Building Partnerships: Northeastern University and the Asian Harmonization Working Party

AHWP Asian Regulatory Affairs
Certificate Program

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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

- Doctorate in the history and sociology of science from MIT
- Masters in the history and philosophy of biology from the University of Maryland
- Assistant Dean of Academic and Faculty Affairs
- Responsible for curriculum development, faculty training, and student complaint resolution
- He is also responsible for the growth of Northeastern University's programs in regulatory affairs, clinical trails, and biotechnology

BSC & NEU Partnership

- Boston Scientific & Northeastern University have a history of working together to educate and train Boston Scientific employees
- NEU's RA Master's Program provides internship candidates for the International RA team at Boston Scientific

Northeastern University

ONLINE

Northeastern University

Asian Harmonization Working Party

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Northeastern University at a Glance

- Founded 1898 in downtown Boston
- Ranked in top 100 of U.S. universities
- Leader in interdisciplinary research
- Over 1,200 faculty engaged in teaching and research
- More than 180,000 alumni worldwide
- Established partnerships with global companies

US News & World Report

- High Success Rate of Graduates
- Productive Faculty
- Private and Publicly Funded Research

Northeastern UNIVERSITY ONLINE

NEU's Online Education Delivers Superior Content Around the Globe

- Pioneer in distance learning
- More than 125 courses offered annually
- Over 8,000 students studying online in 62 major degree areas
- World-class faculty matched with high-caliber students from around the globe
- Rigorous training and sophisticated technical support for online instructors

Northeastern UNIVERSITY ONLINE

Online Learning at Northeastern Tailored to the Online Student's Unique Needs

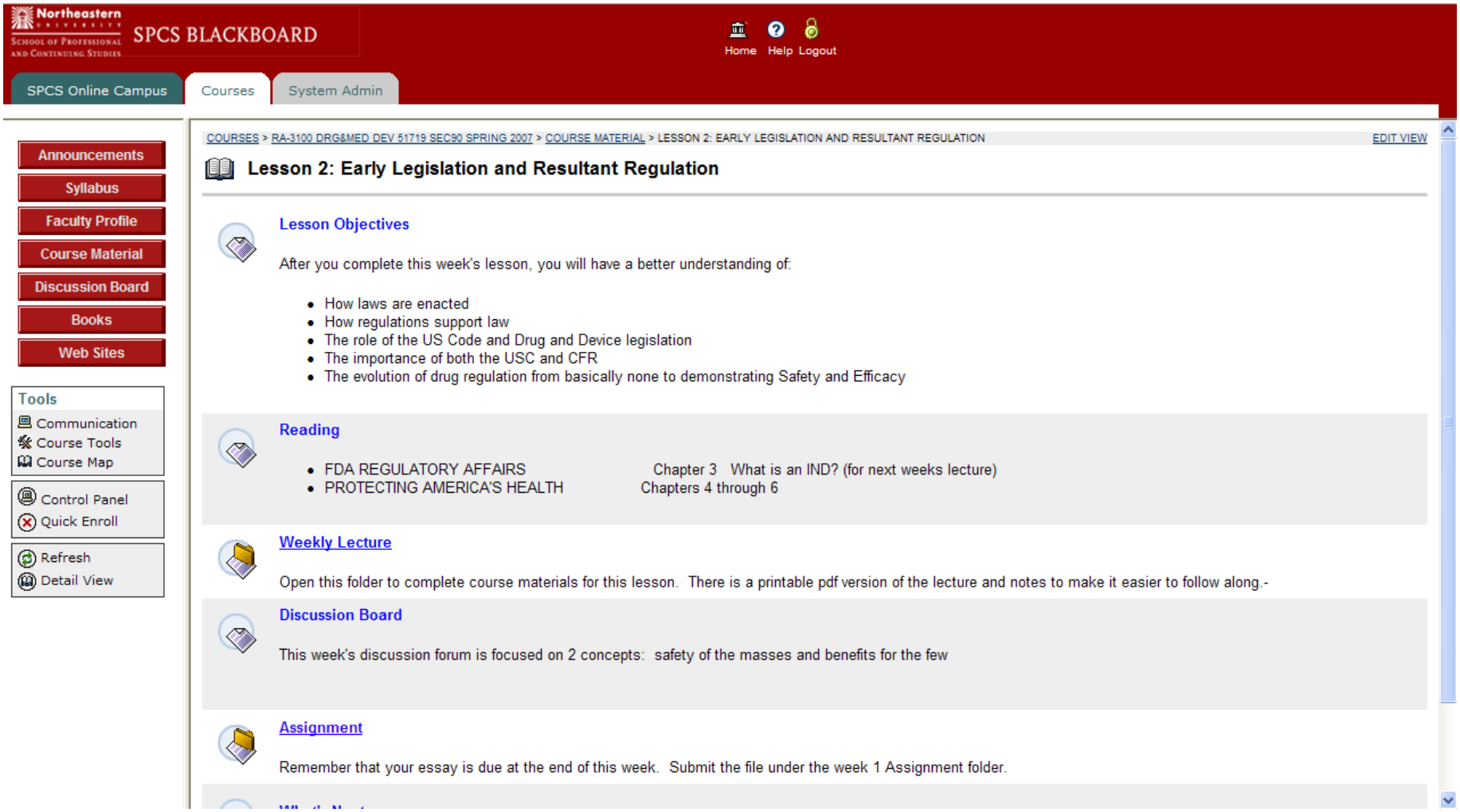
- Streaming video
- Multimedia lectures
- Podcasting
- Web collaboration
  - Synchronous presentations
  - Live audio chats
- Video lectures
- Word or PowerPoint lectures
- Handouts with links to supplementary online content

