PL-1

Regulatory Science in Drug Development

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Keywords: *Regulatory science, regulatory research, science based regulations, regulatory tools*

1. What is regulatory science?

"Regulatory science is the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of (US Food and Drug Administration, FDA) regulated products." It involves scientific tools, information-gathering and analytical systems to study data, people, health systems and communities. To be most effective, advances in regulatory science must be fully integrated into the entire product development process. The regulatory science can be utilized to speed innovation and improve regulatory decision making process.

Regulatory Science is a broad umbrella term for all different kinds of science that impact drug development or device development. This oversight is based on the sound science, called regulatory science, and is the foundation of FDA's day-to-day decisions. Scientists throughout the agency research the development of new ways to evaluate FDA-regulated products.

FDA utilizes varieties of tools to communicate policies and to invite scientific discourse - advisory committee meetings, publications, sponsor research, conferences / symposia / workshops to discuss scientific issues / develop consensus / develop reports (White papers), publication of guidance – product specific guidances. The aim is to have 'science based regulations'.

Pharmacokinetics of the drug – Absorption, distribution, metabolism and Excretion (ADME), bioavailability (BA) and bioequivalence (BE) concepts has been the focus for evaluation of different formulations of new drugs and also generic drugs. These concepts have provided strong scientific basis for bioequivalence based approval of all generic drugs. Principle of dissolution has been utilized as a product quality and performance tool. The scientific basis of Biopharmaceutics Classification System (BCS) provides biowaiver for certain classes of generic drug products, thus reducing regulatory burden without sacrificing drug product quality.

Generic Drugs User Fee Act (GDUFA): - Regulatory science priorities of GDUFA included post-market evaluation of generic drugs and determining equivalence of complex dug products. The scientific research supports the development of guidance and policy that clarifies the Abbreviated New Drug Application (ANDA) pathway for complex products.

The research in regulatory science has been used in innovative statistical approaches to provide the most reliable treatment outcome information to patients and clinicians, in supporting drug development through Physiologically based pharmacokinetic (PBPK) modeling and in developing tools to evaluate complex drug products, e.g., for complex Active pharmaceutical ingredient (API) like Peptides, for complex mixtures of APIs like iron sucrose, for complex formulations like Liposomes and Colloids, for complex dosage forms like Transdermal Drug Delivery System (TDS), Long acting injectables, for complex route of delivery like Topicals, Inhalation products, and for complex drug-device combinations like Auto-injector, Metered Dose Inhalers (MDI). The scientific research supports the development of guidance and policy that clarifies the ANDA pathway for complex products. Regulatory science is also utilized in strengthening US drug product manufacturing.

FDA/Center for Drug Evaluation and Research (CDER) publishes a quarterly Regulatory Science newsletter featuring new developments, opportunities, and initiatives in drug development regulatory science, with the goal of advancing medical product development.

Division of Applied Regulatory Science (DARS) performs studies to characterize the performance of new translational models and tools to assess the efficacy or performance of new drugs, biosimilars and complex generics. In the area of simulation and modeling, a physiologically based pharmacokinetic modeling is used to support dosing recommendations for antidepressants during pregnancy; to support determination of bioequivalence for dermatological drug products.

A major focus for the year was advancing translational models and tools into the drug review process studying the reproducibility of micro physiological systems for use in drug development. These micro physiological systems are three-dimensional (3D) cell culture platforms that can be used as drug development tools. These novel computational modeling methods can be used for diverse topics including to predict the efficacy and potential toxicities of new drug candidates and in the area of pediatric cancer.

Regulatory Science and various tools utilized play an important role in drug development and science-based regulations and drug approval.

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