



**HKU SPACE**

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A Proposal To Partner with AHWP  
in offering  
A Training Programme in Medical Device Regulatory Affairs

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by

Stephen Wu, Ph.D.

Head of Health & Applied Sciences  
School of Professional & Continuing Education  
University of Hong Kong



**HKU SPACE**

- Part I : Brief Background About HKU & HKU SPACE
- Part II : Proposed Course Structure & Finance
- Part III: A Demonstration on the On-line Learning Platform

# Part I : Brief Background About HKU & HKU SPACE (1)



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## HKU

- World Ranking : 33 (Times Higher Education Supplement 2006)
- No. of students : 11,584 (undergraduates)  
7,928 (taught postgraduate programmes)  
1,996 (M.Phil / Ph.D.)
- **No. of publications published in refereed journals : 2,712 (2005)**
- **Research Grant secured from RGC : HK\$146M (2006)**
- **Donations / Benefaction Received : HK\$252M (2004 / 05)**

# Part I : Brief Background About HKU & HKU SPACE (2)



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## HKU (cont'd)

- Library stocks : 2.47 Million bound volumes (June 2006)  
>1M Electronic titles
- **Expenditure on library resources : HK\$92.5M (2005 / 06)**
- A member university of Universitas 21.

(Universitas 21 is an international network of 19 leading universities in 11 countries to facilitate collaboration and student exchange.)



## HKU SPACE

- An extension arm of HKU, established in 1956
- Self-financing but NON-PROFIT making, re-investing its surplus on professional education
- Diversified and balanced offering of programmes
- Large scale operation
  - > 800 full-time staff
  - > 1,000 programmes and > 111,000 enrolments (2005/06)
  - 12 off-campus Learning Centres

# Part I : Brief Background About HKU & HKU SPACE (4)



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## HKU SPACE (cont'd)

- Programmes managed by full-time academic staff
- Developed its own on-line learning platform – SOUL (since 1999)
- Supported by a 40+ member IT Support Team
- Effective Quality Assurance System
- Extensive network of collaborators
- “Bringing the University to students”
- Committed to expand its on-line offering → Cyber SPACE

# Part I : Brief Background About HKU & HKU SPACE (5)



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## HKU SPACE (cont'd)

### ■ International Collaborations

60 academic institutions in UK, Australia, U.S.A., Mainland China and H.K.

### ■ We emphasize on Quality

### ■ University Review 2002 re-affirmed the quality of our programmes

- 'The School ... giving the University much pride and satisfaction.'
- Impressed by the quality assurance processes

### ■ Report of Second UGC's Teaching and Learning Quality Process Review (TLQPR), 2002-03 was complimentary

- QA handbook ... 'is highly recommended to other institutions as a reference for quality assurance processes.'
- 'HKU SPACE has demonstrated convincingly that self financing need not affect or compromise the quality of its programmes.'

## Part II : Proposed Course Structure & Finance (1)



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### 1. General

- An Executive Diploma in Medical Device Regulatory Affairs to be delivered on-line and in English
- Supported by the HKU SPACE on-line learning platform – SOUL
- Participants will be awarded the Executive Diploma after successfully completing written assessments
- Executive Diploma issued by HKU SPACE as empowered by the University Council
- To be completed within a normal period of 1 year
- Hopeful to commence in October 2007



## Part II : Proposed Course Structure & Finance (2)



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### 2. Course Structure

- 4 modules – contents tailored to suit AHWP's needs, e.g.
  - Medical Device Regulatory Affairs in the U.S.
  - Medical Device Regulatory Affairs in the E.U.
  - An Introduction to Medical Device Regulatory Affairs in Asia, **PLUS**
  - Option Modules, e.g.
    - ◆ Regulatory Affairs in a selected Asian country ; or
    - ◆ Post-market Surveillance / Incident Reporting; or
    - ◆ Pre-market Conformity Assessment

## Part II : Proposed Course Structure & Finance (3)



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### 3. Quality Assurance

- Following HKU SPACE Quality Assurance procedures
- Course / Academic Committee
  - AHWP-TC Chairperson,
  - AHWP Representative,
  - Course Leader,
  - Teacher Representative,
  - University Representative,
  - Student Representative.

## Part II : Proposed Course Structure & Finance (4)



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### 4. Finance

- Proposed course fee US\$1,000 or US\$250 per module
- Fees include:
  - Provision of course material
  - Administrative and overhead costs
  - Management and support of the on-line learning platform
  - e-Tutoring
  - Assessment
  - e-Library – optional (requires separate subscription)
  - Issuance of certificates
  - Student record management

## Part II : Proposed Course Structure & Finance (5)

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### 4. Finance (cont'd)

- Any surplus will be shared EQUALLY between AHWP & HKU SPACE
- HKU SPACE to absorb development costs if necessary
- AHWP need NOT invest up-front, hence NO financial risk
- Minimum student number : ~ 15
- Ideal number : 50 or more

## Part II : Proposed Course Structure & Finance (6)



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### 5. Professional Accreditation

- To enable benchmarking of the academic status of training programme
- To seek accreditation from:
  - RAPS, FDA, TOPRA
  - Engineering / Professional bodies of member economies, e.g. HKIE, IES, EIT, KIEE, IEM, etc ...
  - Universities in the member economies
- To provide basis for further advancement / articulation for participants
- To give flexibility to participants to pursue higher qualifications in their home countries.

## Part II : Proposed Course Structure & Finance (7)

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### Benefits to AHWP

- Partner with an institution of high regard globally & in Asia
- Able to launch training programme within months
- Readily accessible on-line learning platform without extra investment
- Provide possible articulation paths for further advancement of participants
- Very affordable course fee, and hence more participants can be benefited



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Part III : A Demonstration on the  
HKU SPACE Learning Platform

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Thank You

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