



University of Pittsburgh

Office of Enterprise Development, Health Sciences

presents

"From Benchtop to Bedside *What Every Scientist Needs To Know*"

**A 10-week course for scientists and physicians who want to move
basic research discoveries to the patient**

**Course Syllabus
January 25 – April 5, 2011**

Offices of Enterprise Development and Technology Management

Marc Malandro, Ph.D., Associate Vice Chancellor and Director

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From Benchtop to Bedside **Course summary**

This 10-week course is offered by the University of Pittsburgh's Offices of Enterprise Development and Technology Management. The course is designed to give research scientists, clinicians, and other interested parties the basic information necessary to assess the therapeutic or diagnostic potential of basic science research discoveries. The course will help scientists understand the focused development of additional information, including proof of concept and validation experiments, that increase the value of the technology and reduce the investment risk. The course will also give scientists insight into how intellectual property creates a barrier to entry for the competition. The course will also cover the fundamentals of investment from the private sector to help finance the climb over regulatory hurdles and meet critical developmental milestones.

The course content consists of highly interactive seminars that outline the steps necessary to develop a scientific or clinical discovery from the laboratory to the patient. Topics covered include how to: recognize an opportunity and the commercial potential of a scientific discovery, protect the intellectual property, disclose the invention to the university, initiate the university licensing process to a partner company or startup, begin early development of a drug candidate or a device for clinical use, and plan for success within the regulatory guidelines. In addition, the course will clarify the scientist's expected role and responsibilities as the process moves forward through clinical and commercial development.

Goals

Upon completion of the course, attendees are expected to understand the following:

- A process that a scientist can use to screen an invention for commercial potential as a therapy, diagnostic, or device for ultimate use in people;
- How to participate in the process of moving a potentially important therapy or diagnostic towards clinical trials, or an equally important device through the regulatory pathway;
- The University and regional resources available to life science researchers to help them in the process of getting an innovative therapy, diagnostic, or device from the lab to the patient; and
- The need to thoroughly prepare in order to present new technologies to companies, and how to conduct effective industry interactions.

Course instructors

This course is designed and hosted by the Offices of Enterprise Development and Technology Management (OED and OTM respectively), established to encourage and support entrepreneurial activities throughout the University of Pittsburgh Schools of Health Sciences through education and resource support. The instructors associated with the OED/OTM include the following:

- **Babs Carryer** has been President of Carryer Consulting for 15 years (www.carryer.com), providing strategic marketing and business planning services to

technology companies and organizations in the software and life sciences sectors. Babs is widely experienced in the start-up community, having been involved with hundreds of early-stage companies seeking financing, growth, or acquisition partners. Currently, Babs is Director of Deal Flow for BlueTree Allied Angels, and is Embedded Entrepreneur for Project Olympus, which was founded within the School of Computer Science at Carnegie Mellon University to stimulate commercialization of new technologies developed by faculty. Babs co-founded, was past president, and still serves as a secretary, consultant, and board director, of LaunchCyte (www.launchcyte.com), a development company that creates, seeds, and harvests life sciences innovations from leading research universities across the U.S. Currently, LaunchCyte has five life sciences portfolio companies that have collectively raised approximately \$45 million in capital and which have a combined value of approximately \$180 million. Babs has a Masters in Management from Carnegie Mellon University, and is Adjunct Professor of Entrepreneurship at CMU in the Don Jones Center for Entrepreneurship, Tepper School of Business, and in the Heinz College. She is also Innovation Advisor for CMU's Institute for Social Innovation.

- **Marc Malandro, PhD**, is the Associate Vice Chancellor of Technology Management and Commercialization, and the Director of the Office of Enterprise Development and the Office of Technology Management at Pitt. Prior to joining the University, Dr. Malandro co-founded Sagres Discovery, a functional biology company focused on understanding the molecular basis of cancer, where he served as Vice President of Technology and Strategic Alliances. His responsibilities included developing and implementing high-throughput gene identification and gene expression analysis platforms, managing company intellectual property, technology licensing and overseeing scientific collaborations. Sagres Discovery was acquired by the Chiron Corporation, now a part of Novartis. Prior to Sagres, Marc served as Director of Genomics and Applications Development at Celera Agricultural Genomics (Celera AgGen), a division of Celera Genomics, and as Director of Research at PE Agricultural Genomics (PE AgGen), a division of Applied Biosystems. At Celera and Applied Biosystems, Marc was responsible for developing and implementing high-throughput molecular marker technologies and products in plants and animals. He also developed a high-throughput platform for expression-based gene discovery in agriculture that led to the development of several large research collaborations with leading agrochemical and biotechnology companies. Marc received his PhD in Biochemistry and Molecular Biology from the University of Florida College of Medicine, and completed his postdoctoral fellowship in the Department of Human Molecular Genetics at Case Western Reserve University. He is the co-inventor on 15 issued patents and patent applications.
- **Paul Petrovich, CPA**, is the Assistant Director, Technology Commercialization, at the Office of Enterprise Development, where he works closely with Office of Technology Management and university researchers to promote spin-out and start-up companies that utilize University/UPMC discoveries. As a veteran consultant, Paul has provided management consulting services in all business sectors: service, retail, manufacturing and technology-based companies. He maintains an expertise in the federal Small Business Innovation Research (SBIR) program and has consulted with over 80 participant companies, with successful awards of over \$25 million. In 2006, he received the prestigious national Tibbetts Award recognizing his services connecting Western Pennsylvania's technology innovators with SBIR funding for product development. Paul holds a Bachelor of Science in Business Administration from Indiana University of

Pennsylvania, and is a member of the Pennsylvania and American Institutes of Certified Public Accountants.

