Course Title: Biomedical Product Development: From Concept to Market

Course Description:

This course offers a comprehensive overview of key elements involved in commercialization of biomedical technologies. Fundamental concepts around various business models, protection of IP, capital and financing, mathematical modeling of business valuation and transactions will be discussed. Course also covers regulatory process for technical and clinical validation of biomedical solutions, as well as mechanism for raising capital to support product development. Each student is required to complete two projects: (1) individual project, (2) and team project. These projects are selected from ongoing research activities in UConn and other leading research centers and are designed to apply concepts learned throughout the course.

Notes:

- It is expected that some of ongoing research projects in UConn to into products and business opportunity, via course and follow-up events
- Attracting corporate partners and sponsors for lecturing and support of BME program
- Creating internship opportunities
- Gateway for technology transfer and fostering new business opportunities
- Content needs to be finalized based on other courses currently being offered in UCONN curriculum.
Course Outline

1. Biomedical Global Market: Current State and Key Challenges
   a. Global outlook in 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

2. Key Elements from Concept to Market
   a. Innovation
   b. Patient needs
   c. Regulatory pathway
   d. Market demand
   e. Finance
   f. Team
   g. Execution of business plan

3. Discovery, Technical and Clinical Validation
   a. Technical proof of concept
   b. Clinical trials
   c. Ethical issues in conducting preclinical and clinical studies

   a. Various mechanisms for protection
   b. US PTO
   c. International IP flavors

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

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

8. Valuation
   a. Qualitative approaches
   b. Quantitative methods
      i. NPV
      ii. Monte Carlo
   c. Examples from most recent transactions

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

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

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

12. Manufacturing, Sales and Distribution
    a. Pricing COG and Margin
    b. Cost of Sales
    c. Marketing approaches
**Case Studies:** Total of eight case studies will be presented throughout the course. Elements of each case will be covered according the topic under discussion. Cases include examples from 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 UConn. Concepts will be nominated by UConn 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.

**Guest Lecturing:** Local and regional leaders with expertise in relevant subjects will be invited to cover segments of this course.

**3 Credit Hour**

**Pre-requisite:** Graduate Level Standing from BME, MBA, MD programs (student with graduate standing in Engineering school can be consisted). While mathematical and accounting are essential, additional support will be provided for students who may need help in these areas.

**Exams and Grading:**

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

**Textbooks and References:** TBA