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Dr. Dr. Michel Mikhail has more than 20 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, he is a chartered Clinical Expert as well as a chartered Analytical Expert. Dr Mikhail is an Expert in Biosimilars. He 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 Board, Executive Committee and the Biosimilars & Regulatory and Scientific Affairs Group of the European Generic medicines Association (EGA), as well as on different associations and organisations. He is member of The Organisation for Professionals in Regulatory Affairs (TOPRA). Dr Mikhail is member of the Expert Committee for Toxicology of the United States Pharmacopeia (USP), Washington DC and member of the Expert Committee of the Federal Institute for Risk Assessment, Berlin.