"ONE NATION ONE SYLLABUS ONE PORTAL" TBP is being created to provide study material in simple, innovative, and self explanatory form focussing newly introduced revised syllabus for B.Pharm and M.Pharm by PCI. Our services includes "ORALS" i.e Our Reading and Learning Space, Bread & Butter (Q&As for interview preparation), Consultancy services, Career guidance based on mind-mapping approach, Video ar Audio tutorials, Webinars and many more.

Sunday, September 16, 2018

TECHNOLOGY TRANSFER

TECHNOLOGY TRANSFER

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Introduction

It is highly desired to improve a quality assurance system and regulations. Under these circumstances, it is highly desired to improve a quality assurance system of drugs at all stages through research and development (R&D), manufacturing and marketing in line with the trends by reviewing the current quality assurance system and its methods including existing Good Manufacturing Practice (GMP) to comply with the new system and adopting achievements of technological progress and international harmonization of pharmaceutical regulations.

In recent years, there is a growing awareness that an appropriate transfer of manufacturing technologies (technology transfer) is important to upgrade drug quality as designed during R&D to be a final product during manufacture as well as assure stable quality, it is desired to make sure 5 W's 1H approach that is What, When and Why information of the technology transfer each other between stake holders related to drug manufacturing. For that purpose, it is necessary to establish an appropriate guideline for the technology transfer and upgrade the quality assurance system. This guideline categorizes information generated in the processes through pharmaceutical R&D and manufacturing as well as the information flows, discusses information necessary for the technology transfer and communication route, and proposes ideal technological transfer.

Definition

Transfer of technology is defined as "a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture sites"

or

Technology transfer is both integral and critical to the drug discovery and development process for new medicinal products.

or

Technology transfer is helpful to develop dosage forms in various ways as it provides efficiency in process, maintains quality of product, helps to achieve standardized process which facilitates cost effective production. It is the process by which an original innovator of technology makes its technology available to commercial partner that will exploit the technology. Technology transfer is both integral and critical to drug discovery and development for new medicinal products.

or

In Pharmaceutical industry, "Technology Transfer" refers to the processes of successful progress from drug discovery to product development, clinical trials and ultimately full-scale commercialization.

or

"Technology transfer" refers to the processes that are needed for successful progress from drug discovery to product development to clinical trials to full-scale commercialization or it is the process by which a developer of technology makes its technology available to commercial partner that will exploit the technology.

or

Technology transfer is important for such research to materlise on a larger scale for commercialization especially in the case of developing product. Technology transfer includes not only the patentable aspects of production but also includes the business processes, such as knowledge and skills.

Labels

- 505(b)(1) Applicants (1)
- 505(j) Applicants (1)
- 8W's1H Approach (1)
- AADA (1)
- Abbreviated Antibiotic Drug Application (1)
- Abbreviated New Drug App (1)
- Agencies Involved in Drug Regulation (India) (1)
- ANDA Applicant (1)
- ANDAs (1)
- APA (1)
- Approval of New Drug in In
- BACPAC (1)
- Bio-activity (1)
- Bioequivalence (1)
- Bioequivalent Product (1)
- Brand Name Drugs (1)
- Branded Product (1)
- Bulk Active Chemical Post A Changes (1)
- CDSCO (1)
- CFR (1)
- Clinical Activities (1)
- Clinical Protocols (1)
- Clinical Research Process (1
- Clinical Studies (2)
- Clinical Trials (4)
- Code of Conduct (1)
- Code of Federal Regulation
- Comparative study betweer Innovators and Generics (1)
- Contract Research Organiza
- Copies (1)
- CRO (1)
- DCGI (2)
- Developers (1)
- DMF (1)
- Drug Development (1)
- Drug Discovery (1)
- Drug Discovery and Develo (1)
- Drug Manufacturing (1)
- Drug Master File (1)
- Drug Price Competition and term Restoration Act (1)

Facets of technology transfer

The transfer of technology could happen in any of the following ways:

-Government labs to private sector firms.

-Between private sector firms of same country.

-Between private sector firms of different country.

-From academia to private sector firms.

-Academia, government and industry collaborations.

