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A Review on Regulatory Agencies of Different Countries and Clinical Trials in India

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ABSTRACT-

As it`s miles the new career which changed into developed from the favored of everywhere in the international to protect the general public fitness through providing correct excellent of drugs such as safety and efficacy within the region of now not handiest pharmacy however also inside the area of the veterinary medicinal drug, scientific tool, pesticides, pesticides, agrochemical, beauty and complementary medication.The goal of the regulatory affairs professional is the protection of human health, ensuring safety, efficacy, and quality of drugs, making sure appropriateness and accuracy of product facts. Clinical studies are an important part of the drug development process to ensure drug safety and efficacy. new medicine. In today's global scientific age, clinical trials are essential to achieve new and better results Market a drug. In clinical trials, potential treatments are tested on human volunteers (subjects) to see if they work. It should be approved for general public use. India was considered a global center for clinical trials Due to various factors in the last few years, this article will discuss clinical trials and trials in India.

Keyword – Regulatory Affairs , Clinical Trials , Regulatory Agencies ,

INTRODUCTION

Regulatory affairs –

Regulatory Affairs (RA), also called Government Affairs, is a profession 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, foods, cosmetics and complementary medicines etc.

Pharmaceutical Drug Regulatory Affairs (DRA) is a dynamic field that includes scientific, legal and commercial aspect of drug-development. Drug development to commercialization is highly regulated. Every drug before getting market approval must undergo rigorous scrutiny and clinical trials to ensure its safety, efficacy and quality. These standards are set by regulatory authorities of their respective countries such as FDA in US and CDSCO in India etc

Regulation of Drug products involve following areas –

Non-clinical and Clinical Drug Development Guidelines

- Licensing (Patent)
- Drug Registration
- Manufacturing
- Quality and safety Guidance
- Pricing and Trademark
- Marketing, Import and Distribution of Drug products

Pharmacovigilance (Adverse Drug Reactions monitoring) (1)

Historical background of Regulatory Affairs

In 1950's, multiple tragedies such as the sulfanilamide elixir, vaccine tragedy and thalidomide tragedy have resulted in substantial increase of the legislations for drug products quality, safety and efficacy. This has also resulted into stricter norms for marketing authorization and good manufacturing practices. In 1937 due to diethylene glycol poisoning, 100 people died and in 1956 a thalidomide disaster which majorly triggered for the development

of the modern regulatory controls on the drug development and supply. Hence to ensure the quality, safety and efficacy of drug products and in order to assure the continued protection of public health the regulatory agencies were introduced in the late 1950's**.**

International Pharmaceutical Drugs regulatory authorities

Introduction **–**

Drugs regulatory authority plays a vital role in regulations of drug, its safety, efficacy and quality is maintain by this. However this agencies secures public health by maintaining it. National level of drug regulatory bodies maintain quality, safety of drug within nation or Country, and on this purpose to maintain quality, and safety of drug all over world there are some International Drug Regulatory authorities and this maintain the quality, purity, safety, and efficacy, and quantity of drug molecule or drug components all over world equally.

This authorities make some nominations, Rules, regulations, and guidelines as View of drugs and this all rules follow by all over globe for the purpose of drug efficacy, and quality. And main goal is to protect public health condition, give A1 grade health facilities to the public and to protect and maintain public health.

Some of most important International drug regulatory bodies are as per belongs

1. International Council for Harmonisation (ICH).
2. World Health Organization (WHO)
3. World Intellectual Property organization (WIPO**).**

International Council for Harmonisation (ICH).

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. Harmonisation is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side. Key to the success of this process is the commitment of the ICH regulators to implement the final Guidelines.

OBJECTIVES OF ICH

Promote public health by early availability of drug in the market.

- Maintaining safeguards on quality, safety and efficacy.
- Improve efficiency of new drug development,Reduce registration cost.
- Less expensive drugs for patients.
- Prevent the duplication of clinical trails in humans. Minimize the animal use with out compromising in safety efficacy of the product.
- Mutual acceptance of clinical data by regulatory authority. Reducing testing duplication

It is divided into four categories (QSEM):

Q: Quality guidelines - It includes stability, impurities testing, GMP.