- **Andrew Remes, PhD**, is the Associate Director of the OED. Andrew co-founded Remes Biomedical, which worked with leading edge pharmaceutical and tissue engineering companies developing computerized image analysis methods for examining the interaction of biomaterials with tissue and developing wound care products. Remes Biomedical won the Glasgow John Logie Baird award for Innovation in 1999, and won two United Kingdom millennium product awards. Andrew moved to the U.S. to join TissueInformatics in Pittsburgh. Subsequently, he joined the OED. For the OED, Andrew reviews hundreds of technologies developed by university scientists. His primary responsibility is as business development liaison to biopharmaceutical industry partners. Andrew holds a BSc in Immunology from Glasgow University, and a PhD in Bioengineering from Liverpool University. In 2006, one of Andrew's papers was honored by the publisher Elsevier and an international scientific committee as being one of the best 25 papers to be published in the journal *Biomaterials* in the last 25 years.

Projects

There is no exam at the end of this class. The final project for this class is a group presentation of a technology developed from a biomedical research project and the detailed analysis of whether that technology can and should be developed into a product(s) for ultimate use in patients. There is a significant cash prize award for further commercialization development that is offered by the OED to the top two group presentations. See project handout for more detail. Course attendees are encouraged to invite guests to the final presentations.

For-Credit Attendees

A written mini-business plan is required only for University of Pittsburgh attendees taking this course for credit. More detail can be found in the handout for this project.

Course materials

We provide a folder with certain course documents, including the syllabus, project handouts, and HBR case studies. All powerpoint slides will be printed for handout on the day on any particular lecture or talk. We will use Blackboard (Bb) for all course materials plus secondary materials including articles and publications relating to a particular topic. To access Bb, you need to use your Pitt username and password to log onto the course web system at <http://courseweb.pitt.edu>.

Administrative support

Administrative support for this course is provided by Karen D. Zellars, who can be reached at the OED at 412-624-3160 or by email at zellars@pitt.edu.

Babs Carryer can be reached by cell at 412 310-3502, or by email at babs@carryer.com.

Guest Speakers

In addition to the OED faculty, there will be numerous guest speakers, including:

- **Barbara Barnes, MD**, is Associate Vice Chancellor, Continuing Education and Industry Relationships for the University of Pittsburgh and Vice President, Sponsored Programs, Research Support, and CME for UPMC. In these roles, she is one of the individuals responsible for implementing the Health Sciences and UPMC industry relationships policy, overseeing commercial support for continuing education, administration of the contracting of industry-initiated clinical trials, and monitoring compliance with billing of clinical services associated with research conducted in UPMC facilities. Barbara is also past chair of the board of directors of the Accreditation Council for Continuing Medical Education, participated on the Association of American Medical College's task force on industry relationships and medical education, and serves on the AAMC's steering committee for the Forum on Conflict of Interest.
- **Carolyn Green** is President and Chief Operating Officer of Logical Therapeutics, a biotechnology company based in Boston developing medicines to treat diseases associated with poorly controlled or excessive inflammation. Carolyn was the founding Director of the OED at Pitt, and in this role facilitated numerous spin-outs. She has held various leadership and sales positions, including CEO of Mobot, Inc., which specialized in artificial intelligence software and hardware for human-computer interactions, Director of North American Marketing and Sales for publicly-traded AEA Technology plc, in the computer-aided engineering software sector, and Business Manager for Algor, Inc., where she was responsible for the business development, sales and customer service sectors. Carolyn has a BS in Chemistry from the University of Pittsburgh.
- **Anne Mathias, JD**, is Research Integrity Officer for Carnegie Mellon University. She is responsible for CMU's research compliance office including the IRB, IACUC, conflict of interest and research misconduct. Prior to joining CMU, Ann served in many roles for the University of Pittsburgh Medical Center (UPMC). Her most recent position there was that of Director, Research Policy and Compliance. Prior to that she served as Director of Ethics and Compliance at UPMC and the Compliance and Privacy Officer at Magee-Womens Hospital of UPMC. Throughout her career, Anne's work has focused on regulatory issues, privacy, health information, clinical research in academic medical centers, health care payment and managed care. She holds a JD from the University of Pittsburgh School of Law and a Masters of Health Services Administration from The George Washington University School of Business.
- **Larry Miller, MBA**, is an Executive-in-Residence at Innovation Works, one of Pittsburgh's regional economic development organizations. Larry has more than 20 years experience in leading and managing medical device companies. Previously, Larry was President and CEO of Biomec, a privately held technology accelerator and investment company, which raised over \$20M in SBIR grants and provided contract engineering and manufacturing as well as business development consulting for radiology product manufacturers and distributors. Larry was President of the Healthcare Products group at Picker International and Philips Medical systems, a \$600M distributor of radiology supplies. He also managed the Asia/ Pacific region for sales and service of the diagnostic imaging product portfolio, and was president of the Picker Financial Group, a JV, captive

