AHWP

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP Professional Certificate

In Collaboration With

Northeastern UNIVERSITY

13th AHWP Meeting

NEW DELHI, INDIA, 5-6 November 2008

Agenda

Matters before the Advisory Board

- Approval of scope and purpose of training (approved)
- Approval of curriculum development (approved)
- Finalize training tuition fee (approved)
- Finalize training budget (approved)
- Draft MoH curriculum development contract (approved)
- NEU website for AHWP online training (completed)
- Finalize and sign contract with Northeastern University
- Recruit & confirm member economy authors
- Finalize contract with MoH authors
- Legal entity, tuition collection mechanisms, and paying MoH authors
- Launch date
- Determine critical soft skills instructor

Scope & Purpose

- Provide a comprehensive online training for individuals to gain the required regulatory knowledge
- Topics aimed to help gain **global** regulatory knowledge
- Designed for all regulatory affairs professionals who work in academia, government agencies, regulatory consulting groups, or medical device companies
- Students should have an undergraduate degree in order to enroll

Scope & Purpose

- Graduates of the AHWP training program will receive a Professional Certificate of Completion
- Graduates can apply this certificate as part of the overall acceptance into Northeastern University's Regulatory Affairs Master's Program (2.5 years) or Professional Certificate Program (1 year)
- AHWP graduates will earn 1 credit hour which can be applied towards their masters or certificate degree

Curriculum Content & Course Structure

There are currently 5 UNITS being developed and each unit will consist of several modules

- Unit 1: Basic Knowledge of Medical Devices & their Life-Cycle
- Unit 2: National and International Regulatory Systems
- Unit 3: Medical Device Technologies
- Unit 4: Critical Soft Skills
- Unit 5: Hot Topics

Curriculum Content & Course Structure

Evaluating Students

- Final test at the conclusion of each UNIT = 4 final exams + critical skills
- Scores of the 4 tests will be one cumulative score
- Northeastern University will set the parameters for passing performance ~ 80%

- Advisory Committee directors will be given aggregate data on exam scores – NO STUDENT names will be revealed
- The RA Professional Certificate of Completion to be presented to students at the annual AHWP meeting after successfully completing all four units

Budget – Summary – Version 1

Enrollment Fees – Recommendations

Government: $1,000 USD

Non-Government: $2,000 USD

Budget based on a minimum of 50 students Government students (N = 35) Non-Government student (N = 15)	
Total Revenue	$65,000 USD
Phase I Costs	$0 USD
Phase II-III Costs	$3,750 USD
Phase III Optional Costs	$4,200 USD
Estimated Net Income for AHWP	***$57,410 USD***

Units on Regulatory Structures in AHWP Member Economies

Brief History

1 slide for:

- Share with the students a brief history about your country. Helpful information may include:
  - Brief History of Country
  - Capital city
  - Population
  - Participation in International Organizations
  - Special Trade Considerations

Government Structure

1-3 slides on:

- National and provincial (and provincial) government structures
- medical device organization falls into the overall organization.
- An organization chart is helpful, but names are not required.

Units on Regulatory Structures in AHWP Member Economies

Medical Device Market

1 to 2 slides to:

- Explain the types of devices you have on your market.
- What products, if any, are manufactured in your country and which ones are imported.
- Key here is to provide the student with a "snap-shot" or a brief overview of the overall medical device market in your country.

Regulatory Documents

1 to 3 slides to:

- Explain the different types of documents that are relevant to the medical device market.
- For example, the EU has Medical Device Directives (MDD), standards, and guidance documents.
- For example, the USA has the Code of Federal Regulations (CFR), regulations, and guidance documents.

Units on Regulatory Structures in AHWP Member Economies

Steps for Approval

5 - 7 slides explaining:

- The different steps on how a medical device is approved in your country.
- It is always helpful to explain:
  - The agency/reviewers involved
  - The time lines for approval
- The different types of submissions such as new product submission, amendments, supplements, etc.

