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A Short Note on the General Aspects of Drug Designing

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Abstract

Emerging and re-emerging diseases are expanding round the globe which drew the mass public health in dreadful condition. Microbial resistance to drugs is a complicated issue for the failure of treatment of a variety of diseases. In this circumstance, designing of appropriate drug(s) is essential which usually involves the computational modeling and simulation followed by cell culture/ animal model experiments, ending up to clinical trials. Current review briefly focused on the general aspects of drug manufacturing; and a short discussion on the fine tune basis of drug designing grounded on the previously published literature.

Keywords: Drug Designing; Microbial Drug Resistance; Public Health

Abbreviations: FDA: Food And Drug Administration; WHO: World Health Organization; BP: British Pharmacopeia; USP: United States Pharmacopeia; EP: European Pharmacopeia; HACCP: Hazard Analysis: Critical Control Points; GMP: Good Manufacturing Practice; TQM: Total Quality Management; QC: Quality Control; QA: Quality Assurance; PPD Product Process And Development; IPC: In Process Checks; CARD: Comprehensive Antibiotic Research Database; ARO: Antibiotic Resistance Ontology; RGI: Resistance Gene Identifier; MTD: Maximum Tolerated Dose; RCTs: Randomized Controlled Trials.

Introduction

Present world population is undergoing COVID-19 pandemic caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) which has already caused 2 209 195 deaths with 102 083 344 infected cases so far in 223 countries [1]. The transmission and rapid dynamics of the disease have been studied extensively in association with different strains of SARS-CoV-2 genome and immunopathogenesis traits as well as the pathogenesis have been compared with those of SARS-CoV-1 and the Middle East respiratory syndrome (MERS-CoV) [2-5]. Accordingly, for mitigation of COVID-19, ongoing research on drug designing for the development of new drugs and the immunomodulatory agents by means of computation simulation, cell/animal culture models and finally by entering the patient trials; or for the repurposing of the previously used drugs against other viral infections is noteworthy [6-9]. Besides, the ongoing COVID-19 pandemic, some other emerging and re-emerging diseases like dengue, chikungunya, or zika virus infection and other chronic and consistent complications including food borne enteric diseases, onset of cancers are prevalent worldwide [10-18]. Moreover, while treating these diseases, the phenomenon of drug-resistance has been introduced to the health professionals for a long time which in turn is posing a serious global health threat towards the global public health [19-27]. Based on such aspects covering the commencement of diseases, and the treatment

complications especially due to the microbial resistance to the antibiotics, current review focused on the inevitability of the drug designing using the modern techniques.

Facets of Drug Designing

Manufacturing Aspects

In general, drugs are given towards the patients according to the nature of disease as well as to kill the etiological agent(s), and the drugs are manufactured according to the set rules recommended by the Food and Drug Administration (FDA), World Health Organization (WHO), the British Pharmacopeia (BP), the United States Pharmacopeia (USP), or the European Pharmacopeia (EP) together with careful maintenance of the Hazard Analysis: Critical Control Points (HACCP) together with the microbiological quality control both of the bulk- and the finished products with the necessary in process checks (IPC) [28,29]. Besides the Good Manufacturing Practice (GMP) and the Total Quality Management (TQM), the appropriate Quality Control (QC) and Quality Assurance (QA) starting from the warehouse materials to the finished products ready for marketing ensure the quality and effectiveness of the drug(s) [28]. However, the Research and Development (R&D) or the Product Process and Development (PPD) departments analyze the objectives of the usage of the drugs; and for the specific application, the drug target site of the infectious agent(s) has to be clearly investigated as well the active moiety of the drug(s) is needed to be known. Such a requisite generated the new aspects of effective drug designing procedure using the *in silico* model, *in vivo* model, patient trials, dealing with the market complaints, deducing the drug-resistance genes, etc. [8,20,23].

Strategies for Drug Development

From a range of published literature as well from the current global practice, it is understandable that the approaches for the designing of anti-bacterial or anti-viral drugs largely depend on the studies based on the analysis of data bank for drugs and the microbial genome, the computational modeling and simulation; identifying the appropriate drug targets; and finally, identifying the specific moiety of the drug imparting the remedial impact [7,8,30]. Such bioinformatics analysis facilitates the extensive study of the pathogenic molecular patterns for screening the drug target site(s) which can be checked using cell culture/ animal models afterward prior to start the clinical/ patient trials [7,8]. In course of timing and costing as well as designing the rationalized clinical cell culture or animal model experiments followed by clinical trials, such computational approach is really helpful at the initial stage of designing a particular drug [7]. Such a strategy is expected to be helpful in detecting the drug-resistance resistance genes which can be counteracted by the novel drugs formed by the genomic annotation of the large data sets like The Cancer Genome Atlas, Comprehensive Antibiotic Research Database (CARD), the Antibiotic Resistance Ontology (ARO), etc., employing the Resistance Gene Identifier (RGI) [7,31].

A very important aspect in the development of effective drugs relies on the drug repurposing whereby the existing drugs are used to treat any emerging disease [7]. Although necessary, yet the assessment of drugs using the cell culture, animal models and the patient trials really appear to delay the treatment in the emergency condition. In such dreadful condition, the repositioned and the repurposed drugs can be employed for a quick remedy [7]. After designing a drug, prior to the clinical trials, the pre-clinical inquiries include the studies with animal models with the concomitant evaluations of drug effectiveness, drug dosage, drug safety, mode of action of the drug in response to the host clinical response, followed by the assessment of drug absorption and metabolism in the host [32]. Afterwards, the phase I to phase IV trial clinical trials, designed for testing the safety and the maximum tolerated dose (MTD); (and specifically randomized controlled trials [RCTs]) are conducted using the legislative rules and ethics as described by the appropriate authorities and published documents [32]. In fine, it's worth to note that the clinical trials persist as the gold standard for assessing innovative drugs prior to commercial launching; and also, it should be added that ClinicalTrials.gov serves as the public trial registry offered by the United States (US) National Library of Medicine and the USFDA, covering 208 countries around the world [33].

Conclusion

The information provided in the current review is apparently known by the scientific community. However, accumulating such general knowledge on the microbial drug-resistance, the drug designing approaches as well as drug manufacturing would be helpful for the pharmaceutical professionals and the health professionals to bring about the excellence in novel drug designing for maintaining a sustainable global public health.

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