

Medical Devices: Engineering's Contributions to the Quality of Life



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NCCAVS Joint Users Group
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Nanobreweries

- Definition: Production < 3 bbl/batch
- As of Dec 2012 - 93 in the US
 - From CA to MA
- 51 in the planning stage
- Watchout - the brewers are taking over!



Presentation Outline

- What is a "Biomedical Device"
- Biomedical Device Industry & Driving Forces
- Where nano and bio intersect
- Some thoughts on "Nanotech"
- Nanotech @ SJSU, Foothill College
- Industry Initiative



Biomedical Engineering

- Deployment of engineering knowledge in the biological and health sciences for the improvement of quality of human life
- Interdisciplinary
- Rapidly growing field
- Opportunities for innovation, entrepreneurship, collaboration, and jobs
- Ability to communicate with life sciences professionals, physicians, regulatory affairs professionals, and others
- FDA-regulated industry



Bio What?

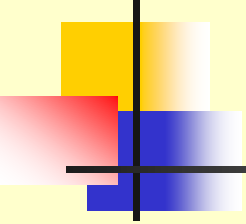
- Biomedical devices
- Biomechanics
- Prosthetics, orthopedics
- Bioinformatics
- Biopharma
- Imaging
- Bio-electronics/
instrumentation
- Biotechnology
- Proteomics, genomics
- Tissue engineering
- Biomaterials
- Microfluidics
- Bio-sensors
- Signal analysis
- Nanotechnology
- Bio-nano or is it Nano-bio?

Many others, some still evolving



What is a "device"?

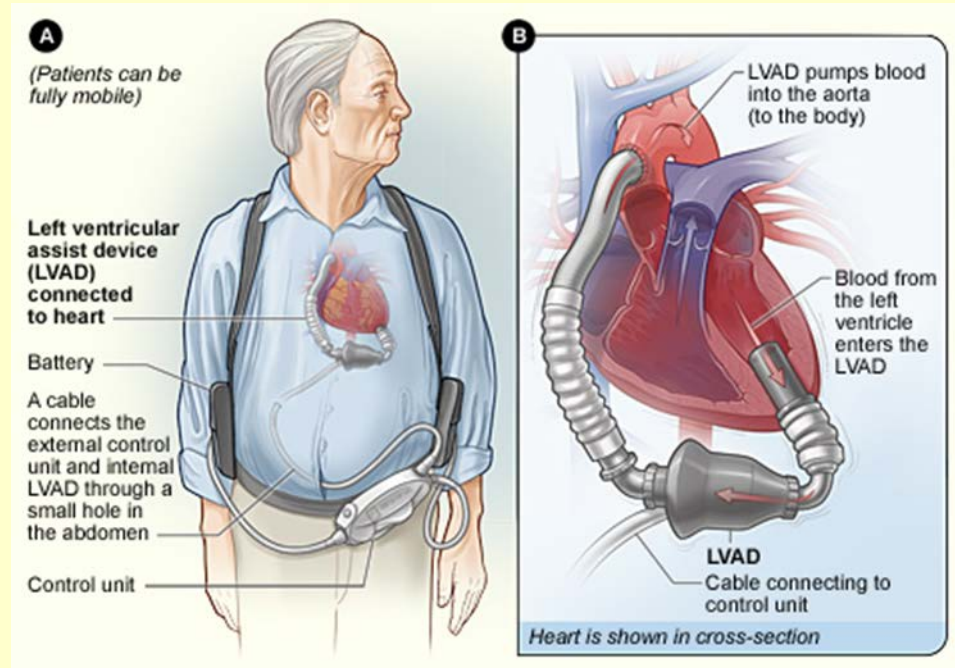
- "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
 - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."



In other words ...

- A broad range of surgical devices and equipment used in cardiovascular, orthopedics, respiratory, ophthalmic, neurology, urinary, disposable, infection and more.