Post-Market Vigilance

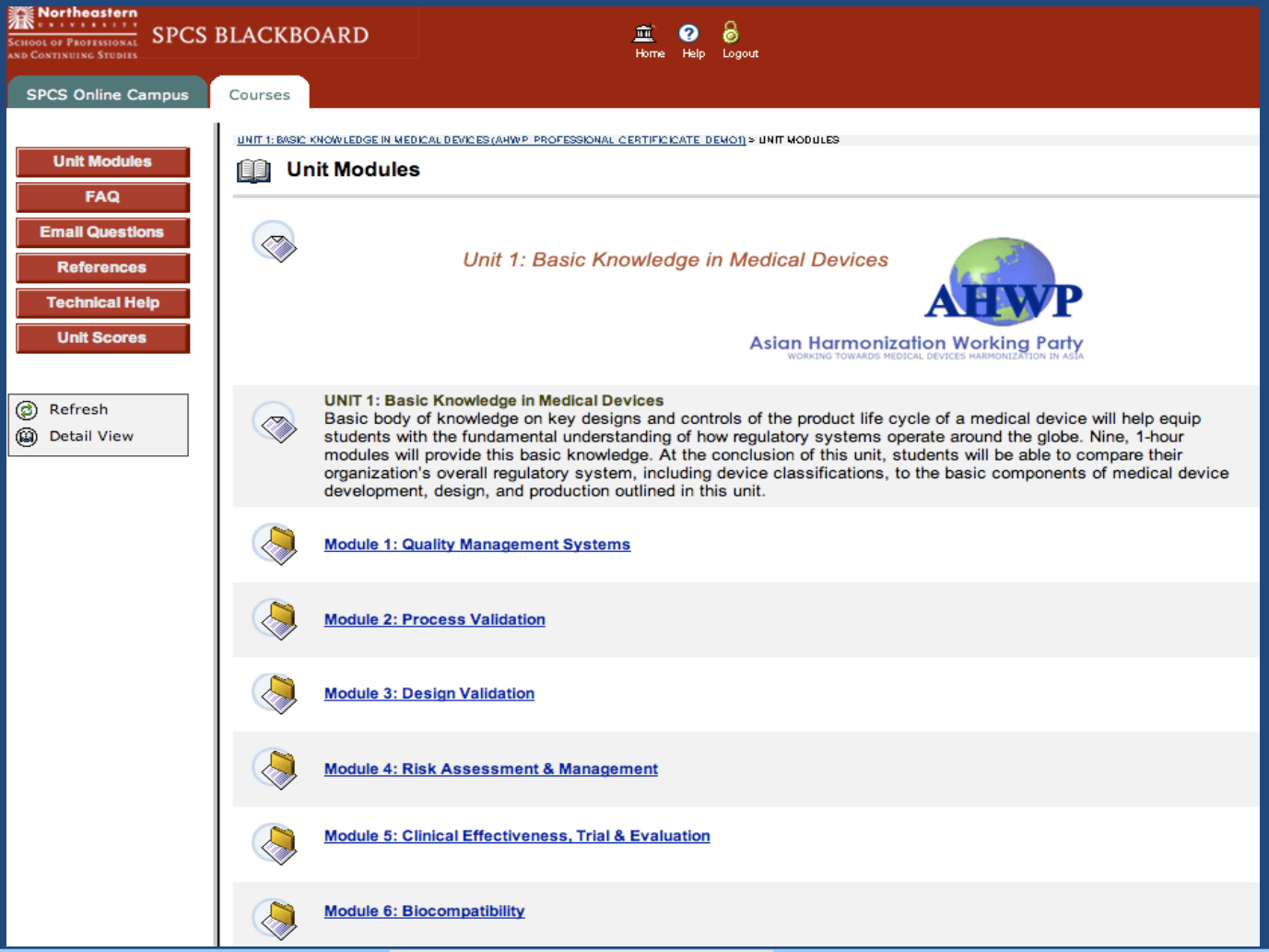
1-2 slides on:

- The post-market requirements, if any.
- It is helpful to mention:
  - The timelines for reporting
  - The types of reporting requirements
  - Any special documents or reports required

