

Regulatory Affairs in the Pharmacy Curriulum: A Review

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ABSTRACT

The Indian pharmaceutical industry is expanding quickly, and there is a need of regulatory affairs specialists to meet the present demands of companies in the face of international competition. The goal of governments to protect public health has led to the development of a relatively new profession known as regulatory affairs. Pharmaceuticals, veterinary medications, medical gadgets, pesticides, agrochemicals, and cosmetics are among the industries where the government regulates the safety and effectiveness of products.

And alternative treatments. The pharmaceutical firms in charge of these drugs' discovery, development, testing, clinical trials, production, manufacturing, and marketing

Items also want to make sure that they are providing products that are secure and beneficial to the health and welfare of the general public. legislative issues

The international regulatory bodies and the pharmaceutical businesses are connected via specialists. It is needed that they.

KEYWORDS: 1] To study various role of drug regulatory affairs departmet 2] Regulatory affairs education, Specrum OF regulatory Affairs 3] Recet advacment

INTRODUCTION

As the pharmaceutical industry around the world develop in order to become more these are becoming aware that the true conflict of Survival depends on carrying out the task through comprehending the rules for the numerous actions taken to provide an confirmation that the procedure is governed by law [1].

Being one of the most tightly regulated industries, the pharmaceutical More workers are needed than ever before in industries. who are capable in handling regulatory concerns comprehensively handle all matters. Regulation of Business Government Affairs, often known as (RA), is a field of work that regulated sectors include the pharmaceutical and medical banking, energy, and gadgets. Regulatory matters (RA) are also within the healthcare industries, has a very specific connotation. (drugs, equipment, biologics, and functional foods)

Pharma regulatory affairs professionals play an essential role in ensuring all pharmaceutical products comply with regulations governing the industry.[4] Those working in pharma regulatory affairs jobs not

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only work in the initial application phase for a new or generic drug, but also in the licensing and marketing stages – making sure all operations and products meet required safety and efficacy standards. Professionals must combine knowledge of the business, legal and pharmaceutical industries to determine if regulations are being followed and in many cases form the link between pharma companies and regulatory authorities, such as the Food and Drugs Agency (FDA) and the European Union.[5] Regulatory affairs jobs in the UK and further afield are generally within the pharmaceutical, chemicals, biotechnology, medical devices and cosmetics industries. Organisations such as the FDA also provide roles for those interested in working in the field. As biotechnology plays an increasing role within drug development and the pharmaceutical industry, growing numbers of biotech regulatory affairs positions are opening up. Inspection of biotechnology facilities requires a high level of technical knowledge due to the ever advancing systems being used.[6] Various Roles of Drug Rgulaory Affairs Given In Below Fig1



Pharmaceutical Drug Regulatory Affairs: The person 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.[7] 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.[8] 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.[9] 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 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. Their Regulatory Affairs (RA) departments must be aware of the regulatory requirements in all the company's export markets.[10] As an added complication, despite recent international efforts towards harmonization of requirements, the regulations laid down by different governments. Therefore great care has to be taken in drawing up efficient and economical research and development programs whose results may be used as widely as possible. Regulatory Affairs professionals, with their detailed knowledge of the regulations and guidelines, are frequently called in to advice on such matters.[11]

