



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP Professional Certificate

In Collaboration With



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
<i>Estimated Net Income for AHWP</i>	<i>\$57,410 USD</i>

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



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UNIT 1: BASIC KNOWLEDGE IN MEDICAL DEVICES (AHWP PROFESSIONAL CERTIFICATE DEMO) > UNIT MODULES

Unit Modules

Unit 1: Basic Knowledge in Medical Devices


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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.

[Module 1: Quality Management Systems](#)

[Module 2: Process Validation](#)

[Module 3: Design Validation](#)

[Module 4: Risk Assessment & Management](#)

[Module 5: Clinical Effectiveness, Trial & Evaluation](#)

[Module 6: Biocompatibility](#)

Sample Course Pages



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UNIT 1: BASIC KNOWLEDGE IN MEDICAL DEVICES(AHWP PROFESSIONAL CERTIFICATE DEMO1) > UNIT MODULES > MODULE 1: QUALITY MANAGEMENT SYSTEMS

Module 1: Quality Management Systems

Unit 1: Basic Knowledge in Medical Devices

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Learning Objectives
After completing this course you should:

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

Module 1 Presentation
[Click here to launch this presentation](#) (1.225 Mb)

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OK



Thank you for your attention!

