARCH &DEVELOPMENT:

Regulatory affairs staff engages with R&D and marketing to produce creative products that benefit from new technology and regulatory advancements in order to speed up market time. The corporation expects new products to generate substantial revenues, and tiny time reductions to market are equivalent to substantial profit-and-recovery advantages.

The use of adaptive clinical trial methodologies, rapid approval from regulatory agencies, and process prevention may speed up the advancement of new items and contribute to reducing expensive mistakes and time delays.

REGULATORY AFFAIRS IN PRODUCTMANAGEMENT:

RA professionals have a larger function than product registration and provide technical &strategic advice to corporations at the highest level. They start their function from product creation through marketing and post-marketing approaches. The company's legal and technical guidance at all levels helps businesses to save money and time in producing and selling the same product. The "World Health Organization" rules on health & the "World Trade Organization" on trade rules between states are followed for countries that do not have regulations.

REGULATORY AFFAIRS IN CLINICAL TRIALS THE REGULATORY AFFAIRS:

Professional is the main connection in the firm and worldwide regulatory bodies like Australia European Medicines Agency, Therapeutic Goods Administration, "US Food and Drug Administration" (USFDA and Centre for Devices & Radiological Health) Medicines & Healthcare Products Regulatory Agency, UK, (UKMCA), OECD:"Organization of Economic Collaboration and Development" as well as Health Canada.

He conveys as well as understands to various divisions of the organization the apparently endless mace of rules, regulations as well as guidelines. The RA professionals establish solutions to overcome delays and provide the regulatory authorities with the conclusion of clinical studies, therefore lowering the time needed to approve the novel molecules rapidly.

The RA professional provides the communication, collection as well as evaluation of the benefits &risks of health items to the regulatory bodies, health, and medical care as well as the public. In operational terms, RA is accountable for ensuring that different stakeholders understand and handle government obligations, market-driven needs, and emerging scientific standards [27][28][29].

COMMUNICATING INFORMATION:

Non-critical information is the simplest method to exchange and communicate information.

The key concern with such material is to reach the proper audience without losing the relevant facts.

Most organizations sign up for news alerts or have email updates on their internal regulatory information. One approach is to utilize prominent websites as guidelines to make them entertaining and user-friendly. Critical information is challenging to express. This might include any essential feedback from the FDA, which is crucial to the project's failure or success.

The first step is to thoroughly record the data to ensure that we should understand it thoroughly and its consequences. Then imagine about those persons who are the mixture of- "need to know" along with "know who else needs to know". In a small company, it must be done with the president or the CEO while in a bigger industry, a project manager, or the head of clinical, must be managed.[30]-[31]

CONCLUSION

Most of the regulatory affair's profession think that this new rule will ultimately be implemented for all healthcare products since it constitutes the greatest strategy for bringing advancement to the market of new healthcare products in a reasonable period with appropriate safety regulatory department affairs are continually changing and increasing and are the most affected during procurement and merger as well as during recession regulatory affairs department in industries.

REFERENCES

[1] Y. Sri Harsha, V.Sharmila Reddy, D. Mary, D.Nagarjuna Reddy, M.V.Nagabhusanam, Brahmaiah Bonthagarala, the role of regulatory affairs in the pharmaceutical industry, Department of Pharmaceutical Management and Regulatory Affairs, Hindu College of Pharmacy, Amaravathi road, Guntur, Andhra Pradesh, India-522002.
[2] Accepted date: 23/04/2017; Published Date: 27/04/2017.
[3] Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at
[4] http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
[5] International regulatory affair updates, 2005. available at http,//www.iraup.com/about.php.
[6] Careers in Regulatory Affairs from Practitioner to professional, Nature Jobs Biotechnology,20(4), 2002,409-410.
[7] What are regulatory affairs available for https://www.topra.org/TOPRA/TOPRA_Member/What_is_regulatory_affairs.aspx
[8] Naila Kanwal, Sr.Executive Regulatory Affairs at The SEARLE Company Limited
- subsidiary of G.D. Searle & Co., U.S.A.
[9] P. Praneeth, Regulatory Affairs, and its Role in pharmaceutical Industry, M.Pharmacy (Pharmaceutical Management and Regulatory Affairs) PG Student, Sri Sivani College Of Pharmacy, Srikakulam, India.
[10] Keshari Roshan,Jha Aayush role of regulatory affairs in pharmaceutical company: an overview Original Research Paper, Delhi Pharmaceutical Sciences, and Research University. (Govt. of NCT Delhi).
[11] Topra brought by dimension associates available at http://www.topra.org/careers/whatregulatory- affairs.
[12] Dr.Ashok A.Hajare M.pharm PhD. professor and head deportment of pharmaceutical technology, Barathi Vidyapeeth college of pharmacy, Kohalpur.
[13] Rahalkar H (2012) Historical Overview of Pharmaceutical Industry and Drug Regulatory Affairs. Pharmaceut Reg Affairs S11:002. doi:10.4172/2167-7689.S11-002.
[14] Regulatory Body Published: February5,2016,|Updated:July31,2017.
[15] The board of nursing education nurses league, Christian medical association of India, south branch. A textbook for nurses in India vol:1 4th edition vi publication. Chennai71-77.