S: Safety guidelines - It includes carcinogenicity, genotoxicity, reprotoxicity.

E: Efficacy guidelines - It includes clinical, pharmacogenomics.

M: Multidisciplinary guidelines - It includes medical dictionary for regulatory activities, electronic standards, non-clinical safety studies, common technical document (CTD)(5)

World Health Organization (WHO)

Introduction- The WHO was established on 7 April 1948.The first meeting of the world Health Assembly (WHA), the agency's governing body, took place on 24 July of that year. The WHO incorporated the assets, personnel, and duties of the League of Nations' Health Organization and the Office International d'Hygiène Publique, including the International Classification of Diseases (ICD). Its work began in earnest in 1951 after a significant infusion of financial and technical resources. The WHO's mandate seeks and includes: working worldwide to promote health, keeping the world safe, and serve the vulnerable. It advocates that a billion more people should have: universal health care coverage, engagement with the monitoring of public health risks, coordinating responses to health emergencies, and promoting health and well-being. It provides technical assistance to countries, sets international health standards, and collects data on global health issues.

The WHO has played a leading role in several public health achievements, most notably the eradication of smallpox, the near-eradication of polio, and the development of an Ebola vaccine. Its current priorities include communicable diseases,particularly HIV/AIDS, Ebola, COVID-19, malaria and tuberculosis; non-communicable diseases such as heart disease and cancer; healthy diet, nutrition, and food security; occupational health; and substance abuse.

Health policy -

WHO addresses government health policy with two aims: firstly, "to address the underlying social and economic determinants of health through policies and programmes that enhance health equity and integrate pro-poor, gender-responsive, and human rights-based approaches" and secondly "to promote a healthier environment, intensify primary prevention and influence public policies in all sectors so as to address the root causes of environmental threats to health(6)

Regulatory Authorities In Different Countries

USA Regulatory Agency

FDA is an regulatory authority which is brought through requirements of legal procedures related to drug development process in a country. as the Pharmaceutical industry throughout the world are moving ahead towards becoming more and more competitive, Regulatory agencies are being established in various countries across the globe

It is an Regulatory agency which particularly works in US (united state) an agency within the U.S public health service which is a part of Department of Health and Human Services.

Agency monitors the manufacture, import ,transport the storage and sale of medicine's medical devices biological products and radiation emitting devices **(9)**

- office of chief council(OCC) office off commissioner (OC)
- centre for food safety and applied nutrition(CFSAN)
- centre for veterinary medicine (CVM)
- centre for drug evaluation and research (CDER)
- office of regulatory affairs (ORA)
- office off commissioner (OC)
- centre for food safety and applied nutrition(CFSAN)
- centre for veterinary medicine (CVM)

Mission of FDA-

With respect such products , protect the public health by ensuring that the food are safe, wholesome, sanitary & properly labelled; human & veterinary drugs are safe and effective.

To Promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.

Responsibilities of FDA-

Responsible for protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, and by ensuring the safety of our nation food supply, cosmetics & product that emit radiation. FDA also responsible for advancing the public health by helping to speed up the innovation that makes medicalproducts more effective, safer &more affordable and by helping the public get the accurate, science based information they need to use medical products and food to maintain and improve their health

What US-US-FDA regulates-

- Biological products
- Product manufacturing establishment licensing
- National blood supply
- Veternay products
- Radiation safety performance standard for microwave, oven, diagnostic x- rays, cabinet x-ray system, laser products, mercury vapour lamps. Radiation emitting electronic products
- Safety of all food products (except meat & poultry)

- to established product standard & to develop improved testing method.(10)(11)

Indian Regulatory Agency

The Central Drug Standard Control Organization (CDSCO)

INTRODUCTION

The Central Drug Standard Control Organization (CDSCO) regulates drugs, cosmetics, diagnostics and devices in India. It is headed by the Drug Controller General of India (DCGI), responsible for safety, efficiency and quality standards for pharmaceuticals and medical and publisher of the Indian Pharmacopoeia. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Commission (DCC). State Government is responsible for licensing, approvals, inspection and recalls of drugs manufactured within their domain.

