



BMES

BIOMEDICAL ENGINEERING SOCIETY™

Entrepreneurship and Innovation in Biomedical Engineering

Moderator

- ▶ **Kunal Mitra, PhD**

Professor

Biomedical Engineering

Florida Institute of Technology

BMES Education Committee Member

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Announcements

- ▶ The archived recording will be available shortly after the webinar on the BMES website.
- ▶ You may submit questions throughout the webinar by using the online chat function. Your questions will be addressed after the featured speaker presentations.
- ▶ Please take a few minutes to complete the brief survey following the webinar to provide us with your feedback.

Speaker

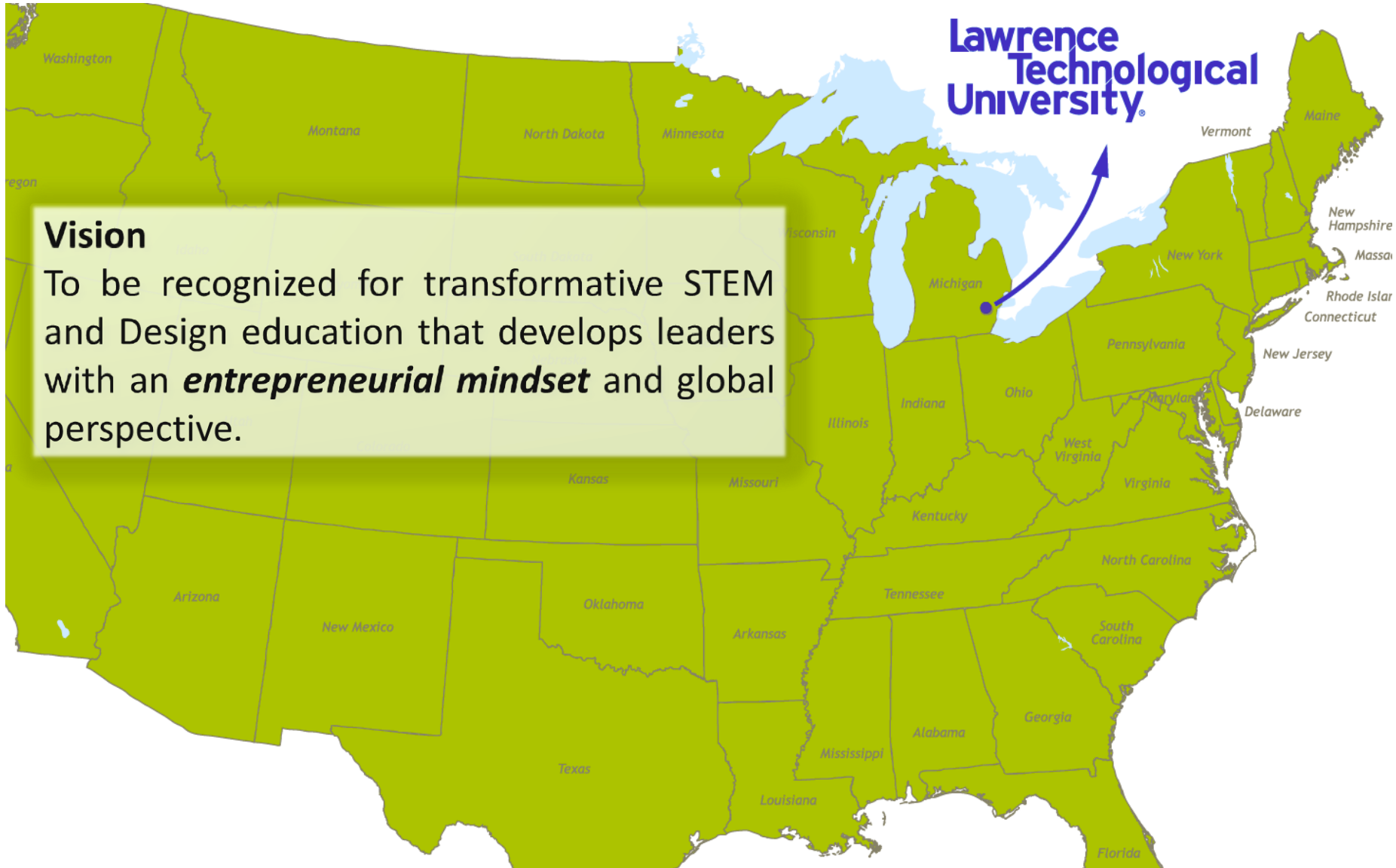
▶ Mansoor Nasir , PhD

Assistant Professor
Biomedical Engineering
Lawrence Technological University

Email: mnasir@ltu.edu



Lawrence Technological University



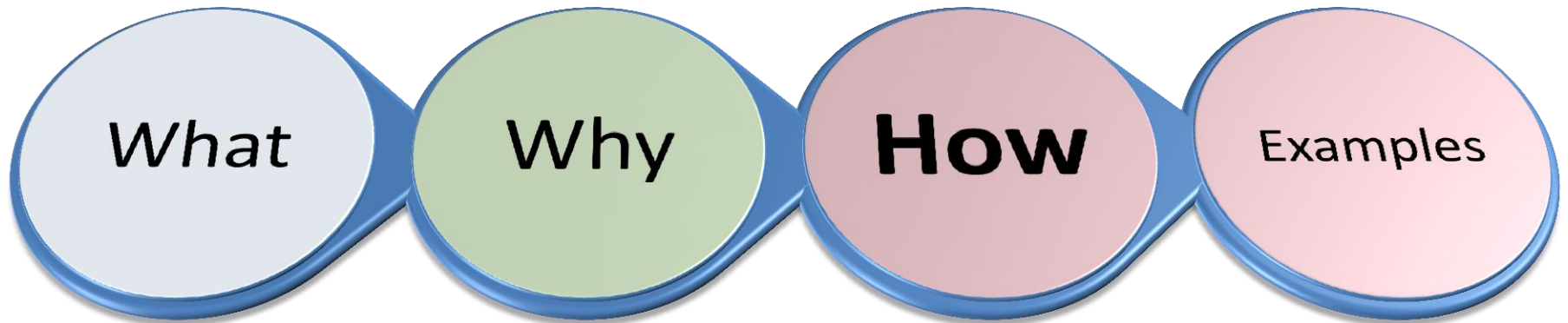
Vision

To be recognized for transformative STEM and Design education that develops leaders with an ***entrepreneurial mindset*** and global perspective.

Lawrence Technological University



Entrepreneurial Thinking



- What is entrepreneurial thinking?
- Why is entrepreneurial thinking important for engineers?
- How can students be exposed to this style of thinking?

Entrepreneurial Thinking

What



Entrepreneurial Thinking

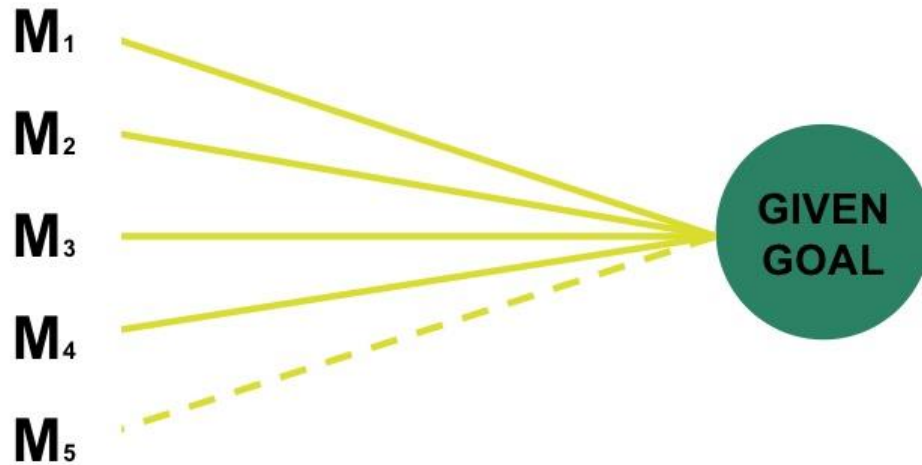
What



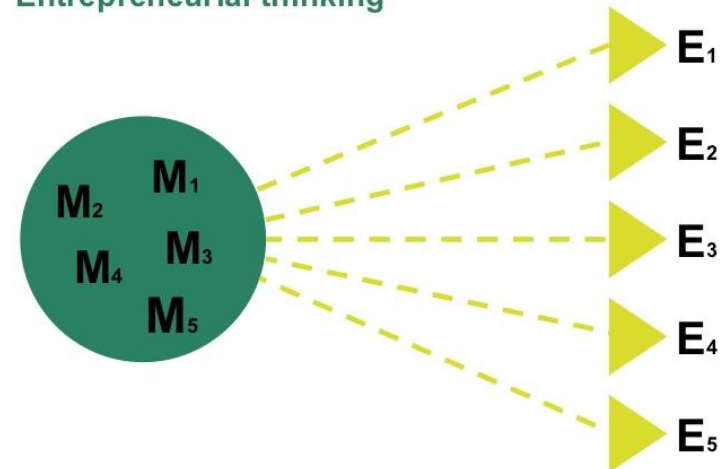
Entrepreneurial Thinking

What

Causal reasoning Managerial thinking



Effectual reasoning Entrepreneurial thinking



Entrepreneurial Thinking Framework

What

OPPORTUNITY	DESIGN	IMPACT
Identify an opportunity	Determine design requirements	Communicate an engineering solution in economic terms
Investigate the market	Perform technical design	Communicate an engineering solution in terms of societal benefits
Create a preliminary business model	Analyze solutions	Validate market interest
Evaluate technical feasibility customer value societal benefits economic viability	Develop new technologies (optional)	Develop partnerships and build a team
Test concepts quickly via customer engagement	Create a model or prototype	Identify supply chains distribution methods
Assess policy and regulatory issues	Validate functions	Protect intellectual property

