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Regulatory requirements and filing considerations for Type II master files

A Type II Master File or Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The information contained in the DMF may be used to support an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or amendments and supplements to any of these. On July 9, 2012, the Food and Drug Administration's Safety and Innovation Act (FDASIA) was signed into law (Public Law No. 112-144, 126 Stat. 993, 2012). This law, among other, establishes new requirements for Type II DMF's. This presentation will discuss on regulatory requirements and filling considerations for Type II DMFs with US FDA.

Biography

Ramnarayan Randad is a Quality Assurance Leader and Master Review Chemist in the office of Life Cycle API, ONDP. In addition to the CMC reviews, he has served on number of working group such as Risk-Based Review, Complex Drug Substance, Question based Review (QbR), Quality by Design based QbR revision, the Office of Generic drugs Education and Training committee, DMF Completeness assessment team, Center for Science and advancement, and US Pharmacopeia monograph development committees. He has frequently represented Agency on CMC issues and regulatory science in public speaking engagements. He is an author of "*FDA Drug Review and Regulation*" to the "*Burger's Medicinal Chemistry, Drug Discovery and Development*". Prior to joining FDA, he worked in private sector for 15 years as a Research Chemist, Principal Investigator, Group Leader, and Director of Chemistry. He has authored more than 25 scientific papers in the peer reviewed journals and has >10 US patents to his credit. His work has led to the design and development of a drug lead. He received PhD from National Chemical Laboatory, Poona University, India in 1985. Soon after, he came to US as a Postdoctoral Associate of Prof. Herbert C Brown, Nobel Laureate, Purdue University.

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