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Labels: 8W's1H Approach, Drug Manufacturing, Full-scale Commercialization, GMP, International harmonization, Large Scale, Quality assurance, R&D, Technology Transfer

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Saturday, September 15, 2018

APPROVAL OF NEW DRUG IN INDIA

APPROVAL OF NEW DRUG IN INDIA

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Agencies Involved in Drug Regulation (India)

The CDSCO is the central authority overseeing the drug industry, as mandated under the Drugs and Cosmetics Act. The Organization has six (6) zonal offices, four (4) sub-zonal offices, thirteen (13) port offices and seven (7) laboratories under its control. Its major functions are controlling drug imports, approving drug development and clinical trials, and overseeing Drugs Consultative Committee and Drugs Technical Advisory Board meetings. DCGI is the main licensing authority, which directly issues permission for new drugs and devices. It supervises clinical trials as well.

Experts from the Drugs Technical Advisory Board advice central and state governments on all technical matters arising out of drug control enforcement. The government can amend rules only with the Board's permission. Members of the Drugs Consultative Committee include Central and State drug control officers, and its main function is to ensure drug control measures are enforced uniformly over all the states. A special Genetic Engineering Approval Committee approves r-DNA (recombinant DNA technology) based pharmaceutical products. Its role is to monitor the bio safety environment of biotechnological products. There are special laws and guidelines for stem cell research and products.

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When a company in India wants to manufacture/import a new drug it has to apply to seek permission from the licensing authority (DCGI) by filing in Form 44 also submitting the data as given in Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945. In order to prove its efficacy and safety in Indian population it has to conduct clinical trials in accordance with the guidelines specified in Schedule Y and submit the report of such clinical trials in specified format. But a provision is there in Rule 122A of Drugs and Cosmetics Act 1940 and Rules 1945 that the licensing authority may waive certain trials if it considers that in the interest of public health it may grant permission for import of new drugs based on the data of the trials done in other countries. Similarly, there is another provision in Rule 122A which says that the clinical trials may be waived in the case of new drugs which are approved and being used for several years in other countries.

Section 2.4(a) of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 says for those drug substances which are discovered in India, all phases of clinical trials are required.

Section 2.4(b) of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 says for those drug substances which are discovered in countries other than India; the applicant should submit the data available from other countries and the licensing authority may require him to repeat all the studies or permit him to proceed from Phase III clinical trials.

Section 2.8 of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 says that the licensing authority may require pharmacokinetic studies (Bioequivalence studies) first to show that the data generated in Indian Population is equal to data generated abroad and then require them to proceed with Phase III trials.

In summary, the exact requirements of clinical trials may change from case to case and depend on the extent to which licensing authority is satisfied about its safety and efficacy.
The process of approval of new drug in India is a very complicated process, which should meet necessary requirements along with NDA to FDA. The need of the present work is to study and document the requirements for the process of approval of new drug in India with emphasis on clinical trials as per Drugs Control Department, Government of India.

The application for permission seeks detailed information including:

- Chemical and pharmaceutical information;
- Animal pharmacology data;
- Animal toxicology data;
- Human clinical pharmacology data;
- Regulatory status in other countries;
- Full prescribing information as part of new drug approval for marketing;
- Complete testing protocols for quality control testing and;
- Complete impurity profile and release specifications for the product

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Labels: Agencies Involved in Drug Regulation (India), Approval of New Drug in India, DCGI, Drugs and Cosmetics Act 1940, Drugs Technical Advisory Board, DTAB, Rule 122A, Schedule Y

Monday, September 10, 2018

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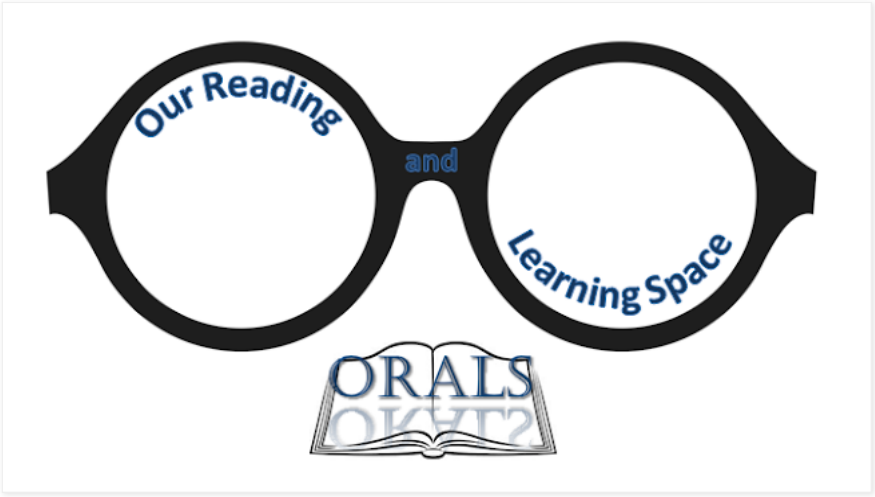

