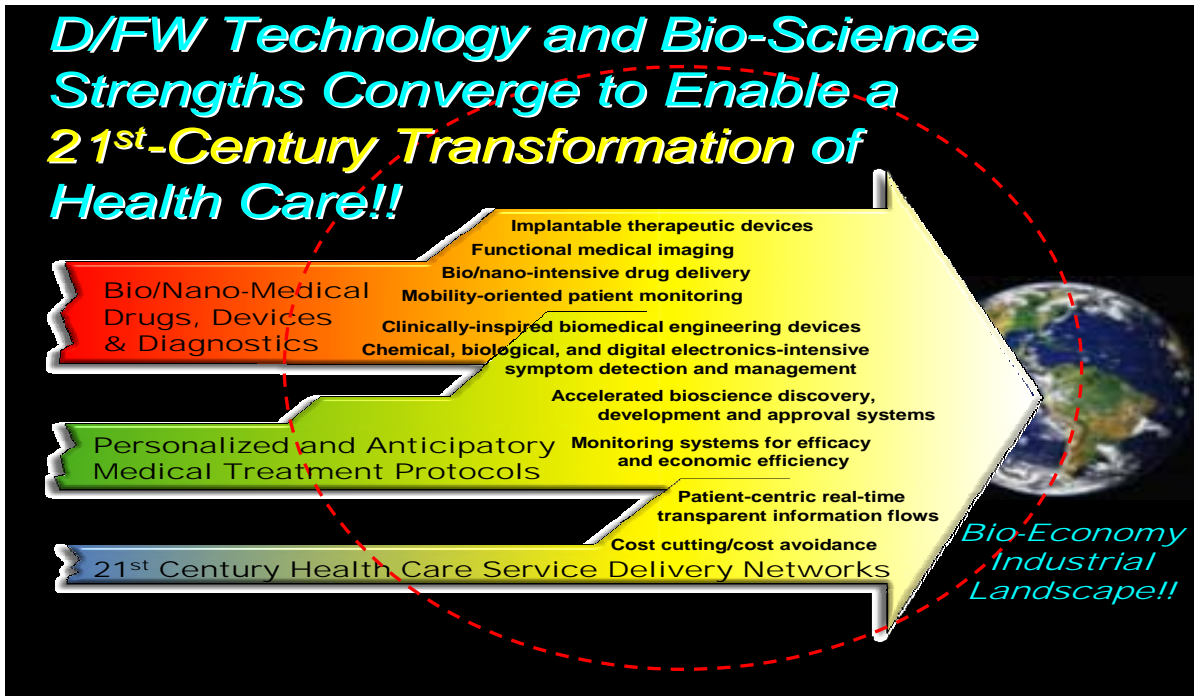


Bringing DFW to Life...

Emerging Opportunities at the Intersection of North Texas ICT and Bioscience Strengths and Health Care Service Delivery

SCI 5V06/POEC 7329
Summer 2007
M 4:00-8:00pm SOM 1.502
Office Hours: TBD

INSTRUCTOR: **D.A. Hicks**
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Distinguished lecturers, including bioscience/engineering entrepreneurs, IT technology/health care executives, and venture capital/angel investors join me in presenting an 11-week graduate course that explores a series of critical factors necessary for incubating a commercial bio-economy in North Texas. This course seeks to identify opportunities for commercializing bioscience discoveries and biomedical engineering technical advances, launching new ventures, and innovating at the intersections of North Texas' technology competencies, world-class biomedical research and health care service delivery.

This unique educational experience brings together an energetic mix of the best and brightest students, industry professionals, and distinguished lecturers to discuss how best to stimulate the innovation and entrepreneurship essential to developing a growing and competitive bio-economy in North Texas region.

Classes will be held in The University of Texas at Dallas, School of Management, Executive Education Center room 1.502 located at 800 West Campbell Road, Richardson, Texas. All classes

will begin at 4:00 p.m. with a short networking period and will conclude by 8:00 p.m. There will be breaks in the schedule for Memorial Day and the July 4th weekend. Regular tuition and fees apply for graduate students taking the course for credit. Enrolled students will be responsible for assigned background readings, participation discussions following guest lectures, and in preparing a research paper on a topic to be chosen in consultation with the instructor.

Student Learning Objectives

After completing this course, students should be able to:

1. Describe and evaluate the ecology of the emerging/potential bio-economy in the DFW region.
2. Understand and articulate the significance of the circumstances that many believe are leading to a 2nd Biotech Industrial Era in which new complementary and clustered assets in new regional locations like North Texas could well play a leadership role.