KEEN
ENGINEERING UNLEASHED

Curiosity
Connections
Creating Value

THESE SPECIFIC **SKILLS** REINFORCE THE DEVELOPMENT OF AN ENTREPRENEURIAL MINDSET

Entrepreneurially Minded Learning

Why

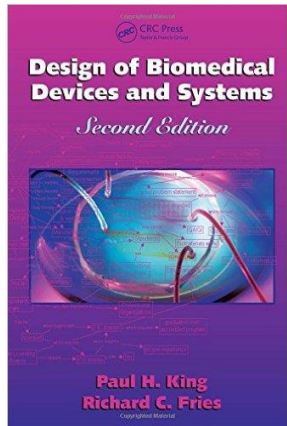
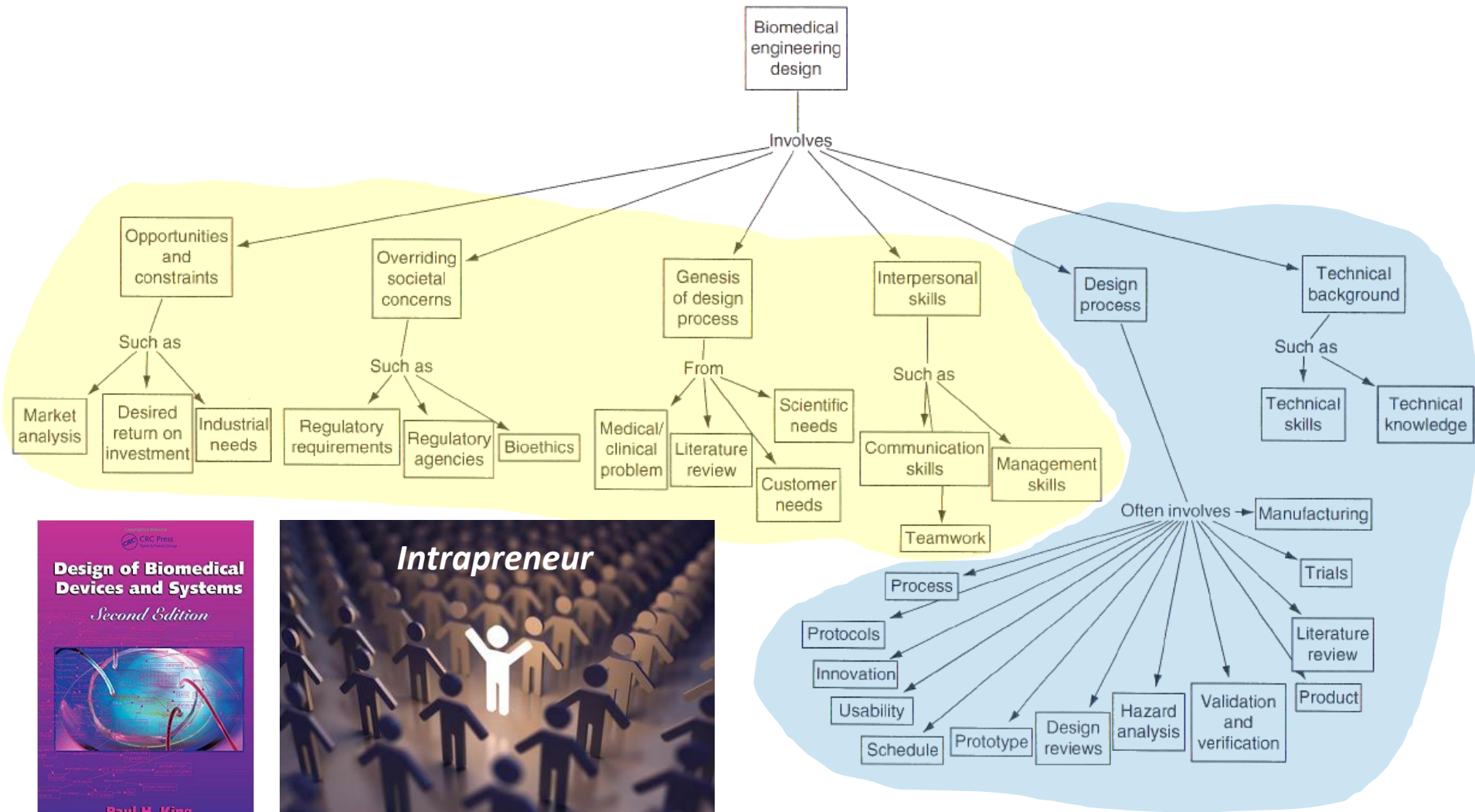
Can enhance.....

- Student learning in classroom
- Understanding of real world constraints
- Student-Instructor
- Retention of fundamental concepts



Biomedical Design Process

Why



Models for Implementation

Degree Programs

- MIT
- Stanford Technology Ventures Program (STVP)

Certificates / Minors

- NSF I-Corps
- Epicenter

Other

- Courses
- University Innovation Fellow - VentureWell
- Idea to Product (I2P) – UT Austin
- Competitions

Models for Implementation

[How](#)

