

Dr. Gopi Vudathala



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Dr. Gopi Vudathala is currently Associate Vice President of Global Regulatory Affairs, CMC Interface, at Sanofi-Aventis. He provides the lead for CMC regulatory aspects of Global Development Projects and Global CMC Submissions, and for setting CMC regulatory strategy. Dr. Vudathala graduated from the University of Alberta with a Ph.D in Pharmaceutics and previously held positions with the Health Protection Branch, Canada, as a Senior Reviewer, and with Procter & Gamble Pharmaceuticals as a Senior Regulatory Manager. Dr. Vudathala has had extensive experience in interactions with the FDA, TPD and other regulatory Agencies on project related CMC matters as well as on key non project-specific CMC issues and initiatives. He is currently the Sanofi Aventis representative to the PhRMA Technical Development and Operations Committee. He was an active member of the PhRMA CTD Quality Task Force, and a working group member of the Subcommittee for Pharmaceutical Sciences on Process Analytical Technologies. He serves currently on the ICH M7 PhRMA GTI Team. He is a past-Chair of the Regulatory Sciences Section of AAPS and served also as the Secretary/Treasurer and Regulatory Sciences Screening Chair, Chair of the Awards Committee, and has been active in program planning activities for AAPS. He was recently awarded the AAPS RS Section Recognition Award. He is also a steering committee member of the AAPS CMC Focus Group. Dr. Vudathala has made several presentations at AAPS, IIR, Barnett and other International workshops and conferences on CMC, genotoxic impurities and CTD topics.

Overview of the Drug Development Process: The IND and NDA Process

Drug development in the US is governed by the Code of Federal Regulations (21 CFR 312.23 and 314.50). This presentation will focus on the drug development process in general and the regulations and guidance's specific to the process. The key to initiating clinical trials in the US is to ensure a good safety and pre-clinical toxicology package is available for review in the IND stage along with a good clinical plan to evaluate proof of concept in healthy volunteers (Phase 1). Subsequently, performing dose ranging studies and confirming efficacy in a small population of relevant patients will need to be done in early Phase 2 studies. Upon successful results from early phase 2 studies and dose-ranging studies, a detailed clinical plan can be developed for phase 2b and 3 pivotal clinical trials in a larger population of the patients. Throughout the drug development process there are a number of opportunities for the industry to meet with the FDA to discuss pre-clinical, clinical and CMC plans and issues for resolution. A pre-IND meeting, end of phase 2 meeting and pre-NDA meetings are key to discuss the path forward and ensure your development plans are vetted by the Agency. Label development occurs in parallel to the above and labeling discussions are an important part of the NDA registration process. Highlights of these processes along with necessary submission requirements will be covered in this presentation.

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