

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

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- 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



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- 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



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



- 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



- 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



- 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

Lesson 2: Early Legislation and Resultant Regulation

Lesson Objectives

After you complete this week's lesson, you will have a better understanding of:

- How laws are enacted
- How regulations support law
- The role of the US Code and Drug and Device legislation
- The importance of both the USC and CFR
- The evolution of drug regulation from basically none to demonstrating Safety and Efficacy

Reading

- FDA REGULATORY AFFAIRS Chapter 3 What is an IND? (for next weeks lecture)
- PROTECTING AMERICA'S HEALTH Chapters 4 through 6

Weekly Lecture

Open this folder to complete course materials for this lesson. There is a printable pdf version of the lecture and notes to make it easier to follow along. -

Discussion Board




This week's discussion forum is focused on 2 concepts: safety of the masses and benefits for the few



Assignment



Remember that your essay is due at the end of this week. Submit the file under the week 1 Assignment folder.

- Announcements
- Syllabus
- Faculty Profile
- Course Material
- Discussion Board
- Books
- Web Sites

Tools

-  Communication
-  Course Tools
-  Course Map

-  Control Panel
-  Quick Enroll

-  Refresh
-  Detail View

Ideal for Student Participation & Group Projects


SPCS BLACKBOARD

 Home
  Help
  Logout

SPCS Online Campus
Courses
System Admin

- Announcements
- Syllabus
- Faculty Profile
- Course Material
- Discussion Board
- Books
- Web Sites

- Tools
- Communication
 - Course Tools
 - Course Map
-
- Control Panel
 - Quick Enroll
-
- Refresh
 - Detail View

Forum: Week 2 Discussion Times Read: 31
Date: Wed Apr 11 2007 15:38
Author: Nielsen, Michaela <nielsen.mi@neu.edu>
Subject: orphan drugs - general information Remove

Since I can't make any contribution that's based on work experience, I would like to share some general information on orphan drugs and their regulation.

Orphan drugs (must be drugs, biologics or antibiotics) are drugs treating rare conditions or diseases. The term "rare" in this context is defined as affecting less than 200,000 individuals in the U.S..

The development of orphan drugs through pharmaceutical companies has begun after the enactment of the "Orphan Drug Act" (ODA) in 1983 that was passed after Congress had realized that no such drugs would be developed if there were no special incentives to do so. The reason for the lack of incentive is that the development costs for drugs are so high, and that a company has no financial interest in developing drugs that won't result in any profit because there are not enough patients that will purchase the drug, or because the drug is administered in minute amount.

Consequently, the ODA provided for several advantages, such as a seven-year patent exclusivity, a substantial tax credit (50%) for costs related to certain clinical research on orphan drugs, protocol assistance and government grants and contracts. The FDA has created an Office of Orphan Product Development (OOPD) that acts as a mediator between sponsors and the applicable FDA review divisions.

In order to obtain orphan drug status for an experimental drug, a company must submit a "Request for Designation of a Drug as Orphan Drug" to the FDA. This has to be done prior to any submission of a marketing application. The OOPD attempts to issue a decision within 60 days.

In contrast to some sponsors' expectations, the orphan drug status does not provide for many advantages in the drug approval process. They face the same safety and effectiveness criteria as regular drug candidates. They do more often receive priority reviews, and oftentimes reviewers are more sensitive to the special issues related to the products. Overall, it seems that mean approval times are slightly shorter for orphan than for regular drugs.

Examples for orphan drugs that have been approved and are somewhat well-known are Erbitux by ImClone, and Epogen by Amgen.