Northeastern University Online

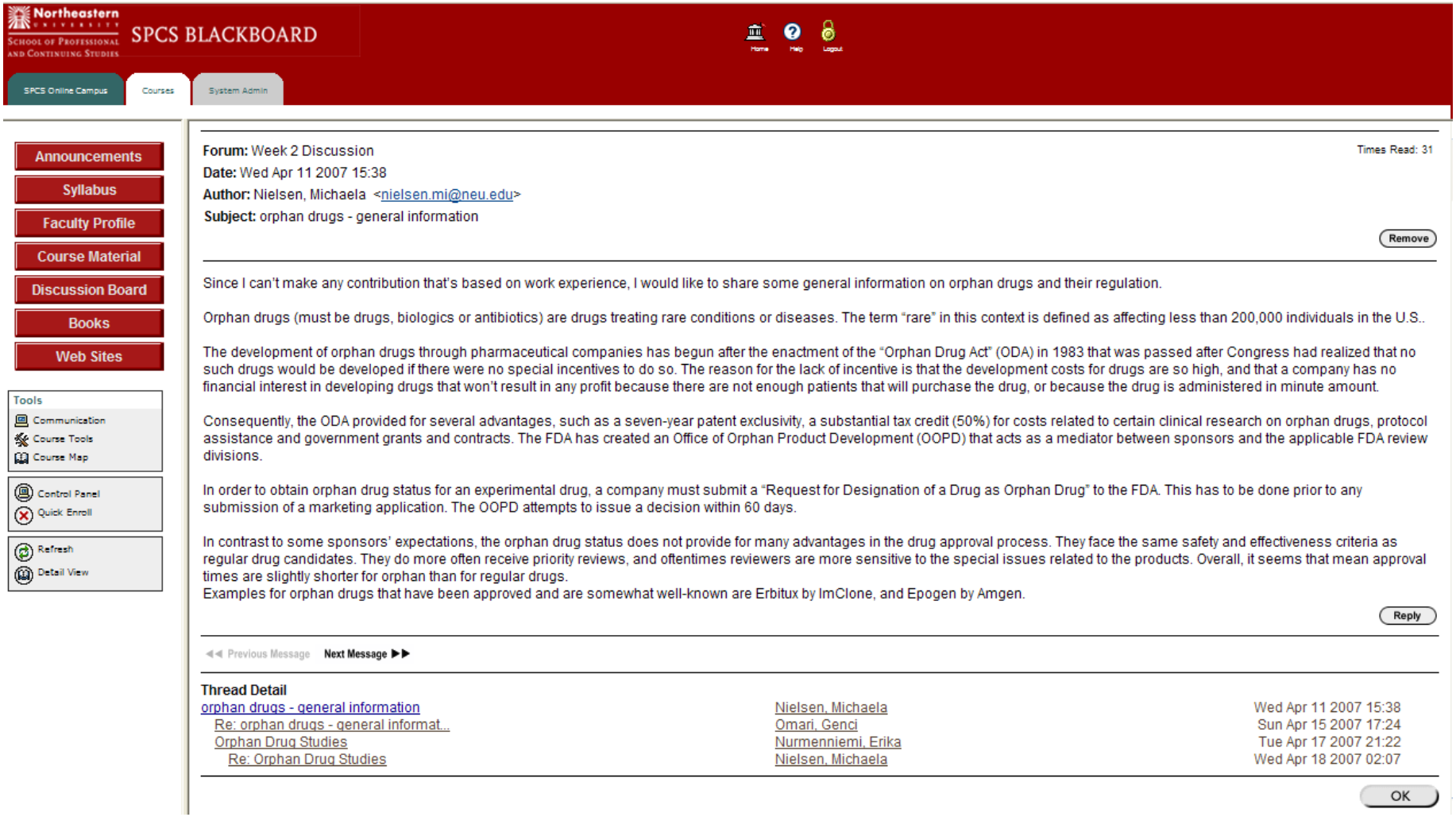
Masters of Science in Regulatory Affairs