The CDSCO works with the World Health Organization to promote Good Manufacturing Practice (GMP) and international regulatory harmony. The organization responsible for approved issuance of license for various categories of drugs such as blood and blood products, I.V. fluids, vaccines,sera etc., either manufacturing in India or imported. It regulates the manufacturing, sale,distribution of drugs through the state authorize and register manufacturing, sale and distribution of drugs

Vision= to protect and promote public health in India

Mission = to safeguard and enhance the public health by assuring the safety efficacy and quality of drugs, cosmetics and medical devices

Values= the mission and mandate of the cdsco by achieve to act transparency, accountability, punctuality,courtesy, openess, responsiveness, professionalism, impartiality, consultancy, integrity, and truthfulness

Functions of CDSCO:

1. Approval of new drugs and clinical trials.

2. Import Registration and Licensing.

3. Licensing of Blood banks, LVPS, Vaccines, Pie-DNA products

4. Amendment to D and C Act and Rules.

5. Banning of drugs and cosmetics.

6. Grant to Test license, Personal License, NOC'S for export.

7. Testing of drugs by Central Labs.

8. Publication of Indian Pharmacopoeia.

Drug Controller General of India (DCGI):

He/She is responsible for approval of newdrugs, medical devices and clinical Trials to be conducted in India. The person who isappointed by the Central Government under the DCGI the state drug control organizationwill be functioning. The DCGI is advised by the Drug Technical Advisory Board (DTAB) andthe Drug Consultative Committee (DCC).

Zonal Office: Mumbai, Kolkata, Chennai, Ghaziabad, Ahmadabad, Hyderabad.These centers are involved in GMP audits and inspection of manufacturing units of largevolume, parental, sera, vaccine and blood products.

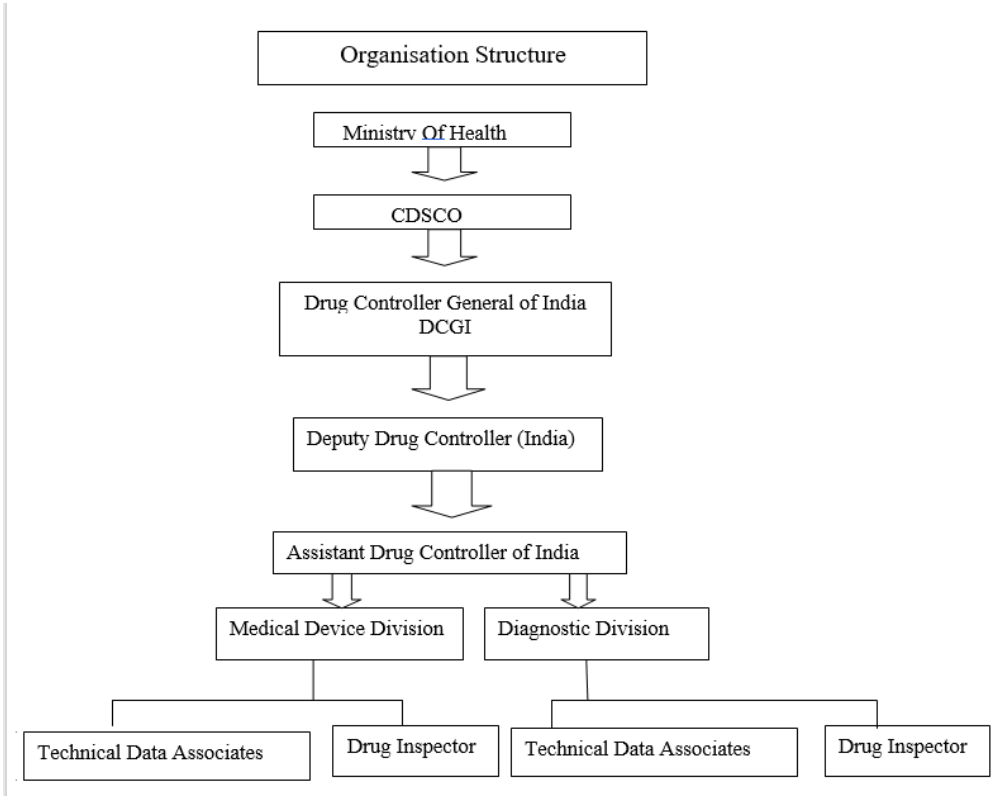
Sub-zonal Office: Chandigarh, Jammu, Bangalore.These centers are coordinated with state drug control authorities under their jurisdictionfor uniform standard of inspection and enforcement.

