



AHWP TC WG06 Report:

AHWP Professional Certificate

Delhi, India
Technical Committee Meeting
And General Assembly
For
3-7 November 2008


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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


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Scope and Purpose

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA

- 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
- 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

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Curriculum Content & Course Structure

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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

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Curriculum Content & Course Structure


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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.

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Budget – Summary – Version 1


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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


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Units on Regulatory Structures in AHWP Member Economies

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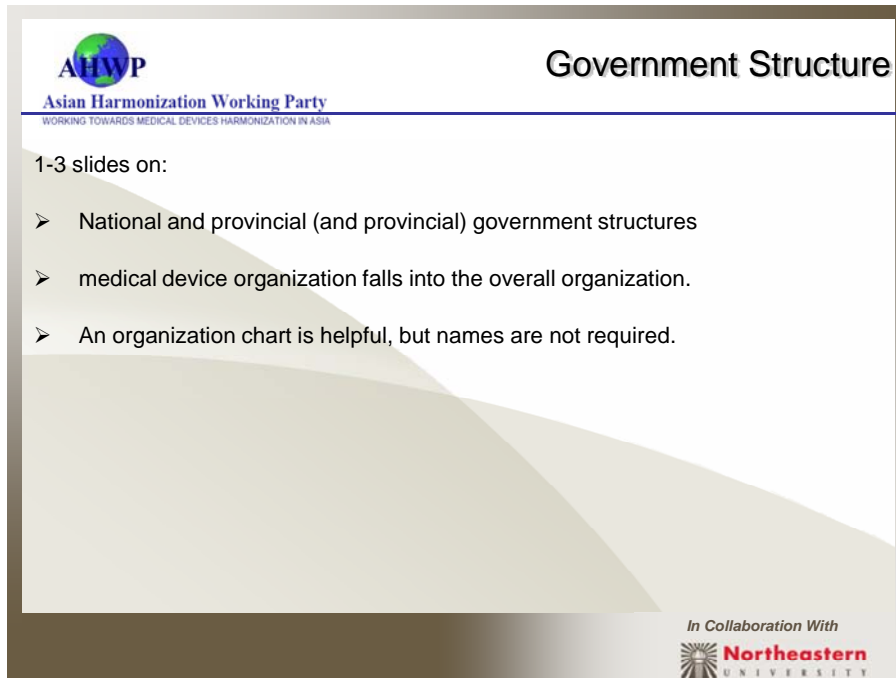
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Brief History

1 slide for:

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

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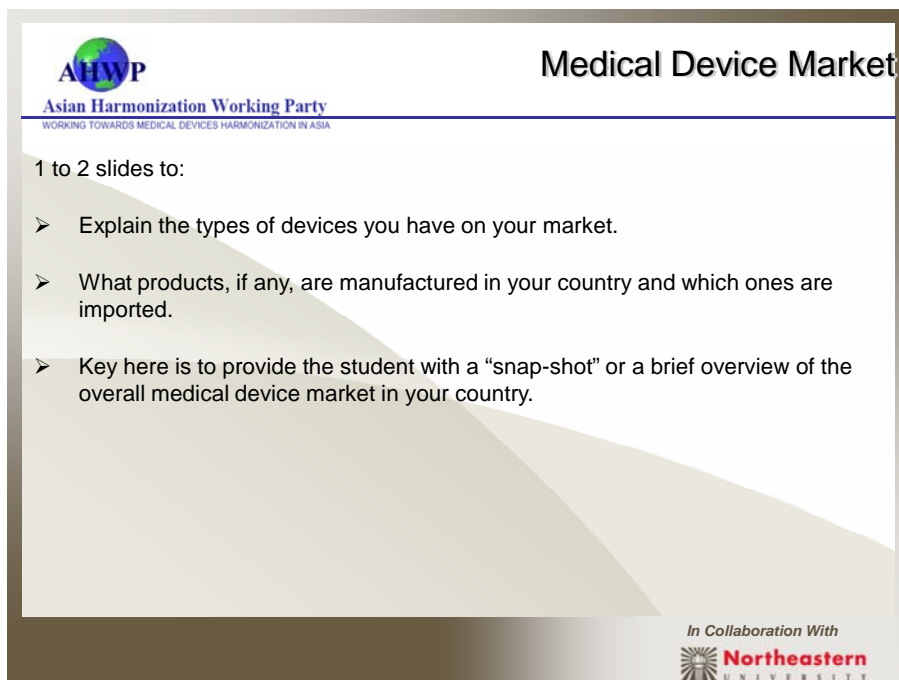
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Government Structure

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.

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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.

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Regulatory Documents

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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.