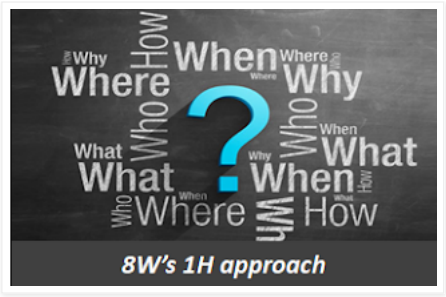

SUPAC and BACPAC

The acronym "SUPAC" stands for "Scale-Up and Post-Approval Changes". This guidance provides recommendations to sponsors of New Drug Application (NDA), Abbreviated New Drug Application (ANDA) or Abbreviated Antibiotic Drug Application (AADA) who intend, during the post-approval period, to change:

- The components or composition;
- The site of manufacture;
- The Scale-Up/Scale-Down of manufacture; and/or
- The manufacturing (process and equipment)

This guidance is the result of
A workshop on the scale-up of immediate release drug products conducted by the

- American Association of Pharmaceutical Scientists in conjunction with the United States Pharmacopoeial Convention and the Food and Drug Administration (FDA).
- Research conducted by the University of Maryland at Baltimore on the chemistry, manufacturing and controls of immediate release drug products under the FDA/University of Maryland Manufacturing Research Contract;
- The drug categorization research conducted at the University of Michigan and the University of Uppsala on the permeability of drug substance;
- The Scale Up and Post Approval Changes (SUPAC) Task Force which was established by the Center for Drug Evaluation and Research (CDER) Chemistry, Manufacturing and Controls Coordinating Committee to develop guidance on scale-up and other post-approval changes.

Why SUPAC?

In the process of developing the new product, the batch sizes used in earliest human studies are small. The size of the batch is gradually increased (Scale Up). The scale-up process and the changes made after approval in the composition, manufacturing process, manufacturing equipment and change of site have become known as Scale Up and Post Approval Changes (SUPAC).

The guidance defines:

1) Levels of change;
2) Recommended chemistry, manufacturing, and control tests for each level of change;
3) In vitro dissolution tests and/or in vivo bioequivalence tests for each level of change; and

Documentation that should support the change.

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Labels: AADA, Abbreviated Antibiotic Drug Application, Bulk Active Chemical Post Approval Changes, Scale-up and Post-Approval Changes

Sunday, September 9, 2018

DEVELOPMENT and INFORMATIONAL CONTENT for INVESTIGATIONAL NEW DRUG APPLICATION (IND)

Development and Informational Content for Investigational New Drug Application (IND)

Investigational New Drug Application (IND) means an Application filed for a drug for the purpose of its registration which is still under investigation. That means, the said drug still requires more trials. Again same questions strike What, How, Why and When (4Ws)?

Drug Approval Process

- Identifying a molecular drug target
- Identifying a first lead compound
- Lead optimization
- Preclinical safety and efficacy trials (in animals)
  Pharmacodynamic responses
  Metabolic profiling
  Cellular receptor interaction
  Physiology that is generally analogous to humans
  5 years time
- Clinical trials in man (Filing an Investigational new drug application with US FDA)

Phase 1
Initial clinical trials to establish safety
Phase 2
Clinical trials to establish efficacy
Phase 3
Clinical trials to establish clinical benefit
Phase 4
Post-marketing studies and surveillance

- Regulatory Approval (Filing New drug application)
- Product Launch

“Patents are important IP safeguards”. Normally the innovating company files a patent application before initiating FDA process because another company could patent the invention before them. Patents attract the notice of potential investors who can provide capital to fund clinical trials.