Degree Programs

- MI
- Sta

Certific

- NS
- Ep

Other

- Co
- Un

– Idea to Product (IZP) – UT Austin

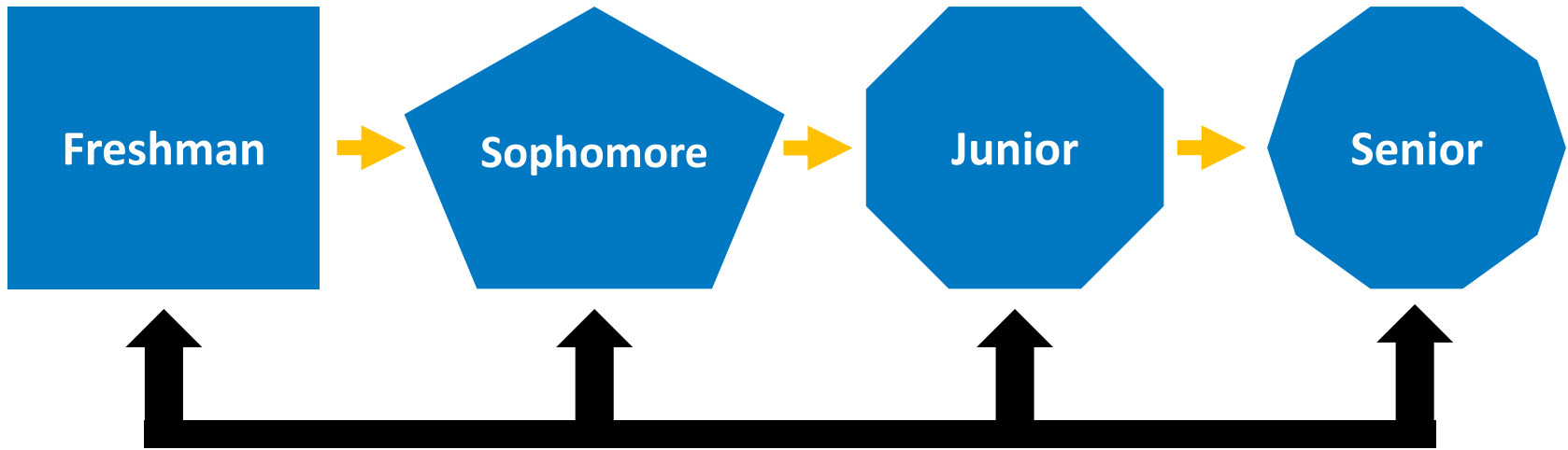
– Competitions



**SUPER
ENGINEERS**

BME: Course Based Approach

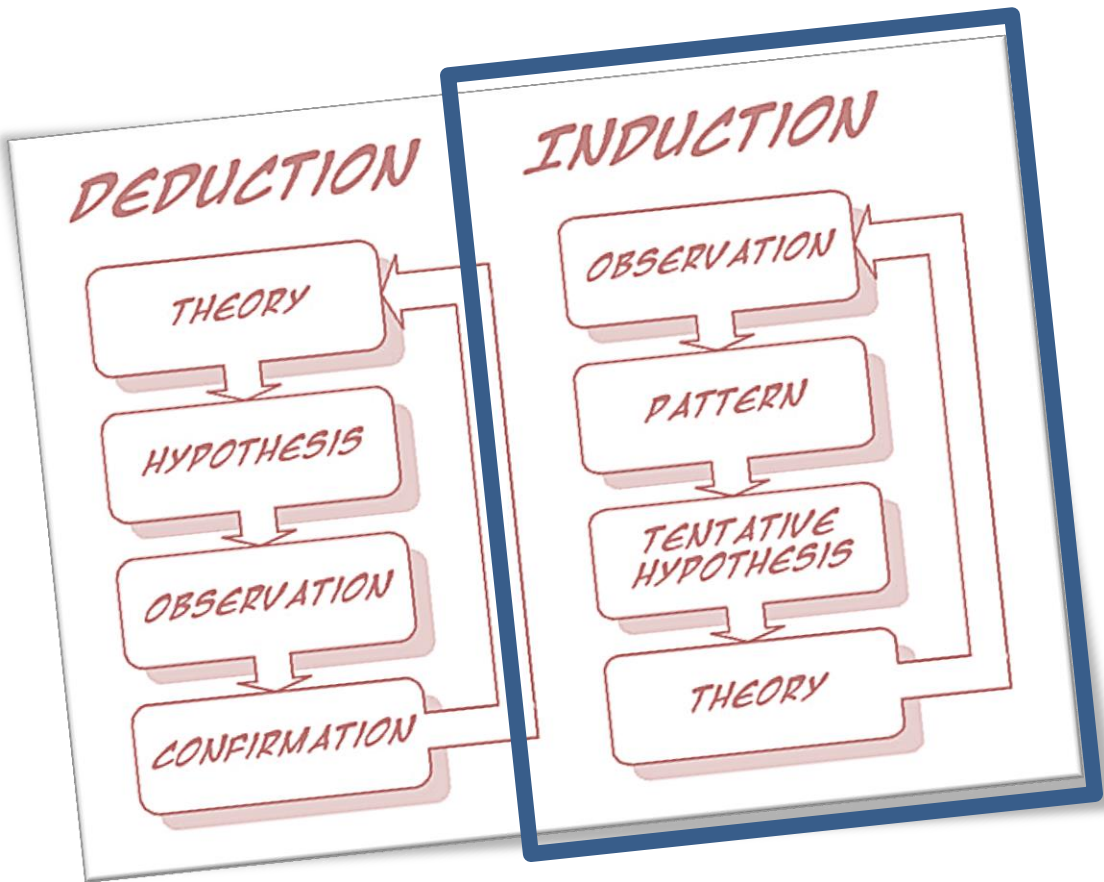
[How](#)



**Learning Modules to Build
Entrepreneurial Skillset**

Implementation in Classroom?

How



DRIVING INNOVATION AND ENTREPRENEURSHIP

PURE MICHIGAN KEEN

QS 4 EML

qs4eml.ltu.edu

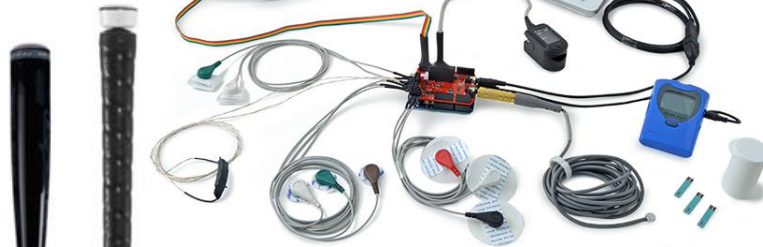
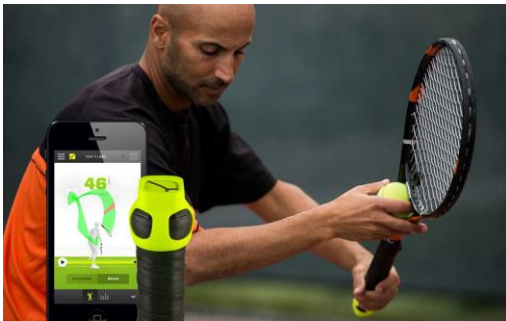
Ignite your students' entrepreneurial mindset with "Quantified-Self"

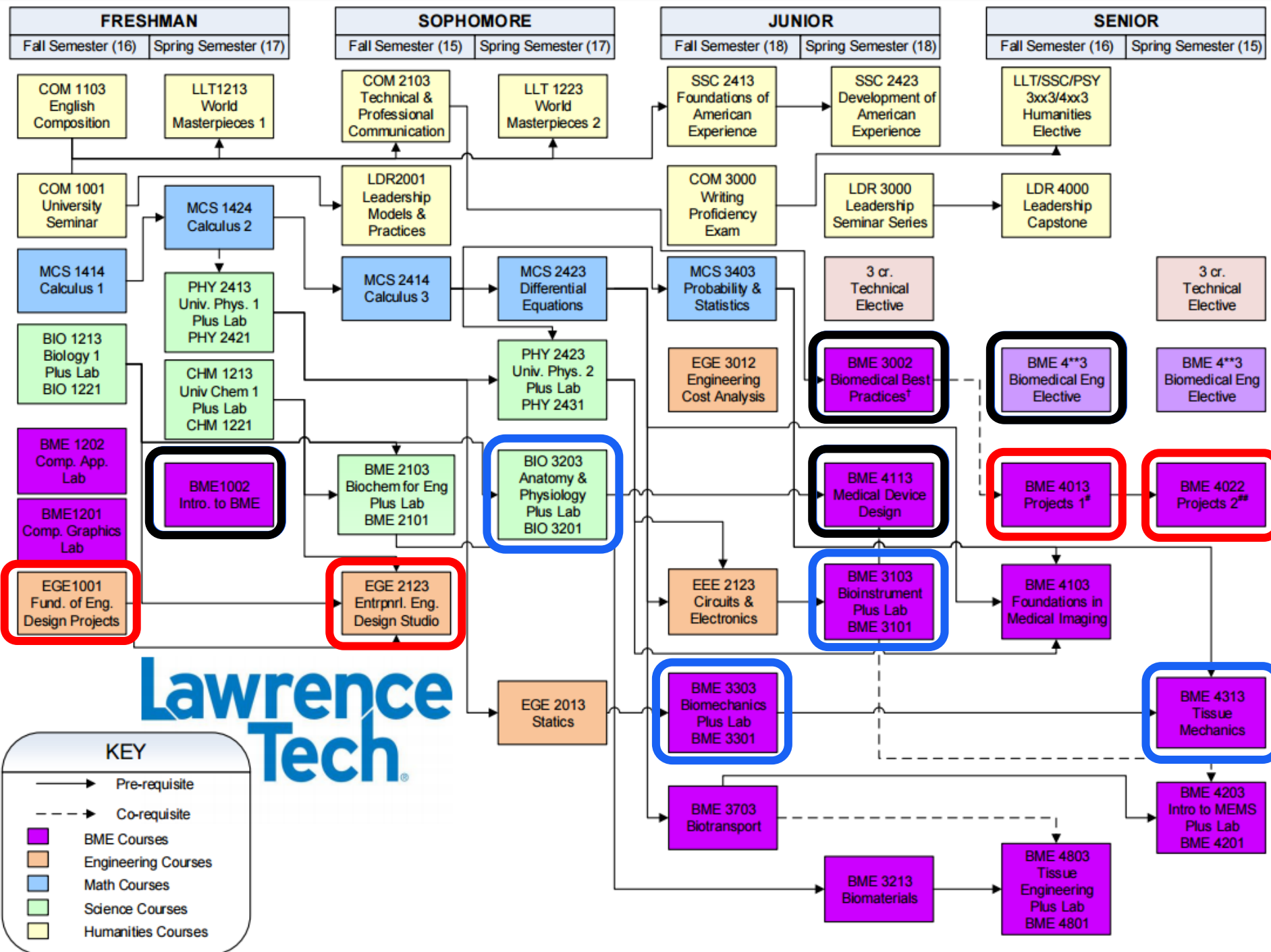
Quantified-Self
SELF-KNOWLEDGE THROUGH NUMBERS

- Big Data
- Mobile Apps
- Data Visualization
- Fitness Industry
- Sensor Technology
- Physiological Properties
- Social Network
- Gamification

Theme: Quantified Self

How





Course Examples

- Intro. to Biomedical Engineering
- Biomedical Best Practices
- Medical Device Design
- Orthopedics

Freshman

Sophomore

Junior

Senior

Target Skills for EML Modules

[How](#)

Level	Freshman	Sophomore	Junior	Senior
<i>Course</i>	<i>Introduction to BME</i>	<i>BME Best Practices</i>	<i>Medical Device Design</i>	<i>Orthopedics</i>
Opportunity Recognition	X		X	
Market Investigation	X	X	X	X
Create a Preliminary Model	X		X	X
Communicate Economic Benefits	X	X		
Communicate Societal Benefits	X	X	X	
Examine technical feasibility Economic Drivers, Needs			X	X
Intellectual Property Protection		X	X	
Regulatory Issues		X	X	X
Collaborate in a team setting	X	X	X	