Central Drugs Testing Laboratories:

- Central Drugs Laboratory, Kolkata.
- Central Drugs Testing Laboratory, Mumbai.
- Central Drugs Testing Laboratory, Chennai.
- Central Drugs Laboratory, Kasauli.
- Regional Drugs Testing Laboratory, Guwahati.
- Regional Drugs Testing Laboratory, Chandigarh.

These laboratories are responsible for quality control of Drugs and Cosmetics in India.(12)(13)

Structure Of CDSCO



Canada- Health Canada

Introduction

The responsibility for assisting Canadians in maintaining and enhancing their health policy falls on Canada Health. Under the direction of the food and medicines, the Therapeutic Products Directorate enforces the medical device regulations as well as the food and drug regulations. Once the drug review process is complete, it is then approved for sale in Canada. TPD is in charge of enforcing the financial administration's fee regulations for drugs and medical devices. While evaluating the safety, efficacy, and quality of a medicine, Health Canada's Health Products and Food Branch (HPFB) occasionally consults with independent specialists. the use of substances for the diagnosis, treatment, mitigation, or prevention of illness disorder abnormal physical state or symptoms in pharmaceutical products, as well as the control of health research What is now known as Health Canada was first established as the "Department of Health" in 1919 in the wake of the Spanish flu epidemic. In 1993, the previous Health and Welfare Canada department (founded in 1944) separated into two independent units, one of which was Human Resources and Labour Canada(16)(17)

Canadian Ministry of Health

The maintenance and improvement of Canadians' health is the responsibility of the minister of health. The Canadian cabinet is in charge of regulating Health Canada and the Public Health Agency of Canada, as well as implementing the Canada Health Act, which governs the country's universal health care system

- Canadian Agency for Food Inspection
- Health Canada Public Health Agency Canadian Institutes of Health Research
- Board for the examination of patented drug costs
- Public Health Agency of Canada

Almost 12,500 full-time equivalent individuals work for the Health Portfolio, which has an annual budget of nearly $3.8 billion.**(18)**(19)

Objectives

Health Canada aims to through cooperating with others in a way that supports Canadians' trust prevent and lessen dangers to each person's health and the ecosystem as a whole Encourage better habits Guarantee that high-quality healthcare is available and effective.

Include longer-term planning for prevention, health promotion, and protection in the system's renewal efforts reducing health disparities in Canadian society; and supplying Canadians with health information to aid in decision-making

Functions:

1. Health

Helping Canadians maintain and enhance their health is the responsibility of Health Canada. It seeks to lower health risks and guarantees access to high-quality healthcare.

2. Food and Nutrition

For food and nutrition, it specifies safety requirements.

Food borne sickness and poisoning are tracked.

Recalls of food are another effect of it.

It issues Canada's Food Guide, which provides details on a healthy diet.

It examines food ingredient labels.

3.It disseminates information and facts concerning signs, risks, and methods for preventing, managing, and treating human diseases and illnesses.

4. Vaccines and Immunization

It evaluates the side effects and safety of the vaccines as well as plans the child's vaccination schedule.

5. Drug and health products

The goal of the health products and food branch (hpfb) is to minimise health risk factors for Canadians while enhancing the level of safety offered by the regulatory system for health products and food.

