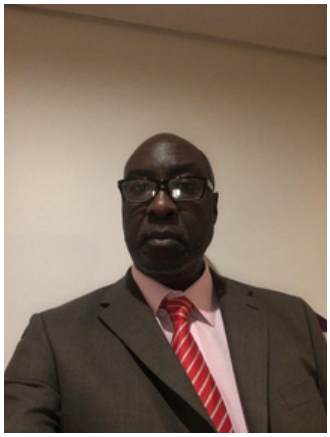
Webinar Speakers

Jenny Burnett

Assistant Secretary of the Manufacturing Quality Branch (MQB), Australia Therapeutic Goods Administration

Jenny Burnett is the Assistant Secretary of the Manufacturing Quality Branch (MQB), Therapeutic Goods Administration. MQB assists in the timely supply of therapeutic goods in Australia, ensuring they are of appropriate quality for their entire lifecycle. This primarily relies on assessing manufacturers' compliance with Good Manufacturing Practice for medicines, blood, tissues and cellular therapy products and conducting product recalls for all types of therapeutic goods. MQB also has responsibility for TGO 93 and quality of medicinal cannabis products.

Jenny has a science background, working as a chemist in both private industry and government laboratories. After a number of years in the TGA Laboratories Branch, and a stint of living overseas for 3 years, she worked in various TGA pre-market assessment areas in medicine regulation before moving to MQB in 2021. Jenny is currently Chair of the Pharmaceutical Inspection Convention/Pharmaceutical Inspection Cooperation Scheme (PIC/S) Sub-committee on Strategic Development.



David Katerere, Ph.D.

Professor, Pharmaceutical Science, Tshwane University of Technology, South Africa

Prof David Katerere is the Research Platform Chair of Pharmaceutical and Biotech Advancement in Africa (PBA^2) at Tshwane University of Technology. He is co-director of the recently established CSIR / TUT Cannabis Research Centre. Prof Katerere holds a PhD in Pharmaceutical Science from the University of Strathclyde, Scotland. He has worked in pharmaceutical and biotech practice and research in the past 25 years in 4 countries on 3 continents. He has several inventions to his name including the nutraceutical, Niselo and CovidConnect App for use in clinical trials and post-recovery and KovaNix hand and surface sanitizer. He has published over 50 journal articles and is co-editor of three books: Ethnoveterinary Botanical Medicines (T&F) (2010), Systems Analysis Approach for Complex Global Challenges (Springer) (2018) and Traditional and Indigenous Knowledge for the Modern Era (T&F) (2019).

He is a member of advisory committees of SAHPRA and the Global Health Supply Chain Consortium, co-founded by faculty at University of Michigan and University of Southern California. Prof Katerere teaches and researches across the pharmaceutical and biotech value chain including product development from medicinal plants (for food, nutraceuticals and medicines) and clinical testing, substandard and falsified medicines / vaccines and medicine governance. He is a past competitive Toastmaster and President of Pretoria Capital Rotary Club.

Webinar Speakers

Somsak Sunthornphanich, B.Sc in Pharm., and MCh

Director, Bureau of Drug and Narcotic, Department of Medical Sciences, Ministry of Public Health, Thailand

Somsak's professional experience within the Bureau of Drug and Narcotic concerns Technical Development, Chemical and Physical Testing, and the quality control of pharmaceutical products. Somsak has an in-depth knowledge of pharmaceutical analysis, analytical method validation, and quality assurance. And of quality control (QC) for the registration of medicines, and the technical assessment of QC laboratories (ISO/IEC 17025:2017). Somsak will discuss the scope of the Thai medicine programme, method development, validation, and the punished Thai monographs.

Charles Wu, Ph.D.

Vice Chair, WHO International Regulatory Cooperation for Herbal Medicine (IRCH)

Dr. Charles Wu, Ph.D., Master Pharmacology/Pharmacognosy Reviewer and the Botanical Review Team Lead in the Office of Pharmaceutical Quality (OPQ) of the Center for Drug Evaluation and Research (CDER), the United States Food and Drug Administration (FDA). Education Dr. Wu trained in Clinical Medicine including Traditional Chinese Medicine (TCM) for his MD and earned his Ph.D. in Medical Science from the Medical Center, University of Amsterdam, the Netherlands. Dr. Wu began his career at FDA in 2001 as a product reviewer in the Center for Biologics, Evaluation and Research (CBER) and then as a senior Pharmacology/Toxicology reviewer in CDER. In 2013 Dr. Wu joined the Botanical Review Team (BRT) and have been promoted to the BRT lead since 2017.

In addition, Dr. Wu also served as the FDA's Focal Information Contact (FIC) to the WHO-IRCH (International Regulatory Corporation for Herbal Medicine) since 2019 and becomes the Steering Group (SG) Member and Vice-Chair (2021-2023), as well as serving as an Expert for Regional Consultation of Traditional Medicine to COVID-19 Response in the African Region. During his tenure at FDA, Dr. Wu has gained extensive regulatory experience and scientific knowledge because of work with a variety of therapeutic products, including chemical, biological, and botanical drugs. Dr. Wu has published over 30 peer-reviewed journal articles including SCIENCE and scientific book chapters.

Moderated by:

Nandu Sarma, Ph.D.

Director, Dietary Supplements and Herbal Medicines, USP

Dr. Nandakumara (Nandu) Sarma is Director, Dietary Supplements and Herbal Medicines at US Pharmacopeia (USP) responsible for strategy and external stakeholder engagement for new and innovative projects, working with global stakeholders and expert volunteers in the development of quality standards (monographs and general chapters) for dietary supplements and herbal medicines that are published in the USP *Dietary Supplements Compendium* and the *Herbal Medicine Compendium*.

Before joining USP 2006, he was a post-doctoral fellow at National Cancer Institute, Bethesda, and Thomas Jefferson University, Philadelphia and was a Senior Scientific Officer at The Himalaya Drug Company, India. His research experience includes isolation and analysis of active components of botanicals and their biologic activity. He published more than 25 scientific articles in peer-reviewed journals. Dr. Sarma holds a Pharmacist degree and a Ph.D. in pharmaceutical sciences (pharmacognosy) from Banaras Hindu University, India.

David Vaillencourt, MS

CEO, The GMP Collective, and Vice Chair, ASTM Committee D37 on Cannabis

David Vaillencourt is the Founder and President of The GMP Collective assisting clients globally to implement best practices that ensure the quality, safety, and compliance of cannabis and cannabinoid products. He is a respected speaker on cannabis business strategy and compliance having spoken at dozens of events nationally and internationally. David serves as the Vice Chair of ASTM International's Committee D37 on Cannabis standards supporting over 1,2000 volunteer members, is the current Chair of NCIA's Facility Design Committee, in addition to serving on several non-profit boards. Prior to founding the Collective, David's experience included the Director of Quality for a large multi-state cannabis operator and supervisory roles in Quality Control and project management for multi-million-dollar life-science projects for the federal government. He holds a Master of Science and has also developed curriculum and taught courses at the college and secondary levels.

Martin Woodbridge, Bsc, PGC.PHC, DPH, MPHC

Woodbridge Research

Martin has consulted for clients in Australasia, Asia and Europe concerning regulatory policy, and quality in production, analytical, and clinical services. He has advised on Government Cannabis-medicine programmes in Oceania, Asia and Europe, and for the UN INCB regulatory framework on Cannabis intended for medical and scientific use.