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Comparison of European Medicines Agency (EMA) and Food and Drug Administration (FDA) procedures for evaluating scientific and regulatory issues of clinical studies during the development of medicinal products: Experience of a global imaging clinical research organization

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Here we compare the procedures for obtaining pre-approval for the Clinical Study Protocols and accompanying documentation by two regulatory agencies - European Medicines Agency (EMA) and Food and Drug Administration (FDA). The procedures called Scientific Advice and Protocol Assistance (SA/PA), and Special Protocol Assessment (SPA), respectively, are compared in terms of duration, scope, cost and possible outcomes. In addition, we discuss the reasons why our clients submitted more than fifty Independent Review Charters (IRC, a document which governs the independent review process) as accompanying material for SPA to FDA, and to our knowledge none for SA/PA to EMA. Research of publicly available documents and company-wide investigation showed that the two procedures are similar in design and purpose. If the sponsor and the agency agree on the design, execution and analyses proposed in the submitted documentation, the agreement becomes part of the administrative record. The agreement is not legally binding on either of the Agencies; however, complying with the agreement significantly shortens the duration of the marketing authorization applications and increases its success. Our data show that pre-approval procedures, if employed, offer a clear benefit to clients; therefore they should be explained and recommended to all clients targeting global markets.

Biography

Katarina Ludajic is a Senior Medical Writer at Perceptive Informatics. She earned a B.S. in Biology at the University of Belgrade, Serbia and Ph.D. in Molecular Biology at the Friedrich-Schiller University in Jena, Germany. She has completed her post-doctoral training at the General Hospital of Vienna, Austria where she performed research in the field of Transplantation Biology. She is the first author on multiple scientific articles published in peer-reviewed journals.

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Formulation and evaluation of extended release capsules of acetazolamide

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The purpose of this research was to develop and evaluate extended release capsules of Acetazolamide to maintain constant therapeutic levels of the drug for over 12 hrs. The concept of controlled drug delivery has proved to provide a solution to several problems encountered in the repeated administration of the drugs. Utilizing the concept of incorporating drug in to the polymer matrices and extend the drug release for long period of time, an attempt was made to design and evaluate Extended Release Capsules of Acetazolamide which is a Carbonic Anhydrase inhibitor used for the treatment of glaucoma.

The optimised formulation was developed by using Eudragit RS100 (6%) and Eudragit RL100 (4%). Regulated drug release in first order manner was attained by using these polymers. This extended release formulation was found similar and comparable to the innovator product based on the f2 value (69.70) obtained. The developed extended release capsule formulation was quite stable with regard to drug content, physical properties and dissolution rate in the accelerated stability studies.

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