

**ENTR 481A/581A- Innovation, Translation and Entrepreneurship
Spring 2016
McClelland 130**

Marvin J. Slepian MD

**Email: chairman.syns@gmail.com - (preferred)
slepian@email.arizona.edu**

Office: Sarver Heart Center – 5th Floor

Teaching Assistant: Michael Dicaro

Office Assistant: Kristen Ginn

Office Phone: (520) 626-8543

Email: kginn@email.arizona.edu

I. Course Topics/Lecture/Discussions

1. Into to Class, Topics, Goals, Mission, People, Team Building

Overall course thesis: There is a methodology that may be utilized to facilitate innovation. Innovation skills may be taught.

2. Innovation and Invention

Terms: Idea, Inventiveness, Invention, Novelty, Innovative, Innovation

Definition and differences

Innovation Theory – Schumpeter, Drucker, Historic waves of Innovation

Innovation – Types, Examples

Historic approach

Current approaches

Pros, Cons, Limitations

3. Innovation Expanded

Can it be taught? How?

Idea to Innovation Continuum

Drivers of innovation

The Unmet Need

Awareness of Science and Technologies

Methods of synthesis

Brainstorming

Thinking

Case examples

4. Innovation – Thinking, Creativity and How to “Go Somewhere”

More on Thinking

Innovation Methodology – Describe, Analyze, “Go Somewhere”

Dreams

Creativity

Connectivity

Open Innovation

Areas in need of Innovation – General, Medical
Attempts at Innovation – Home exercise

5. Innovation – Attention, Selectivity, Selection Criteria

Attention, Selective Attention, Change blindness, Intuition
Need for Selectivity/Choice in moving forward with Innovation
Criteria for moving forward with an idea
Innovation Ranking
Developing ranking systems/metrics

6. Innovation Examples/Cases Studies

Specific Innovations
Innovative Corporations
Innovations – Always good - One step forward, two steps backward?
Group presentations – “chosen” Innovation – what, why, - the defense?

7. Understanding the Market

Market Space
Marketplace
Market Research and Tools
Market forces
The Product Development Cycle
Assessing Clinical and market Potential

8. Unmet Medical Needs

Fields
Diseases
Specifics
Discussion

9. Health care, Medical Device and Pharma Industries, Unmet Medical Needs and Diseases

US Health Care System
World Health care
Population Growth
Stresses to Health Care
Stresses/Reality of Pharma and Medical Device R and D and Costs
Leading Causes of ER presentation, Hospitalization, readmission
Unmet Medical needs – by organ system

10. Cutting edge Science/Technology – Building Blocks for Innovation

Omics – Genomics, Proteomics, Metabolomics, Bioelectromics
Biomaterials/Polymers
Microelectronics
Nanotechnology

Microfluidics
Imaging
Big Data

11. Intellectual Property

Know How
Disclosures
Patents
Assignment, Licensing
Maintenance
Writing patents, Drafting Claims
New IP law changes

12. Translational Research

Definition
The translation process
 Clinic to bench
 Bench to bedside
Device development steps/pathways
Drug development pathways
Combination device developments
Special cases

13. Device Prototyping

Hard building
Computer simulation
Proof-of-principle
Pre-clinical testing

14. The Regulatory Process - Getting a Medical Device Registered, Cleared and/or Approved

Regulatory Agencies - U. S. - FDA, OIG,
Regulatory Agencies - OUS - EU, Notified Bodies
Regulatory process
The Quality System
Device Classification
The Approval Process
Post-Approval Process

15. Project Funding

Funding requirements
Academic Grants
SBIR/STTR
Angel funding
Venture Capital
Corporate alliances

16. Essential of Writing a Business Plan

17. Essentials of Writing an Operating Plan

18. Strategies for Developing a Development and Operating team

19. Ethical Issues and Conflict of Interest

20. Exit and Transition Strategies for Medical Device Start-ups

II. Outside Speakers:

To be announced

III. Video Conference:

The FDA

IV. Homework:

Periodic assignments

Assigned Reading

V. Requirements/Grading

Midterm – 25%

Final/Paper/Project– 25%

Homework Assignments – 30%

Class Participation – 20%

VI. Arizona Innovation 100 List Project

VII. Rationale/ Course Theme:

Innovation continues to be a main driver in the advance of clinical medicine. Increasingly medical devices have emerged as playing a vital role in advanced diagnostics, therapeutics and monitoring of patients with a wide variety of conditions. Yet despite these advances the continued growth and progression of device and novel therapeutic development are presently in increasing jeopardy. Daily in the news are issues related to the precarious state of the economy and the drive to modify and significantly reform the health care system. We are at “the worst of times and we are at the best of times.”

In reality it will be through continued innovation that technologies will emerge that improve diagnosis and therapy, reducing hospitalization and repeat medical visits, reducing costs. It will be through innovation that medical quality and the ratio of outcomes/dollars expended will improve. It is also through innovation and device development that new entrepreneurial ventures may be spun-out which will bolster and help drive economic

recovery. Hence we are at “the best of times” to embrace innovation, translation and entrepreneurship, particularly in the medical sector. In fact, it is the medical sector that has led job growth (>10%), a particularly interesting point in light of the current rise in unemployment.

So how do we innovate? How do we invent? How do we identify areas of need and opportunities with likely success? How do we raise capital in trying times to drive this process? How do we handle intellectual property, navigate the complex FDA regulatory world and obtain reimbursement from CMS? None of this to date exists in a course or in a book. Over the past twenty-five years I have navigated this space, while maintaining an academic life, with a parallel career in medical entrepreneurship.

It is my goal with ENTR 481/581 to teach a course on “Innovation, Translation and Medical Entrepreneurship.” This course will be multi-disciplinary aimed at students in the medical school, engineering school and the business school – all the human elements needed in the medical device/biotech/pharma development process. Through this course not only will critical topics be covered, with the goals of providing working and how-to knowledge of material and steps necessary for innovation and corporate start-up formation, but also outstanding issues will be explored with the goals of identifying problematic areas in need of process improvement. This course will fill a gap in the knowledge base for medical, engineering, business and even law students. Further this course will likely lead to successful networking, critical mass and the “spark” necessary for real innovation, invention and even potential spin-out development. It will also provide for focusing of these activities that has largely been lacking to date in the medical school, with potential long-term practical benefits to all stakeholders.