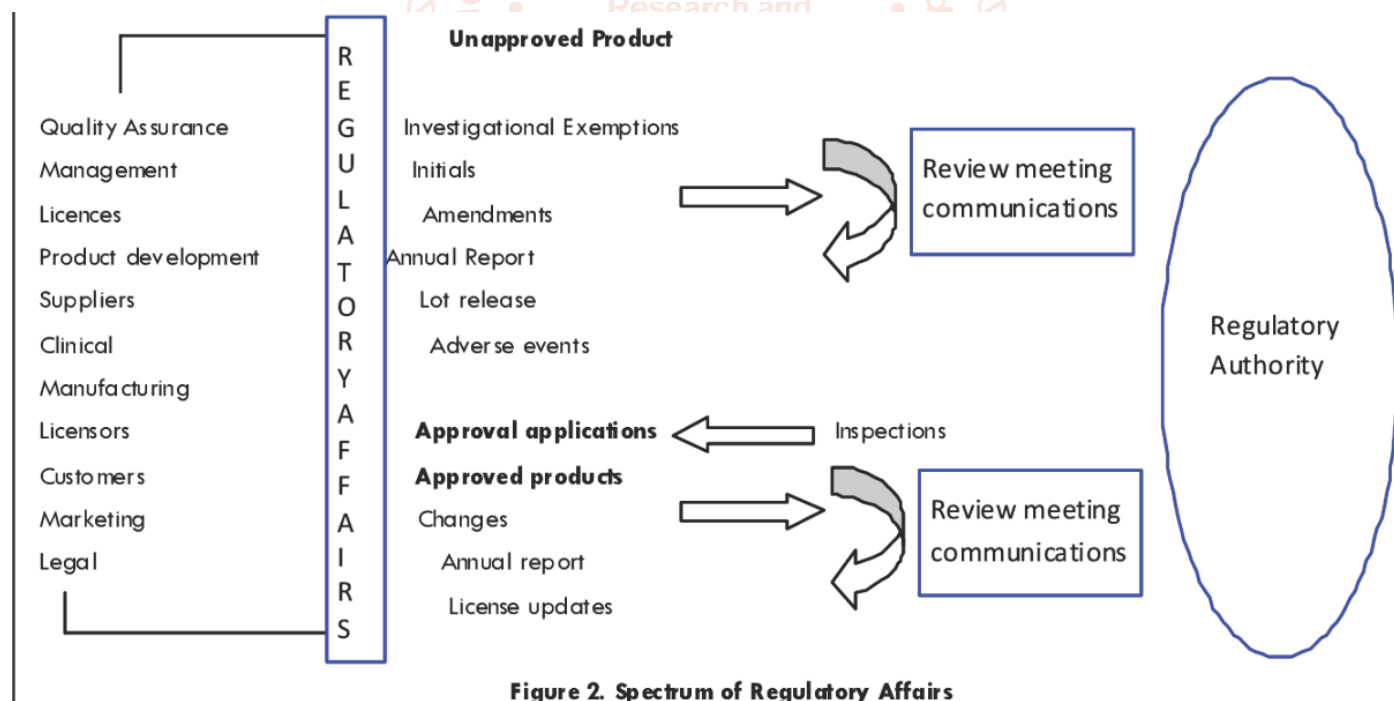


Figure 2. Spectrum of Regulatory Affairs

Education in Regulatory Affairs: A person involved in regulatory affairs must be knowledgeable of all regulations, guidelines, and rules.

Documents. He ought to be well knowledgeable about a specific regulatory document that was written.[12]

These individuals are the main conduit for communication between the company and

international regulatory organisations including the USFDA (Food and Drug Administration of the United States) and European Drug Regulatory Affairs Union (EUDRA).

[13] a number

Regulatory Affairs Professional, among other organisations, Drug Information Association (DIA),

the RAPS Society, and the International and the Food and Drug Law Institute (FDLI) groups like the European Society of Regulatory

A major part of giving pertinent information is affairs.

[14] The programme often consists of introductory a foundation that describes the development of medical products, research, development process and the regulatory oversight of the complex processes. There are both part-time and full-time courses available for the subject.[15] Part-time courses are suitable for the professional who will come across these terms occasionally where as full-time course is meant for the professional who intends to make his career in the regulatory affairs.[16]

Institutions in India offering Regulatory Affairs:

In India huge amount of colleges and universities throughout offer the course of regulatory affairs. The course material is also available in the form of online, distance learning and interactive CDs mode. Regulatory affairs position is in highest demand and fastest growing according to the findings from a recent survey on employment trends in the clinical trials.[17] A pharmaceutical Regulatory affair (RA) is a vast area, which cannot be taught just with the help of books or the course materials. The issues related to the field are often updated so the professionals find it challenging to keep abreast with the recent modifications and inclusions[18]. Importance of Regulatory Affairs 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 (RA) activities is therefore of considerable economic importance for the company.[19] 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.[20]

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 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.[21] 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.[22] 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 (RA) professionals will condition the perceptions of the government officials to the company for better. [23] The importance of the Regulatory Affairs function is such that senior Regulatory Affairs (RA) professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies.[24]

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.[25] These are:

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

National Assessment and Accreditation Council (NAAC) by the University Grants Commission. The Drug Regulatory Affairs Professional 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.[26] 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. The main responsibility of the DRA professional within a pharmaceutical company is to secure approval of drug submissions from Health Therapeutic Products Program (TPP) and to ensure regulatory compliance of marketed and investigational drugs with the Food and Drug Act and Regulations and TPP Guidelines/Policies.[27] 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 knowledge of Indian regulations as well as international regulations.[28] Because the regulatory environment is evolving rapidly toward global harmonization (several ICH guidelines have now been adopted by TPP) and mutual recognition between different health authorities across the world, it is a major challenge for the DRA professional to keep abreast of policy changes and determine how these changes affect the approval process. Consequently, the importance of DRA in the