Reply

[◀◀ Previous Message](#)
[Next Message ▶▶](#)

Thread Detail

orphan drugs - general information	Nielsen, Michaela	Wed Apr 11 2007 15:38
Re: orphan drugs - general informat...	Omari, Genci	Sun Apr 15 2007 17:24
Orphan Drug Studies	Nurmenniemi, Erika	Tue Apr 17 2007 21:22
Re: Orphan Drug Studies	Nielsen, Michaela	Wed Apr 18 2007 02:07

OK

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Proposal A: NEU & AHWP RA Certificate Program



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- 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



- Using its own 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 the 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

A screenshot of a Blackboard course page. The top header is red with the Northeastern University logo and 'SPCS BLACKBOARD'. Below the header, there are navigation tabs for 'SPCS Online Campus' and 'Courses'. The main content area shows a breadcrumb trail: 'COURSES > INTRODUCTION TO E-LEARNING INSTRUCTOR TRAINING (SPRING 2007 - SECTION 1) > ANNOUNCEMENTS'. A large blue heading reads 'Asia RA Certificate – Final Exam'. Below this, there are view options: 'VIEW TODAY', 'VIEW LAST 7 DAYS', 'VIEW LAST 30 DAYS', and 'VIEW ALL'. The date 'April 17, 2007 - April 24, 2007' is displayed. A message states 'No announcements found.' At the bottom, there's a Blackboard logo and copyright information: 'Blackboard Academic Suite™ (7.0.298.0) Blackboard Learning System™ Copyright © 1997-2004 Blackboard Inc. Patents Pending. All rights reserved. Accessibility information can be found at http://access.blackboard.com.'

- 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



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

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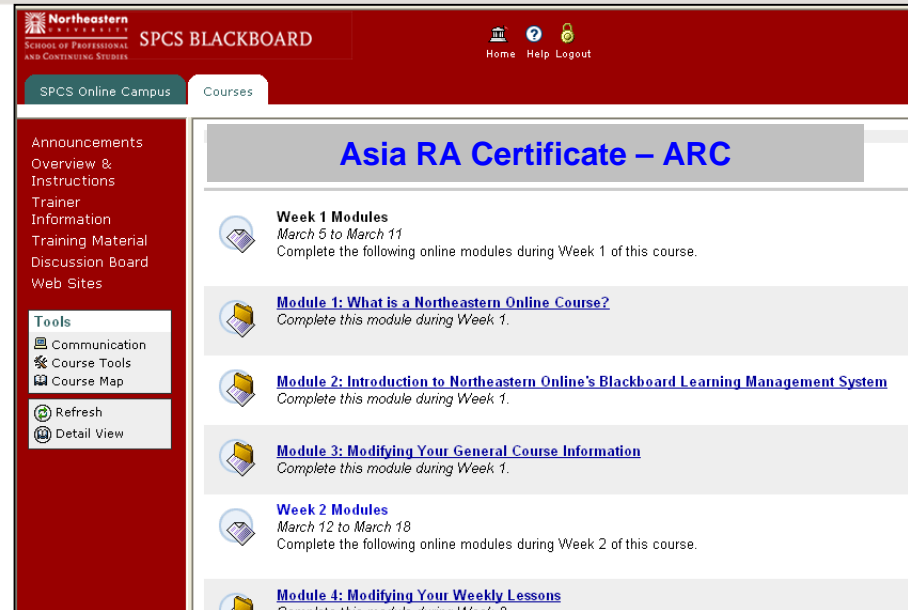
Proposal B: NEU & AHWP RA Certificate Program



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- 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



The screenshot shows the Blackboard interface for the 'Asia RA Certificate - ARC' course. The left sidebar contains navigation links for 'Announcements', 'Tools' (Communication, Course Tools, Course Map), 'Refresh', and 'Detail View'. The main content area lists 'Week 1 Modules' (March 5 to March 11) and 'Week 2 Modules' (March 12 to March 18). Specific modules include 'Module 1: What is a Northeastern Online Course?', 'Module 2: Introduction to Northeastern Online's Blackboard Learning Management System', and 'Module 3: Modifying Your General Course Information'. A 'Module 4: Modifying Your Weekly Lessons' is also listed.

Hyperlink to:



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

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Partnership Benefits



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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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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