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Abstract

Patient-Centric Drug Product Design: Case Studies for Special Populations †

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Abstract: Medication non-adherence poses considerable challenges in managing chronic diseases and is associated with almost 200,000 deaths and EUR 80–125 billion in potentially preventable direct (e.g., hospitalizations, waste of medication) and indirect (e.g., work productivity losses) costs in the European Union alone. The increasing awareness of the contribution of the acceptability of drug products by the patient to medication adherence and clinical outcomes is driving the integration of patient-centric drug product design (PCDPD) into the pharmaceutical development process. Regulatory agencies have addressed the relevancy of placing the patient at the center of pharmaceutical development. The EMA has issued guidelines/reflection papers for pediatric and older populations while the FDA has developed a series of guidance documents on patient focused drug development with the primary goal to better incorporate the patient's voice in drug development and evaluation. PCDPD can be defined as the process of identifying the comprehensive needs of the target patient population to support the design of drug products. Three major factors are analyzed in PCDPD, namely, the patient, drug, and drug product characteristics. This systematic approach integrates this insight, which is translated to a target product profile (TPP) to drive the pharmaceutical product design process. Two case studies are presented focused on the pediatric population and on patients with a chronic skin disorder (psoriasis), which will highlight the roadmap for a successful PCDPD.

Keywords: patient-centric design; pediatric formulations; dermatological formulations; patient preferences; medication adherence

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