development and approval of new drugs has increased significantly over the last decade.[29] Whether a submission is filed to the TPP for the conduct of a clinical trial (Investigational New Drug Submission, or IND), for the approval to market a new drug (New Drug Submission, or NDS), for a new indication or dosage form for a marketed drug (Supplemental NDS, or S/NDS), or for the maintenance of a marketed drug's regulatory status, the submission's preparation entails the close collaboration of a multidisciplinary team.[30] The DRA professional must actively participate in discussions and coordinate team activities to obtain all the necessary documentation as per the current TPP policies and then assess it for completeness and accuracy. Therefore, the effective DRA professional must exhibit the organizational and interpersonal skills of a "team player" and also be thorough and detail-oriented.[31] The scope of responsibilities is wide and may vary significantly according to the organizational structure of the pharmaceutical company. The responsibilities of some DRA professionals may focus exclusively on pharmacovigilance activities or on the electronic representation of information (electronic submissions).[32] The common point, however, is that the DRA professional is the primary liaison between the sponsor and the TPP. In this capacity, the individual must possess excellent writing and communication skills and be an effective negotiator. This is to ensure that the requests or comments generated during the submissions review process are promptly and satisfactorily answered and to negotiate the most favorable labeling (Product Monograph) consistent with the sponsor's business objectives.[33] In line with today's growing technological developments, knowledge of several computer applications is essential to effectively fulfill the job requirements. DRA is a dynamic, rewarding field that embraces both scientific and legal aspects of drug development. DRA professionals are dedicated individuals who take pride in their contribution to improving the health and quality of life of peoples.[34]

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.[35] They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to 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.[36] 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.[37] Regulatory affairs (RA) 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.[38] List of responsibilities of Regulatory Affairs Department

1. Keep in touch with international legislation, guidelines and customer practices
2. Keep up to the date with a company's product range
3. Ensure that a company's products comply with the current regulations.
4. 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.[39]
5. Formulate regulatory strategy for all appropriate regulatory submissions for domestic, international and/or contract projects.
6. Coordinate, prepare and review all appropriate documents for example dossier and submit them to regulatory authorities within a specified time frame in conjugation with the organization.
7. Prepare and review of SOPs related to RA. Review of BMR, MFR, change control and other relevant documents.[40]
8. Monitor the progress of all registration submission.
9. Maintain approved applications and the record of registration fees paid against submission of DMF's and other documents.
10. Respond to queries as they arise, and ensure that registration/ approval are granted without delay.[41]
11. Impart training to R&D, Pilot plant, ADI and RA. Team members on current regulatory requirements.

12. Advising their companies on the regulatory aspects and climate that would affect proposed activities. i.e. describing the "regulatory climate" around issues such as the promotion of prescription drugs and Sarbanes-Oxley compliance.

13. Manage review audit reports and compliance, regulatory and customer inspections.[42]

14. 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.

15. Have a duty to provide physicians and other healthcare professionals with accurate and complete information about the quality, safety and effectiveness of the product.

Pharma regulatory affairs jobs: Professionals working in pharmaceutical regulatory affairs roles will be required to handle a number of different tasks; from keeping on top of the latest developments within the industry to writing product labels and patent information. As well as collecting and collating large amounts of information and preparing licensing submissions, pharma regulatory affairs jobs also include liaising with doctors and scientists, conducting clinical trials and negotiating with regulatory authorities. Workers may also be tasked with undertaking and managing regulatory inspections within the company and reviewing practices when required to meet with new or updated regulatory requirements.[43] Opportunities for regulatory affairs consultants offer professionals the chance to work in a number of fields, which requires high levels of knowledge of multiple industries. Jobs in pharma regulatory affairs generally require a background in the applicable industry, business knowledge, great oral and written communication, good attention to detail and strong IT skills. The international scope of many companies working within the pharmaceutical industry mean that a second language is generally desirable, as it previous work experience within a clinical or pharma setting

Pharma regulatory affairs jobs in India - Asia has emerged as a strong growth region for the pharmaceutical industry in recent years, in particular India which is fast becoming a preferred location for clinical trials and research and development activities. The creation of a new product patent system in 2005 was a driver of this growth, which is expected to increase as the domestic market in India further opens up.[44] This growth has also helped facilitate an

increasing number of pharma regulatory affairs jobs in India. A number of companies have set up in the most populous city in the country, creating a number of regulatory affairs jobs in Mumbai. Figures from a companies and markets.com report show that by the year 2012 the market for clinical trials in India is expected to grow to \$630 million (£404 million), helped by the fact that the cost of conducting research in the country is sometimes less than half that in more developed nations.[45] The United Arab Emirates (UAE) is another country looking to expand its appeal to the pharmaceutical industry, increasing the number of pharma regulatory affairs jobs in Dubai. A report by RNCOS suggests that compound annual growth of 17 per cent will take place between 2010 and 2013 and that the UAE is ripe for investment for pharmaceutical manufacturing operations.