Opportunity Recognition

- Investigation of QS devices
- Using Nike+ Shoe Sensor in a new application
 - Device Concept
 - Business Model and Market Potential
 - Pitch video



Nike+ Hyperdunk Shoe Sensors

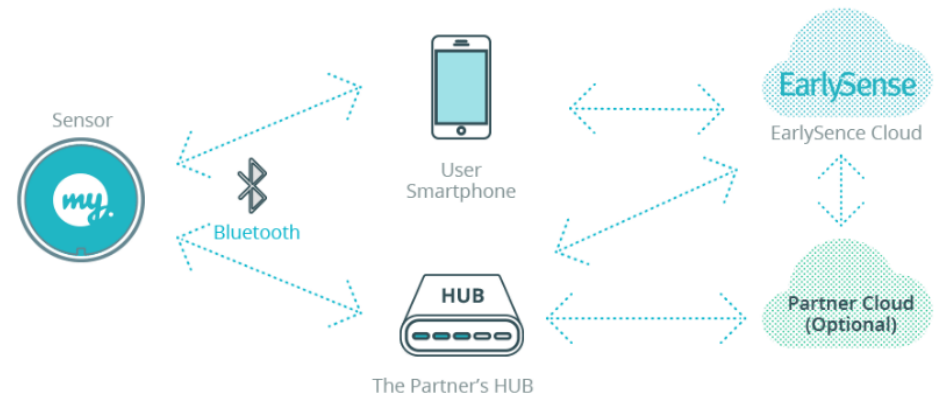


“Repurposing” QS device to solve a Global Health need

- Medical device & patent (IP) search
- Mock 510-k (FDA) application
- Mock invention claims disclosure

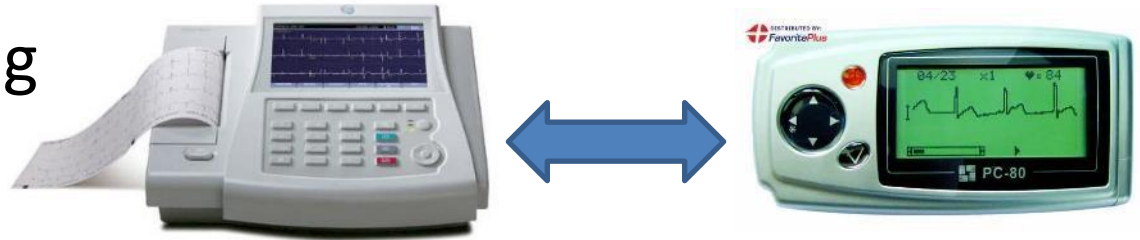


Eclipse Self Breast Exam

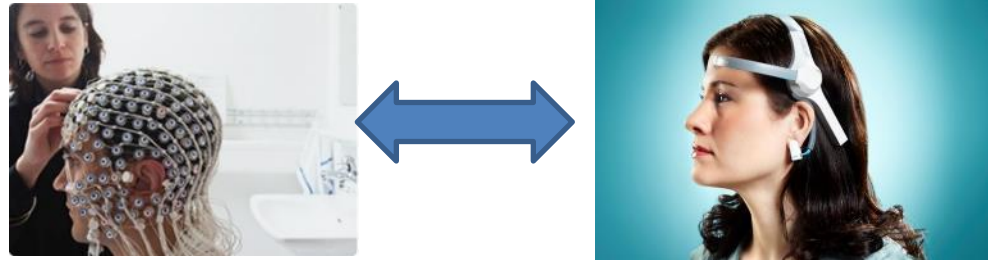


EarlySense Sleep Monitoring

- In class Activities
 - Hands-on Learning



- Homework Assignments
 - Find Similarities
 - Find Differences

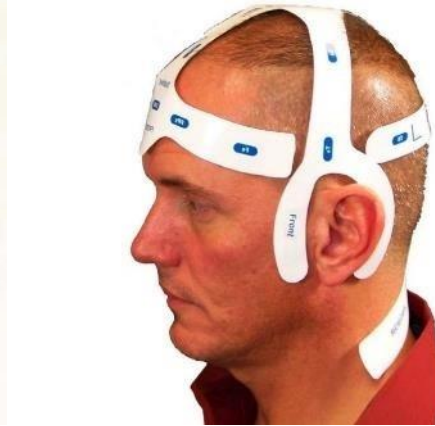


Technical Content Need not be Sacrificed

Differentiators / How to Create Value



IMEC: Wireless EEG



StatNet Disposable EEG



Neurosky



MicroEEG



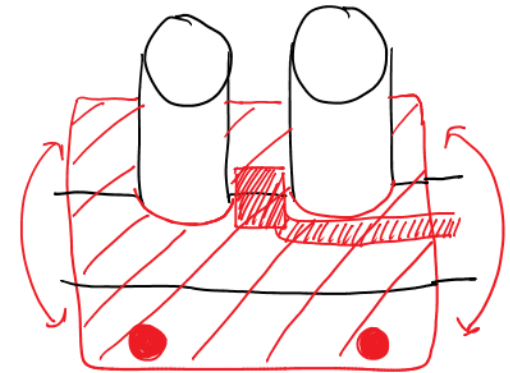
Emotiv



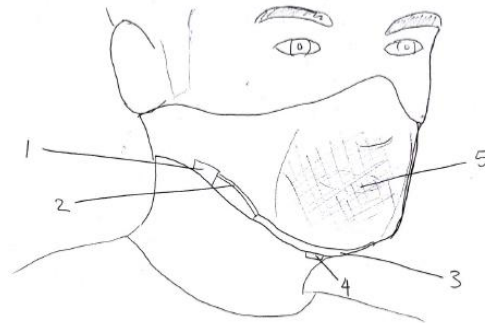
NeuroFocus

Semester long Project

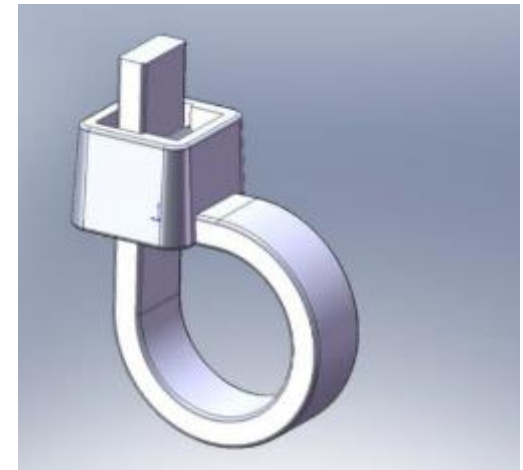
- Finding Medical Needs
- Interaction with Clinician and Users of Device
- Identifying Problem
- Regulatory Pathway
- Patent Generation
- Preliminary Design
- Pitch Video



Sensor to monitor nasal cannula



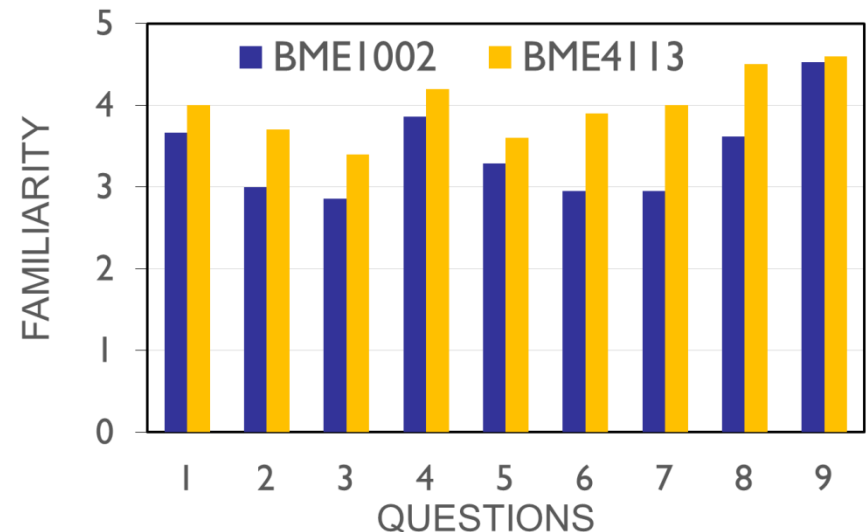
Handsfree Asthma Mask



Cord Cutter

Student Learning Outcomes

1. Define problems, opportunities, and solutions in terms of value creation.
2. Anticipate technical developments by interpreting surrounding societal and economic trends.
3. Identify new business opportunities.
4. Apply creative thinking to ambiguous problems.
5. Apply systems thinking to complex problems.
6. Examine technical feasibility, economic drivers, and societal and individual needs.
7. Communicate engineering solutions in economic terms and with regard to societal benefits.
8. Substantiate claims with data and facts.
9. Collaborate in a team setting.



