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Chemistry manufacturing and controls (CMC) for new drug applications (NDA's)

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New Drug Applications (NDA) are applications to request permission to market a drug product in the US for a specific use. Office of New Drug Quality Assessment (ONDQA) reviews the Chemistry, manufacturing, and controls information submitted in the NDA to ensure product quality (i.e., identity, strength, quality, purity, and potency) as it relates to the safety and efficacy of the drug product. This measure includes all review associated the review of chemistry, manufacturing, and controls information submitted in NDAs prior to approval. Supplements to NDAs are applications to make changes to an approved marketing application. One of the types of changes made to approved NDAs are how or where the drug is manufactured and/or controlled. This measure includes all review associated the review of chemistry, manufacturing, and controls information submitted in NDA supplements.

CMC Regulatory Requirements are full description of the drug substance including its physical chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability, sterility, particle size, and crystalline form. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative sources, process controls, and analytical procedures.

Drug Master Files (DMFs)

Not all the CMC information relevant to drug product is always contained in the NDA, sometimes some of the information will be in a DMF

Biography

Suman Munugoti in verge of completion of Masters in pharmacy in Pharmaceutics Department from Vaagdevi College of Pharmacy affiliated to Kakatiya University. He had completed his Bachelor of Pharmacy from Tamil Nadu. Dr. M. G. R Medical University – Chennai. He is perusing Advance Diploma in Drug Regulatory Affairs (DRA) which has been approved by International Association of Distance Education - London, United Kingdom at NCK Pharma Solution Pvt. Ltd-Delhi. I had participated and presented many posters in National and International seminars.

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