Makes a Good Regulatory Affairs Professional - Most regulatory professionals are graduates in a scientific discipline, commonly life sciences or pharmacy, although increasingly biotechnology based degrees are valuable. Some choose to have an additional legal qualification. The ability to tackle data in a wide range of scientific areas and to quickly grasp new concepts and complex technical information is vital. Analyzing issues and presenting both written and oral evidence before a panel of experts such as scientists, pharmacists, doctors and lawyers who run the government agencies require considerable understanding of both legal and scientific matters.[46] A high degree of sensitivity is required when proposing and executing the strategy and tactics needed to obtain marketing approval in a way which will satisfy the authorities and serve the best needs of the company. Considerable care must be exercised if the best possible case is to be presented to the authorities for the company. It must be done without obscuring the facts, enabling the authorities to arrive at a proper and rightful conclusion regarding safety, efficacy and quality of the product under application. Regulatory professionals must always exercise considerable judgment in the practice of their role. Integrity and the ability to inspire trust and confidence are valuable attributes. Project management skills help to achieve the challenging goals they are set.[47] They can work as part of multi-disciplinary teams and lead them when necessary. They can work under pressure and inspire and motivate others to do the same

Need of Regulatory Affairs in the Pharmacy Curriculum-

One of the most tightly regulated sectors in the nation is the research and development of pharmaceutical,

biotechnology, and medical devices. India is expanding

In the pharmaceutical industry, the need for specialists in regulatory affairs to meet the present needs of industries for the international market.

Professionals in regulatory affairs serve as a bridge between pharmaceutical businesses and international regulation agencies. They must be knowledgeable about the legislation, regulations, policies, and direction provided by the regulatory agencies. The requirement to incorporate the present the standard's requirements for the pharmaceutical industry Pharmaceutical schools' curricula to provide students with the most recent innovations to benefit the industry. the current

The need for regulatory education is discussed in the essay courses offered, instructional resources, courses available, syllabus contents, and job opportunities in regulatory affairs.[48] As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation. Pharmaceutical Industry, being one of the highly regulated industries, which are capable of handling issues related to regulatory affairs in a comprehensive manner.[49]

Conclusion- 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. Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory affairs professionals and Regulatory affairs department is constantly evolving the one which is least impacted during the acquisition and merger, and also during recession. 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 within the company's for their success and growth. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company.

REFERENCE:

[1] Regulatory Affairs from Wikipedia, the free encyclopedia modified [online] 7th April.

Available from http://en.wikipedia.org/wiki/Regulatory_Affairs

[2] International regulatory affair updates [online] 2005. Available from <http://www.iraup.com/about.php>

[3] "Douglas J Pisano and David S. Mantus" 'Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics'. 2nd edition, August 2008

[4] Topra brought by dimension associates [online] Available from <http://www.topra.org/careers/what-regulatory-affairs>.

[5] "Douglas J. Pisano and David S. Mantus" 'Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition, August 2008

[6] Science career brought by American association [online] 2011. Available at http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/1999_12_24/noDOI.12079275980051408699.

[7] Topra brought by dimension associates [online] available from <http://www.topra.org/careers/what-regulatoryaffairs>.

[8] Training Needs in Regulatory Science for the Biopharmaceutical Industry," Nature jobs Biotechnology, 2001;19(12):1187-1188

[9] "Careers in Regulatory Affairs from Practitioner to professional," Nature jobs Biotechnology, 2002;20(4): 409- 41:

[10] Regulatory Affairs Management [online]. Available from: <http://medind.nic.in/haa/t06/i1/haat07i1p51>.