CLINICAL TRIALS:-

Clinical research is an indispensable part of the drug discovery process to ensure the safety and efficacy of any new drug. In today's global scientific era, clinical trialsare the mainstay for bringing newer and better drugs to market. Although a set of robust guidelines is available to govern the conduct of clinical trials in any country, theconduct of clinical research is also looked upon as an area of humanitarian concern. Clinical trials are one form of clinical research that involves a researcher or researchers who directly observe a person or people, and/or collect data to answer a scientific or medical question about the safety or potential benefit of an intervention such as a medication, device, teaching concept, training method or behavioral changes (20)

James Lind is considered as the father of clinical trials, since he was the first to introduce control groups into his experiments. In this manner, he documented the fact that citrus fruits in the diet could prevent scurvy. Lind carried out trials while at sea on board the Salisbury in 1747. All scurvy patients were given the same general diet but this was supplemented with various additional items, including cider, elixir vitriol, vinegar, seawater, nutmeg and (crucially) oranges and lemons. In just six days, those patients taking citrus fruits were fit for duty. Although the results were clear, Lind hesitated to recommend the use of oranges and lemons because they were too expensive. It was nearly 50 years before the Navy eventually made lemon juice a compulsory part of the seafarer's diet and this was soon replaced by lime juice because it was cheaper. This is why British sailors, and later the British in general, were called 'limeys' by the Americans.(21)

In the clinical trials , trials is Anglo-french origin from trier meaning to choose , sort , selector try . clinical trials are the term that Performed the experiments on the Human being for assessing the safty and efficacy of treatment

DATE	AUTHOUR/SOURCE	EVENT
1747	LIND	Experiment with Untreated Control Group(22)
1800	WATERHOUSE	Smallpox Trials
1925	FISHER	ApplicationOf RandomizationTo Experiment(23)
1943		The Medical Reasearch Counsil(MRC) Carried Out Trials TO Investigate Potulin
1944		Publication Of Multicancer TrialsOn Treatment For Common Cold
1946		First Randomised Control Trials Of Streptomycin In Pulmonary Tuberculosis Was Carried Out By MRC Of The Uk(24)
1962	HILL	Book On Clinical Trials
1979	GORDON	NIHClinical Trials Committee
2003		NIH Statement On Data Sharing
2004		RequirementOn Registration Of Trials

CLINICAL TRIALS IN INDIA

Clinical Trials in India refers to clinical research in India where researchers test drugs and other treatments on research participants. NDCTR 2019 and Section 3.7.1 to 3.7.3 of ICMR Guidelines require that all investigators conducting a clinical trial must publicly document it in the Clinical Trials Registry – India.(25)(26)

Various government agencies and laws regulate clinical trials. The Drugs Controller General of India grants approval for clinical trials and is the supreme agency that specifically oversees clinical trials.The Drugs Controller is part of and reports to the Central Drugs Standard Control Organization.Both organizations are the Department of Health, subordinate to Family Welfare, is the highest government agency overseeing everything related to medicine and health.The Indian Council of Medical Research regulates the professional and ethical conduct of physicians and scientists. India's pharmacovigilance program follows up reports of harm from drug use. Outside of the central government, each state has its own regional regulatory bodies that provide some input into the administration of studies(27)

Since the early 2000s, there have been international discussions from academia, medicine and business, noting that India is both an attractive and challenging place to conduct medical research, has a large and diverse population and that research costs in India compare to others research-capable countries are relatively low.Challenging features include a lack of research capacity, evolving and uncertain government regulatory infrastructure, language diversity, and the need for a culture of confidentiality among research participants.(28)

In the years around 2010 there were various scandals in the media and public discussion in which companies conducted clinical trials in an unethical way. There was much debate that generated many complaints, including that researchers failed to obtain informed consent from research participants and that medical research dismissed high rates of injury and death among research participants. Following the 2013 case of Swasthya Adhikar Manch v Union of India in the Supreme Court of India, various government agencies reformed their regulations to make clinical trials more ethical. There were many changes with different reactions. Among the responses, some say the clinical trials are safer for participants and others say the new rules favor large national and international companies over other stakeholder (10) among research participants Since 2009, the Central Drugs Standard Control Organization has mandated that anyone conducting clinical research in India must pre-register in the Indian Clinical Trials Registry before enrolling research participants(29)

