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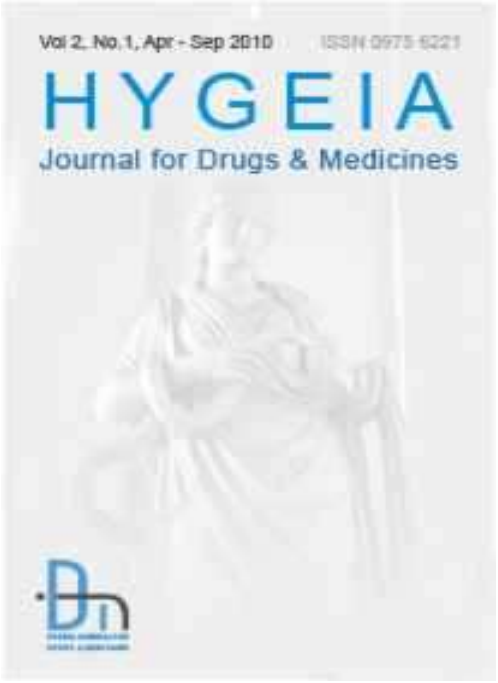

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The Scope of Regulatory Affairs in the Pharmaceutical Industry

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The regulation of medical products has been expanding since early 20th century. Regulatory agencies are being established in an ever increasing number of countries across the globe. Those that have established are reorganizing their systems and attempting to harmonize with organizations of other countries[1]. The pharmaceutical, biotechnology and medical devices are among the most highly regulated industries in the world. Regulatory affairs (RA) professionals are employed in pharmaceutical industry, government, academic research and clinical institutions.

The Indian Pharmaceutical industry is one of the fastest growing industries in India, with a compounded annual growth rate (CAGR) of over 13 % in last 5 years and it is expected to grow at a higher rate in coming 10 years. It is valued at $ 8.0 billion approximately and ranks 4th in terms of volume and 13th in terms of value globally[2]. All companies engaged in R&D worth its salt has an individual RA department to aid them in new product development.

The clinical research industry, which provides opportunities for RA professionals, is also growing at an unparalleled rate. It has opened up new vistas of employment for a large number of trained professionals. The clinical trials market worldwide is worth over USD 52 billion. A study by Ernst and Young indicates that the total market value of Clinical Research activities performed in India is expected to grow to around USD 1.5-2 billion. There is expected to be a huge demand for qualified RA personnel in clinical research[3].

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International Regulatory Environment

Good Manufacturing Practices has been in practice from Old Testament times (Laws of Kashrut). The Nuremberg Code, 1947 on Permissible Medical Experiments[4] provided for basic principles to conduct medical experiments on human beings followed by Declaration of Helsinki (1964)[5], Belmont Report of USA[6] (1978) and WHO GCP[7] (1995) and ICH GCP[8] in 1996. In 1959, Canada instituted its QUAD regulations, which is the first recognizable drug GMP of modern era. It was followed by GMPs of USA in 1963 and that of UK in 1972.

Today 35 member countries along with 11 candidate countries and 4 international agencies have joined together to create the Pharmaceutical Inspection Cooperation Scheme (PIC/S) to promote a globally accepted GMP. The International Conference on Harmonization (ICH) was established in 1990 and has succeeded in harmonizing GMPs for manufacture of Active Pharmaceutical Ingredient (API), validation of analytical methodology, guidelines for performance of stability studies, harmonization of pharmacopoeal monographs and test methods and other guidelines of working of GMP.

Academic Prerequisites

Masters degree in Pharmacy with Pharmaceutical Administration and Management or Regulatory Affairs specialization will be the preferred qualification to qualify for as a RA professional. Within the curriculum he should have covered topics such as Handling laboratory and manufacturing deviations, Pre approval inspections, impact of Total Quality performance, GMP Certification and enforcement actions, Maintenance and Update of Product Master Files, Internal Compliance of Documentation, Coordination and Assembling of Common Technical Document (CTD/eCTD), Quality systems, Quality Assurance, Method Validations, Process Validations, Master Validation Plan, Protocols, Standard Operating Procedures (SOPs), Auditing and Compliance Functions, Regulatory strategies, Regulatory agencies, legislation and documentation systems as required for USFDA, UKMCA/UKMHRA, MCC, WHO etc., FDA/UKMHRA queries and submission, application requirements and guidelines, electronic submissions, medical device regulations, stability as per ICH guidelines & Multi-brand registrations (MBRs); International harmonization, practice of regulatory affairs, USP Pharmacological, Toxicological and Clinical Trial Information, Re-registration Documents Design, Role of the International Business Operations of the Pharmaceutical MNCs in Attracting the FDI, Clinical Pharmacy, Drug Trials and Vaccine Trials Guidelines, Drug Laws , Investigational New Drug Applications? , Formatting, assembling and submitting the New Drug Applications, Human Genetic Research, Clinical Trials, Indian Ethics Committee, Good Clinical Practices (GCP), Pharmaco-vigilance and Adverse Drug Reactions reporting, Clinical Trial Regulation, Intellectual Property Rights, Basis of Patentability, Patent Application Procedure, Compulsory License, Infringement of Patents, Product Registration for Regulated and Non Regulated Markets etc[5].

Responsibilities

The responsibilities of RA personnel in general can be summarized into three

(i) Ensuring that their companies comply with all of the regulations and laws pertaining to their business,
(ii) Working with federal, state and local regulatory agencies and personnel on specific issues affecting their business
(iii) Advising companies on the regulatory aspects and climate that would affect their proposed activities.