Capstone Design Assessment

Results

Learning Objectives	Capability Scale			
	4	3	2	1
Construct a system or process to meet desired needs within such realistic constraints as economic, environmental, social, political, ethical, health and safety, feasibility and sustainability.	52%	48%		
Demonstrate the ability for self-directed learning by planning, research and design for the project.	78%	22%		

Overall Course Satisfaction

2012-2013	2013-2014	2014-2015	2015-2016
3.67 ± 0.9	4.09 ± 0.7	4.83 ± 0.4	4.82 ± 0.4

Example: Capstone Design

Customer Interaction



Problems Identified

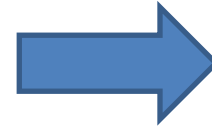
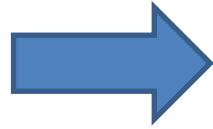
- Can get unstable
- Steering linkage feels loose
- Ride not smooth
- Very heavy

Designed Solution



Example: Capstone Design

Results



Honda Civic – 14.5ft³

2 Full Sized Cart Bags!

Future Direction

- Module development in other courses
- Mapping of learning outcomes
- Metrics for assessment
- Dissemination



Acknowledgements

- **Eric Meyer** Lawrence Tech
- Michael Rust Western New England
- Brent Ulrey Western New England
- Patrick Atkinson Kettering
- Joe Tranquillo Bucknell
- Ziad Youssfi Ohio Northern
- Jeff Morrissette Lawrence Tech
- Giscard Kfoury Lawrence Tech
- Kun Hua Lawrence Tech



<http://qs4eml.ltu.edu>

Speaker

- ▶ **Donald Gaver, PhD**



BMES Education Committee Chair

Alden J. “Doc” Laborde Professor and Chair
Department of Biomedical Engineering
Tulane University

Email: dpg@tulane.edu

Opportunity to Grow and Explore:

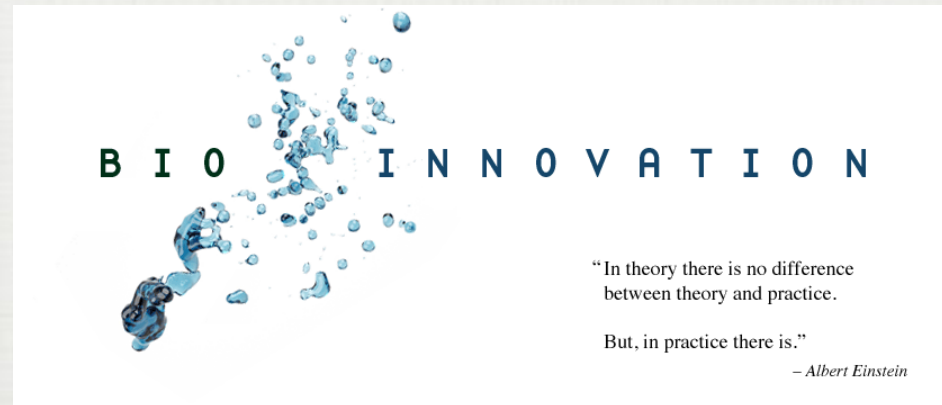
Lessons from a
Bioinnovation PhD student internship
program
at the FDA

Anne-Marie Jacob Job (Tulane University)
Rebecca Zarch (SageFox Consulting Group)
Alan R. Peterfreund (SageFox Consulting Group)
Donald P. Gaver (Tulane University)



Tulane's Interdisciplinary Boinnovation PhD Program

This training program cultivates our trainee's abilities to develop clinically relevant biomedical technologies and devices leading to commercial products.



We couple Research, Non-Academic Experiences, and Entrepreneurship Training.

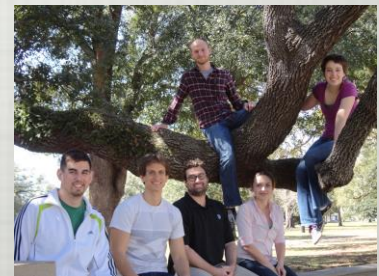
Supra-Academic Graduate Program

‘**Supra-academic**’ refers to a career that expands beyond academic scientific and technological discovery/development to practical application that may best be conducted through with industry or the public sector.



We specifically seek to recruit a **diverse student population** who can contribute vantage points from different cultures and disciplines.

- Laboratory Rotations
- Business Model Experiences
- **FDA Internship Program**



Nouvelle Orleans



Overarching GOAL

We will Create a community for Biomedical Engineering Research and Innovation in New Orleans



Resources:

Tulane University - SSE, SoM, Business, Law, Primate Center



Biodistrict New Orleans

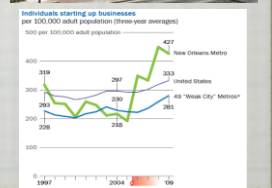


New Orleans Bioinnovation Center

New Orleans Idea Village



New Wave of Entrepreneurship of Region



The New New Orleans

DEMOGRAPHIC DENSITY

CRITERIA BASED ON
Growth of Foreign Born, Domestic, and College Educated Migration

MOVING

Increase in domestic migration

1	AUSTIN, TX	7.5%
2	RALEIGH, NC	7.2%
3	CHARLOTTE, NC	4.9%
4	NEW ORLEANS, LA	4.4%
5	SAN ANTONIO, TX	4.2%
51	DETROIT, MI	-3.2%

BRAIN GAIN

Increase in college grad population

1	AUSTIN, TX	20.6%
2	SAN ANTONIO, TX	20.3%
3	NEW ORLEANS, LA	20%
4	NASHVILLE, TN	14.3%
5	LOUISVILLE, KY	14%
51	TAMPA, FL	-0.3%

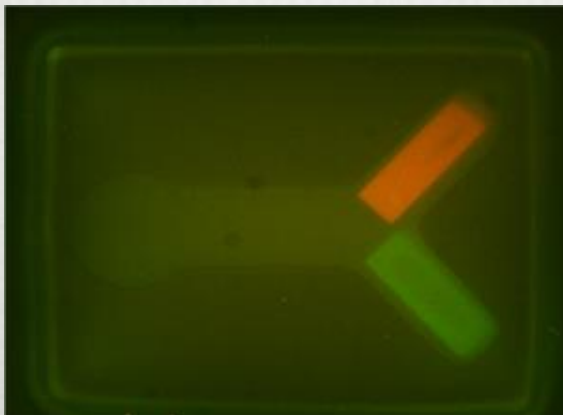
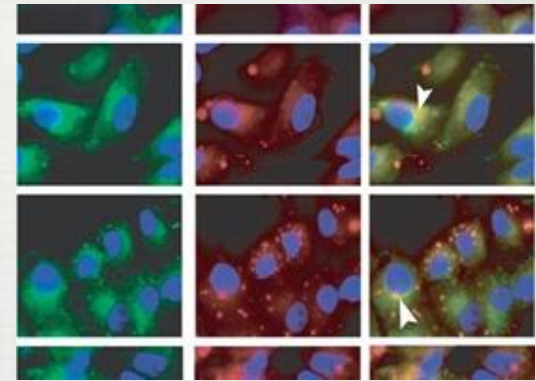
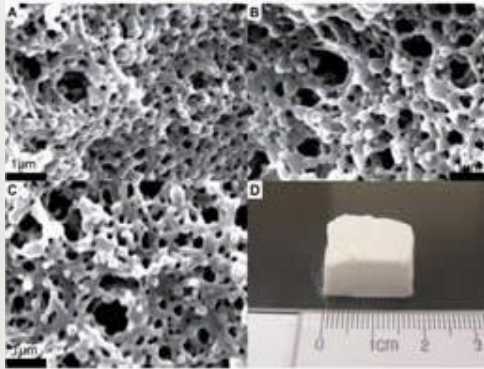
Program Objective #1 (Research)

Translational biomedical research projects.