[16] XustonJ.carol. Professional issues inuring–challengesandopportunities.1st edition, lipincott Williams.andwilans.461-463.
[17] Sruthy, Regulatory Bodies in India and their Heads, September 21, 2019, in Articles, General Knowledge, z removed.
[18] Sumit Kumar*, Rishabh Panwar, Upendra Singh, REGULATORY AFFAIRS IN THE PHARMACY CURRICULUM, Department of Quality Assurance, D.B.I.P.R, Dehradun,Uttarakhand.
[19] SrivastavaDA. Country- level report on the pharmaceutical sector in India'. A report commissioned by DfID,UK.
[20] N.K.Jain,pharmaceutical product development‖ edition 3rd,C.B.Spublishers.
[21] P.P.Sharma–how to practice GMPs‖5th edition,Vandana publication Pvt.Ltd Delhi.
[22] WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-seventh Report. Geneva, World Health Organization, 2003 (WHO Technical Report Series, No.908).
[23] WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-eighth Report. Geneva,World Health Organization,2004
[24] Quality Assurance of Pharmaceuticals. A compendium of guidelines and related materials, Volume 1. Geneva, World Health Organization, 1997.
[25] Quality Assurance of Pharmaceuticals. A compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2 (updated version).Geneva, World Health Organization,2004.
[26] Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products – manual for a Drug Regulatory Authority. Geneva, World Health Organization, 1999 (Regulatory Support Series, No.5, WHO/DMP/RGS/98.5).
[27] Douglas J Pisano and David S. Mantus. –Textbook of FDA Regulatory Affairs - A Guide for Prescription Drugs, Medical Devices, and Biological‖ Second Edition.
[28] Sachin C Iskar, Dr. Ns Vyawahare, –Drug Regulatory Affairs‖, Third edition (2015).
[29] DK Sanghi and Rakesh Tiwle ROLE OF REGULATORY AFFAIRS IN A PHARMACEUTICAL INDUSTRY Principal of Shri Laxmanrao Mankar Institute of Pharmacy, Amgoan, Gondia, Maharashtra, India- 441902.
[30] *Research Scholar of Shri LaxmanraoMankar Institute of Pharmacy, Amgoan, Gondia, Maharashtra, India- 441902
[31] Training Needs in Regulatory Science for the Biopharmaceutical Industry, Nature Jobs Biotechnology, 19(12),2001,1187-1188.
[32] Hägglöf, Å Holmgren in Drug Discovery and Development (Second Edition),2013
[33] Dolita shah, Mayur Mistry, Asst. Professor, Smt. R. B. Patel Mahila Pharmacy College Production officer, Intas Pharmaceutical Ltd,Ahmedabad, India.
[34] M.Shakeel, Shaik Salman Basha, M.V.Nagabhushanam, D.Nagarjuna Reddy, Brahmaiah Bonthagarala, Comparision of Regulatory Requirements for Generic Drugs Dossier Submission in the United States and Canada, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, Issue 6, Vol. 6, November-December 2016,1-19.

