David Heal, J Bioequiv Availab 2011, 3:7
doi: http://dx.doi.org/10.4172/0975-0851.1000107

OMICS Group Conferences
Accelerating Scientific Discovery

International Conference & Exhibition on
Pharmaceutical Regulatory Affairs
6-7 September 2011 Baltimore, USA

Successfully meeting the regulatory challenges of abuse/dependence liability evaluation in the development of new centrally-acting drugs

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The growing problem of the recreational abuse of prescription pharmaceuticals combined with an increasing awareness of drug withdrawal effects have prompted regulatory agencies to place a greater emphasis on abuse/dependence liability assessment for new CNS drug candidates. From the Sponsor's perspective, the classification of a new CNS pharmaceutical as a Controlled Drug, particularly if it is placed in a high Schedule, will substantially impact on the drug's market competitiveness and may also impair its distribution and be a barrier to prescribing. The mandatory abuse/dependence assessment package involves both preclinical and clinical evaluations. The programme needs to determine whether the subjective effects of the compound resemble those of known substances of abuse, whether experience of the drug induces craving (reinforcement), and finally, whether tolerance and/or physical dependence occurs when the compound is administered for prolonged periods. Various preclinical testing procedures will be described with examples to illustrate their strengths and weaknesses. A major complicating factor in abuse/dependence testing is that the evaluation programmes and reporting procedures required by European Medicines Agency (EMA) and Food and Drugs Administration (FDA)/ Controlled Substances Staff (CSS) are substantially different. For example, the determination of abuse liability in drug experienced human volunteers is considered to be critical evidence by CSS, but EMA does not require data from such trials. The presentation will describe the essential elements of both the US and European preclinical and clinical testing procedures together with the outline of a testing programme that would be suitable for the global registration of a new CNS drug candidate.

Biography

Professor David Heal is an Executive Director of RenaSci, a company he co founded in 2001. He started his career in research at Oxford University before transferring to pharmaceutical R&D in the mid-1980's. During his career, he has had key roles in the successful US and European registration of 5 CNS drugs in the indications of obesity, schizophrenia, epilepsy and ADHD. He has had extensive interactions with EMA, FDA, BfArM and other regulatory agencies. His publication record consists of over 130 papers, and 40 patents. He is a Visiting Professor at the Department of Pharmacy and Pharmacology, University of Bath.