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Board on Health Sciences Policy
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Speaker Biographies

Marco Cavaleri, Ph.D.
Head of Anti-infectives and Vaccines, European Medicine Agency (EMA)

Dr. Cavaleri joined the European Medicines Agency in 2008 as Group Leader Anti-infectives in the Safety & Efficacy Sector, Pre-Authorization Human Unit. In 2009 he was appointed as Head of Section for Anti-infectives and vaccines in the Safety & Efficacy Sector, Human Medicines Development and Evaluation Unit, being responsible for the management of pre- and post-authorization activities of centralized applications/marketing authorizations, and particularly the Safety and Efficacy part, related to medicinal products in the above-mentioned therapeutic areas.

Marco Cavaleri is PhD Pharmacologist who spent several years in industry in R&D mainly in the area of anti-infectives covering different positions in preclinical and clinical development.

In 2005 he joined the EMEA as Scientific Administrator in the Scientific Advice and Orphan Drugs Sector, specifically being in charge of anti-infectives and vaccines scientific advice procedures. He returned to the Agency in 2008 following a short period in industry leading clinical and preclinical development in the area of Gastroenterology and Infectious Diseases.

Edward Cox M.D., M.P.H.,
Director of the Office of Antimicrobial Products, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA)

Dr. Cox received his undergraduate degree in chemistry from the University of North Carolina at Chapel Hill and his medical degree from the University of North Carolina School of Medicine. He completed an internship and residency in internal medicine at the Hospital of the University of Pennsylvania in Philadelphia, and he went on to complete a fellowship in infectious diseases at the National Institute of Allergy and Infectious Diseases at the National Institutes of Health in Bethesda, MD. Dr. Cox is board certified in internal medicine and infectious diseases

Robert Hemmings
Statistics and Pharmacokinetics Unit Manager; Medicines and Healthcare Products Regulatory Agency (MHRA)

Dr. Hemmings holds degrees in Mathematics and in Medical Statistics from the universities of Nottingham and Southampton respectively. After a short spell in the pharmaceutical industry he turned 'gamekeeper' and has been with the Medicines and Healthcare products

Regulatory Agency for 13 years. He heads the group of medical statisticians and pharmacokineticists. The group provides methodological expertise to the assessment of marketing authorization applications, 'scientific advice' to drug developers and input to methodological and therapy area regulatory guidance documents. Rob is a member of the European Medicines Agency Committee for Medicinal Products for Human Use (CHMP). CHMP is the body responsible for preparing the Scientific Opinions of the European Medicines Agency on questions concerning medicinal products for human use, in particular on risk-benefit assessments for licensing decisions. Rob also holds the other positions within the European drug regulatory system including chair of the CHMP's Scientific Advice Working Party (SAWP) with responsibility for preparing advice to the pharmaceutical industry on the appropriate tests and trials to conduct in the development of a medicine for marketing authorisation. Rob is also a member of CHMP's Biostatistics Working Party with responsibility for giving advice on matters relating to clinical trial methodology across the EU regulatory network.

Peter Marks, M.D., Ph.D.
Director Center for Biologics Evaluation and Research, FDA

Dr. Marks is the director of the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. The center is responsible for assuring the safety and effectiveness of biological products, including vaccines, allergenic products, blood and blood products, and cellular, tissue, and gene therapies.

Dr. Marks and center staff are committed to facilitating the development of biological products and providing oversight throughout the product life cycle. Examples of these activities include reviewing and providing advice during product development, evaluating applications and making approval decisions based on safety and effectiveness data, monitoring the safety of biological products, and conducting research that supports product development and characterization.

Dr. Peter Marks received his graduate degree in cell and molecular biology and his medical degree at New York University. Following this, he completed an Internal Medicine residency and Hematology/Medical Oncology fellowship at Brigham and Women's Hospital in Boston, where he subsequently joined the attending staff as a clinician-scientist and eventually served as Clinical Director of Hematology.

He then moved on to work for several years in the pharmaceutical industry on the clinical development of hematology and oncology products prior to returning to academic medicine at Yale University where he led the Adult Leukemia Service and served as Chief Clinical Officer of Smilow Cancer Hospital. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in 2016. Dr. Marks is board certified in internal

medicine, hematology and medical oncology, and is a Fellow of the American College of Physicians.