Task I (as per ICH Guidelines)

- Put A (lead compound) into suitable pharmaceutical dosage form
- Stabilization of product (Physical and Chemical)
- Must provide active substance for absorption
- Must be transported to the site of action
- Inactive ingredients compatibility with compound
- Innovator must have approved DMF (Drug Master File)

Task II (as per ICH Guidelines)

- Filing an IND (Investigational New Drug Application) with US FDA
- Kind of document
- Full description of new drug
- How it is manufactured?
- Where it is manufactured?
- Q.C. Information
- Standards
- Stability
- Analytical Methods
- Pharmacology
- Toxicology
- Efficacy in animals
- Clinical Studies Protocol (Proposed)

Under Investigational New Drug program is the means by which a pharmaceutical company obtains permission to start clinical trials in humans. The FDA reviews the IND application for safety to assure that research subjects will not be subjected to unreasonable risk. If the application is cleared, the candidate drug usually enters a Phase 1 Clinical Trials.

During a new drug’s early preclinical development, the sponsor’s primary goal is to determine if the product is reasonably safe for initial use in humans and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, preclinical studies.

FDA's role in the development of a new drug begins when the drug's sponsor (usually the manufacturer or potential marketer), having screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the law and becomes a new drug subject to specific requirements of the drug regulatory system.

There are three IND types:

An Investigator's IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.

Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR, Sec. 312.23 or Sec. 312.20. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.

Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

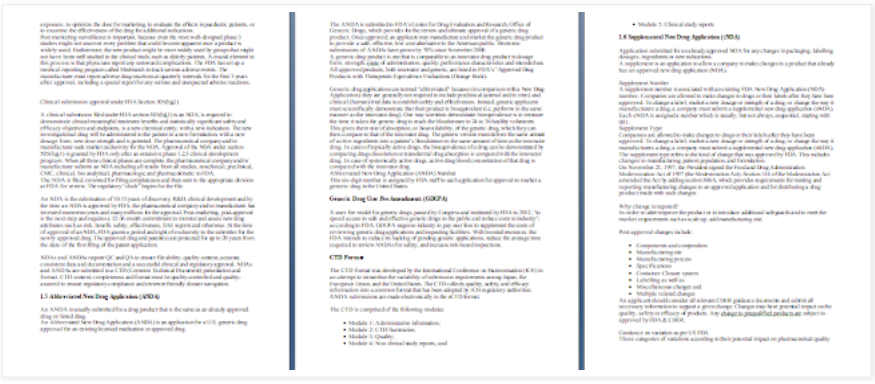
There are two IND Categories

- Commercial
- Research (non-commercial)

The IND application must contain information in three broad areas:

- Animal Pharmacology and Toxicology Studies – Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experience with the drug in humans (often foreign use).
- Manufacturing Information – Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
- Clinical Protocols and Investigator Information – Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators-professionals (generally physicians) who oversee the administration of the experimental compound—to assess whether they are qualified to fulfil their clinical trial duties. Finally commitments to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board (IRB), and to adhere to the investigational new drug regulations.

Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.



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Labels: ICH Guidelines, IND, IND types, Informational Content for IND, Lead Compound, Pharmacology, Q.C. Information, Stability, Toxicology

BREAD & BUTTER: QUESTION & ANSWERS (for exams and interview)

https://thodabahutpharma.com/orals.html

Earn your "Bread & Butter" through our Q&As segment specially designed from interview point of view

We can guide you for interview preparation by our "Mind Mapping" approach, where we can help you to re-visualize and practice your skills which will help you to choose the career opportunities best suited for you considering your plus points.

You can even check our "BREAD & BUTTER" segment for interview preparation. We have consolidated different topics as questions and answers under B&B (Bread & Butter) segment taking reference from US FDA's FAQs.

Quick Bites

What are generic drugs?
A generic drug is a medication created to be the same as an already marketed brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. A generic drug must proved to be bio-equivalent to the brand name drug, which means that a generic medicine works in the same way and provides the same clinical benefit as its brand name version. In other words, you can take a generic medicine as an equal substitute for its brand name counterpart. Generic medicines work the same as the brand name medicines.

Why do brand name drugs (Innovator's product) look different from their generic versions?
Trademark laws in the United States do not allow a generic drug or medicine to look exactly like other drugs already on the market. Generic medicines and brand name medicines share the same active ingredient, but excipients can be different (in case protected by patents) or same.

