

## Dr. Albinus D'Sa



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Dr. Albinus (Abi) D'Sa has been serving at the Food and Drug Administration (Center for Drug Evaluation and Research) since 1992. Prior to his deployment as the Deputy Director of the India Office, Abi served for 16 years in regulatory drug areas of approval, inspection and compliance. He holds a wide range of experience including formulating successful drug approval strategies and developing guidance for industry on complex drug quality and regulatory issues. Abi's background in science has allowed him to successfully negotiate critical policy documents with industry and other world regulatory agencies. He has reviewed and supervised the review of new drug applications. He has served in compliance areas of preapproval and case management of drugs. He has represented FDA as rapporteur at the ICH (International Conference on Harmonization) Q3B in London, UK, and finalized the guidance on impurities in pharmaceuticals. Abi has also represented FDA at the ICH and finalized the guidance on risk management in pharmaceutical manufacturing. He is trained and certified for the FDA Process Analytical Technology (PAT) team. Abi served as Chairperson of the Drug Product Technical Committee, is member of the ICH Expert Working Committee and the Botanical Guidance Committee within the Center for Drug Evaluation and Research.