11th ASIAN HARMONIZATION WORKING PARTY (AHWP) MEETING

Olympic Parktel Seoul Korea

15 September 2006

DRAFT
AHWP TC Committee
Asia Regulatory Training Proposal

1. Introduction

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 are required. During the 2005 AHWP meeting, members agreed the need to develop a systemic training program for approval during 2006 AHWP meeting in Korea.

2. Aims and Objectives

In order to fit the training need and schedule of different members in Asia, an on-line formal training will be developed.

To ensure the training content is the most up-to-date, experts within AHWP will provide the technical knowledge/content of the training.

A formal Education Institute will be invited to manage the on-line training framework and provide accreditation. We aim to have a 1-year part-time Professional Diploma Course in Asia Regulatory Affairs

This training course aims to provide participant who plans or takes a career in the medical device industry or the regulatory sector~~participants~~ with a fundamental understanding of regulatory framework, requirement, assessment process and technical trend. After the course, participants should:

a. have improved their knowledge of regulatory affairs and quality management systems in major countries (e.g. US and EU) and ISO as the core knowledge;
b. have in depth knowledge of Asia regulatory affairs;
c. have developed an understanding of role and operation of AHWP and GHTF;
d. be more confident and competent in providing regulatory service to government or private institutions.

3. Entry Requirement

Students should :

a. have a bachelor degree preferably in science subject; ***OR***

b. more than 2 years of regulatory related experience.

4. Course Duration and Structure

The course consists of 3 core compulsory modules on US regulatory affairs, EU regulatory affairs and AHWP introduction; Optional modules on regulatory affairs in different Asia countries, and soft skills e.g. communication skill, project management skill etc. In addition to this, students need to complete a 30-minutes on-line examination after 3 core modules plus at least 1 optional module, and a 2-hour examination held at AHWP annual meeting each year in order to obtain the completion the certification award (the Professional Diploma granted by a training education institute)

A tentative list of topics covered in each of the modules is shown below.

US FDA Medical Device Regulatory Affairs

- FDA framework
- Quality System Regulation, Medical Device Regulation and Classification system
- Medical Device approval process
- Post marketing issues, clinical trials, etc.

E~~urope~~U ~~FDA~~ Medical Device Regulatory Affairs

- EU framework
- Quality Management system and Risk management
- Medical Device Regulation and Classification system
- Medical Device approval process
- Post marketing issues, clinical trials

~~AHWP operation~~International Co-operation Efforts

- ~~GHTD~~ The role of GHTF and AHWP ~~role~~
- Asia Regulatory overview and trend
- STED

Selective module on regulatory affairs of specific county~~role~~

- Ministry of Health framework
- Medical Device Regulation and Classification system

- Medical Device approval proecess
- STED

~~**Asia Country specific Regulatory Affairs e.g. Hong Kong**~~

- ~~HK DOH framework~~
- ~~Medical Device Regulation and Classification system~~
- ~~Medical Device approval process~~

Regulatory related soft Skills e.g. Project Management

- Definition of Project
- Techniques and tools of project management

5. Medium of Teaching

It will be a on-line training with material in English and may be supplemented with face-to-face training during AHWP meetings.

6. Teaching Schedule

It will be an on-line training

7. Assessment and Award

Trainees will be assessed by a combination of on-line examination at the end of the module and written examinations during AHWP meeting every year, weighted at 30% and 70%, respectively. Distinctions will be awarded to candidates with an overall score of 80% or above. Examination papers will be set by teachers of the course and moderated by an External Examiner. Examination results will be approved by the Board of Examiners, the membership of which is listed in Appendix A. Students who have failed in the written examination or in the continuous assessment may be allowed to be re-assessed. . Failures again in the re-assessment may be permitted to repeat the whole course and re-assessed afresh. A student who wishes to defer his studies should submit a written application to the Academic Committee for consideration. The maximum period of registration is normally 3 years.

8. Award

Upon successful completion of all modules, students will be awarded the Professional Diploma in Asia Regulatory Affairs issued by the School of Professional and Continuing Education, University of Hong Kong.

