

Drug Development and Technology

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Abstract

Drug development is the process of bringing a newly discovered chemical entity that has pharmacological activities into the market as a finished pharmaceutical product. Such newly discovered entities pass through several stages like pre-clinical trials, regulatory approvals, clinical trials on humans, among others, before they are released to the market for use. Technology has played a significant role in improving all the stages of drug development and has helped to enhance the quality, quantity and production speed of drug products. These, it has accomplished through improved machineries and instrumentations for screening, production, monitoring, assays, product recovery and storage.

Keywords: Drug Development; Clinical Trials; Technology; Enhancement; Drugs

Drug development refers to the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of drug discovery [1-3]. Stages involved in drug development include pre-clinical research on micro-organisms and animals, filing for regulatory status, clinical trials on humans, and may include the step of obtaining regulatory approval with a new drug application to market the drug [4]. A typical drug development initiative may commence with about 5,000 to 10,000 chemical compounds out of which, only about 250 may reach the animal studies stage with only about 10 making it to the clinical trials on humans [5]. It has been shown that only about 21.5% of drugs that started Phase I trial get eventually approved for marketing. This high failure rate associated with drug development is referred to as the "attrition rate" problem. Therefore, accurate decision making during drug development is essential to avoid costly failures. In many cases, intelligent programme and clinical trial design will reduce such failure rates and prevent false negative results. Well-designed, dose-finding studies and comparisons against both a placebo and a gold-standard treatment arm play a major role in achieving reliable data. Novel initiatives have been evolved by different countries to help reduce the attrition rate associated with new drug development. Netherlands has the Top Institute Pharma Initiative; Denmark has the Biopeople Initiative, while the

United States through the FDA has the Critical Path Initiative [6,7].

Technology, on the other hand, is the collection of techniques, skills, methods, and processes used in the production of goods or services or in the accomplishment of objectives, such as scientific investigation [8]. Technology is often considered too narrowly; according to Hughes, "Technology is a creative process involving human ingenuity [9].

All through the decades, improvements in technology have consistently played a key role in the development of new drug entities, as well as in the enhancement of already developed drugs. For instance, from the early works of Alexander Fleming who, with simple technology, discovered penicillin, the first antibiotic in use, there have been great improvements in both the yield and diversity of penicillin derivatives, attributable to improved technologies for its production. Similarly, many other discovered drugs, have experienced giant improvements in their scope of production, diversification of drug types and improved derivatives of the same drug, attributable to technological advancement [10,11].

Improved technology has, for instance, provided better research equipment that have enhanced capacity to screen new drug entities

for eventual development into marketable products. The technology of molecular modeling with the accompanying novel software, has for instance helped in the virtual screening of thousands of compounds for possible pharmacological activity, within minutes, what would have taken years, if they were to be screened manually in the laboratory. Technology has similarly provided better assay methods for determination of drug entities in dosage forms and for other pre-formulation studies. The development of the high pressure liquid chromatographic techniques, infrared spectroscopy and mass spectroscopy, among other high-tech assay models, readily comes to mind. Effects of improved technology on drug development are also evident in the novel, highly efficient techniques for recovering drug products from their production processes. Technology has equally imparted on media compositions for drug production by generating improved temperature, pressure and aeration regulatory systems. Improved technology is equally of importance in drug development data generation and data management as well as in improved storage facilities for stability studies. However, there is an apparent drawback to technology generally, and in drug development specifically, and that has to do with the impact of technology on human workforce, as it has been argued that machines have tended to replace human labour, especially in repetitive tasks that do not require complex judgments, thus rendering many, jobless [12,13]. Overall, technology has assisted in the improvement of quantity, quality and diversity of developed drug products.

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