

## DR. DR. MIKHAIL MICHEL BIOGRAPHY

Dr. Dr. Michel Mikhail has more than 25 years Pharmaceutical Industry experience and track record of achievement in R & D and International Regulatory Affairs in large multinational Research-based pharmaceutical companies as well as in the Generic industry. Dr Mikhail is a Chartered Expert in Pharmacology -Toxicology, a chartered Clinical Expert as well as a chartered Analytical Expert. Dr Mikhail served on the Safety working group and Efficacy working Group of the European Federation of pharmaceutical Industry associations (EFPIA) also as a Topic leader. He served on the Regulatory Group of the European branch of the Pharmaceutical Research and Manufacturers of America (PhRMA Europe), on the Regulatory and Scientific Affairs Group of the European Generic medicines Association (EGA), as well as Pharmacovigilance Working Group, Market Access Advisory Committee, among others and on different associations and organisations.

Dr Mikhail is member of the EGA's European Biosmilars Group (EBG). Dr Mikhail is a Board Member of The European Generic Medicines Association (EGA) as well as member of the Executive Committee of the EGA. He is member of the British Institut of Regulatory Affairs (BIRA), the European Society of Regulatory Affairs (ESRA), both now known as the organisation for Professionals in Regulatory Affairs (TOPRA). Dr Mikhail is member of the Expert Committee for Toxicology of the United States Pharmacopea (USP).

Currently Dr. Mikhail is Chief Regulatory Officer & Executive Vice President Global Regulatory – Governmental Relations at Fresenius Kabi, a Multinational Pharmaceutical company.