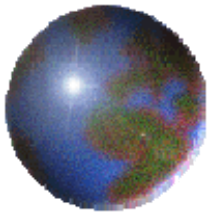
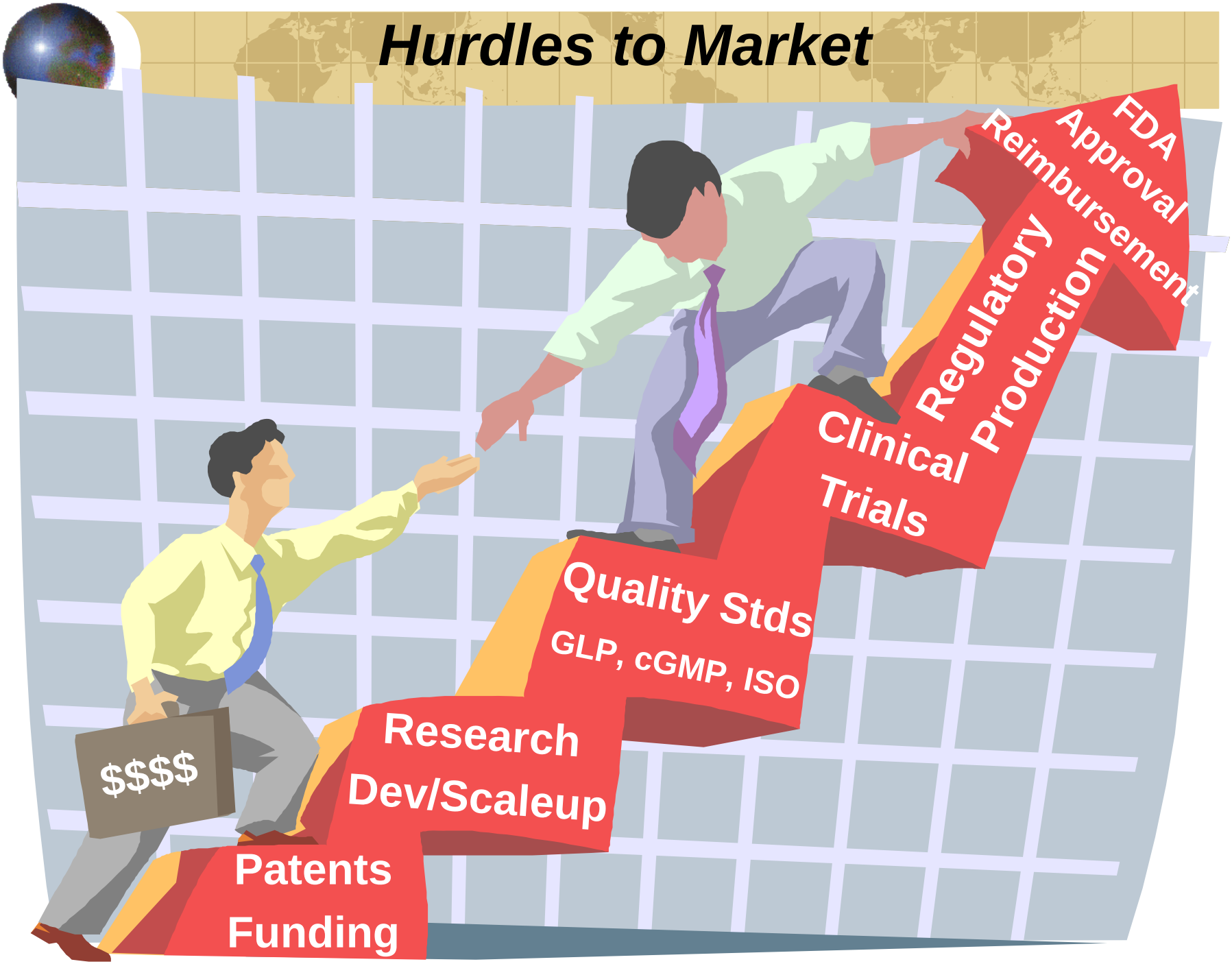