Various government agencies and laws regulate clinical trials. The Drugs Controller General of India grants approval for clinical trials and is the supreme agency that specifically oversees clinical trials.The Drugs Controller is part of and reports to the Central Drugs Standard Control Organization.Both organizations are the Subordinate to Ministry of Health Family Welfare is the highest government agency overseeing everything related to medicine and health.The Indian Council for Medical Research regulates the professional and ethical conduct of physicians and scientists.The Indian Council of Medical Research governs the professional and ethical behavior of the doctors and scientists.The Pharmacovigilance Program of India tracks reports of harm from the use of drug

Clinical Trial Life Cycle

Drug Discovery and Development

Scientists conduct basic research in chemistry, biochemistry, physiology, microbiology, and pharmacology to understand natural products and physiological processes relevant for drug development purposes. For example, drug receptors, enzymes, biological transport, or other metabolic processes serve as targets. This initial investigation may take two to three years. When a new drug is developed for a specific disease, the research and discovery phase centers around understanding the disease, narrowing it down to compounds that may affect it, and creating molecules from the compounds accordingly(36)(37)(38)

A. Development - The data gathered during the research and discovery phase, is translated into disease-specific potential new drugs

B. Screening –

At the stage of screening, chemical compounds are screened in order to observe their pharmacological effects. Rapid, high efficacy drugs screening facilitates the determination of whether a chemical compound has characteristics of a potential drug for the disease intended to be cured(39)

C. Identification –

At the identification stage, a chemical compound's effectiveness is determined. In vitro screening methods are used for this. A lead compound (sometimes known as "Lead") is a chemical that interacts with the target medicine in a desired way. "Other compounds with slightly different structures may be synthesised" if the Lead is not perfect. A lead can also be found by using an isolation technique, which involves separating compounds from natural components. Drugs may be made from isolated compounds with acceptable pharmacological characteristics. Pharmacology and toxicological tests are then performed on a lead or the end product of the synthesis.

II. Preclinical Research –

In vivo testing comes after this in vitro testing. Good Laboratory Practices (GLP) include pharmacodynamics, pharmacokinetics (absorption, distribution, metabolism, and excretion), safety, toxicity, dose, and efficacy investigations as well as both of these testing kinds. The International Conference on

Harmonization's safety themes and regulatory compliances are taken into consideration when curating each GLP component. The pre-clinical stage is essential since it serves as the initial safety valve prior to in vitro testing and aids in figuring out how Lead compounds work. The objective should be to guarantee enough safety and efficacy, which is a requirement for regulatory authorities to approve the progression of a new medicine to the clinical phase. The pre-clinical research timetable in connection to the clinical trial

III. Clinical Research

Clinical research for such drugs is conducted in order to obtain regulatory authorisation for the drug to be tested on humans:

A. Laboratory Testing

a. Laboratory testing is done using computer models and human cells grown in the laboratory itself. This is the first stage of testing the efficacy of the drug and checking for potential side effects

B. Biopharmaceutical Studies

Animal testing accompanies biopharmaceutical research in which the chemical composition and dosage form of a drug are detailed. At this stage, the stability of the drug and the ability of the dose to adequately release the drug in the human body are evaluated. Bioavailability, i.e. H. Ability of the human bodyabsorption of the drug from its dosage form, and pharmacokinetic studies, i. H. the rate and extent of absorption and distribution of the drug in the body, metabolism and excretion are performed

C. Dosage Form

The adequate dosage form that when administered, will elicit a predictable and reliable therapeutic response, is determined. A factor that needs to be considered is whether the dosage form is suitable for manufacture on a large scale with reproducible quality in order to proceed with the clinical trials for the drug to seek marketing authorisation in the country. 26 The determination must be based on pharmacological and toxicological data. 27 The dosage forms may be oral, sublingual, parenteral, epidermal, intranasal, intra-respiratory, etc (43)

IV. Safety Testing in Animals

Safety tests are performed in animals to select the most suitable Lead and the most efficient form of dosage. This set of testing includes acute, chronic, reproductive, and developmental toxicity, carcinogenicity and other relevant tests

V. Approvals for In-Human Trials

Drug regulators regulate the development and marketing of medical interventions for ensuring suitability and safety of the public. Therefore, to administer drugs for the purpose of research through clinical trials also require prior approvals and the trials scrutinised and monitored by the drug regulators. The data collected through pre-clinical trial studies is submitted to regulatory authorities for approvals to conduct first in human studies of the drug along with Form CT-04. Specifically, these include:

i. Chemical and pharmaceutical information

ii. Animal pharmacology data

iii. Animal toxicology data

iv. Human clinical pharmacology data

v. Regulatory Status in other countries (44)

