

**2011 年亞太藥品及醫療器材優良審查規範研討會  
暨『亞太經濟合作藥政管理聯繫網會議』**

**2011 APEC Good Review Practice Workshop on Medical Products and  
the 9th Conference of APEC Network on Pharmaceutical Regulatory Science  
Preliminary Program**

Industries and the public are welcome to register with one-day fee for the sessions on Oct. 15, 2011. Attendees may register online at [www.cde.org.tw](http://www.cde.org.tw) or [www.cde.org.tw/apec](http://www.cde.org.tw/apec).

Saturday, October 15, 2011		
Time	Subjects	Speakers / Panelists
8:30-9:00		Registration
9:00-9:15	Opening Remarks	<b>Wen-Ta Chiu, M.D., Ph.D.</b> Minister, Department of Health, Chinese Taipei
9:15-9:30	Group Photo	All Speakers, Moderators and VIPs
<b>Keynote Speech</b> <b>Moderator: Jaw-Jou Kang, Ph.D.</b> Director General, Food and Drug Administration, Department of Health, Chinese Taipei		
9:30-10:00	Promoting an Effective Approach to Harmonization and Cooperation through GRevPs	<b>Mike Ward</b> Chairman, APEC LSIF Regulatory Harmonization Steering Committee (RHSC) and International Programs, Therapeutic Products Directorate, Health Products and Food Branch, Health Canada
10:00-10:30	Coffee Break	
<b>Session F. Good Review Practices on Medical Products</b> <b>Moderator: Churn-Shiouh Gau, Ph.D.</b> Executive Director, Center for Drug Evaluation, Chinese Taipei		
10:30-11:30	Report I. GRevPs Experience Share by Various Economics	<b>Carole C. Carey</b> Director, International Relations and External Affairs Staff, Medical Devices, Coordinator for Global HBD (Harmonization By Doing) Programs, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, USA <b>Constance Campbell</b> Section Head-General and Restorative Devices Section, Medical Devices Bureau, Therapeutic Products Directorate, Health Canada <b>Hee Sung Kim</b> Korean Food and Drug Administration (KFDA), Republic of Korea <b>Chi-wan Chen, Ph.D.</b> FDA Alumni Association International Network (FDAIA) <b>Chao-Yi (Joyce) Wang, M.Sc.</b> Senior Specialist, Division of Drugs and New Biotechnology Products, Food and Drug

		Administration (TFDA), Department of Health, Chinese Taipei <b>Imelda Halim</b> Senior Regulatory Specialist, Pharmaceuticals & Biologics Branch, Pre-Marketing Division, Health Products Regulation Group, Health Sciences Authority (HSA), Singapore
11:30-12:00	Report II. Scorecard and Measurement of GRevP for Regulatory Agencies- GRevP Survey Report	<b>Neil McAuslane, Ph.D.</b> CIRS - Centre for Innovation in Regulatory Science
12:00-13:30	Lunch	
<b>Session F. Good Review Practices on Medical Products (continued)</b> <b>Moderator: Jin-Ding Huang, Ph.D.</b> Professor and Director, Institute of Clinical Pharmacy and Pharmaceutical Sciences, College of Medicine, National Cheng Kung University, Chinese Taipei		
13:30-14:00	Report III. GRP Roadmap under the Strategic Framework for Regulatory Convergence for Medical Products by 2020	<b>Li-Ling Liu, M.S., R.Ph.,</b> Director, Division of Medical Devices and Cosmetics Food and Drug Administration Department of Health, Chinese Taipei
14:00-14:30	Summary of Sessions A-D for Good Review Practices on Medical Products	<b>Churn-Shiough Gau, Ph.D.</b> Executive Director Center for Drug Evaluation, Chinese Taipei
14:30-15:00	Coffee Break	
<b>Session G. Industry Responses</b> <b>Moderator: Hui-Wen Cheng, Ph.D.</b> Chief Operating Officer, Sinphar Pharmaceutical Co., Ltd., Chinese Taipei		
15:00-16:30	Industry's role, responsibilities, expectations from Pharmaceutical Sector Perspective	<b>Janet Vessotskie,</b> Pharmaceutical Research and Manufacturers of America (PhRMA)
	Industry's role, responsibilities, expectations from Medical Device Sector Perspective	<b>Representative invited,</b> Advanced Medical Technology Association (AdvaMed)
<b>Session H. Panel Discussion</b> <b>Moderator: Ming-Neng Shiu, M.D., Ph.D.</b> Deputy Director-General, Food and Drug Administration, Department of Health, Chinese Taipei		
16:30-17:20	Panel Discussion	<b>All Speakers</b> <b>Zili Li, M.D., M.Ph.</b> Co-chair for the FDA Alumni Association International Network (FDAAA) <b>Duu-Gong Wu, Ph.D.</b> FDA Alumni Association International Network (FDAAA)
17:20-17:30	Closing Remarks	<b>Jaw-Jou Kang, Ph.D.</b> Director General, Food and Drug Administration Department of Health, Chinese Taipei
17:30	Adjournment	