SPEAKERS

Michelle Cheng

Michelle Cheng

Head of Regulatory Affairs (Singapore & Asian Emerging Markets)
Novartis

Michelle is a regulatory affairs professional with over 15 years of experience in the pharmaceutical and medical device industries. A pharmacist by training, Michelle has contributed in a variety of roles ranging from Medical Affairs, Pharmacovigilance, Quality Assurance and Regulatory Affairs at both local and regional levels. She received her Bachelor of Science (Pharmacy)(Hons.) from the National University of Singapore and MMedSc (Drug Development) from the University of New South Wales and is passionate about driving innovation in regulatory science and process simplification.

Dr. Crystal Lau

Crystal Lau, *Ph.D.*

Associate Director
MSD International GmbH

Crystal leads the Biologics and Vaccines portfolio in the company for the Asia Pacific region. She and her team work primarily on CMC related matters including new products, variations, supply related matters and lifecycle management.

Prior to her current position, Crystal was a Global Regulatory Affairs CMC product-lead and she authored CTD Module 2 and 3 dossiers for a 10-valent vaccine new site registration and subsequently variations in major and global markets around the world. During this period, she was located at the manufacturing site and had to oversee the regulatory compliance of site generated reports used for authoring while sitting as a permanent member for site change control, product quality review and agency audits. Amongst other experiences, Crystal also worked as a quality assessor at the Singapore regulatory agency (Health Sciences Authority) and held an American Heart Associate post-doctoral fellowship grant while working at the University of Southern California, Los Angeles.

Crystal receives her *Ph.D.* from The University of Melbourne in the area of Biophysics/Structural Biology and holds an Honors Degree from the same university in Chemistry.

SPEAKERS

Rachel Wong

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Regional APAC Pharmacovigilance Hub – Lead
Roche

Rachel is currently heading the Regional APAC Pharmacovigilance Hub – a centre of excellence that creates global consistency and quality in the way selected key PV activities are performed. She has over 14 years of drug safety experience in APAC where she plays a role as team manager in people development, process development, inspection/audit readiness, and pharmacovigilance communication and engagement with stakeholders. In 2005, she began her career in medical affairs with Bristol-Myers Squibb (BMS). Since 2007, Rachel then worked for other multi-national pharmaceutical organisations (Celgene, Bausch & Lomb, Merck) where she was involved in developing and implementing pharmacovigilance operating model in these organisations.

Rachel has a BSc (Hons) Pharm from the National University of Singapore and is a registered pharmacist. She is passionate in the field of PV and continues to look forward to drive global healthcare improvement through contributing to the drug safety landscape within the pharmaceutical industry.

Dr. Lavina Chaudhry

Lavina Chaudhry

Local Safety Responsible Person
Roche

Dr. Lavina Chaudhry is a medical doctor by training with specialization in pathology. She is currently the Local Safety Responsible person for the Roche pharmaceutical in Singapore and is responsible for pharmacovigilance and drug safety. She has close to 4 years of experience in pharmacovigilance largely by working as Safety physician where she was largely involved in life-cycle management of drugs.

Lim Pui Ching

Lim Pui Ching

Multi-Country Safety Lead – HK/TW/TH/MY/SG
Sanofi

Pui Ching is the Multi-Country Safety Head of Sanofi Hong Kong /Taiwan and Thailand/Malaysia/ Singapore Country Organizations and has over 10 years of experience in Pharmacovigilance, 8 of them being with Sanofi. She holds a Bachelor of Science in Pharmacy from the National University of Singapore. She is a registered pharmacist with experience in the medical publishing industry and has worked in medical information and pharmacovigilance in tertiary hospitals and clinical research organizations. She is currently working on her Masters of Clinical Trials by University of London.

SPEAKERS

Nick Ward

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Director
Pharma To Market

Nick's career in the pharmaceutical industry began in 1997 and since then his roles have spanned international regulatory affairs and strategy, GxP activities, e-Submissions and laboratory roles in pharmaceutical chemistry and manufacturing. Following studies in industrial chemistry, Nick enjoyed a variety of laboratory roles over a seven year period including stability monitoring, manufacturing process validation and analytical method development and validation. In 2005 Nick moved to the UK and began his career in European regulatory affairs where he coordinated marketing authorisation applications to various European authorities. Upon his return to Australia, Nick led a regulatory affairs team responsible for writing, publishing and submitting CTD dossiers for generic products to Europe, USA, SE Asia and Australia.

In 2009 Nick co-founded Pharma To Market and now works with clients locally and around the globe to bring pharmaceutical and biological products to the Australian, New Zealand and Asian markets. Nick's experience covers a wide range of therapeutic areas and dosage forms, including new chemical and biological entities. Nick provides his clients with effective regulatory strategies, and often represents clients at pre-submission meetings; he also has hands on experience with orphan drug designation applications and literature based submissions.

Carl Bufe

Carl Bufe

Senior Drug Safety/Regulatory Affairs Associate
Pharma To Market

Carl leads the drug safety unit at Pharma To Market in Australia, and works in partnership with various international clients in assisting them to maintain effective pharmacovigilance systems in Australia and New Zealand. Prior to his role in Pharma To Market, he spent 17 years working in the arena of clinical drug safety, oncology and haematology at various healthcare institutions in United Kingdom, South Africa, New Zealand and Australia.

Carl completed his pharmaceutical degree at Rhodes University in South Africa after which he obtained degrees in Risk Management and Quality Systems. He actively participates in clinical research as a member of clinical trials protocol committees and provides expert drug safety advice to various tertiary institutions in Australia. As a QPPVA (Qualified Person of Pharmacovigilance), he offers an array of PV services including assisting organisations with Pharmacovigilance inspections, RMP generation and the architecture and implementation of pharmacovigilance systems.