

First Annual Conference on the Medicinal Use of Chinese Herbs

“Challenges in Product Development of Chinese Medicinal Herbs”

September 25, 2004
Kelley Lecture Hall (Dental Science Bldg. Rm: D1002)
University of Western Ontario, London, Ontario. Canada

Speakers

John Thor Arnason

Biography

John Arnason is Professor of Biology and Director of the Phytochemistry, medicinal plant and ethnopharmacology laboratory at the University of Ottawa. Arnason's laboratory and research group has had a continuous interest in phytochemistry and biological activity of substances in plants in collaboration with other lab groups. This research program ranges from ethnobotanical studies and drug discovery from tropical plants to collaboration with the North American herbal industry on commercial phytomedicines. The laboratory acted as one of the two laboratories in the Ginseng Evaluation Project sponsored by the American Botanical Council, which assessed 414 commercial ginseng products. In collaboration with Lemaire's group, the active immunostimulant principle of N. American ginseng and cat's claw has been identified. The lab has developed published quality control methods for assessment of active principles in elethero, echinacea and many other species. Currently the laboratory is collaborating with Klickitat Organics in the investigation of medicinal plants from NE China.

Presentation title: Ginseng and other adaptogenic medicinal plants from NE China.

Abstract: Results of a survey of 440 ginseng products on the North American market and Canadian research on the immunostimulant and antidiabetic activity of ginseng will be discussed. In addition selected promising herbs for North American markets from NE China are reviewed.

Dr. Cai Cao

Center for Drug Certification, Chinese State Food & Drug Administration, Beijing, China.

Biography

Dr. Cao, Pham D., is presently Assistant Director, Center for Drug Certification, Chinese State Food & Drug Administration, Beijing. Previously, Dr. Cao was Associate Director

for herb medicine review at Center for Drug Review, Chinese State Food & Drug Administration (1996-1999). Director of Provincial Research Institute for Innovative Therapeutics of Guangxi Province, China (1994-1996). CEO / CSO of Zhengzhu Herb Medicine Company, Guangxi, China (1988-1994). Pharmacist at Liuzhou Railway Hospital, Guangxi (1982-1987). Dr. Cao obtained her Pharmacy Degree (1982) from Guangxi Medical College for Chinese Medicine and her Pharm D. (1995).

Dr. Cao is a senior review officer in drug certification and review, especially for certifying and reviewing herb medicines in China. She also has extensive experience in research and manufacture of herb medicines. Dr. Cao is a frequent invited speaker and chairman in international symposia and conferences.

Presentation title:

The current status of drug administration for herbal medicine in China

Abstract:

The presentation will be focused on regulation and procedure on registration of herb medicines, and certification and inspection for herbal medicine manufactured in China. Special case studies will be also presented.

Professor Kelvin Chan

Biography

Professor Kelvin Chan, PhD, DSc, FCP, FIBiol, FRPharmS, is presently Chair Professor of Biomedical Sciences and Director of R&D Division, School of Chinese Medicine at the Hong Kong Baptist University. He was the Director of R&D and Chair Professor of Biomedical Sciences at Zayed Herbal Research Centre & Traditional Medicine at the Ministry of Health in Abu Dhabi, United Arab Emirates before returning to Hong Kong (1997-2000, on secondment) in November 2000 and previously Chair Professor and Director of Pharmacy & Biomedical Sciences at Liverpool JM University, United Kingdom 1992 to 2000).

Professor Chan has a wide range of research experience and interests in orthodox medicine and Chinese medicine, R & D and regulatory issues of pharmaceutical and herbal products. He has published more than 350 articles in journals, books and reviews on drug analysis, drug disposition and interactions, toxicology of natural products and R&D and pattern recognition of Chinese herbal products on quality, safety and efficacy issues. He is on the editorial boards and acts as referee of several international journals and Editor of the E-Journal of Complementary & Integrative Medicine.

Presentation title: Problems and Strategies for Assessing Quality of Chinese Herbal Medicinal Products

Abstract:

The increasing popularity in the use of crude Chinese medicinal materials (CMM) and related products has also brought concerns and fears over the professionalism of practitioners, and quality, efficacy and safety of their treatment methods and CMM related products. A scheme is suggested to quality assure (QA) and control (QC) these products, based on several projects performed in our laboratories, for setting up standard operating procedures on assessing them before carrying out Good Clinical Trial Practice (GCTP). An internationally recognized 'system' in QA/QC of CMM is needed.