Education's Role in Biotech's Success

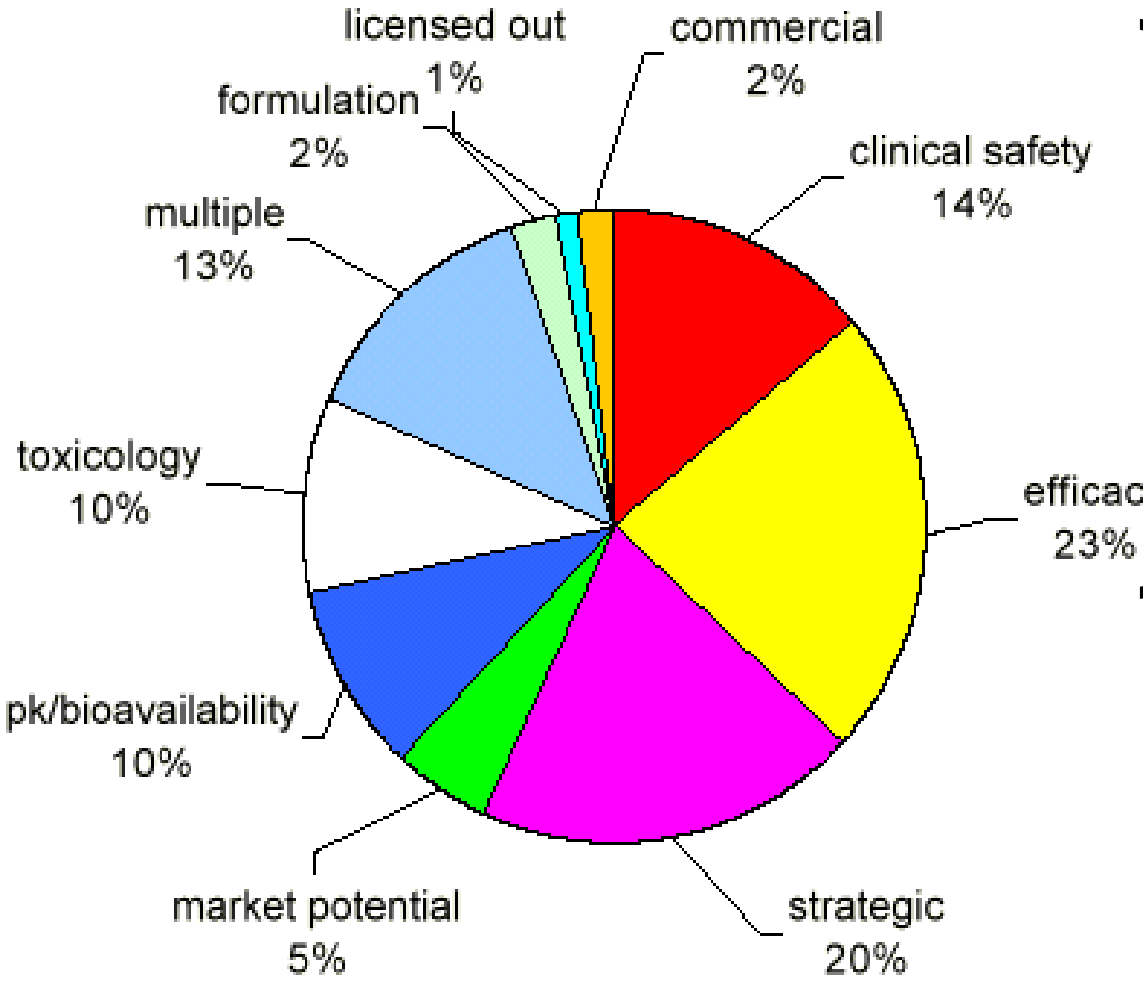
Gail K. Naughton PhD
San Diego State University
August 31, 2009

Understanding the Business of Biotech

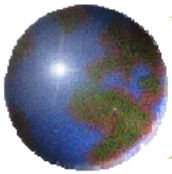
- Long product time lines
- Huge development costs
- Regulatory/clinical hurdles
- Strict manufacturing requirements
- Long IP protection critical
- “fully integrated” often not possible
- Public marketplace now cynical
- ***Scientists need to understand the business, business managers need to understand the science/regulatory!***


Hurdles to Market
FDA Approval
Reimbursement
Regulatory
Production
Clinical Trials
Quality Stds
GLP, cGMP, ISO
Research
Dev/Scaleup
Patents
Funding
$$$$

Causes of Drug Mortality – Pharma



Clinical Reasons ~ 40%



Goals in Biotech Education

- Business leaders trained in basic scientific communication, regulatory and clinical hurdles/requirements, and “best practices” in biotech
- Produce new generation of cell/molecular biologists with expertise in management, business practices and communication. Job opportunities in business development, management, product development, research.