Anything from a tongue depressor to a Left Ventricular Assist Device



Drugs and medications are not included



CA's Biomedical Industry

- 2490 biomed companies
 - Many small, innovative startups
 - Device & diagnostics companies - 1430
 - Biopharma companies - 1060
- Total employment: 764,000
 - 267,000 direct employment
 - 497,000 indirect employment
 - Employment grew even during the 2008-2012 "recession"

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- Second largest high-tech sector in CA
 - Total wages and salaries: \$27 billion
 - Average wage: \$95,740
 - Total revenue (2012): \$96 billion
 - More than 1,400 products in the pipeline - 21% of US total
 - NIH funding: \$3.1 billion
 - Most SBIR and STTR NIH funding



Biomedical Device Industry

- U.S. demand for medical devices and implants expected to grow
- US market still the largest in the world
- Other growth areas: Asia & Latin America
- India, China and Southeast Asia expected to have particularly high growth rates
 - Large population; economic growth



Silicon Valley/Bay Area

- Significant presence of biomedical device companies in Silicon Valley
- Biggest biomedical cluster in CA
 - 847 companies
 - 47,019 jobs
- Home to largest concentration of medical device start-ups in the USA
- Largely engineering oriented field within the biotechnology area



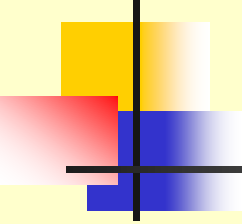
Driving Forces

Societal

- Aging and more affluent population
- Greater demand for, and awareness of, better quality of life
- Preventive & corrective therapies
- Health care cost containment

Technological

- Improved technological capabilities
- Optics & fiber optics
- Miniaturization of electronics
- Micro-fabrication
- Imaging technologies
- IT Improvements
- **Nano, nano, nano**
- Many others

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- Appendectomy
 - Open appendectomy
 - Laparoscopic appendectomy

 - Endoscopy

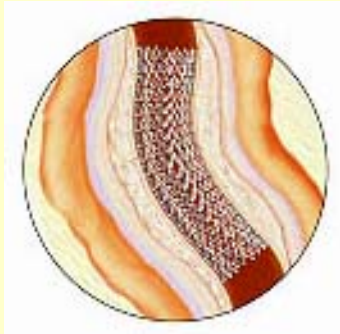
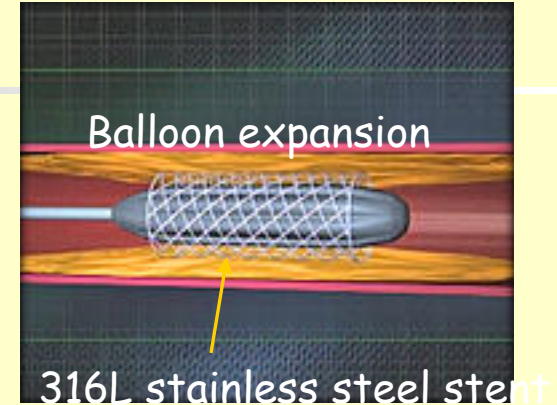
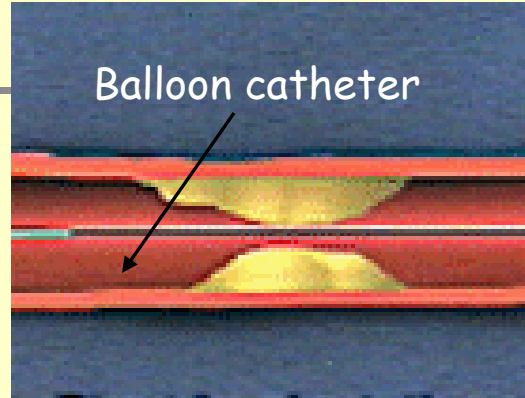
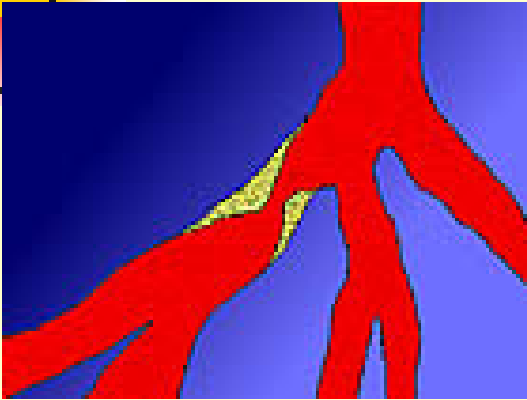