Dr. Peter Chan
Biography

Dr. Chan, MSc, Ph.D., is the Director, Bureau of Product Review and Assessment, Natural Health Products Directorate, Health Canada. Dr. Chan obtained his Bachelor's degree from the University of Victoria in the Chemistry Co-op Education Programme and a minor in Biology. He later received his Master degree in Zoology/Medical Genetics specialized in the study of the health effects of herbal ingredients and a Doctoral degree specialized in the area of toxicology and pharmacology at the University of British Columbia. In 1988, he joined the former Bureau of Drug Research as a Research Fellow on an NSERC Fellowship. He was appointed the Manager of the Natural Health Products Division within the former Therapeutic Products Programme in 1997. In February of 2000, Dr. Chan was appointed as the Director of Product Review and Assessment of the newly created Office of Natural Health Products, now the Natural Health Products Directorate. He has written and been a coauthor of more than 30 scientific publications. He has been a member of the World Health Organization Working Group on Traditional Medicine and is a member of the Hong Kong Department of Health International Advisory Board on Herbal Medicine.

Presentation title: Regulatory challenges of TCM finished products in Canada

Dr. Patrick Choy
Biography

Dr. Patrick Choy, PhD, MD, FAHA, FIACS Director of the Centre for Research and Treatment of Atherosclerosis (CRTA), University of Manitoba and Winnipeg Health Sciences Centre, is currently the Associate Dean of Research in the Faculty of Medicine, and jointly appointed as Professor of Biochemistry and Medical Genetics, with cross-appointment as Professor of Pathology. He obtained his undergraduate degree at McGill, and his doctorates at the University of North Dakota. His research interest is in the metabolism of lipids and lipoproteins. He is currently the Vice-President of the Heart and Stroke Foundation of Manitoba, the Vice-Chair of the Manitoba Health Research Council, the Chair of the Senior Scholarship Committee of the Alberta Heritage

Foundation, a member of the Expert Advisory Committee for Health Canada, and an advisor to the Health Ministry of the European Union. He chairs the grant review committee of the Directorate of Natural Health Products, and serves as a member of the CIHR/NSERC CHRP review committee. He is also a member of the Advisory Committee to the Institute for Biodiagnosics, NRC, the Chair of the Research Advisory Committee to MHSF, a member of the Task Force for WED, and a member of Canada West Health Innovation Council.

Dr. Choy is also interested in the enhancement of academic and cultural understanding between Canada and China. He serves as the Vice-President of the Canada-China Friendship Association, and also Vice-President of the Winnipeg Chinese Cultural and Community Centre. He coordinates the academic exchange between Shantou U and the U of Manitoba with an endowment grant (\$1 million Cdn) from the Li Ka Shing Foundation.

Dr Jean-Paul Collet, MD, PhD

Biography

Dr. Jean-Paul Collet, MD, PhD is Professor in the Department of Epidemiology and Biostatistics at McGill University. He is also director of the pharmacoepidemiology program and Director of the Randomized Clinical Trial Unit at the Jewish General Hospital. Dr. Collet's main domains of expertise are clinical research and drug evaluation with special expertise in design and methodology. He is supported by a personal career research scholarship (senior) from Fonds de la Recherche en Santé du Québec (FRSQ). Since June 2001, Dr. Collet is Director of the GEREQ program for clinical research. This project received 12 million dollars (CFI, VRQ and FRSQ) with three main objectives: 1) developing a centralized web-based electronic data management platform according to ICH and FDA guidelines, 2) teaching and training good clinical practices, 3) setting up a high quality national and international research network for clinical research.

As researcher, Dr. Collet is presently administering several research projects for over 1.5 million dollars. He has published over 100 scientific articles in peer-reviewed journals. His expertise in clinical research methodology, pharmacoepidemiology and drug evaluation is widely recognized nationally and internationally as shown by numerous invitations as guest speaker.

Finally, Dr. Collet's research interests in research include the following: Pain management, COPD and asthma, research on placebo effect, and the use of traditional Chinese medicine integrated with conventional treatments.

Presentation title: Drug and natural health products development – importance of China-Canada collaboration.

Abstract:

Research on Chinese Medicine includes two main domains of activity that are quite different: The practice of Traditional Chinese Medicine (TCM) according to the Chinese philosophy of Yin, Yang and Qi on one hand, and the research for identifying the active ingredients of natural products on the other.

Research on the effects and practice of TCM is important to generate scientific evidence regarding efficacy and safety and to facilitate the widespread use of TCM in Western countries. Designs will be complex and a multidisciplinary approach is necessary.

Research on the properties of Chinese herbs and (safety, efficacy, active components) is also very promising. This domain is well regulated to either developing a natural health product (NHP) or a drug.

