Abstract of Talk

Paradigm Shift in Early Drug Development: Strategic Candidate Selection and FormulationDevelopment

by Dr Kwok Chow, President, Covar Pharmaceuticals Inc.

Modern drug discovery often produces new molecular entities with challenging biopharmaceutical and physicochemical properties that cause delays, increase cost and, eventually, adversely affect the success of product development programs**.** To mitigate these development risks, there is a significant competitive advantage to (1) choose the best (suitable) compounds from a pharmaceutical "Developability" perspective and (2) develop clinical "Phase Appropriate" formulation for rapid execution of first-time-human and/or proof-of-concept studies.

An API (active pharmaceutical ingredient) sparing and time effective program for drug candidate selection will be discussed. This program involves in-vitro assessment of the gastrointestinal permeability and formulation feasibility of drug candidates. Strategies for rapid and cost-effective development of early formulations will also be introduced. Examples of the application of different pharmaceutical technologies and formulation approaches, such as the use of simplified formulations, to accelerate drug development will be provided.

Biography of Speaker

Dr Kwok Chow is an expert in pharmaceutical product development and drug delivery systems. Currently, he is the President of Covar Pharmaceuticals Inc. and Powder Pharma Coating Inc. He also serves as a Scientific Advisor to the Editors of the Journal of Pharmaceutical Sciences and a core member in the Scientific Advisory Committee on Pharmaceutical Sciences and Clinical Pharmacology at Health Canada.

Dr Chow was the Senior Director of Global PDS Technology and Alliances at Patheon Inc. with the responsibility of developing/introducing new technologies, establishing strategic alliances and providing scientific input to support the pharmaceutical development of challenging molecules. Before his promotion to the Senior Director position, he was the Director of Formulation Development responsible for all formulation development activities in Patheon, Canada. His formulation teams were specialized in the development of a wide range of prescription and OTC products including tablets, soft gelatin capsules, liquids, topicals, suspensions, nasal sprays, powder for reconstitution, combination and fast dissolving formulations. Kwok also designed and developed an expert formulation/technology screening program ("SoluPath™") to improve the bioavailability of poorly soluble drug candidates in early development.

Dr Chow began his career at GlaxoSmithKline (previously Glaxo and Glaxo Wellcome) where he led the design and development of a variety of conventional and novel dosage forms. He also played a CMC leader role in the development (Phase I to Phase III) and introduction of a number of new chemical entities as well as line extension products for the North America, Europe, Japan and Asian Pacific markets.

Dr Chow received his B.S. in Pharmacy from the University of Minnesota and his Ph.D. in Industrial Pharmacy from Professor David Grant at the University of Toronto on crystal modification and crystal engineering of drugs. Dr Chow taught undergraduate and graduate courses in formulation development at the University of Toronto and the Chinese University of Hong Kong. He also supervised industrial graduate students and industrial post-doctoral fellows in his research team. His research interest includes solid-state pharmaceutics, miniaturization of processing techniques, fluidization/ filling of powder for inhalation, electrostatic powder coating and drug delivery systems.

Abstract of Talk

Counterfeit Pharmaceutical and Nutraceutical Products Detection

by Dr Herman Lam, CEO of Powder Pharma Coating Inc. and President of the Calibration & Validation Group (CVG)

Counterfeit pharmaceutical and nutraceutical products not only create huge economic losses for drug companies, entrepreneurs, governments, consumers and patients; these fraudulence products also post dangerous threads to public health and safety. Many counterfeit products closely mimic the authentic products that their detections often relay on analytical testing conducted by trained technicians or scientists using sophisticate lab based instrumentations. With the advances in analytical technologies, portable devices are now available to enable on the spot counterfeit detections without sending to samples to the laboratories. Examples of the use of portable devices will be presented to illustrate the power and the ease of use of these new tools for fighting counterfeit products.

Biography of Speaker

Dr Herman Lam received his B.Sc. from the University of Toronto in 1984. After graduated from York University in Toronto with a Ph.D. in chemistry in 1989, he joined Glaxo Canada as a research scientist working on analytical method development and validation. He had managed product development projects to support IND and NDA submissions before the focus of his work gradually shifted to analytical instrumentation and lab automation. He laid the foundation of the lab instrument qualification, performance verification and instrument management program that was the center of attention in many pre-approval and GMP audits. He was a Principal Investigator at GlaxoSmithKline Canada responsible for the implementation of new analytical technologies and laboratory automation before leaving the company in 2007. Currently, he is the CEO of Powder Pharma Coating Inc. The company has developed the next generation of pharmaceutical coating technology based on electrostatic dry powder deposition for a wide range modified release and immediate release applications to replace the existing liquid based coating processes in the pharmaceutical and nutraceutical industries.

Dr Lam also serves as the President of the Calibration & Validation Group (CVG), a government registered non-profit professional organization in Canada with focus on the GMP, calibration, validation and analytical sciences in the pharmaceutical industry. CVG is a Member Organization of the United States Pharmacopeia Convention (USP). He has served in the USP Reference Standards Expert Committee.

He collaborates with Prof. I.K. Chu at the University of Hong Kong on the development of multidimensional liquid chromatography platforms for qualitative and quantitative shotgun proteomics, and the use of multivariate analysis for bioactivity driven MS data to identify biologically active compounds in traditional Chinese medicines. Dr Lam was appointed Honorary Assistant Professor in the Department of Chemistry at the University of Hong Kong from February 2012 to 2015. He is an Adjunct Associate Professor at the School of Pharmacy of the Chinese University of Hong Kong.

Dr Lam is one of the authors/editors of the book titled "Analytical Method Validation and Instrument Performance Verification" published by Wiley Intersciences in 2004. Over 5000 copies have been sold worldwide. He co-edited/authored another book published by Wiley in 2010 on instrumentation methods and performance verification topics not covered in the 2004 volume.