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An Overview on Regulatory Affairs in Pharmacy

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A B S T R A C T

Regulatory affairs is an area of work that involves responsibility for checking whether a business is obeying official rules or laws. Drug Regulatory Affairs in Pharmacy plays an important role as every departments of pharmaceuticals manufacturing such as Quality Assurance, Quality Control, Production, Microbiology also same as Formulation & Development Department & Analytical Development Department work for a vital role as the Pharmaceutical sector is emerging very rapidly and there is a necessity of regulatory affairs professionals to provide the upcoming needs of industries for the worldwide competition. It is a profession which works a link between pharmaceutical industries and government authorities across the universe. The goal of the regulatory affairs is the protection of human health, ensuring safety, efficacy, and quality of drugs, ensuring wellness and accuracy of product information. This present article discusses an historical and present overview of Regulatory Affairs, its usefulness and future prospects.

Keywords: Drug regulatory affairs, Historical Overview, Pharmacy Sector, Regulatory Bodies, Future prospects in RA.

1. Introduction

. The regulatory affairs (RA) department of a pharmaceutical company is responsible for getting approval for recent pharmaceutical products and assuring that approval is maintained for as long as the company needs to keep the product in the market. The Department of Regulatory Affairs was created to protect public health by monitoring and controlling the safety and efficacy of drugs in a variety of protocols involving pharmaceuticals, veterinary medicines, agrochemicals, cosmetics, medical devices, pesticides, and complementary medicine, among others. Chemistry, Manufacturing, and Controls(CMC) Regulatory Affairs (RA) is a sub-discipline of Regulatory Affairs that is in charge of providing CMC regulatory leadership and strategy in order to obtain regulatory approvals. The modern pharmaceutical industry is well-organized and follows international regulatory standards for the production of chemical and biological pharmaceuticals for human and veterinary use, as well as medical devices, traditional herbal remedies, and cosmetics. The Regulatory Affairs department is an important aspect of a pharmaceutical company's organisational structure.

- Drug regulatory affairs
- Historical overview of regulatory affairs
- Regulatory bodies in the world
- Use of regulatory affairs in pharmacy

Drug regulatory affairs:-

Drug Regulatory Affairs covers all parts of the pharmaceutical development process, as well as how they are regulated to varying degrees. The pharmaceutical legislation framework, quality, safety, and efficacy norms, as well as the attitudes and requirements of health authorities, all have a significant impact on the drug development process and its success. These issues are dealt with by regulatory affairs personnel.

Historical overview:-

Several tragedies occurred throughout the 1950s as a result of staff errors during manufacturing and the intentional inclusion of adulterants to pharmaceutical products, resulting in the death of patients. Following a series of occurrences, regulatory organisations enacted new regulations and guidelines to improve product quality, safety, and efficacy. As a result, the Marketing Authorization (MA) and Good Manufacturing Practices (GMP) requirements have become more stringent (GMPs).

- • In Europe, the thalidomide disaster resulted in Directive 65/65/EEC, which governs marketing authorization. The pharmaceutical regulations governing drug development and the marketing authorisation process have become much more explicit and transparent. For centralised application assessment, the EMEA committee was formed..
- • India's pharmaceutical sector has progressed from API manufacture through reverse engineering to pure R&D. The Indian Regulatory Authority has provided guidelines for Fixed Dose Combination, Common Technical Dossier (CTD) implementation, Clinical Trial Registry of India (CTRI), and pharmacovigilance cell.
- We studied at the global, regional, and national regulatory networks under the Drug Regulatory Affairs division. We've discovered that regulatory affairs experts are crucial to the pharmaceutical industry's national and international operations. Communication and advice to various departments in the pharmaceutical sector is very important, according to the regulatory network. It participates actively in the development of national and international guidelines.

