dcvmn
Developing Countries Vaccine Manufacturers Network

Speakers Booklet

eWorkshop (via WebEx)
Regulatory Pathways Part II: CRP, EUL and eCTD
30 September to 1 October 2020

Dr Nora Dellepiane

Dr Dellepiane has 40 years' experience in production and control of biological products. Nora headed the NCL in Argentina for 10 years and worked at WHO for 19 years. She now supports manufacturers and regulators to address challenges in the quality/regulation of biologicals, including providing training in this field.

Mic Mcgoldrick

Mic Mcgoldrick is currently Associate Director of Global CMC Policy at Merck. He has over 29 years of experience in Vaccines and Biologics. For 15 years, Mic worked globally in Regulatory Affairs on INDs, new product filings, post approval submissions, and on evaluation of worldwide guidance's. For the last six years, Mic has been working on CMC Policy for Vaccines and Biologics, advocating for harmonization and greater access of vaccines to patients.

Dr Norbert De Clercq

Dr De Clercq has spent 23 year in vaccines across various departments (clinical research, publication management, marketing, competitive intelligence and regulatory affairs) and infectious-disease areas, spanning early research to life cycle management. His current focus is regulatory intelligence and policy for countries outside the EU and US, including WHO. He represents GSK vaccines at working groups of the IFPMA.