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Introductory Chapter: Drug Development Life Cycle

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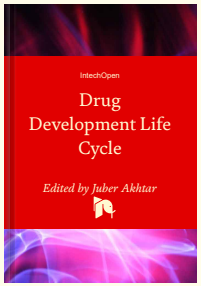
Juber Akhtar and Badruddeen



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Drug Development Life Cycle

Edited by Juber Akhtar, Badruddeen, Mohammad Ahmad and Mohammad Irfan Khan

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1. Introduction

Drug development comprises all the activities involved in transforming a compound from drug candidate (the end product of the discovery phase) to a product approved for marketing, that is, the dosage form which will be available in the market for sale after the approval of the appropriate regulatory authorities (Figure 1).

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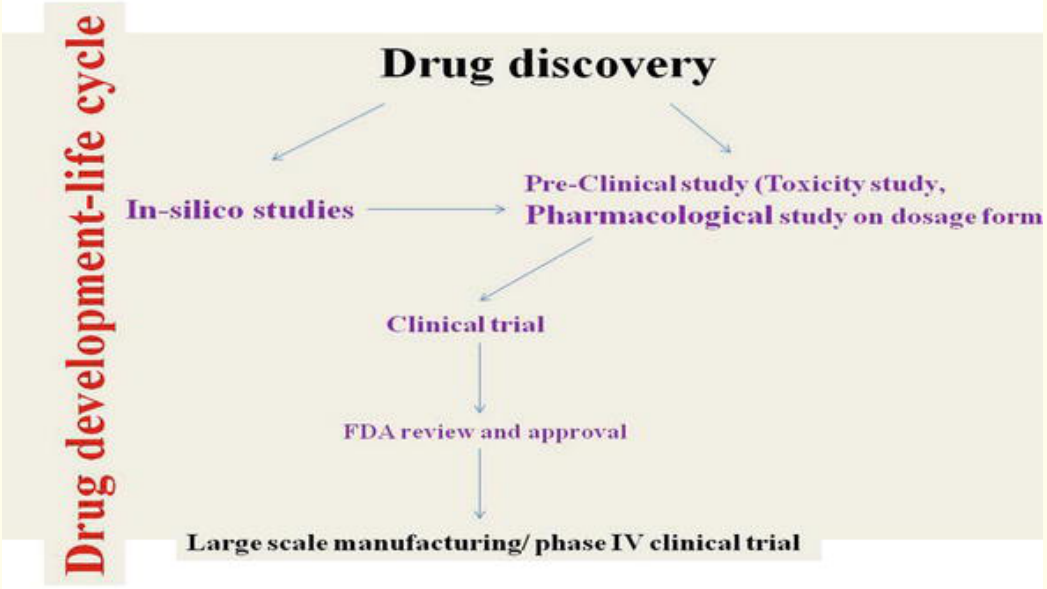

Figure 1.
A brief summary on drug development.

2. Topical formulations

The drug development of topical formulations involving nanoemulgel delivery system in which fusion of two different delivery systems and the physical state of drug containing nanoemulsion is elaborated. A nanoemulsion which is a thermodynamically stable system might be transformed into the nanogel. A formulator thus can make the incorporation of

lipophilic drugs in the system and further might be used in treatment. The poor oral bioavailability, and unpredictable pharmacokinetic and absorption variation of various drugs can be overcome by this technique. Simultaneously, its non-greasy nature and easily spreading ability support the patient compliance. The treatment of acne, pimple, psoriasis, fungal infection, and inflammation caused by osteoarthritis and rheumatoid arthritis is possible.

3. The ophthalmic preparations

The ophthalmic preparations and various barriers affecting drug penetration and distribution inside the eye were also explained. As per World Health Organization, the prevalence of distance or near vision impairment is increasing. Both the anterior and posterior areas of the eyes are affected by various degenerative infections. These may be age-related macular degeneration and diabetic retinopathy at the posterior segment, which can cause severe vision loss. The ocular drug delivery is one of the challenges for delivery of medicaments since it has number of anatomical and physiological barriers. Keeping in mind one full chapter has been compiled in the book in which various barriers that can protect the external and internal structures of the eye from the passage of drugs are elaborated. However, it is very difficult to attain effective

pharmacotherapy because of these barriers. Many conventional dosage forms (eye drops and ointments) cannot achieve therapeutic concentrations in the posterior region of eye since only an extremely small amount of drug (1/100,000) can reach the retina and choroid. Although investigations into novel dosage forms that can be applied topically are underway, the topical dosage form might be formed and may target posterior segment diseases [1, 2].

4. The machine learning and artificial intelligence and computer-aided drug design (CADD)

The machine learning and artificial intelligence (AI) and computer-aided drug design (CADD) are also the new challenges for formulation developer. One can identify and practically implement the number of computational and statistical methods for analyzing biomedical entities, so that target identification will be easy, cost-effective, and validated ones. To complete the drug development processes, CADD can be used to attain biochemical safety and effectiveness, and to stay away from toxicity. The *in silico* techniques that are accepted in academics, firms, and administration [3, 4] may lead to momentous improvement in drug

blueprint and innovations. Since a huge raw data (primary data) were obtained during and after biological, chemical, and pharmaceutical medicine development, there is need of machine learning algorithms that can be optimized and same to be applied in the countryside of CADD. In this way, significant improvement in the competence of drug design and discovery processes is possible. If a formulator apply computational methods and tools during drug design and discovery and development, one can think over an accurate and reliable pre-processed data [5, 6]. Further artificial intelligence (AI) approaches might be useful for pre-processing of huge data [7] and its modeling [8, 9] and overall design of the dosage forms.

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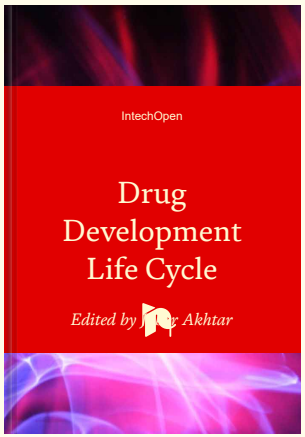

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