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Steps for Approval

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5 - 7 slides explaining:

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

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Post-Market Vigilance

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1 to 2 slides on:

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

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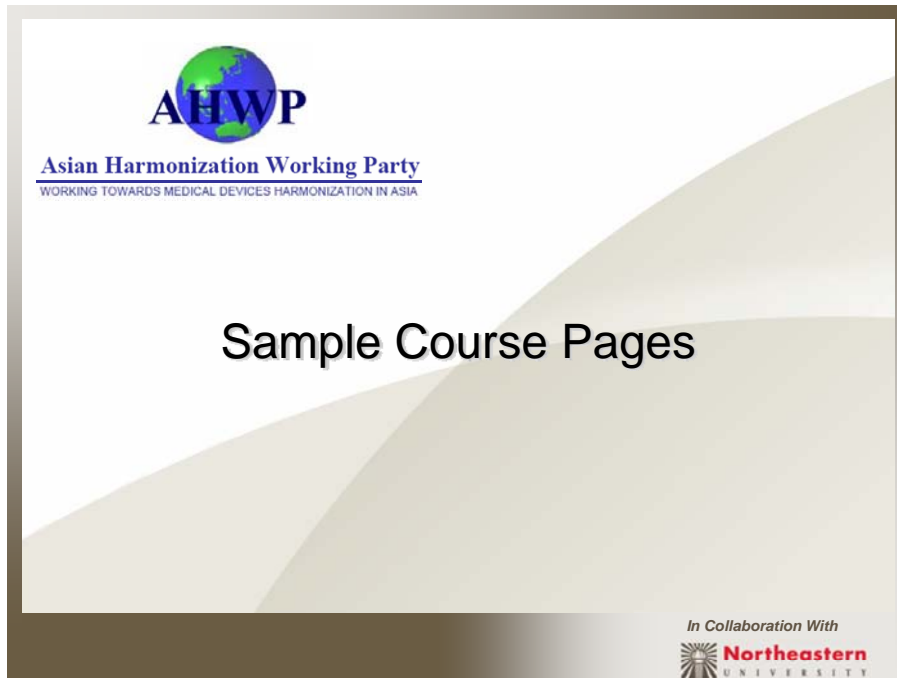


AHWP Countries Committed to Project

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA

- China
- Hong Kong
- Taiwan
- Thailand
- Philippines

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The screenshot shows the Blackboard interface for a course. At the top, there is a red navigation bar with 'Northeastern SPCS BLACKBOARD' and links for 'Home', 'Help', and 'Logout'. Below this, a sidebar on the left contains a menu with items: 'Unit Modules', 'FAQ', 'Email Questions', 'References', 'Technical Help', and 'Unit Scores'. The main content area is titled 'UNIT 1: BASIC KNOWLEDGE IN MEDICAL DEVICES (AHWP PROFESSIONAL CERTIFICATE DEMO) > UNIT MODULES'. It features a heading 'Unit 1: Basic Knowledge in Medical Devices' with the AHWP logo. Below this, a paragraph describes the unit's purpose: 'UNIT 1: Basic Knowledge in Medical Devices Basic body of knowledge on key designs and controls of the product life cycle of a medical device will help equip students with the fundamental understanding of how regulatory systems operate around the globe. Nine, 1-hour modules will provide this basic knowledge. At the conclusion of this unit, students will be able to compare their organization's overall regulatory system, including device classifications, to the basic components of medical device development, design, and production outlined in this unit.' A list of six modules follows, each with a document icon and a blue link: 'Module 1: Quality Management Systems', 'Module 2: Process Validation', 'Module 3: Design Validation', 'Module 4: Risk Assessment & Management', 'Module 5: Clinical Effectiveness, Trial & Evaluation', and 'Module 6: Biocompatibility'. At the bottom of the sidebar, there are 'Refresh' and 'Detail View' buttons.

The screenshot shows the SPCS Blackboard interface. At the top, there is a navigation bar with 'SPCS Online Campus' and 'Courses'. A sidebar on the left contains buttons for 'Unit Modules', 'FAQ', 'Email Questions', 'References', 'Technical Help', and 'Unit Scores'. Below these are 'Control Panel', 'Refresh', and 'Detail View'. The main content area is titled 'Module 1: Quality Management Systems' and includes a sub-header 'Unit 1: Basic Knowledge in Medical Devices'. It features the AHWP logo and 'Asian Harmonization Working Party' text. The 'Learning Objectives' section states: 'After completing this course you should:' followed by a list:

- Understand QMS of a medical manufacturer
- Identify the international standards that apply to QMS
- Summarize US FDA GMP system

 A 'Module 1 Presentation' link is provided with a file size of 1.225 Mb. An 'OK' button is visible at the bottom right of the content area.

The certificate is issued by Northeastern University, School of Professional & Continuing Studies, Boston, Massachusetts. It is awarded to Joe Smith for the successful completion of the certificate program in 'Trends and Issues in Regulatory Affairs' under the Asian Harmonization Working Party. The certificate includes the following details:

- Date: 14 October 2007
- Program Director: Eric D. Kuffenberg, PhD
- Dean, SPCS: Christopher Nopcy, PhD

 The certificate also features the AHWP logo and the text 'In Collaboration With Northeastern University'.