In both domains (evaluation of TCM and development of new NHP or drugs), China Canada collaboration bears interesting potentials for developing successful synergetic activity: a win-win situation!

Dr. Zhuohan Hu

Biography

Dr. Hu is presently CEO of Research Institute for Liver Diseases (Shanghai) and Professor of Pharmacology at School of Pharmacy, Fudan University, Shanghai, China. Previously, Dr. Hu was Director of Pharmacokinetics and Drug Metabolism at In Vitro Technologies, Inc., Baltimore, Maryland, U. S. A. (2000-2002); Associate Director of Drug Metabolism at Huntingdon Life Sciences Inc., Princeton, New Jersey, USA (1999-2000), Research Leader of Pharmacokinetics and Drug Metabolism at BioChem Pharma, Inc. at Montreal, Quebec, Canada (1994-1999), Visiting Fellow in Toxicology and Safety Evaluation at Duke University Medical Center and USDA (1986-1987), Assistant Professor of Toxicology at Shanghai Medical University (1981-1986). Dr. Hu obtained his College Diploma (1977, Preventive Medicine) from Shanghai First Medical College, Shanghai, China, MSc degree (1981, Toxicology) from Shanghai Medical University, and Ph.D. (1992, Pharmacology) from the University of Toronto. He received his doctoral training and performed his dissertation research under Professor Peter. G. Wells and did his postdoctoral training at Ontario Cancer Institute (1993-1994) under Professor Michael Archer.

Dr. Hu is an experienced scientist and dedicated teacher in drug metabolism and toxicology. He is one of the pioneers in the application of in vitro systems, especially human-based experimental models such as human hepatocytes, in the evaluation of human drug properties including metabolic fate, drug-drug interactions, and drug toxicity in China. He is Principal Investigator for the Chinese government sponsored research project of study for herb medicine and drug interaction. Dr. Hu has 30 publications and

professional presentations. He is a frequent invited speaker and chairman in international symposia and conferences.

Presentation title:

In vitro study for metabolism and drug interactions involving Chinese herbs

Abstract:

The metabolic interactions of 15 Chinese herbs including their decoction pieces with small molecular therapeutics were studied by using human hepatocytes and liver microsomes. The inhibition and induction potentials of the test herbs on cytochrome P450 isoforms CYP1A2, CYP2A6, CYP2D6, and CYP3A4 will be presented and the mechanism of metabolic interactions is discussed.

Dr. Stephen Lam

Biography

Dr. Lam, M.D., FRCPC, is Professor of Medicine at the University of British Columbia and Chair of the Lung Tumor Group at the British Columbia Cancer Agency in Vancouver, Canada. He is a co-inventor of the Lung Imaging Fluorescence Endoscopic device for the detection of pre-malignant lesions and early lung cancer. He has published extensively on early detection and chemoprevention of lung cancer. He has successively completed several Phase II clinical trials on lung cancer chemoprevention sponsored by the US National Institute of Health/National Cancer Institute. He is currently the Principal Investigator of two ongoing Phase IIb trials on Green Tea and A Chinese Herbal Preparation called ACAPHA.

Presentation title:

Herbal Agents for Lung Cancer Prevention

Abstract: Lung cancer is the commonest cause of cancer death worldwide. Over one million people die of lung cancer each year. Long-term heavy smokers carry a significant lifetime lung cancer risk despite smoking cessation. Given the large number of current and former smokers, and the increasing incidence of lung cancers among women, lung cancer will remain a major health issue for decades to come. Chemoprevention, using natural or synthetic compounds that can regress existing preneoplastic lesions, prevent the progression of these lesions to cancer, or prevent the development of new lesions is an important strategy to reduce the incidence and mortality of lung cancer. Despite over two decades of efforts, an effective chemopreventive agent has not yet been identified because up until recently, clinical trials have been designed based on observational and pre-clinical studies using single agents. Lung cancer involves alteration of multiple gene expression pathways. A different approach using a combination of agents with activity in different pathways is needed.

Anti-Cancer AND Preventive Herbal Agent (ACAPHA) is a TCM product prepared from 6 botanical agents. It has anti-proliferative, anti-inflammatory, differentiation-inducing and immune modulation activities. Polyphenon E is a standardized decaffeinated tea preparation. Tea is second most commonly consumed beverage in the world second to water. It has putative lung cancer prevention effects but its efficacy has never been tested in randomized double-blind, placebo controlled study. Both agents are currently undergoing Phase IIb clinical trials sponsored by the US National Institute of Health/National Cancer Institute for chemoprevention of lung cancer in former heavy smokers. The clinical trial approach incorporating modern technologies to evaluate the safety and efficacy of these products will be discussed.