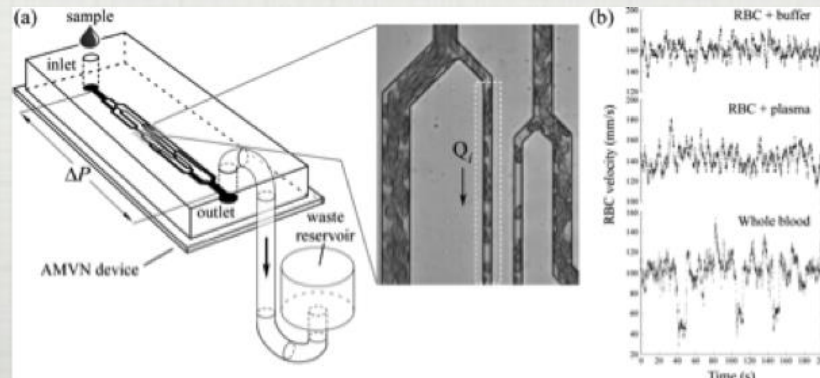
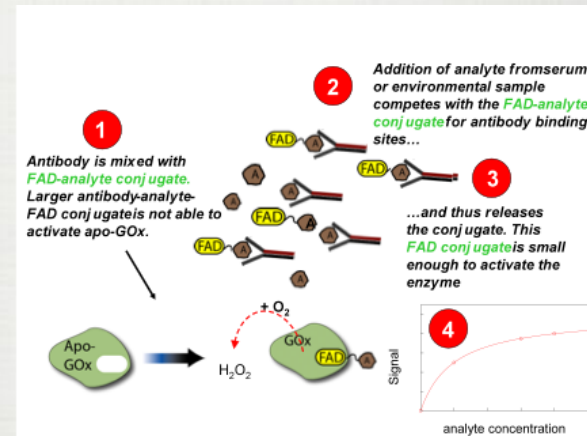
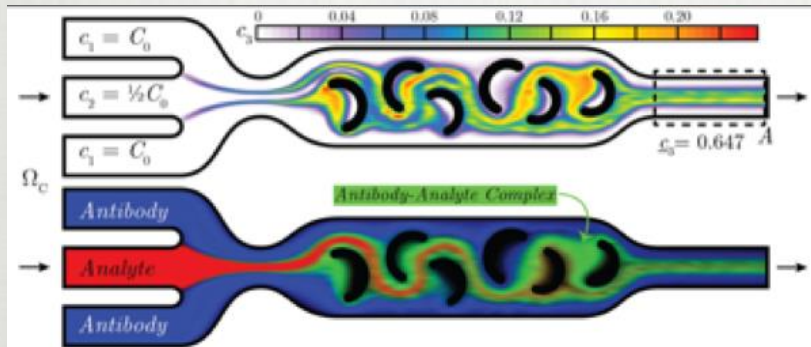
- Emphasis on **transport processes** that are fundamental to elucidating and manipulating physiological and cellular systems and are ripe for the creation of **biomedical technologies and devices**.
- Projects **link laboratories** from Tulane's School of Science and Engineering, the School of Medicine and the FDA.



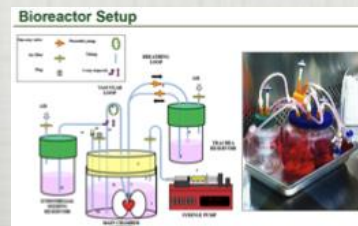
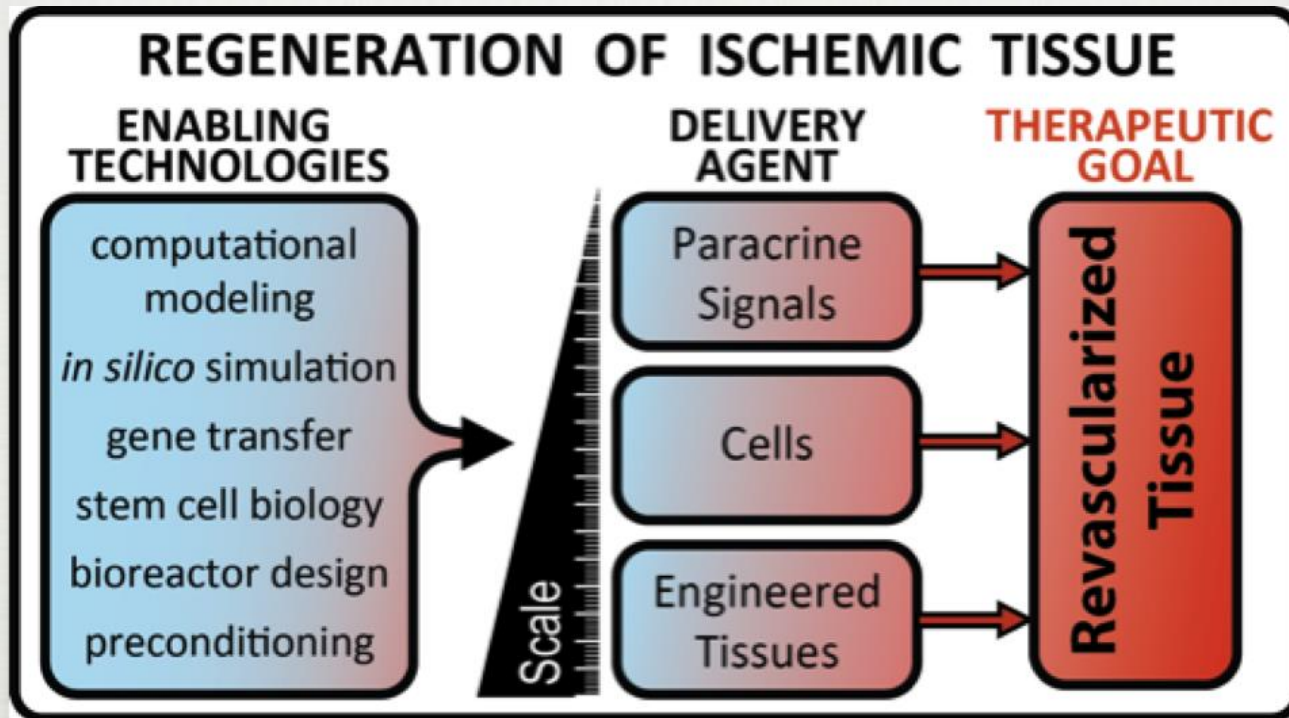
Research Areas (Therapeutic Materials)



Research Areas (Biosensors for real-world application)



Research Areas (Regenerative Medicine)



The Value Proposition: FDA Supra-Academic Experience



- The FDA Experience provides students with an advanced hands-on interaction through which **students understand the regulatory environment and process.** This is important to bioinnovation career development.
- The FDA Experience benefits the FDA by providing a talented and motivated cadre of students who **help with the FDA mission.**



Why is the FDA a Relevant Partner?

- In the **Private-Sector**... who employs the most bioengineers?

Hospitals & Health Care Facilities

(44,100 of them in USA)

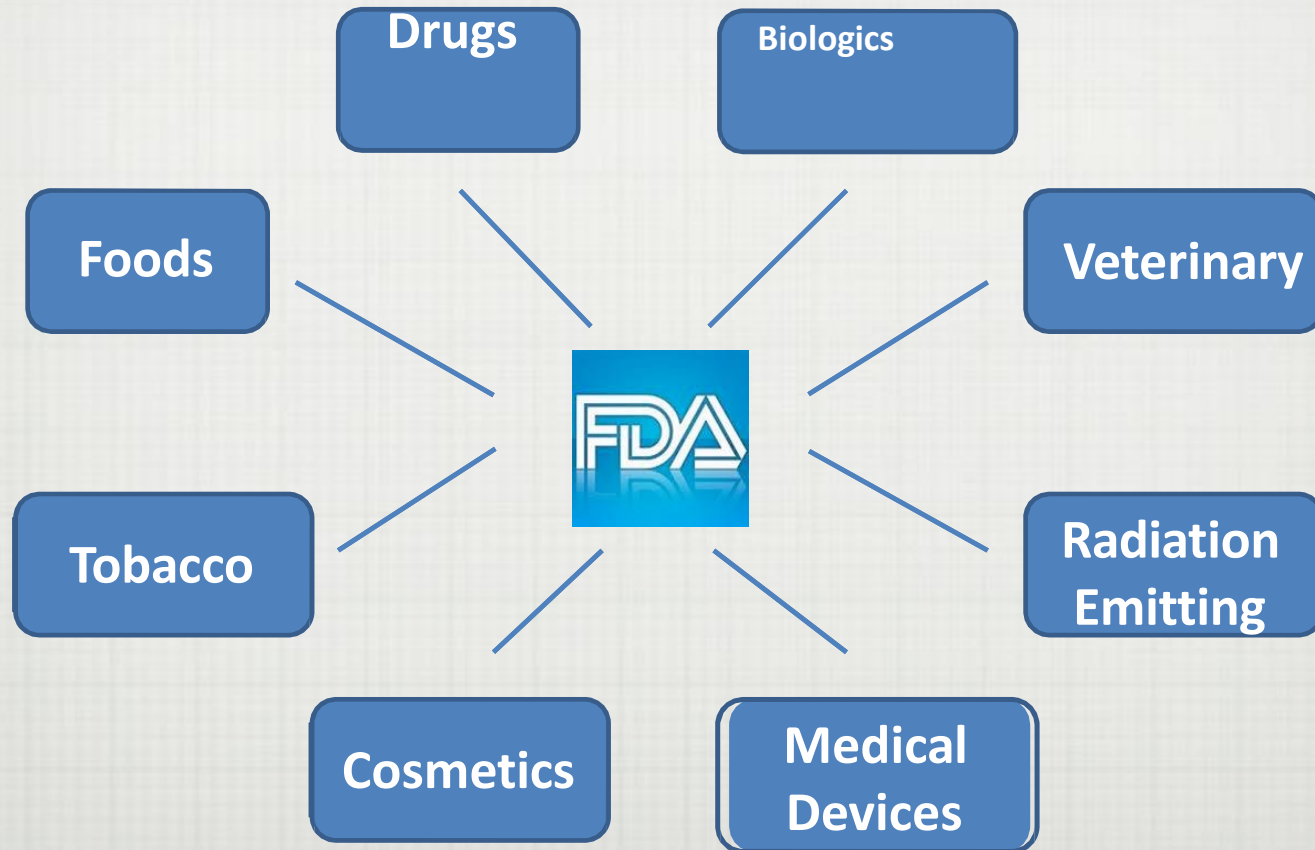
- In the **Public-Sector**... who employs the most bioengineers?