Reading Resources

Course readings will be drawn from a variety of sources. In addition to materials that may be provided by Guest Lecturers, a variety of articles and related instructional materials will be posted on a website hosted by [Blackboard.com](http://blackboard.com) that has been developed for this course. You may enter this site by entering the following URL: <http://blackboard.utdallas.edu/>. You will then be asked to provide a User Name and a Password to enter the site. All of you will be enrolled in Blackboard using your UT-D e-mail address. If you do not know your UT-D e-mail address, contact me. Plan on checking your e-mail regularly – preferably daily – as that will be my primary way of communicating with you between class sessions.¹

You may wish to re-familiarize yourself with basic economic concepts by visiting free tutorial websites such as www.digitaleconomist.com.

COURSE ADMINISTRATION AND GRADING

This course has been designed to follow a lecture-discussion format. While I have a substantial volume of material that I am prepared to cover with you, I want to encourage group discussion on issues of particular interest to us. So, please be prepared to initiate and participate in those discussions. Final details concerning course evaluation criteria will be determined once information on class size and composition is available. Generally, however, I have in mind an evaluation process that assigns priority to a written paper/project on a topic to be selected in consultation with the Instructor.

Final versions of the required paper will be at least 15 pages in length, not counting appendices,

¹ U.T. Dallas provides each student with a free email account that is to be used in all communication with university personnel. This allows the university to maintain a high degree of confidence in the identity of all individuals corresponding and the security of the transmitted information. The Department of Information Resources at U.T. Dallas provides a method for students to forward email from other accounts to their U.T. Dallas address and have their U.T. Dallas mail sent on to other accounts. Students may go to the following URL to establish or maintain their official U.T. Dallas computer account: <http://netid.utdallas.edu/>.

footnotes, and bibliography. The due date is August 6, 2007. **There will be no grades of Incomplete (X) given without appropriate documentation of the reason for the request.** Even if this should create an uncomfortable situation, I WILL ask you to provide documentation. Due to past abuses, I can make no exceptions to this policy.

If you experience a problem or have questions at any time, contact me promptly. In addition to office hour options we will discuss in class, I am ready to arrange to meet with you at almost any other mutually agreeable time. However, in fairness to you and others, it would be wise for you to contact me before/after class or by e-mail to **make an appointment first** so that I can reserve the time for you alone. Some questions can be handled in a phone conversation, if you prefer. Where that is your preference, please call my office *anytime*. If I am not in my office, leave me a voice-mail message with a time window for me to call you back as well as a telephone number. Speak slowly and clearly. I check for messages all through the week, including weekends, holidays and daily when I am out of town. The best way to communicate with me promptly is via e-mail.

TOPIC / GUEST LECTURER SCHEDULE AND KEY QUESTIONS

Note: **Confirmed speakers in bold**, although dates are subject to change

Following introductory material presented by the Instructor, subsequent sessions will be led by Guest Lecturer lecturers who have special competence and experience in respective “Key Question” topic areas:

May 14: **Introduction and Course Overview** [Donald Hicks, Instructor]

The purpose of this course is to describe the landscape of opportunity at the intersection of life sciences-oriented biomedical/bioengineering research and clinical activity and North Texas’ industrial technology strengths in microelectronics- oriented information and communication technologies (ICT). What will it take to unlock the commercial potential at these intersections? Who are the key players and what are the emerging opportunities in the DFW bio-economy? Where will the entrepreneurs come from? And, finally, what is the potential payoff to the region if it succeeds adding biomedical/health services delivery to its industrial strengths?

May 21: **Sizing Up the Biomedical/Biotechnology Venture Sector** [Guest Lecturer: Kenneth Bernstein, Ernst & Young]

- *How has the U.S. biotech sector grown and developed?*
- *What are the drivers, the barriers, and its prospects?*
- *What factors influence the extent to which the growth and development in this domain can be hosted/harnessed by the North Texas region?*

May 28: Memorial Day: No Class

June 4: Moving Biomedical Discovery from Mind to Market

[Guest Lecturers: Lawrence (Joe) Allred, Venture Development and Jim Watson, Technology Development, UT Southwestern Medical Center; Dr. Daniel Scott (Director, Natural Orifice Transluminal Endoscopic Surgery [NOTES], UTSW)]