VI. Clinical Trials

Clinical research can take up to 3–7 years. 30 The CT Rules lay down general principles and practices for a clinical trial including the continuous evaluation of data to achieve safety for the trial subject. The clinical trial is to be designed according to sound scientific principles and the results are to be analysed in accordance with the clinical trial protocol (43)

Phase o

Phase 0 is a newer designation for exploratory, first-in-human studies conducted in accordance with the U.S. Food and Drug Administration (FDA) 2006 Guidance on Exploratory Investigational New Drug (IND) Studies Phase 0 studies to investigate the development of promising drugs or imaging means by establishing very early on whether the drug or compound behaves in humans as expected from preclinical studies. Distinctive features of phase 0 trials include administering subtherapeutic single doses of the study drug to a small number of subjects to obtain preliminary data on pharmacokinetics (how the body processes the drug) and pharmacodynamics (how the drug works in the body).

Phase I -Phase I studies are the first phase of testing in human subjects. A small (20-80) group of healthy volunteers is usually selected. This phase includes studies to evaluate the safety (pharmacovigilance), tolerability, pharmacokinetics and pharmacodynamics of a drug. These studies are often conducted in an inpatient clinic where the subject can be observed by full-time staff. The person receiving the drug is usually observed until several half-lives of the drug have elapsed. Phase I studies usually also include dose finding studies, also called dose escalation studies, so that the appropriate dose

for therapeutic use can be found. The dose range tested is usually a fraction of the dose that causes harm in animal studies. Phase I studies mostly involve healthy volunteers. However, there are some circumstances where real patients are used,

Phase II -Once the initial safety of the study drug has been confirmed in Phase I studies, Phase II studies will be conducted in larger groups (20-300) and are designed to assess the drug's efficacy and continue the Phase I safety evaluations in a larger group of patients subjects and patients. When the development process for a new drug fails, it usually occurs during Phase II trials when it is determined that the drug is not working as designed or has toxic effects. Phase II trials are sometimes divided into Phase IIA and Phase IIB. Phase II A is specifically designed to assess dosing requirements (how much drug should be administered), while Phase IIB is specifically designed to examine efficacy (how well the drug works at the prescribed dose(s)). Some studies combine phase I and phase II, testing both efficacy and toxicity

Phase III- Depending on the disease or medical condition being studied, phase III studies involve large patient groups participating in randomized controlled multicenter trials (300–3,000 or more). and are intended to be the conclusive evaluation of the drug's efficacy in comparison to the current "gold standard" of care. Phase III trials are the most expensive, time-consuming, and difficult trials to design and run, especially in therapies for chronic medical conditions, because of their size and comparably long duration. It is standard procedure for some Phase III trials to continue while the regulatory submission is being processed by the relevant regulatory agency. While it's not always necessary, it's typically anticipated that at least two successful Phase III trials proving a drug's safety and effectiveness are needed before it can be approved.

Phase IV - Post-marketing surveillance trial is another name for a phase IV trial. Phase IV trials include ongoing technical and safety monitoring (pharmacovigilance). support for a drug once it has been given the go-ahead to be sold. For competitive (finding a new market for the drug) or other reasons (for instance, the drug may not have been tested for interactions with other drugs or on certain population groups such as pregnant women, who are unlikely to subject themselves to trials), regulatory authorities may require phase IV studies, or they may be undertaken by the sponsoring company. Unlike what was achievable during the Phase I-III clinical studies, the safety surveillance is intended to discover any uncommon or long-term adverse effects over a much larger patient population and longer time period.

ETHICAL CONSIDERATION

An independent body (review board or committee, institutional, regional, national, or supranational), made up of medical professionals and non-medical members, whose duty it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial and to provide the general public with assurances of that protection, among other things, by reviewing and approving/giving a favourable opinion on the trial protocol, the suitability of the Although independent ethics committees may not operate in accordance with GCP

ICH GCP GUIDELINES

The principals of ICH GCP --

1. Clinical trial should be conducted in accordance withthe ethical principals that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement.

