
# Regulatory Training for AHWP Member Economies

27 April 2007

# WG06 AGENDA

1. Background
2. Progress
3. Presentation by NEU (moh-elearning.com)
4. Q & A
5. Presentation by HKU (SOUL platform)
6. Q & A
7. Floor Discussion and Views for proposal enhancement.
8. Way Forward

(Followed by a short presentation on application of on-line regulatory training programme for MD incident reporting procedures – B&L)

# Background

Medical Device is a highly regulated commodity. Technical requirement and regulation is changing rapidly in this arena. Commencing 2000, many Asian countries are developing their regulatory system and more and more regulatory expertise is required.

During the 2005 Asian Harmonization Working Party (AHWP) meeting in Bangkok, members agreed the need to develop a systemic training program and HK industry was assigned to lead the project.

# Progress

1. HK Industry and TC presented a draft proposal during 2006 AHWP meeting in Korea.
2. Amended proposal posted on AHWP website for further comment and the responses are very positive.
3. An on-line formal training will be developed.
4. Will provide the academic and professional recognition for participants; course is devised to award a university diploma.
5. Aim to have a 300 hours (est. 1-year) part-time on-line Professional/Executive Diploma Course in Asia Regulatory Affairs. A formal Education Institute will be invited to manage the on-line training framework.

# Invited Presentations

1. Northeastern University
   School of Professional & Continuing Studies (SPCS)
   - Eric KUPFERBERG, Assistant Dean
   MOH-elearning.com : Katy PATTERSON

2. University of Hong Kong
   School of Professional & Continuing Education (SPACE)
   - Stephen WU,
     Head, Division of Health and Applied Sciences

Coffee Break first (10 min) and then floor discussion

## Floor Discussion – Items of Interest / Concerns Raised

1. Course content to be developed by a dedicated subgroup of WG06, and any voluntary support from other univ., companies and resource persons;
2. Practical attachment to regulators to be considered;
3. Accumulated knowledge from univ can provide is essential e.g. FDA or EU module (refer para 1 above); Partner with some RA knowledge
4. Participation from industry where the most updated knowledge are available; refer to the Asean survey; Asian flavor;
5. Development funding to be requested to regulators or industry thru' AHWP
6. IP and ownership should be the owner or AHWP;
7. Split levels of competency; cert is basic level and participants should be able to see progressing levels;
8. Include topics on International Trade and Health such as WTO, FTA/ agreements / TBT /TRIPS;

# Floor Discussion (Cont'd)

Items of Interest / Concerns Raised

7.

# Recommendation

Way Forward

1. .
2. .
3. .
4. .

# Experience Sharing

Presentation on application of on-line regulatory training programme for MD incident reporting procedures

- Sharon ADAMS, B&L

(A comprehensive presentation by Sharon will be invited to the Chendu Meeting in Oct 2007)

Thank you for attending WG06;

Next back to TC main meeting