- *How does the University of Texas Southwestern Medical Center (one of the world's leading medical research institutions) enable in-house research discoveries in the molecular basis of metabolism and disease to move onto a commercialization pathway?*
- *How are potential institutional and cultural barriers overcome (or avoided) so that a pipeline of biomedical innovation can be developed linking laboratory activity to eventual patents, licensing agreements and/or the launch of new biomedical ventures?*
- *On what metrics can the stature of UT Southwestern be judged relative to peer institutions in the United States and beyond?*
- *How does UT Southwestern identify and "connect" engineering and related technology strengths in North Texas industry to the biomedical research conducted at your institution?*
- *What factors must be addressed in developing partnerships and working relationships between biomedical researchers and industry-based engineers so as to facilitate and accelerate their collaboration?*

June 11: Expanding Categories of Biomedical Therapeutics and the Transformation of Business Models That Make Them Possible

[Guest Lecturers: Melissa Krauth, Director, Program Development Director, Reata Pharmaceuticals; Rohan Hoare, VP Strategy and Emerging Therapies, Advanced Neuromodulation Systems]

- *Does Reata Pharmaceuticals represent a departure from the conventional biopharma venture startup of the 20th century? If so, in what sense and why?*
- *Does Reata's success symbolize the emergence of a new business model in biopharma? If so, what are its defining features? What are the implications of such transformations for regions like D/FW wishing to incubate industrial/commercial activity in the bio-economy?*
- *The foundations of the century-old pharmaceutical industry as a source of human therapeutics are being challenged by emerging treatment alternatives. Conventional chemistry-based therapeutics (drugs) are being joined by therapeutic options based on*

biology and more recently digital electronics. What are the prospects for treating – or preventing – disease and disability using digital electronics delivered by external and/or implantable biomedical devices?

- *What are the prospects for North Texas to participate in the expanding biomedical device sector? What factors function as barriers to the design and development of new digital electronic therapeutics and their use in treating patients?*

June 18: The Medical Electronics Frontier: Biomedical Devices, Diagnostics and Health Care Services

[Guest Lecturers: Doug Rasor (VP, Emerging Medical Applications) Texas Instruments; Don Hayes, Founder/CEO, MicroFab Technologies]

- *Texas Instruments, birthplace of the integrated circuit, helped launch the Microelectronics Era. What factors influenced TI's recent decision to begin participating in markets devoted to the design, development, and delivery of next-generation medical electronic devices?*
- *What factors influence the insertion of microelectronic technical advances into biomedical diagnostic and treatment protocols and health care service delivery infrastructures?*
- *What is the commercial potential of those markets and what are the possible barriers to fully exploiting their potential?*
- *MicroFab has delivered micro-scale technology solutions to a wide variety of companies and institutions for the past quarter-century. Describe the range of technology solutions that MicroFab provides to biomedical research, engineering and product development communities.*
- *In what ways do micro-engineering specialists like MicroFab interact with health care service delivery providers? What factors help or hinder those interactions?*

June 25: Designing the 21st-Century Health Care Ecosystem for Information-Intensive Patient Care

[Guest Lecturers: Ed Cantwell, CEO InnerWireless Inc.; Torben Warming (VP Strategic Planning and IP Communications, Ericsson, Jon Wells, VP, Verizon Wireless Inc.)]

- *North Texas emerged by 2000 as the leading wireless communications industry cluster in North America and possibly the world. What opportunities have emerged to deploy the resulting technologies – RFID, identity authentication and biomedical monitoring systems and infrastructure into next-generation health care delivery?*

- *In what ways will Metroplex-based ICT competencies enable the transformation – form, mission and performance – of the 21st-century hospital and health care delivery system?*

July 2: Independence Day Weekend

July 9: Evolution of a Serial Biotech Entrepreneur

[Serial Entrepreneur Resource: Art Bollon, Ph.D, Founder/CEO, HemoBiologic

- *The key ingredient to identifying opportunities and shaping/shepherding bio-intensive research through to the point that they can create wealth through new product development and/or service delivery is the enterprising individual. The key to the creation of the handful of “biotech” industry clusters on the planet is the serial entrepreneur. How did you come to be a bio-entrepreneur?*
- *What motivates the biomedical/bioengineering entrepreneur? What triggers their “alertness” to opportunities and/or explains why they often fail to see risk where others do?*
- *Are entrepreneurs born or can they be created? What can research institutions do to increase the likelihood that its graduates will be oriented to bringing their bioscience/bioengineering research to full commercial potential?*

July 16: Managing the FDA Regulatory Approval Process

[Guest Lecturers: Craig S. Rosenfeld, M.D., Co-Founder/Chief Medical Officer, The Vaccine Company; Courtland Imel, Founder/CEO, Ceutical Labs; Tom Turpen, President, ODC Therapy]

