NNMD 5470: NANOTECHNOLOGY AND NANOMEDICINE PRODUCT DEVELOPMENT: FROM CONCEPT TO MARKET (SPRING 2015)

Sponsored By
The IGERT Nanomedicine Science and Technology Center
CaNCURE Undergraduate Co-op Program

Fridays 3:30 PM – 6:30 PM
Forsyth Building, 236

Course Description:
This course offers a comprehensive overview of key elements involved in commercialization of nanotechnology-based R&D. Fundamental concepts around various business models, protection of intellectual property (IP), capital and financing, mathematical modeling of business valuation and transactions will be discussed. This course also covers regulatory process for technical and clinical validation of nano-based products, including nanodiagnostics and nanomedicine, as well as mechanisms for raising capital to support product development. Each student is required to complete three projects: (1) an individual technical project, (2) an individual company assessment, (3) and a team project. These projects are selected from key nanomedicine science and business topics, as well as ongoing research activities in Northeastern University and other leading research centers and are designed to apply concepts learned throughout the course.

Course Credits:
3 Semester Hours

Prerequisites:
Graduate and Senior Undergraduate students from Colleges of Science, Business, Engineering and Bouve Health Sciences are eligible to enroll directly. Students from other colleges and non-Northeastern students are also welcome and are eligible to enroll as special students.

Course Instructors:
Mostafa Analoui, PhD
Head of Healthcare and Life Sciences at Livingston Securities

Anne van de Ven, PhD
Nanomedicine Science and Technology Center, NEU
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Srinivas Sridhar, PhD
Department of Physics, NEU

Guest Lecturers: Successful entrepreneurs, local and regional leaders, venture capitalists, regulatory officials, all with expertise in relevant subjects, will be invited to cover segments of this course.

Textbooks and References:
There are no specific textbooks for the course; assigned readings will be announced weekly based on topics being covered and recommendations by invited speakers. The course will utilize some mathematical and accounting techniques, and additional support will be provided for students who may need help in these areas. Explicit technical background in nanosciences is not required and extra reading materials will provided to those who may want to expand their technical knowledge.

Course Outline:
Week 1. Nanotechnology, Nanomedicine Global Market: Current State and Key Challenges
a. Global outlook in Nano-based Products, Medical Devices, Therapeutics and Diagnostics
b. Key Challenges and unmet medical needs
c. Global health and special needs in emerging economies
d. Current Landscape of R&D and Product Pipeline

Week 2. Key Elements from Concept to Market
- a. Innovation
- b. Patient Needs
- c. Regulatory Pathway
- d. Market Demand
- e. Finance
- f. Team
- g. Business Plan Execution

Week 3. Discovery, Technical and Clinical Validation
- a. Technical proof of concept
- b. Key similarities and differences in biomedical and non-bio products
- c. Clinical trials
- d. Ethical issues in conducting preclinical and clinical studies

Week 4. Business Options and Structures
- a. Licensing
- b. Co-Development
- c. Formation of New Business Entity
- d. Example of most recent deals

Week 5. Intellectual Property: US and International Perspectives
- a. Various Mechanisms for Protection
- b. US PTO
- c. International IP flavors

Week 6. Business Plan
- a. Key Ingredients
- b. Pitfalls
- c. Pitch

Week 7. Capital Market
- a. Diluting vs Non-Diluting Sources
- b. Federal and Foundations Sources
- c. Angel Investments
- d. Venture Capital
- e. Private Equity
- f. Other Financing Options

Week 8. Valuation
- a. Qualitative Approaches
- b. Quantitative Methods
  - i. NPV
  - ii. Monte Carlo
- c. Examples of Recent Transactions

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Week 9. Regulatory Processes
- a. FDA
- b. EMA
- c. China and India

Week 10. Role of Management
- a. Leadership and Team Approach
- b. Key roles and rules
- c. Hiring, Employment contracts

Week 11. Market Entry and Exit Strategies
a. Product-based companies
b. Co-Development and licensing
c. Mergers and Acquisition
d. IPO

Week 12. Manufacturing, Sales and Distribution
a. Pricing COG and Margin
b. Cost of Sales
c. Marketing approaches

Week 13. Group project presentations

Exams and Grading: Students will be evaluated on the basis of their individual technical project, individual company assessment, team project, and level of participation in class discussions.

10% Individual company assessment
20% Individual technical project
50% Group report & presentation
20% Class participation

Individual Company Assessment: Students will conduct a full business and financial analysis of an existing Nanomedicine company.

Individual Technical Project: Students will prepare a technical report describing a current medical need, the state of products in this selected field, and current opportunities and challenges.

Group Projects: Each group will develop a full business plan, market analysis, regulatory process, financing options, and exit strategies around a given concept. Concepts may be selected from ongoing research projects at Northeastern University.

A mini business plan competition will be held to offer students an opportunity for feedback and learning. Students will present their business plan as a group. For future offering this course, this competition can be judged by local and regional investors, with appropriate prizes and support for the most promising ideas to move forward.

Important dates:

Feb 27: Individual project due

March 20: Individual company assessment due

April 10: Group project business plan due

April 17: Business plan competition