Karen H. Noh, R.Ph., Pharm.D.

Dr. Noh is a regulatory leader with experience in developing and implementing regulatory strategies for both drug and biologic products in all phases of drug development, including marketed products. She has served as the US regulatory lead for various development programs and has been involved in INDs, and NDA/BLA filings including major efficacy supplements. Her experience includes developing global strategic regulatory development plans, labeling analysis, pediatric programs, as well as leading Health Authority meetings.

In addition to development programs, Karen has broad expertise with marketed products, including critical issues management, safety related labeling changes, drug shortages, Dear Healthcare Professional letters, and formulation withdrawals and risk management programs.

Karen has also provided regulatory leadership on the development and review of promotional campaigns, including DTC and initial product launch campaigns. She has managed FDA advisory committee meeting preparations by developing and implementing regulatory strategies, assisting in the preparation of briefing packages, as well as identifying key issues and responses.

Karen has led development of US and global publication plans for marketed products and has expertise in researching, and interpreting regulatory intelligence information to shape regulatory strategies.

Previously, Karen worked for Hoffmann-La Roche where she held positions in regulatory affairs, medical information, and publication management.

Karen received her Bachelor of Science and Doctor of Pharmacy degrees from the Philadelphia College of Pharmacy and Science and completed a drug information residency at Roche Laboratories Inc.