9. Quality Assurance

With appropriate attention to teaching and learning quality, the academic and professional standards of the programme will be maintained.

9.1. Feedback from students

Formal feedback from students can be collected by course evaluation conducted half-way and at the end of the programme. The HKU SPACE evaluation form is used to collect comments, suggestions made by students on the quality of various aspects such as curriculum, course structure design, pedagogical design, teaching implementation quality, as well as the effectiveness of the course. Completed questionnaires as well as responses to open-ended questions are summarized and, where appropriate, statistically tabulated, and reported to both the teachers and the Course Team.

9.2. External Examining

An External Examiner who is an academic / professional expert in the discipline will be appointed. The External Examiner functions as the external expert to comment and advise on the standard of the course including all student assessment, such as assessment methods, assessment criteria, grading system and student performance standards.

9.3. Academic Committee

The Academic Committee will be set up to monitor and maintain the overall programme quality and academic standard. Its membership is listed in Appendix B.

9.4. Periodic Review

Notwithstanding the regular ongoing quality assurance mechanisms, the programme will be subject to a periodic review of greater depth to be conducted every three to five years after implementation. This provides an opportunity to have an overview and critical appraisal of the effectiveness of the course and to evaluate changes made over the past period of time.

10. Roles of AHWP and TC

To be discussed

Appendix A

Board of Examiners

Terms of Reference

I. Powers and Duties

The Committee shall

a. Before each examination is held, determine the principles to be adopted for the marking scheme, the manner in which performances in coursework should be judged and weighted, and the award of distinctions and credits where appropriate, and the methods and procedures by which the examiners shall carry out their duties.

b. Receive from the Chief Examiner lists of the examination and the assessment marks or grades of the candidates and consider these lists.

c. Receive and consider such representations as have been made by candidates concerning unusual circumstances arising during the course of the written examinations and/or continuous assessment which might have affected their performance.

d. Determine the results of the examinations.

e. Recommend successful candidates who have complied fully with the regulations be awarded the diploma/certificate.

f. Make a report on the assessment either if it appears desirable or if requested so to do by the Academic Committee of the programme, provided that the actual marks or grades (except in a form approved by the Board for Continuing and Education and Lifelong Learning) remain restricted to the Board of Examiners.

g. Decide upon those candidates who should be required to take a supplementary assessment, repeat the course(s) and present themselves for re-assessment, in accordance with regulations.

h. Recommend the discontinuation of candidates.

II. Membership

Chief Examiner (AHWP TC Chairperson)

AHWP Chairperson

Course leader (AHWP representative)

External Examiner (HKU SPACE representative)

Teacher Representatives

Appendix B

Academic Committee

I. Terms of Reference

1. To ensure the maintenance of academic standards of the programme generally, and specifically, to review and give advice on the teaching and learning processes regularly with particular reference to the following aspects:
   a. the admission criteria, procedures and the appointment of the Admission Committee or Admission Tutor(s);
   b. the programme structure, content, delivery and assessment;
   c. the criteria for appointment of teacher(s) on the programme;
   d. the criteria for appointment of external examiner(s) and/or external assessor(s);
   e. the student feedback on the programme quality and the teaching and learning processes;
   f. any other matters of academic concern

2. To consider where appropriate new programme proposals which are developed from the programme monitored by this Committee, with changes in only a minor portion (no more than 25%) of the curriculum. This will include new programmes leading to a new award level and/or nomenclature.
3. To advise the QAC generally on any matters concerning the quality of the overall programme.
4. To advise the Board for Continuing and Professional Education and Lifelong Learning generally on any matters concerning the overall programme.
5. To scrutinise the formal Annual Monitoring Report on the programme for submission to the QAC.
6. To report annually to the QAC and the parent bodies as required.

II. Membership

Deputy Director, SPACE (Chairman)
HKU SPACE Programme Leader
Course Co-ordinator (if appropriate)
Teacher Representatives
Representative from AHWP and GHTF
Representative from the University
Student Representative(s)