Speakers Brochure

Mr Mike Isles, Executive Director, European Alliance for Access to Safe Medicines

Mike Isles is the Executive Director of the European Alliance for Access to Safe Medicines (EAASM), a pan-European non-profit (CIC) patient safety organisation. The EAASM has been coordinating the Nanomedicines Regulatory Coalition, focused on supporting the development of a robust and harmonised EU regulatory framework in the field of nanomedicines to protect patient safety and guarantee the safety, quality and efficacy of innovative nanomedicines and nanosimilars. Its other key activities include campaigning for the safer use of unlicensed/off-label medicines and compounding medicines, the adoption of medical, pharmacy and nursing practices that aim to eradicate medication errors and the exclusion of falsified and substandard medicines from the supply chain. To this end, the EAASM has formed the European Collaborative Action on Medication Errors and Traceability (ECAMET), a patient safety initiative that brings together 22 organisations working together to tackle the issue of medication errors.

Mike is also the Executive Director for the Alliance for Safe Online Pharmacy in the EU (ASOP EU), a non-profit Community Interest Company. With over 35,000 fake pharmacy websites targeting European citizens on any given day, this multisectoral organisation's mission is to enable patients to buy their medicines online safely – where it is legal to do so. ASOP EU collaborates strongly with ASOP Global (www.buysaferx.pharmacy), and its members and observers involve many key internet stakeholders. Its aim is to campaign for new legislation, as well as concrete voluntary actions that will make a real difference and ultimately benefit the health and safety of patients.

Mike Isles has a professional background in pharmaceuticals, where he held senior management and director positions covering sales, marketing, commercial and supply chain in a 32-year career.

To get in touch with Mike, please send an email to mike.isles@eaasm.eu.

Jon de Vlieger PhD, Coordinator of the NBCD Working Group, Lygature

Jon de Vlieger is Coordinator of the Non-Biological Complex Drugs Working Group at Lygature, an independent not-for-profit organisation based in the Netherlands that catalyses the development of new medical solutions for patients by driving public-private collaboration between academia, industry, and society. The NBCD Working Group contributes strongly to Lygature's mission of accelerating the launch of medicines that improve society's wellbeing.

Jon de Vlieger holds a PhD degree in Chemistry and Pharmaceutical Sciences, division of Biomolecular Analysis at the VU University in Amsterdam. He is a co-editor of the book on NBCDs in the AAPS Advances in the Pharmaceutical Sciences Series and co-author of a series of key-papers on the topic of regulatory challenges for Complex Drug Products.

Prof. Paola Minghetti, Department of Pharmaceutical Sciences, Universita' degli studi di Milano, Italy

Paola Minghetti, Bachelor of Science in Pharmacy and Chemistry and Pharmaceutical Technology, PhD in Pharmaceutical Sciences, is Professor of Pharmaceutical Technology and Legislation at the University of Milan. Her research activity is mainly focused on dermal, transdermal and buccal delivery systems, as well as on legislative aspects of the production and marketing of medicines, medical devices, cosmetics, food supplements and special foods. She is a member of the Technical Table for the support and updating of the Italian Pharmacopoeia. She has been a member of the Italian Medicines Agency's Secretariat for the Evaluation and Authorisation of Medicinal Products since 2012 and is a member of a working group appointed by the European Directorate for the Quality of Medicines (EDQM). She is President of SIFAP (Società Italiana Farmacisti Preparatori) and Vice-President of AFI (Associazione Farmaceutici Industria) and is a member of the Board of Directors of the Order of Pharmacists of the Provinces of Milan, Lodi, Monza and Brianza. She is author of more than 200 publications on legislation and technology. She has presented several invited papers, oral communications and posters at national and international congresses.

Katherine Tyner PhD, Liaison Officer to the European Medicines Agency, U.S. Food and Drug Administration

Katherine Tyner possesses a wealth of medical products policy and technical expertise. She joined the FDA in 2007 as a chemist specializing in nanotechnology and has investigated the quality, safety, and efficacy of complex drug products.

In her most recent role within the Center for Drug and Evaluation Research (CDER), Tyner was the Associate Director for Science in the Office of Pharmaceutical Quality (OPQ). There, she led the OPQ Science Staff in coordinating the intersection between science, review, and policy, facilitating

interactions among other CDER offices and FDA Centers; and overseeing the OPQ project for developing an advanced manufacturing regulatory framework.

Tyner has participated in numerous bilateral and multilateral discussions involving nanotechnology and other complex drug products. She has served as the FDA representative to various standard-setting organizations, including: the International Pharmaceutical Regulator's Program Nanomedicines Working Group, ASTM E56 (Nanotechnology), and ISO TC 229 (Nanotechnologies), and the United States Pharmacopeia's Joint Subcommittee on Nanotechnology.

In 2015, she was selected to lead the Nanotechnology Working Group, which produced draft guidance in 2017 on the development of drug products and biologics that contain nanomaterials.

Tyner received a bachelor's degree in chemistry from Carleton College, and her master of science and Ph.D. degrees in chemistry from Cornell University. She completed a postdoctoral fellowship at the University of Michigan in a joint appointment in the Chemistry Department and the Toxicology Program and is a graduate of the Partnership for Public Service Excellence in Government Fellows Program.

Prof. Anthony Serracino-Inglott, Chief Executive Officer, Malta Medicines Authority

Anthony Serracino-Inglott is Professor at the Department of Pharmacy, Faculty of Medicine and Surgery at the University of Malta. Prof. Serracino-Inglott studied Pharmacy at the University of Malta and is a registered pharmacist. He continued his postgraduate studies at the University of Cincinnati where he obtained a Doctorate degree in Pharmacy and completed a residency at the University of Cincinnati Medical Centre.

Anthony Serracino-Inglott is the Chief Executive Officer of the Malta Medicines Authority which is the national competent authority for the regulation of medicines and medical devices for human use. The Malta Medicines Authority has the mission to protect and enhance public health through the regulation of medicinal products, medical devices and pharmaceutical activities.

Serracino-Inglott published over one hundred scientific papers and delivered a multiplicity of presentations at international conferences related to the pharmaceutical and regulatory sciences. His consultancy experience includes being a court expert in toxicology and forensic sciences, advisory roles to ministers of health and education, as well as Qualified Person for the pharmaceutical industry. His research interests are in the fields of biopharmaceutics and pharmacokinetics, pharmaceutical regulatory sciences, patient safety, personalised medicines and pharmacy education.