Hong Zhao, PhD
Master Pharmacokineticist
FDA

FDA's Approach to Approve the Therapeutic Biologics in Cancer Therapy – Clinical Pharmacology Aspect

Dr. Hong Zhao earned her PhD in Pharmaceutical Sciences from the School of Pharmacy, University of Connecticut. She has been with the FDA over past 25 years as Clinical Pharmacology Reviewer, Team Leader, Master Reviewer and now Master Pharmacokineticist. She has developed her expertise in therapeutic biologics during her early years in the Center for Biologics Evaluation and Research (CBER) and later became team leader covering clinical pharmacology review of all biologics submitted to the Center for Drug Evaluation and Research (CDER). During this period, she conducted many regulatory projects addressing biologics review issues such as biologics comparability assessment, immunogenicity testing, drug-drug interaction potential, QT interval prolongation potential, specific populations including hepatic and renal impairment as well as biosimilar development. She presented the results of these regulatory projects within the FDA and at the National Technology Conference and at other scientific conferences, and contributed to the FDA biologics guidance development. In her later years, she has been mainly working on review of oncology drugs and biologics and has accumulated rich regulatory review experience and institutional knowledges. She is very passionate about the review work she has been doing as it directly impacts America people's health.