Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA

AHWP Professional Certificate

Kuala Lumpur

Technical Committee Meeting

for

March 3, 2008

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Agenda

Advisory Board Update since Chengdu meeting

- Scope and purpose of training
- Curriculum development
- Budget
- Student Fee Recommendation
- Remaining action items for Advisory Board
- NEU website for AHWP online training

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Advisory Board

Co-Chairs:

- Eric Kupferberg - NEU
- Director Pillay - AHWP

Board Members:

- Jack Wong
- Albert Poon
- Director Wang
- Katy Peterson

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Scope and 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 must 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 4 credit hour which can be applied towards their masters or certificate degree

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Curriculum

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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
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

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.

Module 1: What is a medical device?
Module 2: How are medical devices classified?
Module 3: What are the essential requirements?
- safety and effectiveness/performance
- risk-based principles
- biocompatibility and electromagnetic compatibility

Module 4: Sterilization processes
Module 5: What are the basic manufacturing principles?
Module 6: Clinical effectiveness, clinical trials, and data evaluation
Module 7: Fundamentals of post-market surveillance

Curriculum Content & Course Structure

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Unit 2: National and International Regulatory Systems

Understanding different regulatory systems that govern the diverse medical device industry is the basic foundation of an effective Regulatory Affairs professional and a global business partner.

Module 1: Global Perspectives, New Regulatory Systems, and Global Harmonization Efforts
Module 2: GHTF Economy - USA
Module 3: GHTF Economy - European Union & Australia
Module 4: GHTF Economy – Canada
Module 5: GHTF Economy – Japan
Module 6: AHWP Economy – China
Module 7: AHWP Economy – India
Module 8: AHWP Economy – Korea
Module 9: AHWP Economy – Taiwan
Module 10: AHWP Economy – Vietnam
Module 11: AHWP Economy – Indonesia
Module 12: AHWP Economy – Thailand
Module 13: AHWP Economy – Philippines
Module 14: AHWP Economy – Malaysia
Module 15: AHWP Economy – Singapore
Module 16: AHWP Economy – Hong Kong
Module 17: AHWP Economy – Saudi Arabia

Need AHWP members to help draft the member economies course content.

Each author will be paid = $500 USD

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Curriculum Content & Course Structure

Unit 3: Medical Device Technologies

This course will introduce students to the function, purpose, classification, and regulatory considerations of some of the most widely used devices in the global marketplace today and introduce new technological trends of the future.

Module 1: Active Implantable Devices
Module 2: Anesthetic & Response Devices
Module 3: Dental Devices
Module 4: Electro Mechanical Medical Devices
Module 5: Hospital Hardware
Module 6: In-vitro Diagnostic Devices
Module 7: Non-active Implantable
Module 8: Ophthalmic & Optical Devices
Module 9: Re-usable Devices
Module 10: Single Use Devices
Module 11: Assistive products for persons with Disability
Module 12: Diagnostic & Therapeutic Radiation Devices
Module 13: Complementary Therapy Devices
Module 14: Biologically Derived Devices
Module 15: Healthcare Facility Products & Adaptations
Module 16: Laboratory Equipment
Module 17: New Technologies

Curriculum Content & Course Structure

Unit 4: Critical Soft Skills for Successful Regulatory Professionals

To complement the regulatory knowledge gained from the online curriculum, students will also be required to develop critical soft skills.

- Effective communication skills such as finely tuned listening, negotiation, and people management skills
- Taught in a workshop format at the annual AHWP meetings
- Individuals who are not able to attend the annual meetings, critical soft skills will be taught by viewing a 3-hour online video and successfully completing relevant case study scenarios

Curriculum Content & Course Structure

Unit 5: Hot Topics (Draft List)

The purpose of this unit is to provide students with the latest issues and concerns that impact the current medical device industry.

Module 1: The scope, goals, and efforts of AHWP
Module 2: Trade Implications to Consider
Module 3: Nomenclature Considerations
Module 4: Roles and Responsibilities of Distributors and Manufacturers

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.

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BUDGET

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Budget - Summary

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 Costs + Optional Costs	$13,450 USD
Phase III Costs + Optional Costs	$5,500 USD
Estimated Net Income for AHWP	***$46,000 USD***

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Budget - Summary

Itemized Costs

NEU Curriculum Development for Units 1, 3 & 5	$0 USD
NEU website and integrating with AHWP website	$0 USD
NEU online faculty support for questions on module content	$0 USD
NEU 24 hour online technical support	$0 USD
NEU Student registration & enrollment	$0 USD
NEU ongoing curriculum improvements & updates	$0 USD
Online posting and support of critical skills video training	$250 USD
Travel & accommodations for NEU representative at the annual AHWP meetings	$3,000 USD
NEU Critical Skills instructor + travel expenses	$4,200 USD
Curriculum development for RA content on AHWP Economies (12 X $500)	$6,000 USD
Ongoing updates & improvements for RA content on AHWP Economies ($250)	$3,000 USD
NEU student evaluation of final examinations ($300 per Unit)	$1,500 USD
Marketing, branding, promotion of program	$1,000 USD

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Remaining Action Items for Advisory Board

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Action Items

- Branding/naming of the program
- Recruit AHWP Member economies authors
- Finalize enrollment fees & registration process
- Finalize budget & how to manage funds
- Determine critical skills instructor
- Finish Unit 1 & 2 curriculum development prior to initial launch
- Promotion, Launch date, and enrollment

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Sample Course Pages

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Unit Modules
FAQ
Email Questions
References
Technical Help
Unit Scores

Refresh
Detail View

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.

