First Announcement of the Conference on International IVD Medical Devices Regulations

Regulation of medical devices is intended to safeguard safety and quality whilst ensuring timely access to beneficial new products. The current regulatory landscape for diagnostic tests in developing countries with limited resources acts as a disincentive to innovation and a barrier to new diagnostic products entering those markets. Weak regulation allows poor quality tests to be marketed and inefficient regulation causes unnecessary delay and increases costs. Setting international standards and streamlining the regulatory process for diagnostic tests could diminish the regulatory burden, lower costs and reduce delays. Hence, regulatory harmonization bodies like the late Global Harmonization Task Force (GHTF), the Asian Harmonization Working Party (AHWP), the Pan-African Harmonization Working Party (PAHWP), Latin America Diagnostic Association (ALADDIV) and so on have been working on the regulatory framework for IVD medical devices.

In this conference, regulators from all over the world are invited to give updates on IVD medical device regulations. Representatives from the AHWP, PAHWP and ALADDIV will also present the current regulatory convergence status in Asia-Pacific, Africa and Latin America. By far, regulatory convergence initiatives in these regions focus mainly on a common registration file, reducing the duplication in quality management system audit, reducing duplication in clinical trials, and standardized post-market surveillance practices. These priorities have been identified and strategies are targeted to accelerate access to quality diagnostic products for health. Experts from regulatory agencies, conformity assessment bodies and IVD medical device industry are invited to share their insight on the aforementioned initiatives.

Conference on International IVD Medical Devices Regulations	
Hosted by	Food and Drug Administration, Ministry of Health and Welfare
Organized by	Center for Measurement Standards / Industrial Technology Research Institute
Date	**Sep 16, 2013 (Monday)**
Venue	Room 201, National Taiwan University International Convention Center
Registration Deadline	**Sep 13, 2013 (Friday)**
Registration Fee	Free

Agenda：

Time	Topic	Moderator	Speaker
08:30-09:00	Registration		
09:00-09:10	Opening Remark		**Ms. Li-Ling Liu** Chair, AHWP WG1a / Director, Division of Medical Devices and Cosmetics, FDA, MOHW, Taiwan
09:10-09:20	Group Photo Taking		
Update on IVD Medical Devices Regulations			
09:20-10:10 *~5:00 minutes for each session*	China, European Union, India, Indonesia, Japan, Korea, Malaysia, Taiwan, Philippines, Thailand, USA	To be invited	Regulators are to be Invited
10:10-10:30	Tea Break		
Harmonization and Regulatory Convergence			
10:30-11:00 *~8:00 minutes for each session*	AHWP's Experience Sharing	**Mr. Jeffrey Chern** Co-chair, AHWP WG1a / Center for Measurement Standards, ITRI, Taiwan	To be Invited
	EAC/PAHWP's Experience Sharing		To be Invited
	ALADDIV's Experience Sharing		To be Invited
Common Registration File for IVD Medical Devices			
11:00-12:00	Experiences learnt from STED and CSDT		**Mr. Benny Ons** BD Europe, Belgium
	Comparison on MD STED, IVD STED and CSDT		**Ms. Shelley Tang** Stellar Consulting, Australia
	Use of EP and		

	recognized standards		
12:00-13:00	Lunch Break		
Clinical Evidence for HIV, Dengue, TB Diagnostics			
13:00-14:30	Clinical Performance Evaluation & GCP	To be Invited	**Prof. Rosanna Peeling** London School of Hygiene & Tropical Medicine, UK
	Clinical Evidence of Related Products		To be Invited
Quality Management System (QMS)			
14:30-15:30	Process Validation and QC/QA	To be Invited	**Dr. Jane Tsai** Biomedical Technology and Device Research Labs, ITRI, Taiwan
	QMS for IVD Medical Devices		**Mr. Albert Li** Center for Measurement Standards, ITRI, Taiwan
15:30-15:45	Tea Break		
Post Market Surveillance			
15:45-16:45	Addressing specific needs of PMS for IVD medical devices	**Mr. Albert Poon** London School of Hygiene and Tropical Medicine	Regulator from Health Canada will be Invited
	Experiences learnt from NCAR & SADS		To be Invited
	Post market inspection and testing for IVD medical devices		To be Invited
16:45-17:00	Closing Remark and Q & A Session		**Ms. Li-Ling Liu** Chair, AHWP WG1a /

		Director, Division of Medical Devices and Cosmetics, FDA, MOHW, Taiwan

Conference on International IVD Medical Devices Regulations

Affiliation：_____	Contact Person：_____
Address：_____	Contact Phone No.：_____
_____	Contact Fax No.：_____

Name	Affiliation	Tel.	E-Mail (For email confirmation)

* The conference will be conducted in English.
* Completed registration form should be send to us by email or fax before Sep 14, 2012 for enrolment. Registration will be on first come first serve basis.
* Registration Website：
  https://docs.google.com/forms/d/1Chf3cbRuHVCigfEZC4RvEFPDIcWCTWopHDhRVSmsLdk/viewform
* Contact person：Ms. Jamie Liu, Center for Measurement Standards, Industrial Technology Research Institute

  TEL：(03) 5743771 ； FAX：(03) 5734092 ；
  E-mail：cs1108@itri.org.tw
* Travel information for National Taiwan University International Convention Center：
  http://www.thcc.net.tw/en/about04.htm