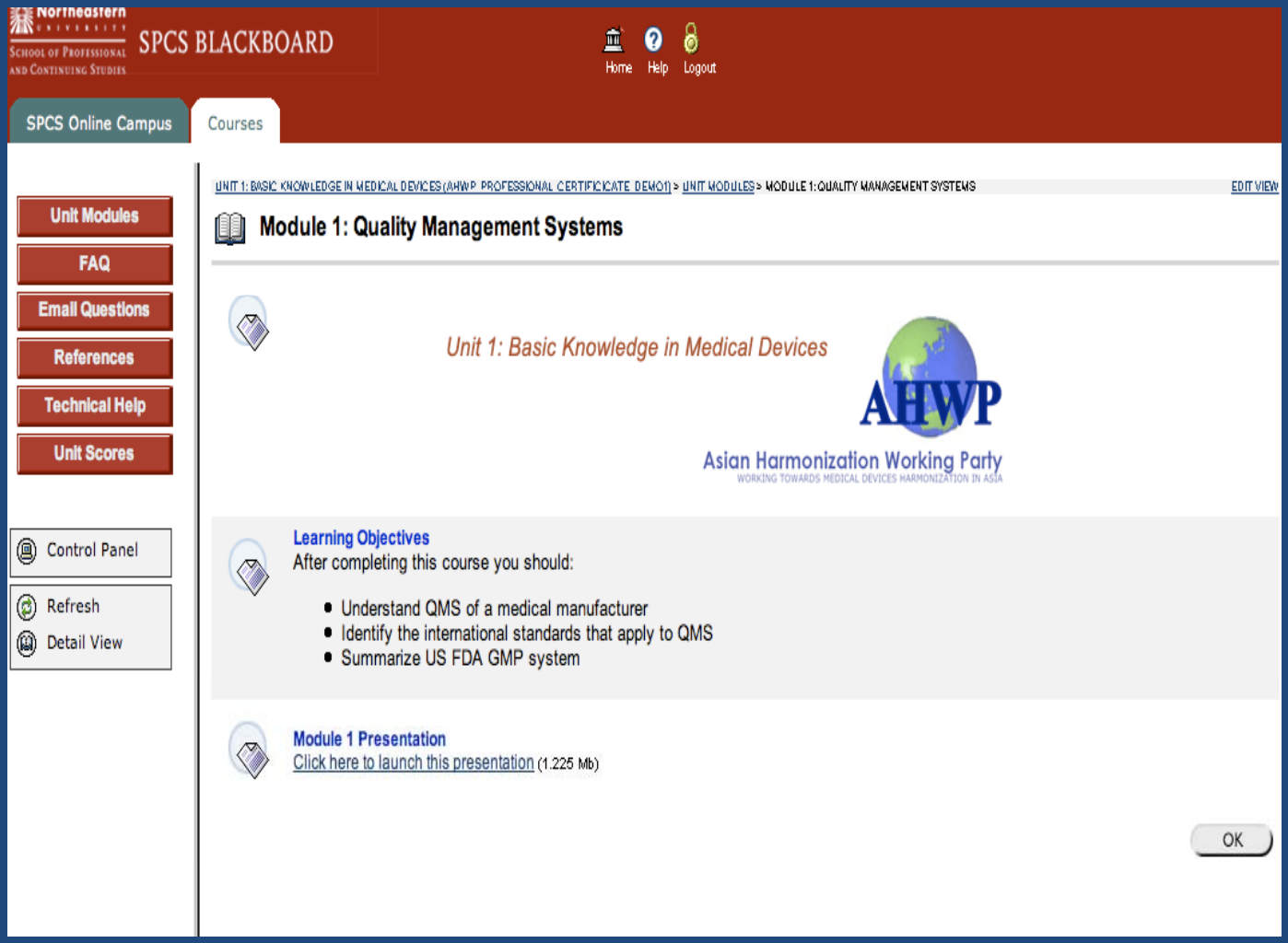
AHWP Countries Committed to Project

- China
- Hong Kong
- Taiwan
- Thailand
- Philippines

Sample Course Pages



Sample Course Pages



Thank you for your attention!