

Clinical Problem Solving Through Strategic Analysis I

Course Abbreviation: BIOEN 6901

Designation: Required for Graduate BME students in the BioInnovate track

Course Description:

This is a two semester graduate level course focused on the process of strategic analysis of complex clinical problem solving through evaluation of diagnostic processes, current therapeutic approaches and clinical outcomes. Students will learn to critically evaluate real-world clinical problems from a global perspective, and then identify diagnostic and therapeutic deficiencies that can be addressed through process of innovating medical technologies. The academic-based lectures in clinical problem solving through bioinnovation will be reinforced through applied application of course material in clinic-based workshops. The course will provide the academic foundation for mastery of the entire spectrum of the problem solving process from clinical needs finding to needs analysis, concept generation and refinement to prototyping, intellectual property protection, and business planning. The text-based lecture series will be complimented with interactive lectures that provide real-world examples of the medical innovation process given by guest lecturers who have successfully navigated the strategic biodesign process and impacted healthcare through innovating technologies.

Course Prerequisites: Instructor approval required for enrollment.

Credit Hours: 3

Number of Weekly Instructional Contact Hours: 3

Courses will be offered: Fall and Spring Semesters

Class Times: Mondays and Wednesdays from 1:00-2:30 PM Room TBA

Semester of Implementation: Fall 2011

Course Director:

John Langell, M.D., Ph.D., M.P.H.

Office Hours: Mondays 10:00-12:00 in SOM 3B150 or by appointment

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Course Objectives:

1. Students will gain competency in the methodology of strategic clinical problem solving through a lecture-based format with enhancement of the foundational knowledge through interactive discussions, clinical case studies and clinical workshops.
2. Students will learn and retain the core elements of biodesign needs finding, concept generation and refinement, market analysis, strategic planning, intellectual property protection and business planning.
3. Students will learn to identify and assess ethical issues associated with innovating clinical technologies and the resources available to ensure ethical standards are appropriately applied to the innovation process.
4. Students will gain an appreciation of the pitfalls encountered in real world application of the clinical innovation process through firsthand accounts of case studies presented by experienced entrepreneurs who have successfully navigated the process.
5. Students will learn the intricacies and pitfalls of market analysis and business plan development involved in the clinical introduction of new medical technologies.

Teaching and Learning Methods: Teaching and learning will be accomplished through a combination of lectures, hands on clinical workshops and text-based readings.

Tentative Class Schedule:

Week	Date	Seminar Topic	Assignments
1	8/22 8/24	Introduction and Course Description Clinical needs finding: Strategic Focus	Clinical workshop (Assigned needs finding I)
2	8/29 8/31	Clinical needs finding: Observation process Clinical needs finding: Needs statement development	Clinical workshop (Assigned needs finding II)
3	9/5 9/7	Holiday Clinical needs finding: Case study	
4	9/12 9/14	Needs screening: Disease state fundamentals Needs screening: Disease state fundamentals part II	Written Assignment I due by end of class on 9/14
5	9/19 9/21	Needs screening: Clinical treatment options Needs screening: Clinical case study of screening initial screening process	Clinical workshop (Clinical specialty selection)
6	9/26 9/28	Needs screening: Stakeholder Analysis Needs screening: Market analysis	Clinical workshop (Specialty needs finding I)
7	10/3 10/5	Needs screening: The filtering process Needs screening: Case Study	Clinical workshop (Specialty needs

			finding II)
8	10/10 10/12	Fall Break Concept generation: Ideas & Brainstorming	Written Assignment II due by end of class on 10/12
9	10/17 10/19	Concept generation: Concept screening Concept generation: Case study	Clinical Workshop (Specialty needs screening)
10	10/24 10/26	Concept selection: Intellectual property I Concept selection: Intellectual Property II	Clinical Workshop (Specialty needs selection)
11	10/31 11/2	Concept selection: Regulatory basics I Concept selection: Regulatory basics II	
12	11/7 11/9	Concept selection: Case study Concept selection: Financial viability	Written Assignment III due by end of class on 11/19
13	11/14 11/16	Concept selection: Business Models Concept selection: Business model case review	Clinical Workshop (Concept generation)
14	11/21 11/23	Concept selection: Prototyping I Concept selection: Prototyping II	Clinical Workshop (Concept selection)
15	11/28 11/30	Concept selection: Selection prioritizing Concept selection: Final selection process	
16	12/5 12/7	Clinical Case Studies Introduction to the implementation process	Written Assignment IV due by end of class on 12/7

