



## **AHWP TRAINING PROGRAM**

### **Background**

Medical Device is a highly regulated item. Technical requirement and regulation is changing rapidly. Many Asian countries are developing their regulatory system and more regulatory expertise is required. During the 2005 Asian Harmonization Working Party (AHWP) meeting, members agreed the need to develop a systemic training program and Hong Kong industry was assigned to lead the project.

### **The Training Proposal and Updates**

Hong Kong Industry worked closely with AHWP Technical Committee (TC) to draft a proposal and presented during 2006 AHWP meeting in Korea. The amended proposal was also posted on AHWP websites for further comment and the responses are positive so far. Detail of the proposal can be found from the following link;

<http://www.asiahwp.org/index.php?page=article&id=215>

In order to provide systemic support and for Hong Kong Industry (Jack Wong is the project leader) to develop the finalized training proposal, TC also formally formed a working group (WG06) with Albert Poon as the Chairman and Jack Wong as the vice-Chair to provide support for the training.

### **Training platform needs AHWP member economy representatives' inputs**

Representatives from two (2) universities are invited to present their training proposal for TC comment during last TC meeting on 27 April in Hong Kong. They are Northeastern University (NEU) from US and University of Hong Kong (HKU) from Hong Kong.

Members of the TC meeting participants were provided a list of criteria for proposal selection. The criteria mentioned are

- regulatory knowledge of University
- reputation of University
- expense/investment require and revenue return
- ease of use of the on-line platform
- course development time
- independence

- intellectual property ownership for course content

A comparison table showing 2 universities inputs on the above 7 criteria was attached.

### Next steps

1. AHWP Member Economies Representatives (regulator and industry) would require to provide scoring and comments on the table and email to Mr Jack Wong at [jack.wong@bsi-global.com](mailto:jack.wong@bsi-global.com) before 31<sup>st</sup> July 2007.
2. Get final AHWP approval during the 12<sup>th</sup> AHWP Meeting in China and start course promotion/enrolment in October 2007
3. Create project team with the selected University, supporting organization/experts (US FDA, RAPS, TORPA, Virginia Polytechnic Institute and State University), AHWP Member Economies Representatives, and WG06 in TC by the end November 2007
4. Start course material preparation in December 2007 – February 2008
5. On-line course aim to be started at 2<sup>nd</sup> Quarter of 2008