

European regulatory framework for drug approval through the centralized system

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The European drug regulatory system offers a number of different ways to approve medicinal products for human use. Besides national registration pathways and authorization in several EU member states via the Decentralized Procedure there is growing use of the Centralized Procedure for approval in all member states. The focus of this overview aims at explaining the main features of the centralized authorization process in Europe. At the heart of the centralized system the European Medicines Agency (EMA) coordinates all applications from Sponsors. Delegates/experts from member states and local staff of the EMA contribute to a multitude of scientific committees and working groups. Regulatory requirements and support during product development are given by various guidelines and scientific advice. The latter is provided to Applicants by the Scientific Advice Working Party. For development of a new medicinal product or a new indication in most instances a paediatric investigation plan needs to be approved by the Paediatric Committee. Orphan designations, qualifying a product as orphan, are assessed by the Committee for Orphan Medicinal Products. The regulatory decision making process for concluding on the benefit/risk balance of a medicinal product is one of the main tasks of the Committee for Medicinal Products for Human Use. This scientific body issues an opinion to the European Commission and thereby either recommends or rejects the marketing authorization. A number of drugs, such as biotechnology compounds, orphan drugs and products for several therapeutic classes have to be evaluated via the centralized system on a mandatory basis, whereas for others an optional scope exists. The post-approval measures will now significantly change with the implementation of the new Pharmacovigilance legislation and introduction of a new committee, the Pharmacovigilance Risk Assessment Committee, with a mandate to regulate the life-cycle of products after approval. An intimate cooperation will ensure that drugs brought to the European market are efficacious and safe and continue to have a positive ratio of benefit and risk.

Biography

Andrea Laslop joined the Austrian Agency for Health and Food Safety in 2006. She heads the Scientific Office, which constitutes the link to the European Medicines Agency (EMA), focussing on centralized procedures during drug development, marketing authorization applications and life-cycle management. Andrea Laslop is a member of the Scientific Advice Working Party of the EMA since 2003 and Austrian delegate in the Committee for Medicinal Products for Human Use since 2007. Previously she worked as professor of pharmacology and toxicology at the Medical University of Innsbruck, Austria. She studied medicine there and then specialized as pharmacologist. Her professional career included research fellowships at NIMH in Bethesda, Albert Einstein College of Medicine in New York and Clinical Research Institute of Montreal. Since November 2007 she served as president of the Austrian Pharmacological Society and from November 2011 as vice president.

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GLPs in pharmaceutical industry and the differentiation factor

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The objective of the presentation is to bring out the differences between various GLP guidance like Schedule L1, Drugs and Cosmetics Act, 1940, Government of India and the WHO Good Practices for Pharmaceutical Quality Control Laboratories and so on.

Biography

B. Anil Kumar Singh has completed his M.Sc (Organic Chemistry) from Andhra University. He is also lead auditor through experience in the auditing and through certification in ISO 9001:2008 from TUV SUD. He is the General Manager of Quality Operations (QA/QC/RA), who has an experience in premier pharmaceutical manufacturing organizations Like Dr.Reddy's, Fresenius Kabi Oncology Limited, Aanjaneya Lifecare Limited involved in APIs/HPAIs and Formulations. Presently associated with Vegesna Laboratories Pvt. Limited.

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