Evaluation Methods:

	Percentage
Attendance	30%
Participation	20%
Evaluation of written assignments	50%

Grade Scale:

A	95-100%
A-	90-95%
B+	87-89%
B	84-86%
B-	80-83%
C+	77-79%
C	74-76%
C-	70-73%

Required Text:

BIODESIGN, The Process of Innovating Medical Technologies. Zenios, Makower, Yock. 1st Ed, Cambridge University Press, 2010

ADA Statement: The University of Utah seeks to provide equal access to its programs, services and activities for people with disabilities. If you will need accommodations in the class, reasonable prior notice needs to be given to the [Center for Disability Services](#), 162 Union Building, 581-5020 (V/TDD). CDS will work with you and the instructor to make arrangements for accommodations.

Academic Honesty: All honesty and plagiarism policies established by the University of Utah will be upheld in this class. Academic misconduct includes, but is not limited to, representing another's work as your own, collaborating on individual assignments without instructor's written permission, and submitting the same work for more than one course without the written permission of both instructors. Any of these actions will not be tolerated.

If you include information from outside of the class or quotes in your written assignments, you must provide citations and a reference list.

For further information about the University of Utah's academic misconduct policies please refer to the online Student Handbook at:

<http://www.acs.utah.edu/sched/handbook/toc.html>

University Drop and Withdrawal Policies: Students may withdraw from this course or receive an "Incomplete" as per standard university policy and in accordance with established timelines noted in the University of Utah's academic misconduct policies please refer to the online Student Handbook at:

<http://www.acs.utah.edu/sched/handbook/toc.html>. **Because participation in this course is limited to students enrolled in the BioInnovate Fellowship, unsuccessful completion may result in removal from the fellowship and loss of matriculation status from the School of Bioengineering.**

Student Responsibilities:

1. Attend and participate in class activities and discussions
2. Complete assignments on time or make arrangements for extensions with the instructor in advance of the assignment due date.
3. Arrive to class on time and stay for the entire period of instruction.
4. Listen attentively and conduct yourself in a manner that is respectful of classmates and the instructor.
5. Turn off cell phones and other disruptive devices for the entire class period.
6. Seek the course instructors guidance during published office hours for assistance with questions regarding class policies or for assistance with the academic materials.
7. Read and abide by the class syllabus

8. review the University policies on student rights and responsibilities at:
<http://www.admin.utah.edu/ppmanual/8/8-10.html>

Instructor Responsibilities:

1. Show up to class on time and prepared to provide the scheduled instruction
2. Provide students with appropriate feedback in a timely fashion.
3. Be available for consultation during scheduled office hours or by appointment.
4. Treat all students fairly and with respect
5. Ensure an appropriate teaching environment is maintained that will optimize student learning objectives.
6. Provide feedback on graded assignments in a timely fashion.
7. Abide by University of Utah policies regarding faculty responsibilities. For full details please refer to: <http://www.admin.utah.edu/ppmanual/8/8-12-4.html>

Institutional Impact of New Course

Rationale for addition of course: This is a new course that will introduce graduate students to the strategic process of bioinnovation to include; clinical needs finding, concept generation, market analysis, intellectual property protection, and business model design and implementation. The goal is to provide students with the foundational knowledge to successfully implement the bioinnovation process through a multidisciplinary team approach.

Financial Impact of New Course

Resources Needs: A qualified instructor, guest lecturers and part-time administrative support.