Understanding the FDA

PSM: MS in Regulatory Affairs

- Courses focus on requirements for device, biologic, and drug approval
- Taught by industry regulatory experts
- On-line offering allows full-time employees world-wide to take advantage of the training
- Feedback underscores the importance of learning industry “best practices” and benefits resulting in more efficient product approval both in the US and OUS

Keys to GMP Manufacturing

PSM: MS in Quality Control: on-line offering that addresses:

- Documentation Control and SOPs
- Principles of Good Manufacturing Practices and ISO regulation
- Release criteria, product testing
- Transition of products from development to pilot to final manufacturing

MBA in Biotechnology/Life Sciences

- Case Studies in Management & Marketing chosen from biotech/pharma
- Manufacturing highlights GMP/ISO regulations and costs and MRPII
- IDS: Knowledge Management focus
- Product Development/Project Management modified from Engineering to reflect biotech challenges/timelines

MBA in Biotechnology/Life Sciences

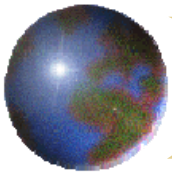
- Business Law highlights IP protection
- Courses borrowed from SDSU MS in Regulatory Affairs: submission process, timelines, costs, “best practices”
- Bioethics course co-developed by biology and management
- Business plan/competitive landscape courses from Entrepreneurial Management MBA adapted to biotech

MBA in Biotechnology/Life Sciences

- VC partners lecture on funding criteria, selection criteria, expectations
- Domain Partners: “real time” business plan review/funding decisions by all partners
- Finance courses modified to include methods of valuation, funding options, IPO hurdles in biotech
- Corporate Governance course added

MBA in Biotechnology/Life Sciences

- Courses developed with Communications Department: IR/PR, handling expectations, insider information
- Biotech certificate from College of Sciences provides electives in scientific principles, GLP, GCP, “jargon”
- Workshop on managing interdisciplinary teams and communicating scientific results to non-scientists



MORE ISSUES!

- Biology PhDs need training in skills necessary for non-academic careers
- Biocommerce surveys report management, business and communication abilities highly valued but rarely available in PhD-level employees
- ***Action: Joint PhD (cell and molecular biology)/MBA***

Joint PhD/MBA

- Year 1: basic coursework in cell biology, students attend local BIOCOM and national BIO meetings, workshops on bioethics/business ethics and communication skills
- Year 2: Core courses for MBA, dissertation research continues, internship at biotech company in lieu of teaching assistantship
- Year 3: MBA courses, qualifying exams include focus on applied aspects and internship focus

Joint PhD/MBA

- Year 4: MBA theme courses, PhD research continues
- Year 5/6: MBA electives, PhD dissertation on applications-based research, MBA thesis is business plan based on PhD research
- ***Status: 3 student piloted in Fall 2003 (industry funded), graduates are thriving at Los Alamos and many start up companies, program continues with tremendous student interest***

The Global Entrepreneurship MBA from San Diego State University

About the program

- **The Global Entrepreneurship MBA program's first class is scheduled to begin January 2010**

- •Each class will consist of approximately 30 students who will study and travel together for the length of the program
- •This concentration blends two of our most recognized programs, Entrepreneurship and International Business, and gives students a variety of skills needed for success in a rapidly changing, global marketplace

5 Corporate Partners

KPMG

intel Leap ahead™

invitrogen™

Microsoft

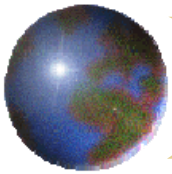
QUALCOMM®

Corporate Topics

- Setting new standards: the CDMA story of QUALCOMM
- Establishing and maintaining a corporate culture of risk-taking and innovation
- Manufacturing pros/cons of each region
- Life science regulations: FDA versus OUS

Accelerating Innovation

- SDSU CCAT (Center for the Commercialization and Advancement of Technology) has helped to accelerate over 100 products to market
- Based on this success, the International Institute for the Commercialization of Biomedical Innovation was formed
  - multiple global universities
  - scientific advisors from partners
  - seasoned business advisory BOD



Executive Education

New Seminar in Integrated Marketing Communication for Biotechnology

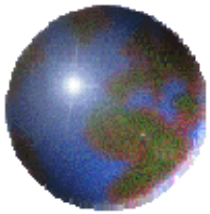
- Advertising regulations for medical products: in clinical trials and on the market
- Public Relations: rules and best practices
- Dealing with the SEC
- Co-promotion and co-marketing

What about K-12 and beyond?

- High School immersion for students and teachers- Universities and biotechs
- Undergraduate major in entrepreneurship
- Industry mentors/intern opportunities
- Selection of students cross campus for specialized mentorship
- Cross-campus business plan competition focused on hi and biotech

What Do We Need More Of?

- Case studies in biotech and hi-tech- the good, bad and ugly
- More interaction with industry leaders
- Getting students involved at earlier and earlier stages
- More internships for students and teachers
- Opportunities for students to live the passion
- NETWORKING, NETWORKING!!!!



Accelerating the Path for Innovation
through Business Education