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New era for inhalation drug delivery: Clinical applications and regulatory challenges

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The inhalation drug delivery has entered a new era with two parallel pathways on generics and new indications respectively. Following the expiration of patents for inhaled drug blockbusters currently being used for asthma and chronic obstructive pulmonary diseases (COPD), development of generics has been a hot area for pharmaceutical industries. Considering the complexity of inhalation products, however, the regulatory agents are encountering a series of challenges on equivalence and bioequivalence requirements. Different approval pathways are observed between USA and Europe markets. The administration route via inhalation is also being explored for new clinical applications such as on the treatment of infections, cancers, diabetes and etc. These new indications lead to appearance of new pharmaceutical and device technologies. This article critically reviews the most recent advances from perspectives of regulation, technology and clinical applications to provide future directions to industrial and academic researchers.

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Friendly reporting system in pharmacovigilance: iCURE

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Pharmacovigilance plays a major impact on public health, reducing patients, increasing quality of life and decreasing risk factors of the drugs. Under current conditions the Adverse Drug Reactions (ADR) are reported less than 5 %, when compared to the occurrence of the ADR's. According to many surveys conducted by NGOs, it was reported that about 95% of the health care professionals (HCP) are not interested to report any ADR's due to lack of time & facilities, poor reporting systems, lack of proper laws, lack of knowledge on pharmacovigilance and its importance in public health and etc. In order to make reporting for more user friendly, quick and translucent, iCURE adverse event mobile application was developed and this application was live in android play store from 25, Nov 2015. This mobile application would really help the HCP's for reporting ADR's. New complaint, verification of your compliant and suggestions to the company (Page 1), Reporter Identification (Page 2), Patient details (Page 3), Drug information (Page 4) and Event description and document attachment (Page 5). When a user raises a complaint, it first reaches to the common mail box which is controlled by the application (iCURE) holder and from there it will be distributed to the individual company folders (like GSK, Pfizer, Ranbaxy etc. based on the product manufacture). This complaint will be then distributed to the concerned MAH or manufacturing company of the country where the drug was manufactured, along with a duplicate copy to the concerned health authority. Currently we had around 50 plus downloads' and around 25 users who had registered in our application database. In future, this mobile interface will be contacted to eCRF (electronic case report form). By this, usage of paper form will be reduced, timelines for reporting and be met more efficiently.

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