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RESEARCH ARTICLE

DRUG DISCOVERY AND DEVELOPMENT

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ABSTRACT

With the help of advanced science and technology, Modern medicine has open a new era. It has dramatically changed of the countless people life. But discovery of a drug is a complex process which faces scientific, technical and regulatory challenges. In spite of such challenges, every day, many scientists in the biopharmaceutical industry research at the molecular level, screen and make a new disease target and trails at animals and human to get a desired result. This result help to fine new drug or medicine that will help to improve medical care. Researchers are working to search a more effective way of drug discovery and development process that's lead to maintain highest safety and efficacy standards. This paper is a survey report on the hierarchical step of drug discovery and development process.

INTRODUCTION

Drug discovery and development has a long background history. In ancient ages, drugs were not only just used for physical remedies but were also associated with religious and spiritual healing. Drugs had been derived from mainly plant and supplied by supplemented by animal materials and minerals. But after huge research and combination of trial and error experimentation, drugs were discovered (Rick, 2008). In the 1800s, Drug discovery and development process started to follow scientific procedure. It is mainly carried out by pharmaceutical companies, universities, and government research agencies. To make a new drug for a new disease is long and complex process.

Drug Discovery and Development Process

The most and difficult part of the whole drug discovery procedure is the optimization of Absorption, Distribution, Metabolism, Excretion, and Toxicity (ADMET) properties of a drug. The ADMET profile has a major impact on producing a successful drug. The ADMET profile is discussed following (Doug, 2011).

A. Absorption

Absorption is the process of transferring a drug from its site of administration to the bloodstream.

B. Distribution

When a drug is absorbed into the bloodstream, it can be carried throughout the body. This process is defined as a distribution and reversible process.

C. Metabolism

The drug is not readily metabolized. Drugs are removed from the body either unchanged through the kidneys and bile, or they may undergo chemical changes that allow them to be more easily excreted.

D. Excretion

The drug is not readily secreted. Basically drug excretion is a mechanism of eliminating a drug from the body. The greatest proportion of drugs are excreted through kidneys but there are some others route for eliminating such as lungs, milk, sweat, tears, skin, or saliva

E. Toxicity

The drugs may not affect all others tissue or cell. Drugs toxicity is also called Adverse Drug reaction (ADR). Drugs

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become toxins when a patient has accumulated overdose of drugs or drugs combine with other drugs that leads to the adverse effect like breathing suppression, lowers oxygen levels and finally fatal.

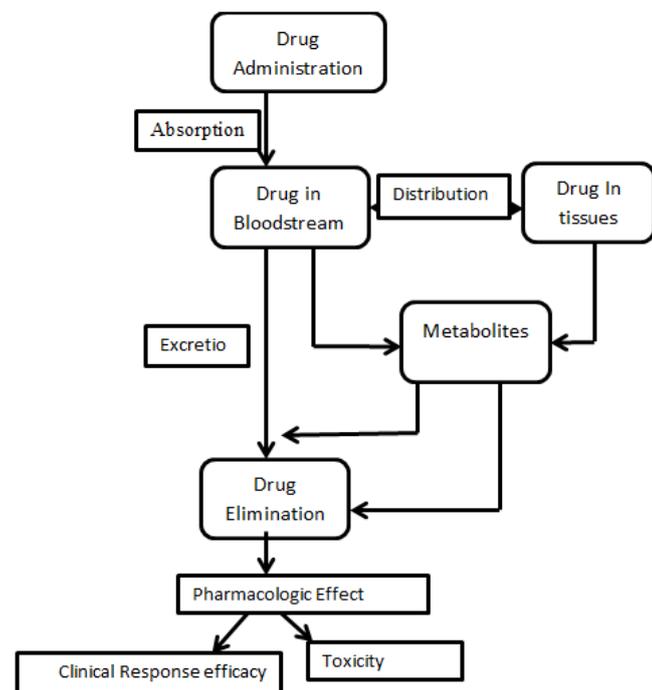


Figure 1. ADMET profile

As it is known to that entire drug discovery is a long and complex process with the ADMET properties, the scientist and researcher are given their best effort to design a new drug. They always follow a standard steps or procedure for developing a new drug. The hierarchical process is follows:

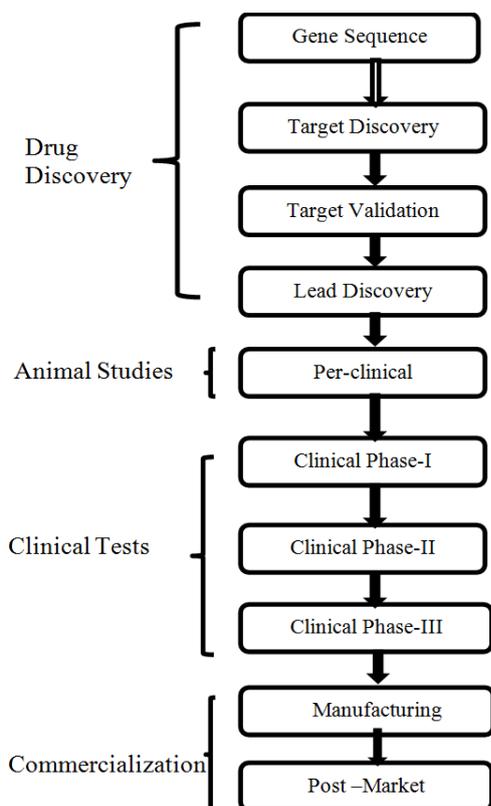


Figure 2. Hierarchical steps of Drug discovery and development process

Drug discovery and Development process consist of many smaller task and function. At the top level, the process is mainly divided into two major parts, one is Drug discovery and another is Development (Benjamin, 2015).

Drug Discovery

The drug discovery may include all the experimentation and studies that are associated with genome or diseases to identify a primary concept of diseases. Drug discovery may further divided into three parts such as:

a. Target Discovery

Target discovery is the first steps of drug discovery process. For targeting a genome of diseases, it is needed to build a library function which consists of gene information. Then Look for genes in which causes for diseases or associated with the diseases or pathways unique to the disease.

b. Target validation

Target validation is another step of drug discovery. In the drug discovery process there is no way of clinical test option. So obtaining target from target discovery is needed to undergo a validation process. For validation process, there are three levels of measuring a valid target such as (Doug, 2011).

- **Molecular level:** Screen enzyme inhibitors or activators or antibodies to enzyme.
- **Cellular Level:** Verify and understand the involvement of the protein in the disease state.
- **Organismal level:** Verify critical nature of target and uniqueness.

c. Lead Discovery

After discovering a target and validation of these target, lead discovery is the last part of drug discovery. Lead discovery means finds leads that affect the target gene, or protein or pathways. Lead selection and optimization are the main concept for lead discovery. There are some essential pharmaceuticals for lead selection and optimization such as

- Structural Characterization
- Impurity Identification
- Solubility assessment
- Prototype formulation
- Stability testing

Drug Development

The second major step, Drug development, is typically related to the laboratory based for producing drug and also measuring the safety, efficacy, and toxicity of those drugs. The stage of drug development is also divided may functional unit which are given below:

a. Pre-clinical

In this stage, drugs are not used in human body. There are three process follow for pre-clinical testing (Food and Drug Administration, 2018; Autoimmunity Research Foundation, 2012).

- **In vitro:** In vitro is like an artificial environment, as in a test tube or culture media. It is one of the pre-clinical testing that takes place with microorganisms, cells, or biological molecules outside of the living organisms or cells.
- **In vivo:** Latin for “with the living”. In vivo pre-clinical testing takes place within the living organisms or cell like testing on animals.
- **In Silico:** In silico is a process where all drug discovery and development related testing held on computer or via computer.

These testing result help to the researcher to measure the side effect or toxicity of a drug. Theses result also predicts that which drug is used for which diseases.

b. Clinical Phase –I

Performing of drug testing on a small group of healthy people is to access for drug –ranging. The amounts of participant are 20-100 normal healthy volunteers. The rate of success is approximately 70%. The purposes of clinical phase- I are safety and dosage (Phase of clinical research, 2018).

c. Clinical Phase –II

Testing of drug on people to access is not only efficacy but also side effect. The total number of participant are 100 -300 patients with a specific diseases. The rate of successive chance is approximately 33% (Phase of clinical research, 2018).

d. Clinical Phase –III

Testing of drug on people and also measuring the efficacy, effectiveness and monitoring of adverse reactions. The total numbers of participants are 300-30000 with specific disease. The rate of success is 25-30 % (Phase of clinical research, 2018).

Manufacturing

Manufacturing process is different from drug to drug. For making a high quality of drug is needed a large scale take care. The drug is manufactured with approved procedures by setting up a quality system.

There must also be Traceability of materials, processes appropriate tests being conducted on the raw materials, intermediates, and finished products. The emphasis is that drugs should be safe, pure, effective, and of consistent quality to ensure that they are fit to be used for their intended functions (Benjamin, 2015).

Post Marketing Monitoring

After manufacturing a drug, post marketing monitoring is essential stage for selling a new drug. Because a drug is not permitted for sale until the marketing application for the new drug has been reviewed and approved by regulatory authorities such as the US FDA, the EU EMEA, or Japan ’ s MHLWGLP, GCP, and cGMP requirements. After the drug has been approved and used for diseases the monitoring is needed to see the reaction of patients and the drug. From the use of the medicine to the patients, companies must report for occurring any serious and unexpected adverse events.

Conclusion

Though drug discovery and development is a long and complex process, researchers are always looking for new and better ways to innovate. Researchers have redoubled their efforts to improve drug development process. They are using new technologies and more sophisticated methods for developing drug. The aim of the every step of drug discovery and development is to ensure the highest possible level of safety and bring effective medicines to patients as quickly as possible.

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