What is ANDA?
An abbreviated new drug application (ANDA) contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand name drug it references.

Why abbreviated?
Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product performs in the same manner as the innovator drug.

What is "Drug Price Competition and Patent Term Restoration Act of 1984"?
The "Drug Price Competition and Patent Term Restoration Act of 1984" also known as the Hatch-Waxman Amendments,.....***for continued reading, write an E-mail and send it to*** **thodabahutpharma@gmail.com.**

We have diligently prepared following questions and answered them in a simplified way for better understanding along with an added feature of their Hindi translation.
For full series, **E-mail us at thodabahutpharma@gmail.com**

Is an Authorized Generic Drug the same thing as a Generic Drug?

How is an Authorized Generic Drug different from what is commonly understood to be a Generic Drug?

What does this statement mean "Generics need to prove that their product is Bioequivalent to the Innovator's product?

What are guidance documents?

When are guidance(s) developed?

How are guidance(s) developed?

What is a rule?

What is a regulation?

What is the rulemaking process?

What is the "Administrative Procedure Act" and why is it important?

What is the Federal Register?

Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA regulations, and FDA guidance

Pre-Hatch-Waxman Regulatory?

Why Hatch-Waxman act?

Experimental-Use-Doctrine/Research Exemption/Bolar Provision

.....more than 100 questions

Currently, We have included more than three-hundred (300) questions including 60 questions from students, faculty and industry persons which is updated in the list. Stay tuned with TBP.

***For full series,* E-mail us at thodabahutpharma@gmail.com**

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Labels: APA, Drug Price Competition and Patent term Restoration Act, FDA Guidance, Federal Register, Guidance Documents, Guidelines, Hatch Waxman Act, Orange Book, Regulation, Rule, Rulemaking

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Wednesday, September 5, 2018

PRINCIPLES OF DRUG DISCOVERY Contd.

We have been reading or hearing the most common word "Principle" since our childhood. To our understanding word "Principle" in conjunction with drug discovery and development means a basic idea or rule that explains or controls how something happens or works or fundamental norms that serves as the foundation for a system (Pharmaceutical industry) of belief or behavior or for a chain of reasoning. In pharmaceutical industry, drug *per se* is the foundation on which this huge industry has its standing from ages. If we think about the phrase "Principles of drug discovery and development" The first thought that comes to our mind is some fundamentals or rules or more appropriately "code of conduct" by which a drug is discovered and developed or we can say a clear conceptualization or explanation of how the pharmaceutical industry works.
In nut shell, four very common questions strike our mind

1. What is drug discovery and development?
2. Why any drug discovery and development is required?
3. How any drug is discovered and developed?
4. When a drug is discovered and developed?

The principle covers and explains the complete drug discovery process, from obtaining a lead, to testing the bio-activity, to producing the drug, and protecting the intellectual property idea for anyone interested in learning about the drug discovery process and those contemplating careers in the industry.

Each government has its own regulatory process with the goal of providing high-quality, affordable care to its citizens. In India, the central regulatory agency is the Drug Controller General of India (DCGI), which works under the Central Drugs Standard Control Organization (CDSCO).

The text introduces the fundamental principles of drug discovery and development, also discussing important

- Clinical research process
- Development and informational content for investigational new drug application (IND)
- New drug application (NDA)
- Abbreviated new drug application (ANDA)
- Supplemental new drug application (sNDA)
- Scale up post approval changes (SUPAC) and Bulk active chemical post approval changes (BACPAC)
- Post marketing surveillance
- Product registration guidelines

@ CDSCO (Central Drugs Standard Control Organization)
The Central Drugs Standard Control Organization is the national regulatory body for Indian pharmaceuticals and medical devices, and serves parallel function to the European Medicines Agency (EMA) of the European Union, the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan and the Food and Drug Administration (US FDA) of the United States...

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Labels: BACPAC, Bio-activity, CDSCO, Code of Conduct, DCGI, Drug Discovery and Development, EMA, Fundamentals, Lead, PMDA, Principle(s), sNDA, SUPAC, TGA, US FDA

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REGULATORY CONCEPTS and DOCUMENTATION in PHARMACEUTICAL INDUSTRY
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