- *Few industries are more tightly regulated than the pharmaceutical, biotech and biomedical device industries. What are the defining features – and weaknesses – of the U.S. regulatory review process? How well does this regulatory system work?*
- *Are there ways to redesign the system for greater efficiency and faster, less costly delivery of regulatory approvals?*

July 23: Emerging Opportunities, Entrepreneurship, and Strategic Investment

[Guest Lecturers: William Paiva, Sevin-Rosen; Keith Brown, President/CEO, TissueGen; Stephen Fluckiger, Jones-Day; Elizabeth Jones, Executive-in-Residence]

- *North Texas has not been a center of biomedical/biotech entrepreneurial activity, although there are signs that that may be slowly changing. What are the barriers that have operated to limit the region's participation in the rapidly-emerging bio-economy?*
- *What evidence is there that entrepreneurs are staking out opportunities that draw on the region's unique mix of technology strengths?*
- *What options are there for accelerating the pace at which the region identifies and capitalizes on emerging biomedical bioengineering opportunities?*

July 30: Bio-Processing Frontiers: Nutraceuticals, Bio-Processing, Environmental Remediation

[Guest Lecturers: Peter Balbus, CEO, Pragmaxis, LLC; Dan Foster, President, CapRock Bio-Processing; Sam Hatcher, Liberty Industries, Ltd.; Noble Foundation/TAMU]

- *The biosciences have a commercial "reach" well beyond human-oriented drugs, devices and diagnostics. Increasingly, opportunities in "industrial biotechnology" have multiplied with the prospects for bio-processing in alternative energy sources, waste management and environmental remediation, and applications new food products with therapeutic properties.*
- *What are the linkages between North Texas technology strengths and natural resource applications?*

August 6: Course Wrap-Up and Graduate Paper Presentations
[Donald Hicks, Instructor]

- *Graduate students enrolled for course credit will give brief presentations of their written course paper/project. Enrollees for certificate credit will give brief presentations of their report on applications of course materials to their professions and/or place of business.*

Student Conduct & Discipline

The University of Texas System and The University of Texas at Dallas have rules and regulations for the orderly and efficient conduct of their business. It is the responsibility of each student and each student organization to be knowledgeable about the rules and regulations which govern student conduct and activities. General information on student conduct and discipline is contained in the UTD publication, *A to Z Guide*, which is provided to all registered students each academic year.

The University of Texas at Dallas administers student discipline within the procedures of recognized and established due process. Procedures are defined and described in the *Rules and Regulations, Board of Regents, The University of Texas System, Part 1, Chapter VI, Section 3*, and in Title V, Rules on Student Services and Activities of the university's *Handbook of Operating Procedures*. Copies of these rules and regulations are available to students in the Office of the Dean of Students, where staff members are available to assist students in interpreting the rules and regulations (SU 1.602, 972/883-6391).

A student at the university neither loses the rights nor escapes the responsibilities of citizenship. He or she is expected to obey federal, state, and local laws as well as the Regents' Rules, university regulations, and administrative rules. Students are subject to discipline for violating the standards of conduct whether such conduct takes place on or off campus, or whether civil or criminal penalties are also imposed for such conduct.

Academic Integrity

The faculty expects from its students a high level of responsibility and academic honesty. Because the value of an academic degree depends upon the absolute integrity of the work done by the student for that degree, it is imperative that a student demonstrate a high standard of individual honor in his or her scholastic work.

Scholastic dishonesty includes, but is not limited to, statements, acts or omissions related to applications for enrollment or the award of a degree, and/or the submission as one's own work or material that is not one's own. As a general rule, scholastic dishonesty involves one of the following acts: cheating, plagiarism, collusion and/or falsifying academic records. Students suspected of academic dishonesty are subject to disciplinary proceedings.

Plagiarism, especially from the web, from portions of papers for other classes, and from any other source is unacceptable and will be dealt with under the university's policy on plagiarism (see general catalog for details). This course will use the resources of turnitin.com, which searches the web for possible plagiarism and is over 90% effective.

Email Use

The University of Texas at Dallas recognizes the value and efficiency of communication between faculty/staff and students through electronic mail. At the same time, email raises some issues concerning security and the identity of each individual in an email exchange. The university encourages all official student email correspondence be sent only to a student's U.T. Dallas email address and that faculty and staff consider email from students official only if it originates from a UTD student account. This allows the university to maintain a high degree of confidence in the identity of all individual corresponding and the security of the transmitted information. UTD furnishes each student with a free email account that is to be used in all communication with university personnel. The Department of Information Resources at U.T. Dallas provides a method for students to have their U.T. Dallas mail forwarded to other accounts.

