ASIA PACIFIC CHAPTER
2013 Outstanding Outside North America Chapter of the Year

Association of Clinical Research Professionals (ACRP) Asia Pacific Chapter
国际临床研究专业人员协会 - 亚太分会
Annual Research Symposium 2013
"Clinical Research Regulatory Systems"

Mira Hotel Hong Kong, Tsim Sha Tsui (TST), Kowloon, Hong Kong

Saturday, 9 November 2013

8:15 – 8:45 Registration and Continental Breakfast

8:45 Opening Remarks

Dr. Bing-wen Soong MD, PhD, FAAN, CPI (宋秉文教授), Professor and Chairman, Depts. of Neurology, National Yang-Ming University (國立陽明大學) Taipei Veterans General Hospital (台北榮民總醫院)

9:00 – 9:45 Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects

Dr. C. K. Kwan, Certified Physician Investigator and Specialist in Clinical Oncology, Hong Kong

9:45 – 10:45 Introduction to FDA's international work and the China Office

10:45 – 11:00 Refreshment Break

11:00 – 12:00 High-Level Overview of FDA's Bioresearch Monitoring Program Regulatory Requirements - the China Region

Nicole Taylor Smith, JD, Assistant Country Director, U.S. Food and Drug Administration (FDA), China Office [美国食品和药物管理局 (FDA) 中国办事处]

12:00 – 1:00 Lunch with the FDA, and Q/A Session

1:00 – 1:45 Overview of CFDA (国家食品药品监督管理总局 的概述)

1:45 – 2:15 Oversight of Medical Device Research by CFDA (監測醫療器械研究)

Yuan Bin Hua, MD, Chief, Medical Device Regulation (醫療器械監管處袁斌華處長), Drug Administration of Shenzhen Municipality (深圳市藥品監督管理局), China Food and Drug Administration (国家食品药品监督管理总局醫療器械)

2:30 - 3:00 Global and Asian Medical Device Regulatory Affairs

Bryan So, Senior Consultant, Biomedical Engineering Unit, HK Productivity Council

3:00 – 3:15 Refreshment Break

3:15 – 4:00 Globalization of Clinical Research in Hong Kong: The Regulatory Systems

Professor Benny Zee, Assistant Dean (Research) of Faculty of Medicine, Professor and Head of Biostatistics, School of Public Health, Chinese University of Hong Kong

President's Message

ACRP Asia Pacific Region (ACRP-AP) is a 501(c)3, and a non-profit organization duly registered with the Hong Kong government, serving Asia's clinical research professionals. With our new board of officers, ACRP-AP has developed different educational programs and social networking events for our geographically diverse area in 2013-2014. We are proud to present our first educational symposium on various regulatory systems in the region. I hope you will take home information, guidance and insights valuable in your research endeavors.
Enjoy the day.
Joanna Louie, Pharm.D., CCRC

Program Description

The increase in IND and CFDA clinical research studies in the Asia Pacific (AP) region has drawn interest in clinical research professionals from all sides including clinical investigators, administrators and legislators who are at stake. The regulatory and administrative requirements associated with clinical trials have changed dramatically in the last several decades, as has the increasing complexity of the science being regulated. In order to ensure the ethical conduct of human subject research in accordance with federal and global regulations, this program provides a platform for clinical research professionals in AP region to refresh themselves, to gain knowledge about the various regulatory systems and to share insights with each other.

Program Learning Objectives

- Discuss the emerging importance of Asia Pacific Region as a research and development (R & D) hub
- Understand the responsibilities of a new drug or device investigator to protect the welfare of the research subjects
- Demonstrate knowledge of the region's different regulatory requirements and their use in clinical trials

Conference Location

MIRA Hotel Hong Kong
18th Floor, Ball Rooms 4 and 3
118 Nathan Road,
Tsimshatsui (TST)
Kowloon, Hong Kong

香港美丽华酒店
香港九龙尖沙咀
弥敦道118号18楼

PARKING ARRANGEMENT
Complimentary parking coupon of twelve (12) hours at Miramar Shopping Center car park. An additional hour for regular car parking service is HKD$30 net, valet parking service is priced at HKD$50 net.

