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WHO/GMP based pharmaceutical industries and their concepts, challenges and opportunities in regulatory strategy

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The demand for globally acceptable products heightens the imperative for harmonization of regulatory requirements to lend efficiency and cost effectiveness to the process of product development, manufacturing and expediency to global access. In addition, biopharmaceutical companies have continued to expand their frontiers to attain a global reach, with presence in many regions and countries, and therefore exposed to myriad, and sometimes diverse, regulatory requirements and operating standards. The challenges of globalization in a heterogeneous world with an evolving regulatory landscape and expectations of multiple stakeholders have increased the complexity, unpredictability and intensity of the biopharmaceutical product development and registration process. These challenges likewise reinforce the crucial role of the regulatory team and underscore the need for enhanced global regulatory function with regulatory professionals who are strong leaders, business partners and strategic contributors. Evolution in the regulatory profession has been largely driven by: Expanding scope and global reach of industry, Keen attention to global regulatory intelligence, Need for innovative and cutting edge technologies including e-submission, Complexity of disease area targets for development, Need for comprehensive and robust global regulatory strategies. The functional units of biopharmaceutical industries are: Product development HQ & regional; Chemistry, manufacturing and control (CMC), compliance, conformance; Policy and regulatory intelligence; Promotion and advertisement; Regulatory submission management; Product Labeling and its marketing.

Biography

Nandita Dasgupta is in B.Tech Biotechnology Final year at the age of 21 years from VIT University, Vellore, Tamil Nadu. She has published 3 papers in reputed journals. She was the Student coordinator of VIT Biosummit'12, a meet between industrialists and academia. She was also student coordinator in many college tech and cultural fests. She has good subject command in depth and technical skills with excellent management skills.

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Common technical dossier for the registration of pharmaceuticals

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The word "Dossier" has its English meaning as - a collection or file of documents on the same subject, especially a file containing detailed information about a person or a topic. Any preparation for human use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient is called as "pharmaceutical product for human use". Process of reviewing and assessing the dossier of a pharmaceutical product containing its detailed data (administrative, chemistry, pre-clinical and clinical) and the permission granted by the Regulatory Agencies of a country with a view to support its marketing / approval in a country is called as the "Marketing Approval or the "Registration" "Marketing Authorization" or the "Product Licensing".

"Registration Dossier" of the pharmaceutical product is a document that contains all the technical data (administrative, quality, nonclinical and clinical) of a pharmaceutical product to be approved / registered / marketed in a country. It is more commonly called as the New Drug Application (NDA) in the USA or Marketing Authorization Application (MAA) in the European Union (EU) and other countries, or simply Registration Dossier. Basically, this consists of data proving that the drug has quality, efficacy and safety properties suitable for the intended use, additional administrative documents, samples of finished product or related substances and reagents necessary to perform analyzes of finished product. Therefore, they are the vehicle in a country through which drug sponsors formally propose that the Regulatory Agencies approve a new pharmaceutical for sale and marketing.

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