Withdrawal from Class

The administration of this institution has set deadlines for withdrawal of any college-level courses. These dates and times are published in that semester's course catalog. Administration procedures must be followed. It is the student's responsibility to handle withdrawal requirements from any class. In other words, I cannot drop or withdraw any student. You must do the proper paperwork to ensure that you will not receive a final grade of "F" in a course if you choose not to attend the class once you are enrolled.

Student Grievance Procedures

Procedures for student grievances are found in Title V, Rules on Student Services and Activities, of the university's *Handbook of Operating Procedures*.

In attempting to resolve any student grievance regarding grades, evaluations, or other fulfillments of academic responsibility, it is the obligation of the student first to make a serious effort to resolve the matter with the instructor, supervisor, administrator, or committee with whom the grievance originates (hereafter called "the respondent"). Individual faculty members retain primary responsibility for assigning grades and evaluations. If the matter cannot be resolved at that level, the grievance must be submitted in writing to the respondent with a copy of the respondent's School Dean. If the matter is not resolved by the written response provided by the respondent, the student may submit a written appeal to the School Dean. If the grievance is not resolved by the School Dean's decision, the student may make a written appeal to the Dean of Graduate or Undergraduate Education, and the dean will appoint and convene an Academic Appeals Panel. The decision of the Academic Appeals Panel is final. The results of the academic appeals process will be distributed to all involved parties.

Copies of these rules and regulations are available to students in the Office of the Dean of Students, where staff members are available to assist students in interpreting the rules and regulations.

Incomplete Grade Policy

As per university policy, incomplete grades will be granted only for work unavoidably missed at the semester's end and only if 70% of the course work has been completed. An incomplete grade must be resolved within eight (8) weeks from the first day of the subsequent long semester. If the required work to complete the course and to remove the incomplete grade is not submitted by the specified deadline, the incomplete grade is changed automatically to a grade of F.

Disability Services

The goal of Disability Services is to provide students with disabilities educational opportunities equal to those of their non-disabled peers. Disability Services is located in room 1.610 in the Student Union. Office hours are Monday and Thursday, 8:30 a.m. to 6:30 p.m.; Tuesday and Wednesday, 8:30 a.m. to 7:30 p.m.; and Friday, 8:30 a.m. to 5:30 p.m.

The contact information for the Office of Disability Services is:
The University of Texas at Dallas, SU 22
PO Box 830688
Richardson, Texas 75083-0688
(972) 883-2098 (voice or TTY)

Essentially, the law requires that colleges and universities make those reasonable adjustments necessary to eliminate discrimination on the basis of disability. For example, it may be necessary to remove classroom prohibitions against tape recorders or animals (in the case of dog guides) for students who are blind. Occasionally an assignment requirement may be substituted (for example, a research paper versus an oral presentation for a student who is hearing impaired). Classes enrolled students with mobility impairments may have to be rescheduled in accessible facilities. The college or university may need to provide special services such as registration, note-taking, or mobility assistance.

It is the student's responsibility to notify his or her professors of the need for such an accommodation. Disability Services provides students with letters to present to faculty members to verify that the student has a disability and needs accommodations. Individuals requiring special accommodation should contact the professor after class or during office hours.

Religious Holy Days

The University of Texas at Dallas will excuse a student from class or other required activities for the travel to and observance of a religious holy day for a religion whose places of worship are exempt from property tax under Section 11.20, Tax Code, Texas Code Annotated.

The student is encouraged to notify the instructor or activity sponsor as soon as possible regarding the absence, preferably in advance of the assignment. The student, so excused, will be allowed to take the exam or complete the assignment within a reasonable time after the absence: a period equal to the length of the absence, up to a maximum of one week. A student who notifies the instructor and

completes any missed exam or assignment may not be penalized for the absence. A student who fails to complete the exam or assignment within the prescribed period may receive a failing grade for that exam or assignment.

If a student or an instructor disagrees about the nature of the absence [i.e., for the purpose of observing a religious holy day] or if there is similar disagreement about whether the student has been given a reasonable time to complete any missed assignments or examinations, either the student or the instructor may request a ruling from the chief executive officer of the institution, or his or her designee. The chief executive officer or designee must take into account the legislative intent of TEC 51.911(b), and the student and instructor will abide by the decision of the chief executive officer or designee.