[11] Recent Advancements [online]. Available from http://en.wikipedia.org/wiki/Regulatory_Affairs

[12] Measurement of Quality [online]. Available from: <http://www.pharmainfo.net/reviews/total-qualitymanagement-pharmacy-education-potentials>

[13] Careers in regulatory affairs from practitioner to professional, nature jobs biotechnology, 2001; 20(4): 409- 410

[14] Available online: www.centrewatch.com

[15] Training needs in regulatory sciences for the biopharmaceutical industry. 2001; 19(12),1187-1189

- [16] Cutting, Thomas. "How to Survive an Audit". PM Hut. [http://www.pmhut.com/how-to-survive-an-audit.2008;2\(4\)13-21](http://www.pmhut.com/how-to-survive-an-audit.2008;2(4)13-21)
- [17] Available online: <http://en.wikipedia.org/wiki/Audit>
- [18] Available online: <http://ezinearticles.com/?10-Steps-toMaximize-Your-Energy-Audit&id=3633861>
- [19] The Fourth Quadrant: A Map of the Limits of Statistics Nassim Nicholas Taleb an Edge Original Essay [online]. Available from <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm#toc> US FDA Compliance Program Guidance manual <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM>
- [20] Gehl Sampath, Padmashree. 'India's Pharmaceutical Sector in Emerging Strategies and Global and Local Implications for Access to Medicines'.2008
- [21] OPPI. 2008. Indian Pharmaceutical Industry: Vision 2015.
- [22] Singh, Seema. 2007. 'Indian Pharma enters the global arena'. Cell. 128 March 9. Elsevier.
- [23] Das, Anjan & Kumar, Subodh. 'Innovation, IPR and Public Good'. Express Pharma Pulse. 2008;3(7)16-31
- [24] FICCI. 2005. White Paper on 'Clinical Trials in India'.
- [25] Srivastava DA. Country level report on the pharmaceutical sector in India'. Report commissioned by DFID, UK
- [26] Central Drugs Standards Control Organization. (Website: www.cdsc.nic.in).
- [27] http://www.medindia.net/indian_health_act/drugs-andcosmetics-act-1940-introduction.htm
- [28] www.vakilno1.com/bareacts/drugsandcosmeticact/drugsandcosmeticsact.htm
- [29] <http://www.dancewithshadows.com/pillscribe/cgmpregulations-in-india-to-be-diluted/>
- [30] <http://www.prescriptiondrug-info.com/topics/drug-andcosmetic-act/>
- [31] N. K. Jain, pharmaceutical product development" edition 3rd, C.B.S publishers
- [32] P.P.Sharma "how to practice GMPs" 5th edition, Vandana publication Pvt. Ltd Delhi
- [33] WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty seventh Report. Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 908).
- [34] Guide to good storage practices for pharmaceuticals. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty seventh Report. Geneva, World Health Organization, 2003 (WHO Technical Report Series, No. 908, Annex 9).
- [35] WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-eighth Report. Geneva, World Health Organization, 2004 (Technical Report Series, No. 917).
- [36] Good trade and distribution practices for pharmaceutical starting materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty eighth Report. Geneva, World Health Organization, 2004 (WHO Technical Report Series, No. 917, Annex 2).
- [37] Quality Assurance of Pharmaceuticals. A compendium of guidelines and related materials, Volume 1. Geneva, World Health Organization, 1997.
- [38] 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.
- [39] Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products – A Manual for a Drug Regulatory Authority. Geneva, World Health Organization, 1999 (Regulatory Support Series, No. 5, WHO/DMP/RGS/98.5).
- [40] A Model Quality Assurance System for Prequalification, Procurement, Storage and Distribution of Pharmaceutical Products. Geneva, World Health Organization, 2003 (unpublished draft).
- [41] Managing Drug Supply. The selection, procurement, distribution, and use of pharmaceuticals. Management Sciences for Health in collaboration with World Health Organization. 2nd Ed. Connecticut, USA. Kumarian Press, Inc., 1997.
- [42] Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C63/03). European Agency for Evaluation

- of Medicinal Products. Directive 92/25/EEC of 31 March 1992.
- [43] Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use. Therapeutic Goods Administration, Australia. November 1991.
- [44] Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of drugs and Current Good Manufacturing Practice for Finished Pharmaceuticals. Code of Federal Regulations Parts 210 and 211. Food and Drug Administration, USA.
- [45] Principles and Guidelines of Good Manufacturing Practice for Medicinal Products for Human Use. Commission Directive 2003 794/356/EEC, 13 June 1991. European Agency for Evaluation of Medicinal Product
- [46] Guidance Document: Good Manufacturing Practice for Medicine in South Africa. Medicines Control Council, South Africa, 2003.
- [47] Guide to Good Manufacturing Practices for Medicinal Products. Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, July 2004.
- [48] Guide to Good Manufacturing Practices for Medicinal Products. Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, July 2004.
- [49] Loan G. M., Wafai Z A., Qadrie Z L., Zargar S A., A review on “Therapeutic drug monitoring in psychiatry: an important step in clinical practice”

