

## New drug development process: Regulatory perspective

**Sanjay Reddy Akula and Jyothi Edla**

Samskruti College of Pharmacy, India

New drug discovery is the process of identifying compounds that have the potential to become useful new therapies. The potential must be sufficient to justify further research and development. A crucial step in the drug development process is the submission of nonclinical and clinical data and information in a New Drug Application (NDA) to the food and drug administration (FDA) by the sponsor for seeking marketing authorization. A typical new molecular entity (NME) has most likely been studied pre clinically and has been in clinical trials. Stages in new drug development is Synthesis and isolation of compound 1-2 years, pre clinical studies (screening tests, tests on isolated organs and bacterial cultures, tests on animal models of human studies, general observational tests, confirmatory tests and analogous activity, mechanism of action, systemic pharmacology, quantitative tests, pharmacokinetics and toxicity tests) 2-4 years, Scrutiny and grant of permission for clinical trials 3-6 months, Pharmaceutical formulation and standardization of the compound 0.5-1 year, Clinical studies 3-10 years and grant of marketing permission 0.5-2years. The average cost of bringing an NME to market is nearly between 501 and 805 million dollars. The International Conference on Harmonisation (ICH) Guidelines is available providing a common format for new drug and biological regulatory submissions. The drug development process, including regulatory aspects can be in three areas. First one is providing a greater understanding of human health at molecular level. Second one is improve the safety of medicines. Third one is optimizing drug doses and dosing schedules. The drug approval process is divided in to an Investigational New Drug (IND) Application Process; New Drug Approval, and the post approval activities. The process of new drug evaluation to determine the risk or benefit is affected by many conflicting factors. A detailed study of all the aspects of drug related studies and their procedures of clinical trials are evaluated before the approval. As long as an approved drug remains in the market, all aspects related to its safety are under constant scrutiny by the FDA.

[drsanjay137@gmail.com](mailto:drsanjay137@gmail.com)

## Induced pluripotent stem cells (iPSCs): A novel anti-cancer therapy

**Sanjay Reddy Akula and Jyothi Edla**

Department of Pharmacology, Samskruti College of Pharmacy, India

Induced pluripotent stem cells, commonly abbreviated as iPS cells or iPSCs. Induced pluripotent stem cells (iPSCs) are a new type of stem cell that is generated by reprogramming the genome of an adult somatic cell, such as a skin fibroblast, to a pluripotent state. Such iPSCs share many similarities with embryonic stem cells (ESCs). Recently Scientists reported that there is a consistent, signature difference between embryonic and induced pluripotent stem cells. The findings could help overcome hurdles to using the induced stem cells in regenerative medicine. iPSCs are already useful tools for drug development and modelling of diseases. Reprogramming of adult somatic cells to iPSCs requires certain pluripotency factors, including the transcription factors Oct4, Sox2, and Klf4. iPSCs might be of value in cancer in two ways. First, one could envisage using iPSC-derived tissue to replace or repair tissues of cancer patients that have been injured by radiation, chemotherapy, or the surgical treatment necessary to eliminate the tumors. Because most cancers involve acquired genetic mutations in a specific tissue, iPSCs derived from other healthy tissues of the same patient theoretically could be used to regenerate those tissues damaged by the tumors themselves or subsequent treatments. However, human iPSC-mediated regenerative therapy requires that the iPSC-derived tissue shows robust engraftment in vivo. Unfortunately, only a few human ESC- or iPSC-derived cell types such as ESC-derived dopaminergic neurons or ESC- and iPSC-derived hepatocytes have been shown to engraft successfully in animal models of liver cirrhosis, it suggests that it may be possible to generate human hepatocytes from iPSCs derived from the nonliver tissue of patients with liver cirrhosis that could then be transplanted into these patients to promote liver regeneration and repair. Such a strategy might also have the potential to prevent patients with liver cirrhosis from progressing to hepatic carcinoma. A second way for cancer treatment is immune therapy. It has been shown that human iPSCs derived from T lymphocytes retain the pre-rearranged T cell receptor (TCR) gene, suggesting that these iPSCs could be induced to differentiate into functionally active T cells. One of these approaches is safety. As research develops treatments are more specific for cancer one of such specific research product is Induced pluripotent stem cells (iPSCs).

[drsanjay137@gmail.com](mailto:drsanjay137@gmail.com)