Target Audience

Physicians, Investigators, Biomedical Engineers, Device Manufacturers, Pharmaceutical Multi-National Companies, Clinical Research Coordinators, Clinical Research Associates, Project Managers, Ethics and Human Research Administrators, Compliance Professionals, and anyone working in Clinical Research.

College / Association (CME/CPD Accreditations)	Points
Hong Kong College of Physicians	5
ACRP Re-certification Contact Hours	6.5
Continuing Medical Education (CME) Credits from ACCME	To be confirmed
CME have been applied from the respective colleges. Please check for updates: www.acrpnet.org/AsiaPacific	

Cost

Members of ACRP and IEEE / Individual of a Group of 3 or more	**USD 90**
Academic / Government / Health Care / Sponsors' Affiliates	**USD 120**
Industry	**USD 150**

This fee includes the presentations, the special session Lunch with the FDA, course material, and networking. Breakfast, refreshment breaks, AND lunch are included.

About the Speakers (in the order of their presentations)

Dr. Bing-wen Soong (宋秉文教授), MD, PhD, FAAN, CPI is Professor and Chairman of the Depts. of Neurology in both National Yang-Ming University (國立陽明大學) and Taipei Veterans General Hospital (台北榮民總醫院). He finished his medical education and his double fellowships in the U.S.A. An avid researcher in academic medicine, Dr. Soong serves as the Physician-Investigator and CPI Liaison for ACRP Asia Pacific Region.

Dr. Chung-Kong Kwan is a fellow of the Hong Kong College of Radiologists and the Royal College of Radiologists. He is a specialist in clinical oncology. He has particular interest on thyroid cancer, lung cancer, and head and neck cancer. He is a Certified Physician Investigator (CPI) and has been the investigator of various international and local multi-center clinical trials (phase II, III and IV) on cancer treatment in the past ten years. He is a Board member and Investigator Liaison of the ACRP Chapter of Asia-Pacific Region of Hong Kong, Singapore and Taiwan. He also teaches research personnel on Good Clinical Practice (GCP) which regulates and guides human medical research. Dr. Kwan has been a reviewer of the high impact journal International Journal of Radiation Oncology, Biology, and Physics. He is also a Master Project Manager certified by the American Academy of Project Management.

Nicole Taylor Smith, JD is Assistant Country Director, Beijing, China, United States Food and Drug Administration (FDA). Prior to coming to the FDA China Office, Ms. Smith was the Associate Chief Counsel for Medical Devices, US FDA for 3 years. She was with the law firm King & Spalding at Washington DC before joining the FDA. Ms. Smith went to the International School of Kuala Lumpur. She obtained her BA from Vanderbilt University and J.D. from Vanderbilt University Law School.

Dr. YUAN Bin Hua (袁斌華處長) Section Chief, Medical Device Regulation Section (醫療器械監管處), Drug Administration of Shenzhen Municipality (深圳市藥品監督管理局), China Food and Drug Administration (國家食品藥品監督管理總局) has been working for more than 10 years on medical device regulation at Shenzhen Drug Administration, since the establishment of China FDA. As an experienced auditing expert, he often takes part in CFDA's different meetings for formulating or revising the law and regulations. He is familiar with all medical device rules of CFDA, including the rules on registration, selling, using and manufacturing of medical devices. He is also the training professor of CFDA's advanced training college. Dr. Yuan has vast experiences and ideas regarding China medical device supervision.

Bryan So is the Executive Deputy Secretary General of the Asian Harmonization Working Party (AHWP) on the harmonization of medical device regulatory. As the Senior Consultant in the Biomedical Engineering Unit of the Hong Kong Productivity Council (HKPC), he provides consultancy services to the medical device industry in medical device design verification and validation, pre-market submission (USFDA 510(k), MHRA, CFDA, etc.), supply evaluation, clinical evaluation, quality management system (ISO13485, GMP, GDP, etc.), and risk management system (ISO14971), among his many other functions. Bryan is deeply involved with many biomedical organizations including the Hong Kong Institution of Engineers (HKIE-BMD), the IEEE Engineering in Medical and Biological Society Hong Kong-Macau Joint Chapter (IEEE-EMBS) and the Hong Kong Medical and Healthcare Device Industries Association (HKMHDIA).

