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An overview of role of public regulatory authorities in implementing guidelines for drug development and approval globally

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The research, development, and approval of a drug product is a continuous but lengthy process involving drug discovery, laboratory development, animal studies, clinical trials, and regulatory registration. This lengthy process is necessary to assure the effectiveness and safety of the drug Product. In this paper a brief history and an overview of the regulatory process for drug approval globally through illustrations of Investigational New Drug (INDs) Applications and New Drug Applications (NDAs), abbreviated new drug applications (ANDAs) and supplemental new drug applications (SNDAs) is provided. For NDAs, issues regarding the application of expanded access, the submission of abbreviated NDAs for a generic drug, the submission of supplemental NDAs for labelling changes, and the role and responsibility of advisory committees are addressed. Along with this a brief description of review of role of regulatory authorities is explored. These regulatory authorities operate in three groups: staff, Advisory committee and the agency board which makes decisions about the safety and performance of medicines and medical devices. Advisory Committees – groups of independent experts and representatives advise on whether medicines and devices work and are acceptably safe, based on an evaluation of all relevant evidence, including that from the Agency. The Agency Board – which is made up largely of external members, acts in a supervisory and advisory capacity and has a particular role in assuring the quality of decision-making.

Keywords: Investigational New Drug Application; New Drug Application, regulatory authorities

Biography

Dr. Sandeep Arora, Director of Chitkara College of Pharmacy. He has a professional experience of around 16 years (3.5 years of Pharma Production and Quality Assurance and 12 years of Teaching/Training, and research) in the field of Pharmacognosy and Natural Products. He has to his credit editorial and authorship assignments as Hon. Editor – Advanced Drug Review (a quarterly drug pharmacology review index) since 2005, authored book titled "Pharmaceuticals- Issues for Industrial Management" and has 40 national and international research publications. He attended 20 conferences, out of which 4 are international. His area of specialization and research is medicinal natural products (phytochemical, pharmacological evaluation and standardization) and development and regulatory aspects of herbal and other products and industrial management.

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