Acta Scientific Pharmaceutical Sciences (ISSN: 2581-5423)

Volume 3 Issue 2 February 2019

Perspective

The Significance of Technology in Drug Discovery and Development

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Received: February 04, 2019; **Published:** February 15, 2019

Drug development is the process of bringing a new drug to the market place once a lead compound has been identified in a laboratory through the process of drug discovery. Drug discovery and development are two faces of a coin which are inseparable. This process includes pre-clinical research- *In vivo* and *In vitro* (on animals and microorganisms), filing for regulatory status for an Investigational New Drug (IND) to initiate clinical trials on humans, and may include the step of obtaining regulatory approval for a new drug application to market it [1].

Stages of drug development

To become a successful drug candidate, the new chemical entity has to go through these steps

- Developing a New chemical entity
- Pre-Clinical study
- Clinical study

The chemical entities that pass the first stage are tested on animals in preclinical trial. Later, the chemical entity are subjected to clinical trials to establish their safety as well as efficacy (Phase III). This journey makes the chemical entity into a drug.

The NDA (New Drug Application) is the journey through which drug manufacturer officially proposes that the FDA approve a new drug for sale and marketing. The data gathered during the preclinical and clinical trials (involving subjects) of an Investigational New Drug to become part of the NDA [2,3].

The drugs may be designed and tested using computer assisted models followed by human cells grown in the laboratory (*In vitro* study). Many substances fail this test because they damage cells (toxic) or do not seem to work (less potent). However this type of study (*In vivo*) is very essential to justify that the drug is going to work in the body. In few cases enzymatic studies are also conducted to justify the effectiveness of the drug including the MoA, wherever needed [3].

Developing a commercially successful drug is a tedious process and involves a series of challenges, each of which may result in costly bottlenecks, ineffectiveness and high failure rates. That is the reality of drug discovery. Not more than 1% of drugs in the discovery and development process (Phase III and IV) will be able reach the market. Failure rates are too high, and perhaps. often drug candidates consume relatively more time in development, having already consumed substantial time and resources [3,4].

Technology in Drug development

As pharma industry has grown over a period of time, from a small industry to large size, worth billion dollar business globally, there is need to develop and introduce new technologies into this sector which shall fasten the drug discovery and development process. In India alone, it is estimated to be worth over 2 lacks crores.

As demands for safe and efficacious pharmaceutical drugs grow, modern technology will be of increasing importance that shall reduce barriers to clinical efficacy rather than shifting bottlenecks.

The modern technology is revolutionizing the pharmaceutical industry especially drug discovery and development process, empowering conventional researches for the best compounds with computer-aided technology support. Nowdays *In silico* experiments have become essential for modern pharmaceutical and biotech companies, enhancing their research at a faster pace and also economical cost which has reduced the expenses by sending only the most promising drug candidates to preclinical followed by clinical studies. This has becomes possible with advancement of new technology which are perhaps reshaping the drug discovery and development process landscape scenario by incorporation of

artificial intelligence which has accelerated the entire discovery and development process [4,5].

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