U.S. Food and Drug Administration



Most importantly, the FDA regulates the products created by Bioinnovation students.

What is the FDA?



CDRH Mission Statement

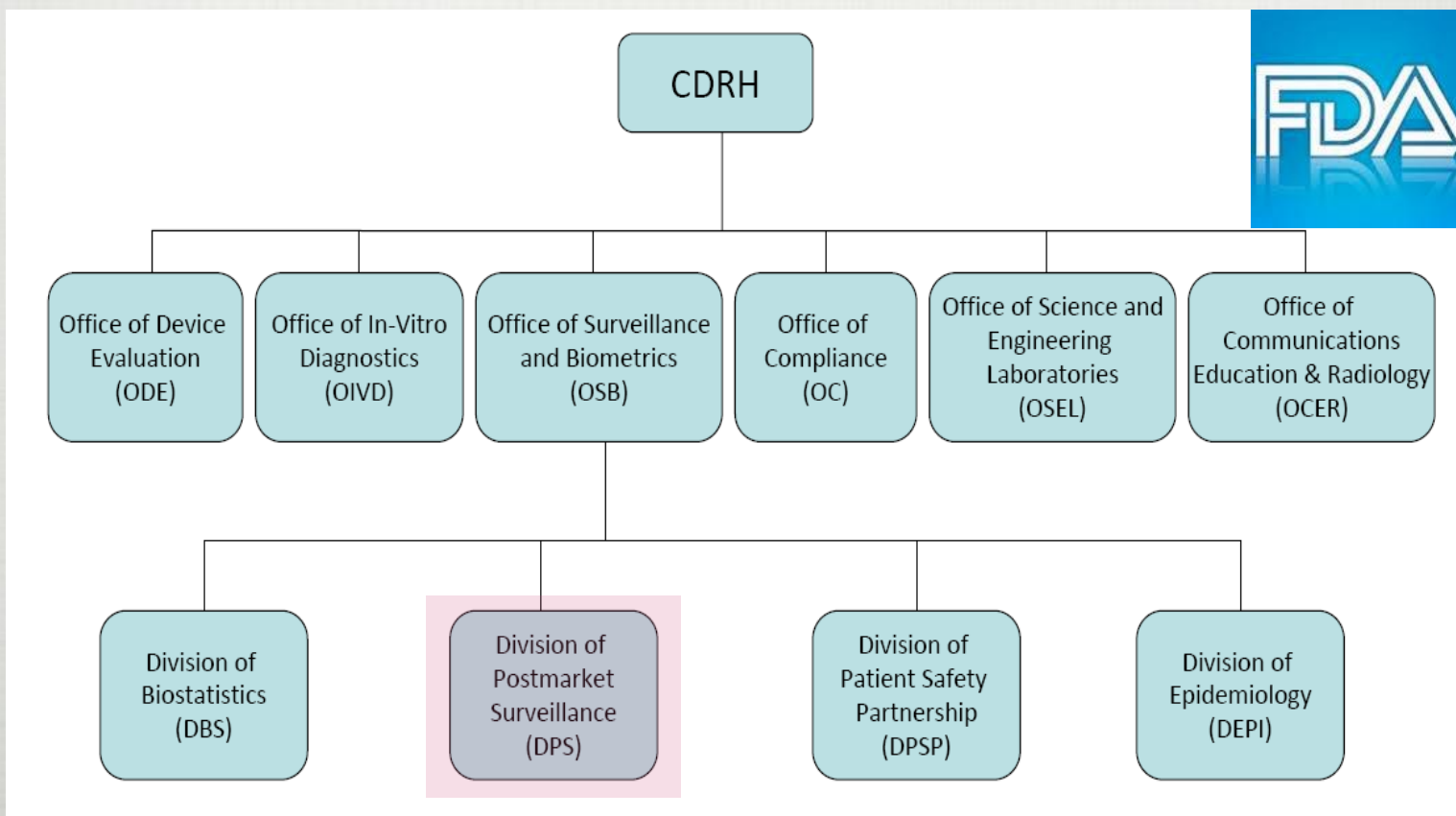


To promote and protect public health by insuring the safety and efficacy of medical devices.

KEY Issues:

- **Efficacy** – Devices work as intended.
- **Safety** – Devices do not injury people.
- **Public Health** – Device-based therapies reach intended population.
- **Protect** – Get the **bad products** off the market.
- **Promote** – Get the **good product** on the market.

CDRH Organizational Chart



How Do the Bioinnovation Students help the PRODUCT EVALUATION BRANCH?

PEB analysts routinely monitor postmarket medical device adverse event reports for actual or potential risks to patient safety through:

Postmarket Signal Development:

- Identify, investigate, trend, and analyze safety signals
- Initiate actions with CDRH offices to resolve issues

Safety Reviews for Center Activities:

- Query database
- Prepare analyses for all CDRH Center Offices by providing postmarket data (TPLC):
 - to aid in premarket review (e.g., 510(k), PMA, HDE)
 - to support OC in postmarket actions
 - to support Working Groups and Center Initiatives
 - to support analysis for post-approval studies



Medical Device Reporting Regulation

Medical Device Reporting (MDR, 21 CFR Part 803)

- Establishes the reporting requirements for device user facilities, manufacturers and importers.
- A mechanism for FDA and manufacturers to identify and monitor significant adverse events involving marketed medical devices.

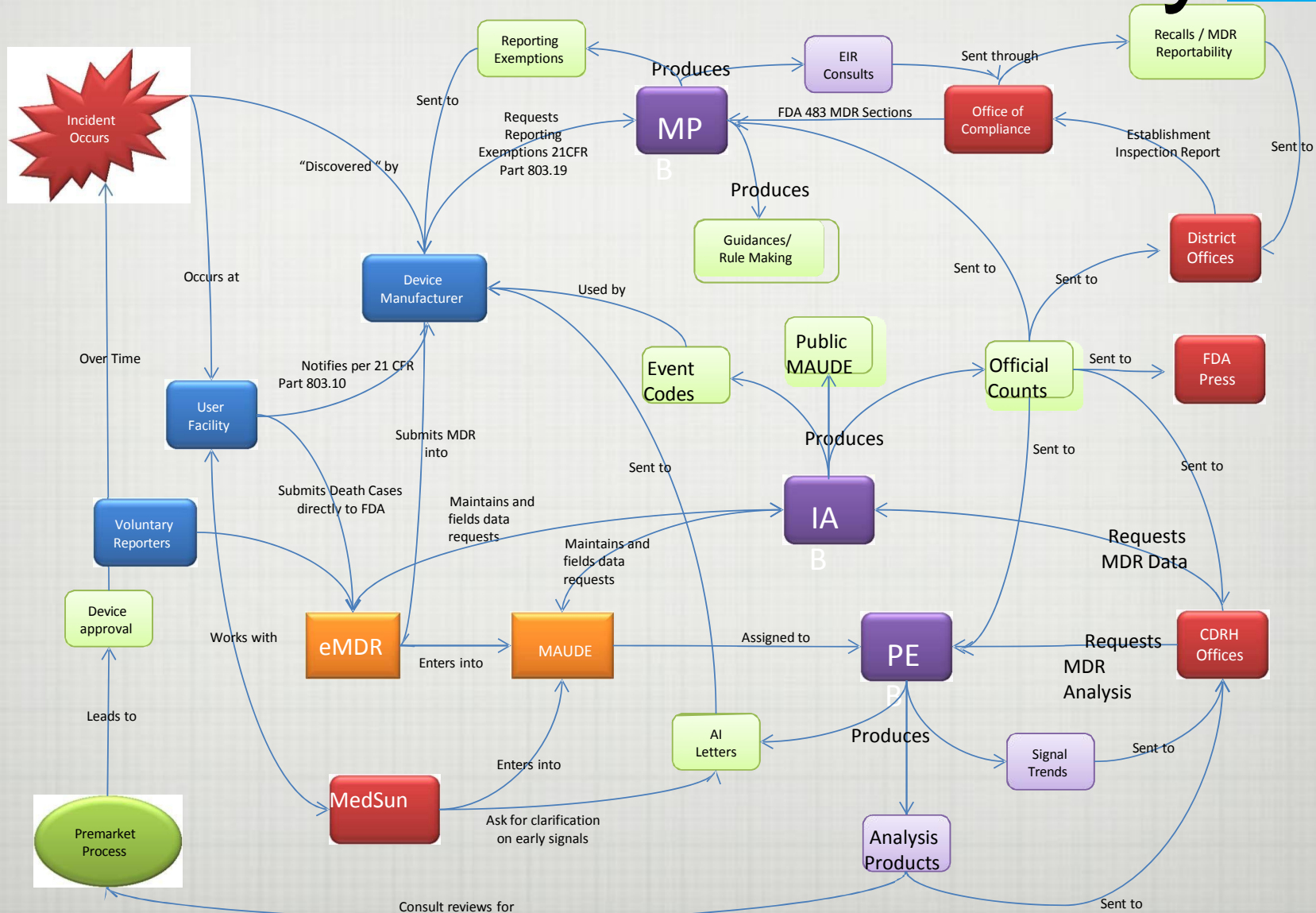
What Types of Events Must Be Reported to FDA?