Prof. Benny Zee is Assistant Dean (Research) of Faculty of Medicine, and Professor and Head of the Division of Biostatistics in the School of Public Health and Primary Care, Chinese University of Hong Kong (CUHK). Professor Zee obtained his Ph.D. in Biostatistics from the University of Pittsburgh, USA in 1987. Prior to coming to Hong Kong, he worked at the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) as Senior Biostatistician. Previously he worked at the Department of Community Health and Epidemiology, and at the Department of Mathematics and Statistics of Queen's University, Canada.

Registration & Payment Method

❒ **Register Online and Pay Fees with Credit Cards** (PayPal account is optional, not required.)
Register NOW: http://www.acrpnet.org/asiapacific.aspx

❒ **Register by EMAIL and Pay Fees by Electronic Transfer**
(1) EMAIL the **name, address** and **email** of each attendee to: ACRPasiapacific@gmail.com
(2) Please wire remittance to: Bank of Communications, Hong Kong
Account No. **027 578 93016220**
Account Name: Association of Clinical Research Professionals (Please do not use abbreviations.)

PROPER IDENTIFICATION IS REQUIRED. Please bring your email confirmation to the event.

Terms and Conditions

1. Registration is confirmed **only upon receipt of payment**. All successful registrations will receive a confirmation from ACRP-Asia Pacific Region via e-mail. ACRP reserves the final right of decision if there is any dispute.
2. Cancellation Policy: No refunds are made upon confirmation. Substitutes are acceptable with written notice to ACRP-Asia Pacific Region at least 2 days prior to the event date of November 9, 2013.

Hotel Booking Information (旅店)

Hotel rooms are very tight in Hong Kong, especially in the popular area of TST. Please book your room early.

Hotels near The Mira	Address	Quoted Price for Friday 11/9 (as of 9/5/2013)	Reservations
The Mira Hotel (Conference Hotel) www.themirahotel.com	118 Nathan Rd., Tsim Sha Tsui (TST), Kowloon, Hong Kong	HKD 2,150 (USD 277)	*Toll Free Numbers*: Australia – 1800 054 132, China – 400 120 2300, Singapore – 8008 523 808. Please ask for Mr. Wing Shek.
Hyatt Regency, Tsim Sha Tsui 15 minutes walk to The Mira.	18 Hanoi Rd, TST, Kowloon, Hong Kong	HKD 2,350 (USD 303)	Tel: + 852 2311 1234 www.hyatt.com
B P International Hotel 10 minutes walk to the Mira.	8 Austin Road, TST, Kowloon, Hong Kong	HKD 1,309 (USD 168)	Tel: +852 2525 5696 http://www.bpih.com.hk

Certificate of Participation

Certificates of participation will be available for collection at the Registration Counter on the day of the Symposium. Membership is not required to register for this event / to get contact hours.

Sponsors and Declaration: No Influence on the Content of the Presentations

This symposium is co-organized by The Hong Kong Productivity Council (HKPC).

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Supporting Organizations:

香港醫療及保健器材行業協會
Hong Kong Medical and Healthcare Device Industries Association

EMB IEEE
Hong Kong – Macau Joint Chapter

世界华人生物医学工程协会
World Association for Chinese Biomedical Engineers

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

HONG KONG DOCTORS UNION
香港西醫工會

SAMD

香港城市大學
City University of Hong Kong

HONG KONG ASSOCIATION OF MEDICAL LABORATORIES LIMITED
香港醫務化驗所總會

Hong Kong Paediatric & Adolescent Dermatology Society
香港兒童及青少年皮膚醫學會

APAI HK
Association of Professional Aestheticians International

HKAMP

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