Francis C.P. Law Institute of Health Research and Education & Department of Biological Science, Simon Fraser University. Burnaby, B.C. Canada. V5N 1S6

Biography

Dr. Francis C.P. Law is a Professor at the Department of Biological Sciences, Simon Fraser University (SFU). He also serves on the editorial boards of the American Journal of Chinese Medicine and the Journal of Integrative and Complementary Medicine. Dr. Law is a member of the Pharmacological Society of Canada, Society of Toxicology of Canada and the American Society of Pharmacology and Experimental Therapeutics. He is also a founding member of the Natural Health Products Research Society of Canada. Dr. Law completed his Bachelor and Master of Science Degrees in Chemistry at the University of Alberta. From here he went on to complete his Ph.D. at the College of Pharmacy, University of Michigan. Dr. Law had held many positions during his career including a Visiting Fellowship at the Pharmacology/Toxicology Branch of the US National Institute of Environmental Health Sciences (NIEHS). In 1975, Dr. Law was appointed an Assistant Professor at the College of Pharmacy, Dalhousie University. He was promoted to Associate Professor before relocating to SFU and found the Environmental Toxicology Program at the Department of Biological Sciences in 1983. Dr. Law has received numerous research grants and contracts from agencies such as the CIHR (formerly MRC of Canada), US Food and Drug Administration and NIH to support his research studies. He has published over 150 scientific papers and presentations in areas related to toxicology, drug metabolism and pharmacokinetics. Dr. Law's current research interests include pre-clinical and clinical development of prescription drugs, biopharmaceuticals, nutraceuticals and natural health products.

Presentation title: The use of computer simulation to predict natural health product pharmacokinetics: the soy isoflavones experience.

Short Abstract: The objective of the present study was to use a physiologically based pharmacokinetic (PBPK) model to predict the overall plasma and tissue kinetic behavior of genistein and daidzein, the active components of soy beans, in rodents and humans. Model performance was assessed by comparing the model-predicted plasma concentration-time profiles of the soy isoflavones with those observed experimentally in mouse, rat and human. PBPK modeling is an inexpensive and less time consuming

approach to obtain pharmacokinetic information on Chinese medicinal herbs or natural health products.

Prof. P.C. Leung

Biography

Professor Leung Ping Chung, OBE, JP, Hon DSSc, DSC, MBBS, MS, FRACS, FRCS(Edin), FHKCOS, FHKAM(Orth); is Professor of Orthopaedics & Traumatology, Faculty of Medicine; Director of Centre for Clinical Trials on Chinese Medicine; and Chairman of the Management Committee of the Institute of Chinese Medicine, The Chinese University of Hong Kong.

Professor Leung's research areas including Orthopaedics, Osteoporosis, Microsurgery Health, Traditional Chinese Medicine and General Education. He is also the author of over 300 scientific manuscripts in journals and 17 books. Examples of publication related in Chinese medicine include: "A Comprehensive Guide to Chinese Medicine", "Book in preparation: A Scientist View on Traditional Chinese Medicine", "Limb Salvage for Diabetic Ulceration with Traditional Chinese techniques", "Treatment of Low Back Pain with Acupuncture" etc. In addition, Professor Leung has also been appointed as editor of 5 International Journals since 1982.

Professor Leung has been awarded many different kinds of honors, such as Far Eastern Economic Review – Asian Innovation Silver Award (2000), Order of the British Empire (1995) and Liston Victoria Jubilee Prize by Royal College of Surgeons (1990).

In his capacity of the Chairman of the Management Committee of the Institute of Chinese Medicine, Professor Leung has put enormous efforts in modernizing traditional Chinese medicine. He is the Co-Convener of the Clinical Trials Section and has adopted the Efficacy Driven Approach in Clinical Trials. Currently, there are more than 40 clinical trials research projects underway in the Institute of Chinese Medicine. Extensive network has been developed internationally. One notable collaboration that goes on is a NIH international centre project with the participation of Harvard University, Keio University (Japan), Beijing University and Chinese University of Hong Kong.

Presentation title: A Practical Comprehensive Approaches to Chinese Medicine Research

Short Abstract: Traditional Chinese Medicine, as a form of complementary / alternative medicine is widely used in the Chinese community and even outside the Chinese community in recent years. The need to obtain objective proofs for the efficacy of various herbal preparations is therefore genuinely required so that on the positive consideration, further development could be supported.