- If device may have **caused or contributed** to a death or serious injury.
- Certain malfunctions must also be reported.

Additional requirements:

- Device manufacturer must conduct a complete investigation of each event (as per 21 CFR Part 820.198)
- All information required in 21 CFR Part 803.52
- Develop and implement written MDR Procedures (21 CFR Part 803.17)
- Establish and maintain MDR event files
- Have a system in place that ensures access to information that facilitates timely follow-up/inspection by FDA.

The Incident Pathway



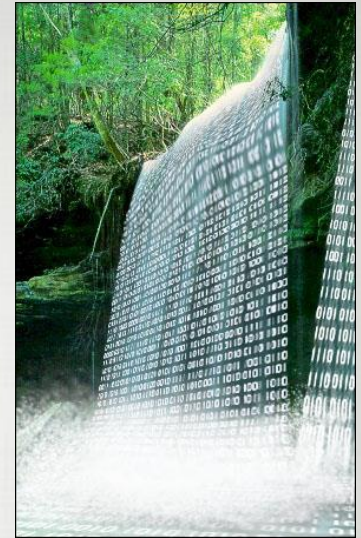
The need for Data Analytics



Over 1 Million MDRs Annually with 45 Employees in the Division of Post-Market Surveillance

BiInnovation FDA Projects

- **IMPROVING** Electronic MDR
- **EXPLAINING** the increase in Adverse Event Reports
- **ALTERNATE** Summary Report Data
- **LONGITUDINAL STUDIES** to track devices from original premarket submission through adverse incident reports from manufacturers, user facilities and end users.

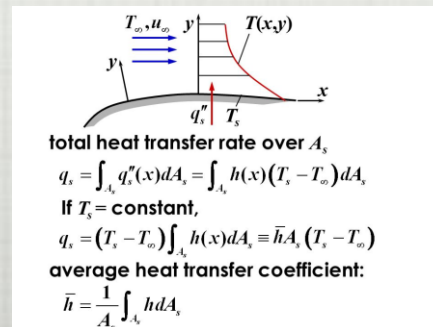


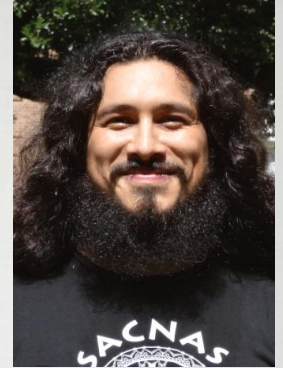
Office of Science and Engineering Laboratories



Supports the CDRH mission of protecting and promoting public health by:

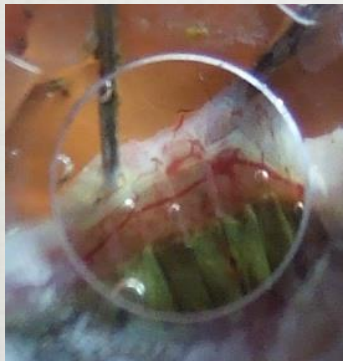
- **Conducting laboratory-based regulatory research;**
- **Providing scientific and engineering expertise, data, and analyses** to support regulatory processes, and
- **Collaborating with colleagues** in academia, industry, government, and standards development organizations.





OSEL Lab Experiences

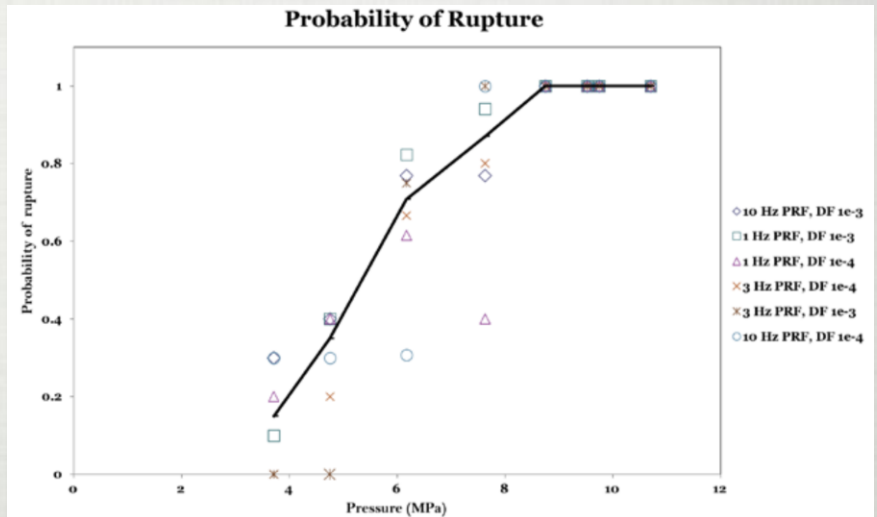
Microvessel Rupture from Exposure to High Intensity Therapeutic Ultrasound



a



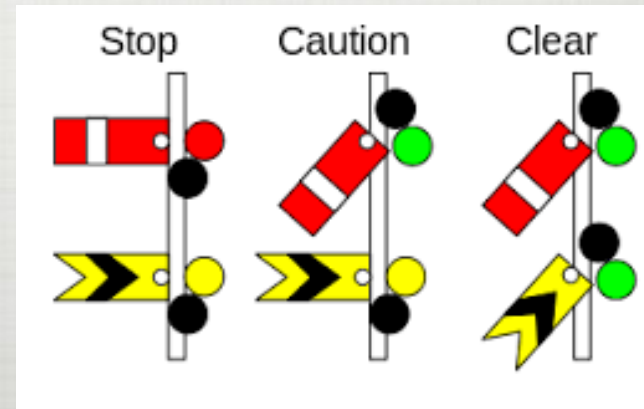
b



Signal Meetings



- **Interdisciplinary multi-divisional meeting**
 - Includes Pre- to Post-Market Divisions
 - Each party describes perspectives of what the problems are and how to move forward.



Positive Consequences of FDA Internship Program

- Provides a big draw to the Bioinnovation program
- Has affected changes in device design by helping students to understand the regulatory pathway.
- Provides insight to careers in non-academic positions.

Negative Consequences of Internship Program

- ❶ Distraction from research during the first year.
- ❷ The allure of non-academic careers may cause attrition.



COMPETITIONS

- ★ TULANE BUSINESS MODEL COMPETITION (2ND PLACE 2015, FINALIST 2016)
- ★ 2014 NOVELTECH TULANE CHALLENGE (1ST PLACE, SEMI FINALIST)
- ★ 2015 NEUROSTARTUP CHALLENGE (NIH) — MULTIPLE AWARDS
- ★ 2016 NOVEL TECH CHALLENGE (KG, SK, NP ARE FINALISTS, 2016)
- ★ RICE UNIVERSITY BUSINESS PLAN COMPETITION (DD; NP, KK, DT)
- ★ STAGE 1 E-TEAM PROGRAM GRANT RECIPIENT; VENTUREWELL
- ★ INTERNATIONAL BUSINESS MODEL COMPETITION
- ★ USC MARSHALL INNOVATION CONFERENCE TECH BUSINESS PITCH



PLACE 2015, FINALIST 2016)

★ 2014 NOVELTECH TULANE CHALLENGE (1ST PLACE, SEMI FINALIST)

Successes

★ 2015 NEUROSTARTUP CHALLENGE (NIH) — MULTIPLE

★ 2016 NOV... SK, NP ARE FINALIST

★ RICE UN... COMPE

★ STAGE... VENTU... ENT;

★ INTER... COMPETITION

★ USC MARSHALL INNOV... TECH BUSINESS PITCH

★ SEMI-FINALIST FOR MASSCHALLENGE (DD)

★ VENTUREWELL E-TEAM STAGE 1 RECIPIENT (DD)



Successes

AWARDS

- ★ NSF I-CORPS FELLOWSHIPS (4) AND COUNTING
- ★ NSF I-CORPS SITE
- ★ VENTUREWELL UNIVERSITY INNOVATION FELLOW
- ★ ENGAGED LEARNING AWARD FROM SISE @ TULANE
- ★ ROSENMAN INNOVATION AWARD FOR MEDICAL DEVICES





BMES

BIOMEDICAL ENGINEERING SOCIETY™

QUESTIONS?

BMES Activities and Events

- ▶ 2017 Professional Development Webinars
<http://www.bmes.org/content.asp?contentid=147>
- ▶ 2017 BMES/FDA Frontiers in Medical Devices Conference
<http://www.bmes.org/medicaldevices>
 - May 16–18, 2017 – Washington, DC
- ▶ 2017 BMES Annual Meeting
<http://www.bmes.org/annual%20meeting>
 - October 11–14, 2017 – Phoenix, AZ
 - Abstracts Submission Deadline: **April 26th**
<http://submissions.mirasmart.com/BMES2017>