In an marketing organization their prime responsibilities involves preparation and presentation of registration documents to regulatory agencies and carrying out all discussion to obtain and maintain marketing authorization (MA) for the products concerned. They need to keep track on ever changing legislation in all countries where the companies is looking to market their product. They play a pivotal role in facilitating the commercial progression of new health products and technology through product life cycle.

Skills

As regulatory affairs professional, they are often responsible for tracking changes in regulatory guidelines as they may occur. In order to do this, they must take the initiative to keep current on all changes in regulations. For example, they have to check the FDA Web site and read professional journals. They can learn about new guidelines from different sources like peers, print releases of regulatory authorities and by attending conferences. All changes in regulations must be documented in the manner required by the company. Changes must also be interpreted and communicated to appropriate people in the company, including management. Management may then determine what changes in company procedures and process may be required to stay in compliance. They are also involved with coordinating and implementing the changes which calls for much sensitivity so that changes suggested are smoothly accepted by the company's management and the regulatory bodies. They have a major contribution to make in company's success both commercially and scientifically.

Regulatory Affairs in Product Management

The key role of RA professional is broader than registration of products, they advise companies both strategically and technically at the highest level. Their role begins right from development of a product to making, marketing and post marketing strategies. Their advice at all stages both in terms of legal and technical requirements help companies save a lot of time and money in developing the product and marketing the same. For countries that do not have their on regulations the World Health Organization guidelines on health matters[16] and World Trade Organization on trade regulations between nations is followed[17].

Regulatory Affairs in Clinical Trials

The RA professional is the primary link between the company and worldwide regulatory agencies such as US Food and Drug Administration (USFDA & Center for Devices and Radiological Health)[18, 10] , Medicines and Healthcare Products Regulatory Agency, United Kingdom, (UKMCA)[19], Therapeutic Goods Administration, Australia[20] European Medicines Agency[21] , Organization of Economic Collaboration and Development (OECD) and Health Canada[14, 23]. He also communicates and interprets the seemingly endless mace of laws, regulations and guidelines to the other departments of the company. The RA personnel develops strategies to overcome delays and presents finding of clinical trials to the regulatory bodies so as to get quick clearance thus reducing the time for approval of new molecules.

At its core, the RA professional facilitates the collection, analysis and communication about the risks and benefits of health products to the regulatory agencies, medical and health systems and the public. Operationally RA is responsible for assuring that government obligation, market driven demands and evolving scientific conventions are understood and addressed by various stakeholders.

Regulatory Affairs in R&D

The regulatory affairs personnel work hand in hand with marketing and R&D to develop, innovative products that take advantage of new technological and regulatory developments to accelerate time to market. With new products expected to add significant revenues to the company's bottom lines, small decreases in time to market equate to large material gains in revenue and profit. Employing adaptive clinical trial strategies, obtaining quick approval from regulatory authorities and avoiding pitfalls in processes can accelerate development of new products and help to reduce costly errors and time lags[6].

Changes in regulatory environment

Guidelines on clinical trials for import and manufacture of new drug was introduced in the Drugs and Cosmetics Rules as **Schedule Y** in 1998. This heralded the entry of clinical trials organization like Quintiles into India and encouraged the pharmaceutical industry to conduct phase III trials. **Ethical Guidelines for Biomedical Research on Human subjects** was brought by Indian Council of Medical Research (ICMR) in 2000. Good Clinical Practices were adopted by India in 2001 by Central Drugs Standard Control Organization (CDSCO)[15]. The National Institute of Medical Statistics of ICMR also set up a clinical trails registry in 2009. A new amendment to the Drugs & Cosmetics Act is seeking to replace the Central Drugs & Services Control Organization (CDSCO) with the Central Drug Authority (CDA) comprising of Drugs Controller General of India as the chairman and five other members[7]. Ten departments will be controlled by the authority include regulatory affairs, imports, new drugs, biotech products, pharmacovigilance, medical devices and diagnostics, organizational services, training, quality control and legal & consumer affairs. Moreover new bill for regulation of medical devices industry is also in the gambit. Medical Devices Regulatory authority is a body; government is yet to implement to regulate the ballooning medical devices industry whose products are largely approved in other countries and eventually finds entry into Indian market[8].

Regulatory Scenario of Herbal Medicines

With the Drugs and Cosmetics (Amendment) Act of 1964, the definition of Ayurveda, Siddha and Unani (ASU) medicines were introduced into the perview of the Act and all necessary provisions for control of this class of drugs were introduced[4,10]. According to the law licence is required for manufacture of ASU drugs but exempts the same for sale provided drugs are manufactured under licence, appropriate labeling and packaging are also necessary for marketing these products[12]. GMP implemented Schedule T for manufacturing plants of ASU drugs. In foreign countries premarketing approval and documentation to prove efficacy and safety is required before approval of herbal products[13].

Conclusion

Regulatory Affairs within the biomedical and health products sector is a relatively young, multidimensional profession that is international in scope. RA professionals come from a variety of disciplines such as law, academics, industrial research and medicine. It is a promising field for scientists searching for alternative careers because it offers a multitude of jobs and opportunities for development. The modern view of RA as a dynamic, business oriented unit, focused on getting products to the market with a commercially viable label as quickly as possible is a visionary and competitive paradigm.

With increasing outsourcing of jobs to India coupled with flamboyant salaries, burgeoning technically educated middle class proficient in English, the regulatory affairs industry is poised for rapid growth. Regulatory Affairs, therefore, promises to be an interesting career option in India for pharmacy graduates. It will definitely pave the way for greater development and integration of careers with the global workforce and improve the competencies of graduates in the country.

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