2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

3. The rights, safety, and well being of the trial subjects are the most important considerations and should prevail over interests of science and society.

4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

ROLE OF PHARMACISTS IN CLINICAL TRIALS

Pharmacists play an active role in research and research. We do clinical trials first and provide what you need Facilities required for proper storage of Investigational Medicinal Product (IMP) in refrigerated or controlled room temperature. Regular temperature monitoring is guaranteed and recorded It is also the pharmacist's duty to ensure that there is a constant supply of IMP and that it is dispensed to the patient accordingly. Informed consent form or patient information leaflet regarding correct use of IMP in addition to the written information provided. Patient returns of IMP will be counted and documented to determine treatment adherence. For injectables, the pharmacist also ensures that they are manufactured to specifications established in research and that they are administered properly. In addition to clinical trial management, cancer pharmacists We often conduct research projects aimed at improving outcomes for patients receiving medications such as chemotherapy and other adjuvant medications such as antiemetics and blood growth factor injections. DUE) is a research project commonly conducted by pharmacists. These projects aim to promote the rational use of medicines by patients. Essentially, we provide insight into how patients are using medicines and observe physicians' prescribing patterns. DUE may be considered proof pharmacists to make sure that the drug is used properly In addition, observation by a pharmacist is also performed. Patient survey Physician Perspectives and Attitudes dosage. The results of the survey will be used to improve the services we provide to our patients. NCC Oncology Pharmacy is currently conducting two studies. They aim to explore patient use of complementary and alternative medicines and to explore patient perspectives on the safe use of oral cancer drugs. Pharmacy students who are sufficiently trained to conduct research work are very often called upon to conduct research. Patience. We would like to take this opportunity to thank all patients who agreed to participate in the study(48)

Clinical Trials Market Value in India - Clinical trials market in India has recorded significant growth trends in the recent past. Clinical research experienced over 84% growth during 2006-2008 and it has its own merit in regards to further prospect considering that global clinical market is growing at 12% rate. Clinical research industry in India touched US$ 320 million in 2009, up from US$ 140 million in 2006. An estimate shows that clinical research in India is expected to be US$ 320 million by 20094. According to the Associated Chambers of Commerce and Industry, an influential national industry association, India is set to grab clinical trials business valued at approximately US$ 1 billion by 2010, making the subcontinent one of the world's most preferred destinations for clinical trials.(49)

Conclusion

On Overview throughout the project report we can understood the whole mechanism of regulatory affairs department, regulatory bodies, structure and function, process of working, norms, Rules, & regulations, there guidelines etc. In short whole process of the regulatory department can be recommended by this report. Also the work of different regulatory bodies, authorities & agencies that work on the national & international level is mentioned in this project work. This is very important by the aspect of this report. What are the important of regulatory bodies in the nation's health is determined by this report And the important of this pharmaceutical regulatory bodies in accordance to the public health. Not only in the public health but also in veterinary products, biological products, cosmetics, pharmaceutical device's all this compounds are covered by any national pharmaceutical regulatory body. This component indirect falls an impact on the public health.

Clinical Trials is another topic is covered in this project report. Clinical trials are performed on human subjects to check drugs safety, efficacy, quality, and total ADME profile of the drug. Before entering the drug molecule in the market. Before human volunteers this trials are performed on the animals and animal models & then administered to the humans. The overall process flow, Rules, regulations, guidelines and the nominations of the clinical trial are involved in this project report. Also the different phases of clinical trial are mentioned, there flow proces An overall review of Indian process of the clinical trial is mainly explained in the report. Steps & phases, whole mechanism of clinical trial is mainly focus in this project report. In this process of the clinical trial whole trial is under the supervision of respective authority or may be sponsored. The main focus of this review project report is mainly on the International regulatory bodies as well as national pharmaceutical authorities and whole process of the clinical trial. And all this mentioned in the report very informative & knowledgeable way s , number of human subjects are involved in each trial are briefly explained in this report

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