- Currently over 100 students from 9 countries
- Experienced and highly-trained faculty
- Graduates employed in both government and private sectors
- Comprehensive instruction from early IDAs to post-market surveillance
- Expansive curriculum covering drugs, biologics, and medical devices
- Unique emphasis on market dynamics and strategic planning
- Focus on understanding the role of compliance with applicable laws and regulations in the global commercialization of healthcare products

Self-Contained Study Modules



Ideal for Student Participation & Group Projects



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Proposal A:

NEU & AHWP RA Certificate Program

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AHWP RA Certificate Program Proposal A

- AHWP can contract to use at, no cost, the existing government elearning website www.moh-elearning.com as the main portal to host core modules & training materials
- 2 of the 3 core modules are complete and available for AHWP modification on current site (FDA, EU)
- 3-5 year contract where BSC covers all costs of maintaining and improving site per AHWP's directive
- Contract will allow AHWP to have own portal to control the look, functionality, and student fees of the RA certificate program

AHWP RA Certificate Program Proposal A

- Using it <u>own</u> portal, AHWP can set a nominal enrollment fee for government and industry representatives
- All start-up costs will be covered by BSC & NEU
- 100% of the enrollment fees go to AHWP to cover of cost of program development, including tutor and author fees, and to repay BSC/NEU initial investment
- RA certificate final exam can be hosted on NEU's online portal to ensure confidentiality and to allow outside expert evaluation of final test scores

AHWP RA Certificate Program Proposal A

- Program accredited by Northeastern University and possibly by University HK
- Successful completion of Asia RA Certificate can be used to waive application requirements to NEU's RA Master's program
- 25% tuition discount for government cohort groups of 10 or more
- 50% discount for critical-skills training program
- Create an program Advisory Board with members from NEU & HKU faculty as well as AHWP industry & government representatives

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

AHWP RA Certificate Program Proposal A

Estimated Budget for Proposal A

Start-up Costs in USD	
Develop web portal to host core modules	$0
NEU portal for final exam & evaluation	$500
Content for EU & FDA core modules	$0
E-tutors to support students with the EU & FDA core module content	$0
Content for AHWP Asia Regulatory core module	$3,500 - $5,000
E-tutors to support students with the Asia RA core module content	$0
Final exam evaluation costs	$1,000
ESTIMATED TOTAL	$5,000 - $6,500 USD
On-Going Costs to Maintain / Expand Program	
Web portal for final exam & evaluation	$500
Final exam evaluation costs	$1,000
New module content & E-tutor support	$350 - $500 per module
ESTIMATED TOTAL	$1,850 – $2,350 USD

Northeastern University
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Proposal B:

