

Chapter 1

Drug Discovery: Current State and Future Prospects

S. Lakshmana Prabu
Anna University, India

ABSTRACT

Modern chemistry foundations were made in between the 18th and 19th centuries and have been extended in 20th century. R&D towards synthetic chemistry was introduced during the 1960s. Development of new molecular drugs from the herbal plants to synthetic chemistry is the fundamental scientific improvement. About 10-14 years are needed to develop a new molecule with an average cost of more than \$800 million. Pharmaceutical industries spend the highest percentage of revenues, but the achievement of desired molecular entities into the market is not increasing proportionately. As a result, an approximate of 0.01% of new molecular entities are approved by the FDA. The highest failure rate is due to inadequate efficacy exhibited in Phase II of the drug discovery and development stage. Innovative technologies such as combinatorial chemistry, DNA sequencing, high-throughput screening, bioinformatics, computational drug design, and computer modeling are now utilized in the drug discovery. These technologies can accelerate the success rates in introducing new molecular entities into the market.

INTRODUCTION

Drugs/Active pharmaceutical ingredients are chemicals used to treat disease or helping to restoring the health of diseased individual human being. Active pharmaceutical ingredients are substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form.

Active pharmaceutical ingredients are classified as

- Inorganic substances
- Organic substances (isolated from materials of animal or human origin)
- Organic substances (synthetic or semi-synthetic or isolated from herbal sources or micro-organisms) (Regulatory control of active pharmaceutical ingredients. Version 1, Appendix 14).

The aim of the drug discovery and development process is to identify the compounds with desired pharmacological property to treat the diseases leads to improve the quality of the diseased individual life.

DOI: 10.4018/978-1-5225-7326-5.ch001

Innovation of a new drug begins with a scientific 'idea' from basic research, subsequently discovery and development of a compound followed by approval from regulatory authority. Drug discovery and development are in a parallel situation. Recently drug discovery and development process has considerable changes like discovering the drug from botanicals to synthetic chemistry is a fundamental scientific development. Last few decades majority of new drug molecules are discovered through synthetic chemistry process (Lakshmana Prabu, *et al.*, 2014).

Process involved in the development of new chemical entity is

1. Preclinical
2. Investigational new drug application
3. Phase I
4. Phase II
5. Phase III
6. New drug application
7. New drug approval (Mathieu, 2002)

Objectives of Drug Discovery and Development

- Determination of medical needs by availability of current drugs, disease burden and its epidemiological trends.
- Recent available drug properties such as efficacy, safety and costs.
- Opportunities available through R&D activities.

Stages in Drug Discovery and Development

Drug discovery and development of a new chemical entity for a disease or existing therapeutic area is based on the emergency medical need or market potential of the disease. Drug discovery and development process includes:

1. **Understanding the Disease:** Before discovering a new drug molecule, understand the nature of disease, gene which is responsible for the disease, role in protein, protein encoding and changes in the living tissues.
2. **Target Identification:** Identification of the target gene or protein responsible for disease which can interact with the drug molecule.
3. **Target Validation:** Verifying the interaction between the target gene or protein and the drug molecule (www.slideshare.net/anisha88shah/rd-brochure).

Product Development Team

Product Development Team (PDT) includes the scientist from various disciplines such as

1. **Medicinal Chemist:** Synthesis of new molecule
2. **Animal Toxicology:** To assess the toxicity in the animal models

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