



Commissioned Officers Association of the U.S. Public Health Service

CDR Nikhil Thakur

Engineering Category Representative



Commander Nikhil Thakur is an Engineer Officer in the United States Public Health Service. At his current duty station at the FDA, he is a Regulatory Policy Advisor for the Office of Policy for Pharmaceutical Quality (OPQ), within the Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Quality (OPQ). He develops guidance for Drug Manufacturers focused on quality of the drug product and process throughout the product lifecycle. His role necessitates frequent interaction with Intra-Agency and external Federal Partners, and with Public and Private Sector Stakeholders.

Commander Thakur is also the Section Chief for the Planning Section for the

USPHS Rapid Deployment Force PHS-1, where he is responsible for ensuring that PHS-1 is equipped with the appropriate tools and training to successfully meet mission needs during a deployment. His prior involvement with the RDF include Deputy Safety Officer for PHS-1, and Mission Related roles as the Acting Chief Safety Officer for PHS-1.

Prior to his position in CDER, he worked as Regulatory Policy Advisor for the Emergency Preparedness, Operations and Medical Countermeasures (EMCM) Program, within the Center for Devices and Radiological Health (CDRH), Office of the Center Director, where he worked with Subject Matter Experts within FDA, and with external Federal, Public and Private Sector partners on policy issues that impact the regulation of and guidance concerning the Public Health Emergency Preparedness and the Medical Countermeasure workspaces.

He has had a combined 15 years of pre-market and post-market experience within the CDER and the Center for Devices and Radiological Health (CDRH). During this period, he had excelled in his roles as a compliance officer, reviewer, Team Leader, Regulatory Policy Advisor and Mentor. CDR Thakur has significant experience working with pre- and post market issues that impact drugs, devices, biologics and combination products, and has worked on several high profile post-market regulatory actions and premarket reviews for drugs and medical devices. CDR Thakur has a B.S. in Chemical Engineering from Rutgers University, and comes to the FDA from the Pharmaceutical Industry, where he focused on pharmaceutical process design, scale-up and validation.