NEU & AHWP RA Certificate Program

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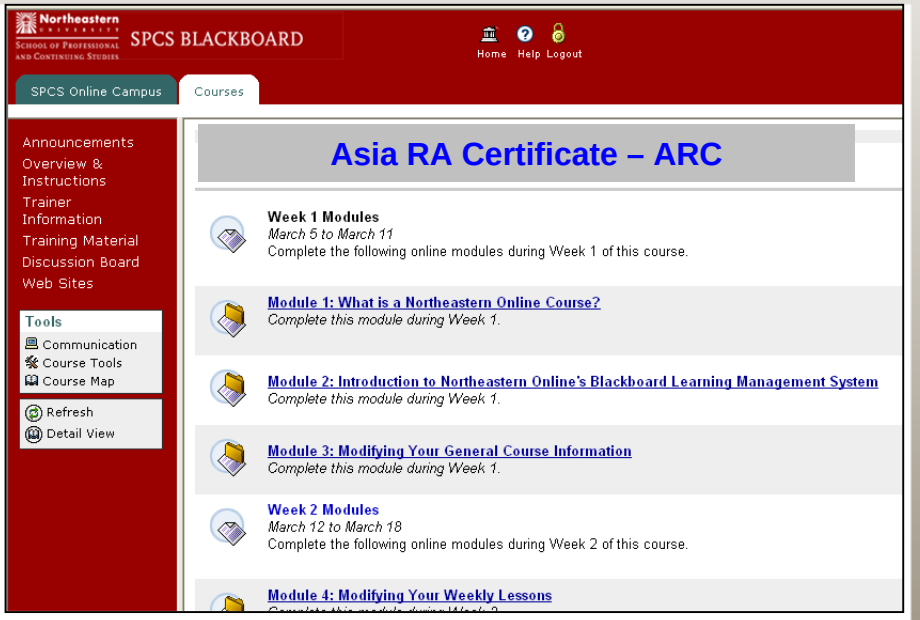
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP RA Certificate Program
PROPOSAL B

- Use NEU portal to host core modules & final exam
- Use current government elearning website www.moh-elearning.com to host supplementary training materials or video tutorials to help students prepare for final exam
- All start-up costs will be covered by NEU only
- After NEU initial investment is paid back through student enrollment fees, all additional fees will be split 60% AHWP and 40% to NEU



Hyperlink to:

AHWP RA Certificate Program Proposal B

Estimated Budget for Proposal B

Start-up Costs in USD	
Use of NEU portal to host core modules & final exam	$2,500
Content for EU & FDA core modules	$0
E-tutors to support students with the EU & FDA core module content	$0
Content for AHWP Asia Regulatory core module	$3,500 - $5,000
E-tutors to support students with the Asia RA core module content	$0
Final exam evaluation costs	$1,000
ESTIMATED TOTAL	$7,000 - $8,500 USD
On-Going Costs to Maintain/Expand Program in USD	
Web portal for final exam & evaluation	$500
Final exam evaluation costs	$1,000
New module content & E-tutor support	$350 - $500 per module
ESTIMATED TOTAL	$1,850 – $2,350 USD

Northeastern University
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Partnership Benefits

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Northeastern University Online

Why Partner with Northeastern?

- Experienced in developing distance educational programs with 36 years of proven success
- Access to faculty experts to help develop and/or advise on core curriculum such as EU and FDA content
- Access to university's learning and development department for critical skills training
- Opportunity to attend an accredited RA Masters program with an AHWP RA Certificate
- Use existing online platform www.moh-elearning.com site at no cost
- Launch certificate program by October 2007 is achievable
- No cost associated with partnership and mutually beneficial for both organizations

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Northeastern UNIVERSITY ONLINE

Benefits of Asia RA Certificate

Regulatory Affairs Program Requirements

Non-AHWP International Students

- Completed application
- Statement of intent
- College transcripts with 3.0+ GPA
- 3 years relevant experience
- Two letters of reference
- English language exam

- Must complete 8 required courses and 3 electives
- Must complete 40 credit hours
- Each course = 12 hours per week
- Maintain “B” or better

AHWP Program Graduates

- Completed application
- Statement of intent
- College transcripts with 3.0+ GPA
- *Waived*
- *Waived*
- *Waived*

- Must complete 7 required courses and 4 electives
- Must complete 38 credit hours
- Each course = 12 hours per week
- Maintain “B” or better