

**NNMD 5470**  
**NANOTECHNOLOGY AND NANOMEDICINE PRODUCT DEVELOPMENT: FROM CONCEPT TO**  
**MARKET**  
**(SPRING 2014)**

**SPONSORED BY THE IGERT NANOMEDICINE SCIENCE AND TECHNOLOGY CENTER**

**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 two projects: (1) an individual project, (2) and a team project. These projects are selected from ongoing research activities in Northeastern University and other leading research centers and are designed to apply concepts learned throughout the course.

**Lecture Time and Place:**

Spring 2014 Wednesday: 4:35 PM – 7:35 PM

Location: TBD

**Course Credits:**

3 Semester Hours

**Pre-requisite:**

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.

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 be provided to those who may want to expand their technical knowledge.

**Course Instructors:**

Mostafa Analoui, PhD

Head of Healthcare and Life Sciences at Livingston Securities.

Professor Srinivas Sridhar

**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.

**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

**SPRING BREAK**

Week 8. Valuation

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

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. Project Review and Selection

**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.

**Assessment:**

**Case Studies:** A total of eight case studies will be presented throughout the course. Elements of each case will be covered according to the topic under discussion. Cases include examples from non-medical products, and medical devices (implants, imaging, Point of Care Diagnostics), Therapeutics (cardiovascular, oncology and diabetes) and healthcare tools (EMR/HER, Genomic-based solutions).

**Individual Project:** Each student will receive individual assignments around each of cases.

**Group Projects:** Each group will have to develop full business plan, market analysis, regulatory process, financing options, and exit strategies around a given concept. Concepts will be selected from ongoing research projects at Northeastern University. Concepts will be nominated by Northeastern University faculty members and graduate students.

A mini business plan competition will be held to offer students an opportunity for feedback and learning. 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.

**Exams and Grading:**

Overall grade is based on weekly homework, individual and team projects. The final grade is heavily based on class participation and project performance.

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