Regulatory bodies in the world:-

Country	Name of Regulatory Authority
USA	Food and Drug Administration (FDA)
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
India	Central Drug Standard Control Organization (CDSCO)
Canada	Health Canada
Europe	European Medicines Agency (EMEA)
Denmark	Danish Medicines Agency
Costa Rica	Ministry of Health
New Zealand	Medsafe - Medicines and Medical Devices Safety Authority
Sweden	Medical Products Agency (MPA)
Netherlands	Medicines Evaluation Board
Ireland	Irish Medicines Board
Italy	Italian Pharmaceutical Agency

Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)
Ukraine	Ministry of Health
Singapore	Centre for Pharmaceutical Administration Health Sciences Authority
Hong Kong	Department of Health: Pharmaceutical Services
Paraguay	Ministry of Health
Sweden	Medical Products Agency (MPA)
Thailand	Ministry of Public Health
China	State Food and Drug Administration
Germany	Federal Institute for Drugs and Medical Devices
Malaysia	National Pharmaceutical Control Bureau,Ministry of Health
Pakistan	Drugs Control Organization, Ministry of Health
South Africa	Medicines Control Council
Sri Lanka	SPC,Ministry of Health
Switzerland	Swissmedic , Swiss Agency for Therapeutic Products
Uganda	Uganda National Council for Science and Technology (UNCST)
Brazil	Agencia Nacional de Vigiloncia Sanitaria (ANVISA)
Japan	Ministry of Health, Labour & Welfare(MHLW)

INTERNATIONAL ORGANIZATIONS
World Health Organization (WHO)
Pan American Health Organization (PAHO)
World Trade Organization (WTO)
International Conference on Harmonization (ICH)
World Intellectual Property Organization (WIPO)

Use of regulatory affairs in pharmacy:-

REGULATORY AFFAIRS IN PRODUCT MANAGEMENT

The essential duty of a RA expert goes beyond product registration; they provide strategic and technical advice to organisations at the highest levels. Their function extends from product creation to manufacturing, marketing, and post-marketing initiatives. Their assistance at all levels, both in terms of legal and technological requirements, saves organisations a lot of time and money when it comes to producing and selling products. The World Health Organization's instructions on health matters and the World Trade Organization's trade regulations between states are followed by countries that do not have their own regulations.

REGULATORY AFFAIRS IN CLINICAL TRIALS

The RA professional is the company's primary point of contact with international regulatory agencies such as the US Food and Drug Administration (USFDA & Center for Devices and Radiological Health), Medicines and Healthcare Products Regulatory Agency, United Kingdom, (UKMCA), Therapeutic Goods Administration, Australia, European Medicines Agency, Organization of Economic Cooperation and Development, and the World Health Organization. He also informs and interprets the company's other departments about the seemingly infinite maze of rules, regulations, and guidelines.The RA team develops and implements ways to avoid delays and presents clinical trial findings to regulatory agencies in order to obtain speedy clearance and shorten the time it takes for novel compounds to be approved. At its core, the RA professional assists regulatory bodies, medical and health systems, and the general public in gathering, analysing, and communicating information on the risks and benefits of health products. In terms of operations, RA is in charge of ensuring that diverse parties understand and address government obligations, market-driven needs, and advancing scientific conventions.

REGULATORY AFFAIRS IN R&D

Regulatory affairs professionals collaborate with marketing and R&D to create creative products that take advantage of new technology and regulatory advances to reduce time to market. Small reductions in time to market correspond to huge material gains in revenue and profit, with new goods projected to add considerable revenues to the company's bottom lines. Adaptive clinical trial tactics, securing speedy regulatory approval, and avoiding traps in processes can all help to speed up the development of new products while reducing costly errors and time lags.

WORKING OF REGULATORY AFFAIRS INFORMATION

Regulatory is the link between the company/sponsor and the rest of the world. The regulatory department is a hub for both incoming and outgoing information. To succeed in regulatory practise, both in objective public measurements (e.g., approvals) and internal ones (e.g., recognition and reward), etc.

GATHERING INFORMATION

All of the information should be documented in an ethical manner. Any chance to see, hear, or speak with a regulator, a more seasoned drug development professional, a colleague, or a sworn enemy is a chance to learn something new..

COMMUNICATING INFORMATION

Non-critical information is shared and communicated in the simplest way possible. The biggest challenge with such data is distributing it to the correct audience without boring them so much that they forget they're obtaining vital information. The majority of businesses receive news updates or internal regulatory information updates via email..

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