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

Unit Modules
FAQ
Email Questions
References
Technical Help
Unit Scores

Control Panel
Refresh
Detail View

Module 1: Quality Management Systems

Unit 1: Basic Knowledge in Medical Devices

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Learning Objectives

After completing this course you should:

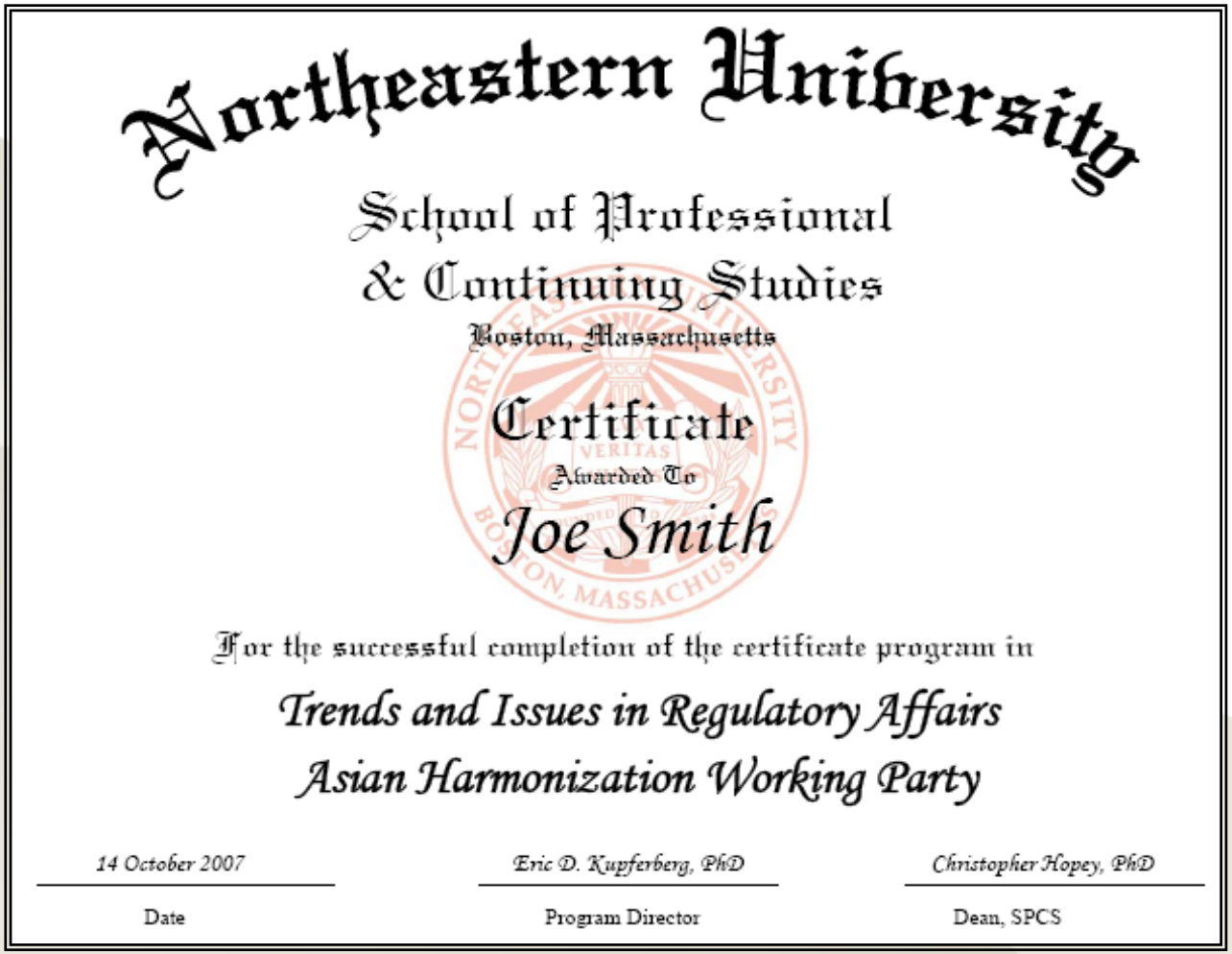
- Understand QMS of a medical manufacturer
- Identify the international standards that apply to QMS
- Summarize US FDA GMP system

Module 1 Presentation

Click here to launch this presentation (1.225 Mb)

OK

Certificate



Northeastern University

School of Professional
& Continuing Studies

Boston, Massachusetts

Certificate

Awarded To

Joe Smith

For the successful completion of the certificate program in

Trends and Issues in Regulatory Affairs

Asian Harmonization Working Party

14 October 2007	*Eric D. Kupferberg, PhD*	*Christopher Hopey, PhD*
Date	Program Director	Dean, SPCS

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