Edmund M.K. Lui

Biography

Dr Lui, PhD., is Associate Professor in the Department of Physiology and Pharmacology, Faculty of Medicine & Dentistry, University of Western Ontario. He received his education and research training in Pharmacy, Pharmacology, and Toxicology from Dalhousie University and the National Institute of Environmental Health Sciences. He is the Founding Editor of the Journal of Complementary and Integrative Medicine (Berkeley Electronic Press). He served on the Expert Advisory Committee on Complementary Medicine of the Therapeutic Product Programme of Health Canada (1997-2000).

Dr. Lui's research focuses on elucidating the mechanisms of action of herbal products to provide the pharmacological plausibility for their medicinal use. Research is targeted at herbal medicines for the treatment of cancer, arthritis and cardiovascular diseases.

Various *in vitro* (cell/organ culture, organ-bath) and *in vivo* experimental models are used to study treatment effects on angiogenesis, metastasis, inflammation, immunological functions, atherosclerosis, and vascular reactivity. Chemical, biochemical, histological, intravital videomicroscopic and molecular biological techniques are used to examine the sites and mechanisms of action of selected products. These studies contribute to the evidence-based practice of herbal medicine as well as the development of pharmacological markers or bioassays for the standardization of natural health products.

Dr. Lui has been active in the educational aspects of complementary medicine in undergraduate medical curriculum and he is currently a member of the Executive Committee of the National Working Group on Complementary and Alternative Medicine for Undergraduate Medical Education in Canada. He offers a course in the Pharmacology and Toxicology of Natural Sourced Medicines at the University of Western Ontario.

Presentation title: The vasculature as a target for Chinese herbs with anti-inflammatory and antiangiogenic properties.

Abstract:

The vasculature has been recognized as a tissue involved in many important diseases; we will discuss two areas of our research targeting blood vessels. We have used an organ-bath based bioassay to examine changes in vascular reactivity induced by inflammatory and cytotoxic stimuli on aortic tissues grown in culture and the protective effect of extracts derived from Danshen and *Tripterygium wilfordii* Hook on vascular injury. Angiogenesis plays an important role in cancer metastasis. We will discuss our experimental approach in studying the anti-angiogenic and antimetastatic property of the polysaccharides isolated from *Coriolus vesicolor*.

Dr. Pingniang Shen

Biography

Dr. Shen Ping Niang completed her undergraduate studies in Pharmaceutics at East China University of Science and Technology in 1978, and had a MSc. Degree from Shanghai University of Traditional Chinese Medicine (1987). Dr. Shen passed qualification of Pham. D. in 1997. Presently, she is CEO of National Engineering Research Center for Chinese Traditional Medicine and professor of East China University of Science and Technology. As principal investigator, Dr. Shen contributed greatly into R&D of Traditional Chinese Medicine (TCM) in the past 20 years. She is commissioner of the committee of experts for programs of TCM, commissioner of China pharmacopoeia committee, commissioner of National Committee on the Assessment of the Protected Traditional Chinese Medicine Product P.R.C. She has more than 20 publications and professional presentations in research area of TCM.

Presentation title: The applications of recent developed technologies of isolation, purification, and anti-moisture in research and development of Traditional Chinese medicines

Short Abstract: Ones of the challenges for evidence-based research of herb medicines are the techniques of isolation, purification, and anti-moisture of the tested herb medicines. The speaker will present current developed techniques of isolation and purification by using supercritical fluid extraction (SFE), sonic extraction, microwave-assisted extraction, and super high-pressure extraction, and anti-moisture techniques by using modern granulating and pan-coating. The detail for using these techniques for ensuring the quality of test article is also discussed by presenting the actual cases.

Dr. Joseph Tai

Biography.

Dr. Joseph Tai, Ph.D, is Associate Professor in the Department of Pathology and Laboratory Medicine, University of British Columbia; and Associate Director of the Complementary Medicine Research/BC's Research Inst. for Children's & Women's Health. He also as VP Development of Global Cancer Strategies. From 1993-95 he served as the Science Editor of the Global Child Health News & Review/Global Child Health Society.

His research interests focus on natural health products research and complementary/alternative medicine in the treatment of chronic disorders. In addition, he has extensive experience in research involving cell transplantation, diabetes, and tumor immunology.

Presentation title: What does it take to bring a traditional Chinese medicine to clinical trial in North America?

Short abstract:

Before anyone can initiate clinical trial of traditional Chinese medicine in humans in Canada and the US, it must provide data on the product to Health Canada, or Food and Drug Administration (FDA) in the US, requesting approval to begin testing. The

application called Clinical Trial Application (CTA) in Canada, or Investigational New Drug Application (IND) should contain sufficient Chemistry, Manufacturing, and Control (CMC) information, preclinical safety information, and description of the proposed human trial