leasing company. Larry earned his BS in Mechanical Engineering from the University of Pennsylvania and an MBA from the Wharton School.

- **Jenifer Slinsky Tarasi, JD**, is the Associate Director, Intellectual Property of the University of Pittsburgh's Office of Technology Management. Prior to joining the University, Jenifer was a practicing IP attorney with a mid-sized Pittsburgh law firm for more than 10 years. Her practice at the law firm spanned all areas of intellectual property law, including: patent, trademark and copyright prosecution; negotiating and drafting license agreements, assignments, confidentiality and non-compete agreements; and preparing patentability and non-infringement opinions. Additionally, Jenifer's transactional work has included drafting, reviewing and negotiating asset purchase agreements and joint developments agreements. She has participated in numerous due diligence projects and consulted in IP litigation matters. Jenifer's science background is based in chemistry. However, she has prosecuted patent applications that span the chemical, biotech and mechanical fields. She received a BS degree from Allegheny College, and her JD from the University of Dayton School of Law.
- **David Wehrle, CPA**, is the founding director of the University of Pittsburgh's Conflict of Interest (COI) Office in 2004, and, since 2006, has concurrently held the position of Associate Director of the Office for Investigator-Sponsored IND & IDE Support (O3IS).

Course schedule

Date	Topic	Instructors	Assignments
#1 Jan 25	Academic Entrepreneurship: Recognizing Opportunity <ul style="list-style-type: none"> • Introductions • The business of academic research • Overview of OTM • Overview of OED • The difference between scientists and business people • Syllabus, course project, teams • Jerry McGinnis video and discussion 	<ul style="list-style-type: none"> • Marc Malandro, PhD • Andrew Remes, PhD • Paul Petrovich, CPA • Babs Carryer 	
#2 Feb 1	Understanding Intellectual Property <ul style="list-style-type: none"> • Intellectual property overview • Pete DeComo video and discussion • Teams, projects, and prepare brief presentation for next week • Special discussion with for-credit participants re: final commercialization report 	<ul style="list-style-type: none"> • Jenifer Tarasi, JD • Babs Carryer 	Prepare presentation for next week
#3 Feb 8	The Commercialization Leap		
#4 Feb 15	Assessing Markets and Competition <ul style="list-style-type: none"> • Commercial application of new technologies • Market analysis • Competition • Surface Logix case study discussion • Sean McDonald video and discussion 	<ul style="list-style-type: none"> • Babs Carryer 	Work on projects
#5 Feb 22	When 1+1=4: Building the Value Chain <ul style="list-style-type: none"> • Economic development funding for early stage opportunities • SBIR/STTR programs • Equity and debt financing • Original case studies discussion • Glen Meakem video • Prep for elevator pitches 	<ul style="list-style-type: none"> • Larry Miller, MBA • Paul Petrovich • Babs Carryer 	Work on projects
#6 Mar 1	Voice from the trenches: Starting a new biotech	<ul style="list-style-type: none"> • Carolyn Green • Babs Carryer 	

	company <ul style="list-style-type: none"> • Presentation of the origins of a company, including the investor pitch and results 		
Mar 8	SPRING BREAK PITT no class		Work on projects
# 7 Mar 15	Scientist-Entrepreneur: Managing Conflict of Interest <ul style="list-style-type: none"> • Panel discussion <p>Business models and partnering</p>	<ul style="list-style-type: none"> • David Wehrle • Barbara Barnes, MD • Anne Mathias, JD • Babs Carryer 	<p>Prepare elevator pitch of project for next week</p> <p>Read Biopure case study for next week</p>
#8 Mar 22	Regulatory & Reimbursement, Why These are Important <ul style="list-style-type: none"> • Guest speaker on the regulatory and reimbursement pathways and potential hurdles 		Work on projects
#9 Mar 29	Refining the pitch <ul style="list-style-type: none"> • Elevator pitches of projects (and cash prize winner!) • Opportunity assessment exercise of each project • Case study discussion – Biopure • Work on projects • Roger Byford video and discussion 	<ul style="list-style-type: none"> • Babs Carryer 	Prepare final presentation (and report for those earning credit for course)
#10 Apr 5	Final presentations for judges' panel (and cash prize winners!) <ul style="list-style-type: none"> • Survey • Graduation • Party! 		