Developing Countries Vaccine Manufacturers Network
Speakers Book

Chemical Manufacturing and Controls to foster implementation of vaccine release test methods aimed at reducing animal use (3Rs)

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Dr. Nora Dellepiane 	Independent Consultant	Dr. Dellepiane has 40 years of experience in production and control of biological products and worked at WHO for the past twenty years. She has experience in quality assurance, quality systems and understanding of GMP. She now focuses on assisting manufacturers of Biological Products and regulators to address challenges in the regulation of novel biologicals, including providing training in this field.
Dr. Sunil Kumar Goel 	Additional Director, Serum Institute of India	Dr. Goel is a microbiologist with 31 years of experience in the field of human vaccines. Having worked in the Indian National Control Lab (CDL)/Central Research Institute, Kasauli for 27 years he retired from Government service and joined the quality control department of Serum Institute of India at Pune in 2015 where he works as an Additional Director. Dr. Goel has eight publications in national and international journals and two patents to his credit.
Mr. Paddy Peng 	Technical Manager, Sterile Filling Division, Tofflon	Mr. Paddy Peng has engaged in the design of sterile filling lines for over 10 years. He is familiar with process design, risk management and project management of sterile liquid filling lines, especially vaccine filling lines. As a technical manager, he has been responsible for the planning and design of over 200 sterile filling lines in the Chinese and Global markets.

Dr. T. M. Chozhavel Rajanathan 	Deputy General Manager, Analytical Development, Zydus Cadila	Dr. Rajanathan heads the Vaccine Analytical Team for development of bacterial, viral and recombinant vaccines. He has more than 14 years of research experience in the development and validation of bio-analytical methods for vaccine molecules. Dr. Rajanathan is involved in complete characterization of different candidate vaccines as per regulatory requirements and previously held positions with the Department of Biotechnology (DBT), Indian Immunologicals Limited, Hyderabad and Shantha Biotechnics (a Sanofi company).
Dr. Ute Rosskopf 	Leader, Vaccines Testing, World Health Organization (WHO)	Dr. Rosskopf established and leads the WHO-national control laboratory network for biologicals (WHO-NNB), which fosters information sharing among authorities and stakeholders and facilitates access to and availability of prequalified vaccines through recipient countries' reliance on the batch release of the responsible authorities. Dr. Rosskopf also coordinates vaccines testing conducted in the context of prequalification of vaccines and is responsible for the qualification of laboratories.
Dr. Dibyendu Saha 	Senior Scientific Liaison, Global Biologics, United States Pharmacopeia (USP)	Dr. Saha has over 19 years of industrial experience in quality control functions of the life science and healthcare industry, involving both diagnostic and therapeutic products. He has worked at USP since 2012 and is involved in the development of vaccine chapters and standards. Before joining USP, Dr. Saha worked as a Deputy General Manager in PanEra Biotec Limited, an associate company of Panacea Biotec Limited.

Mr. Sarin Simon 	Head of Projects, BiOZEEN	Mr. Simon is a mechanical engineer with expertise in manufacturing best practices and process control in the biopharmaceutical industry. At BiOZEEN, he leads project execution across regulatory and statutory regimes in 19 countries spanning four continents. With multifaceted experience in production, bioprocess and design, Mr. Simon has led and mentored cross-functional teams for more than a decade.
Mr. Gopal Singh 	Bharat Biotech International Ltd.	Mr. Singh is a quality control professional with 30+ years of career experience in diverse leadership roles with renowned vaccine / biotechnology companies associated with government and private sectors. He is actively involved in eradication of poliovirus from India by producing and supplying quality products for national and international requirements. Mr. Singh has been a part of policy making for quality control of various immunobiologicals with a vision to implement 3Rs.
Dr. Surinder Singh 	Director, National Institute of Biologicals (NIB), Ministry of Family Health & Welfare, Government of India	Dr. Singh is the Director of the Indian NIB, which is the national control laboratory responsible for testing of all biologicals. He previously served as the Drug Controller General of India from 2008 to 2011. Dr. Singh has received numerous awards throughout his career and was recognized as one of the 40 most influential people in the global pharma industry for three consecutive years, 2009-2011, by the UK Pharma magazine "World Pharmaceutical Frontiers".

Dr. Christina von Hunolstein 	Research Director and Coordinator, Bacterial Vaccines Section, National Centre for Control and Evaluation of Medicines (CNCF), Istituto Superiore di Sanità, Rome, Italy	Dr. Hunolstein is responsible for batch release of bacterial vaccines and for advising on the evaluation of the quality part of the vaccine CTD. She has participated in collaborative studies for the establishment of an alternative to in vivo testing for potency of DT vaccines and currently co-leads a project on an alternative potency testing method for wP. Dr. Hunolstein is an expert member of Group 15 - Vaccine and Sera - of the European Pharmacopoeia.
Ms. 	Deputy Drugs Controller (India), Central Drugs Standard Control Organisation, Hyderabad	Smt. Visala Annam has over 21 years of drug regulatory experience with Government of Andhra Pradesh. She joined CDSCO in 2012 as Deputy Drugs Controller (India) and since 2013 has been assisting the DCGI in matters relating to global clinical trials, implementation of the new Rules for clinical trials, ethics committee registration, regulatory actions on GCP inspections, compensation and is based at CDSCO, New Delhi. She has headed the CDSCO-Hyderabad Zonal office since October 2017.
Dr. Dianna Wilkinson 	Principal Scientist, Division of Virology, National Institute for Biological Standards and Control (NIBSC), UK	Dr. Wilkinson's scientific interests include control testing of HPV and HepB vaccines for Europe and WHO; establishment of WHO International standards for HPV DNA and antibodies, Ebola antibodies, Rabies vaccines, Rabies IgG, HbsAg; laboratory training to NCLs from developing countries undertaking HPV vaccine batch release; and drafting WHO guidelines for the production and quality control of HPV and HepB Vaccines.

Ms. Sireesha Yadlapalli 	Senior Director, Strategic Marketing & External Affairs, United States Pharmacopeia - India	Ms. Yadlapalli oversees strategic marketing, market research and analytics, public policy, regulatory affairs, government and stakeholder relations and education functions for USP India. She has 20 years of experience in the healthcare and education sectors. In the US, she worked with Johnson & Johnson and in India, she worked with Dr. Reddy's in the Biologics division, as the Director, Strategic Initiatives and later as the Program Manager for two biosimilar programs.