Biomedical Devices

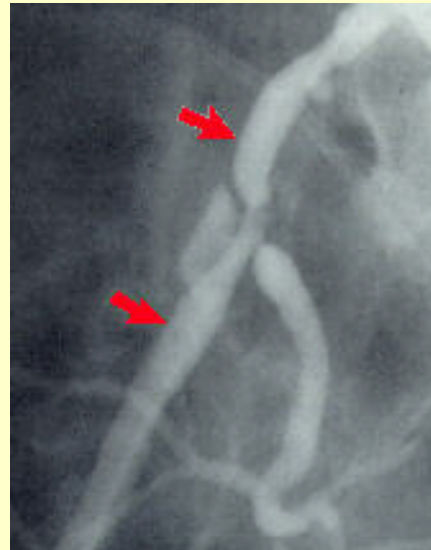
- Marriage of engineering know-how and biomedical science.
- Engineered products
- Designed by multi-disciplinary team of engineers
- Need to work, and communicate, with life sciences professionals, e.g., biologists, physicians, etc.
- Customer: Physician
- Operating environment: Human body
- Regulated by Food & Drug Administration
 - Need to work with Regulatory Affairs and Quality Control professionals



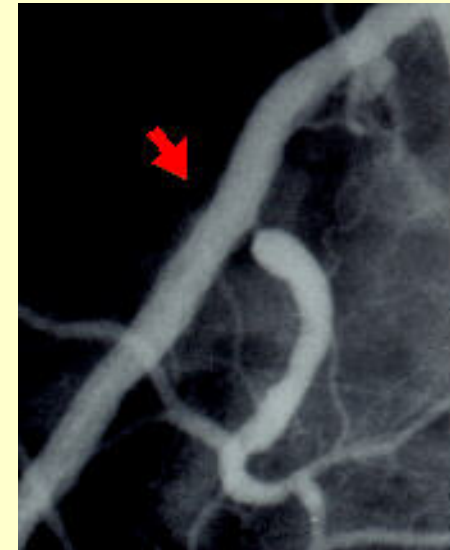
Stenting



NiTi
self-expanding
stent

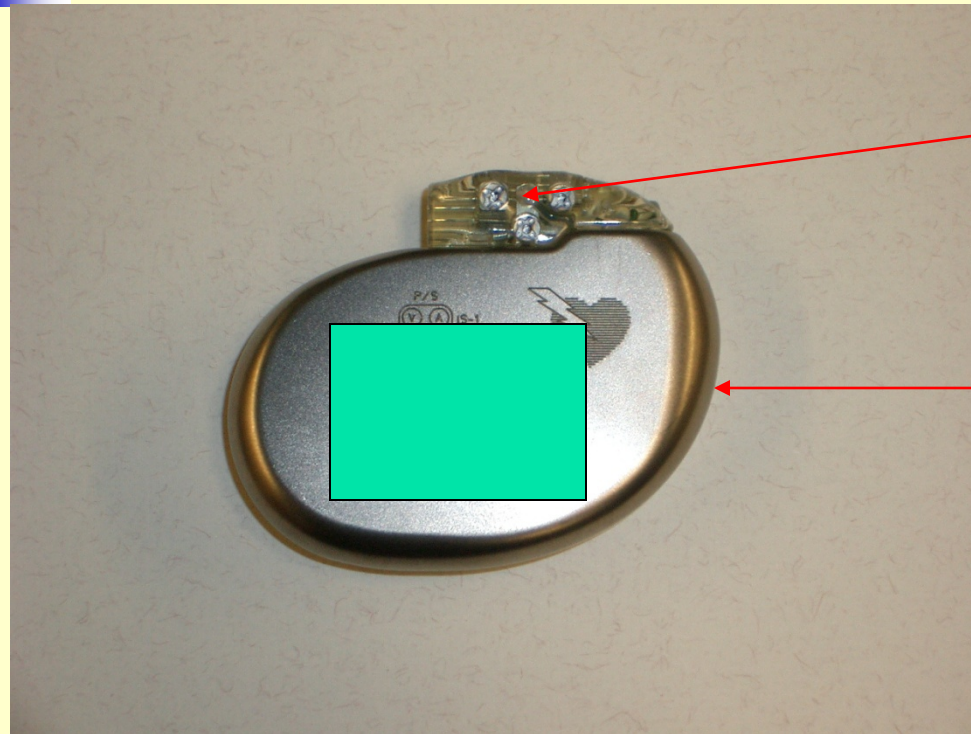


Before stenting showing blocked artery



After stenting

Defibrillator

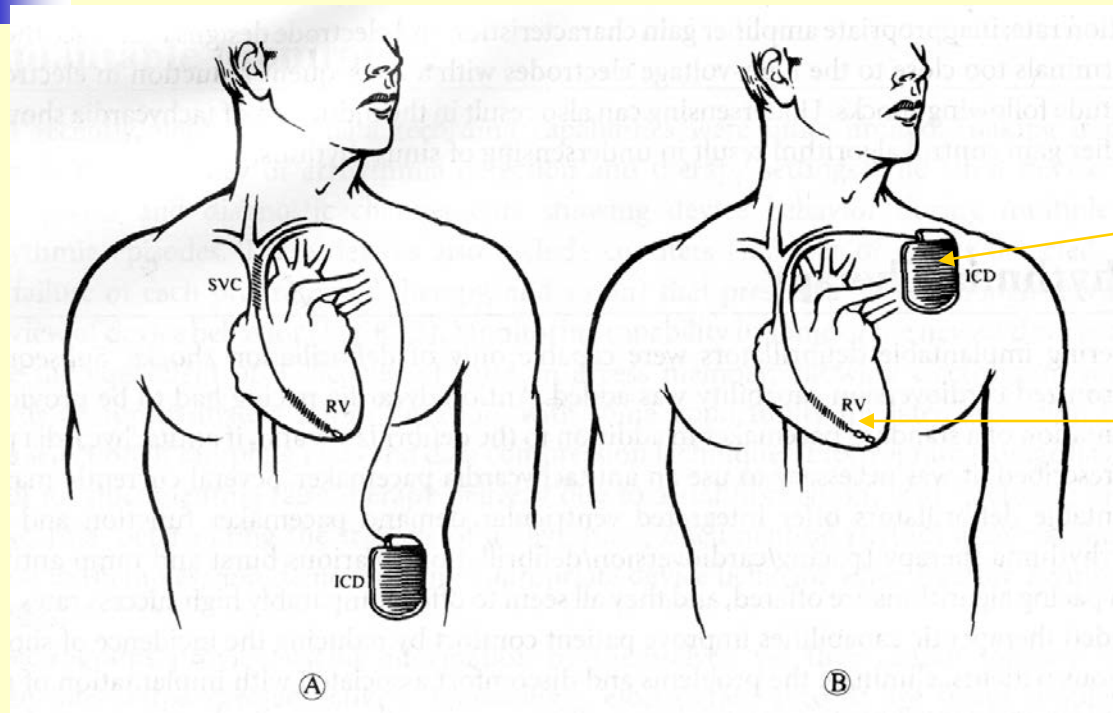


Electrical contacts

Outer body (Ti)

Device for arresting the uncontrolled twitching or quivering of the auricular or ventricular heart muscles

Defibrillator Implant



Pulse Generator

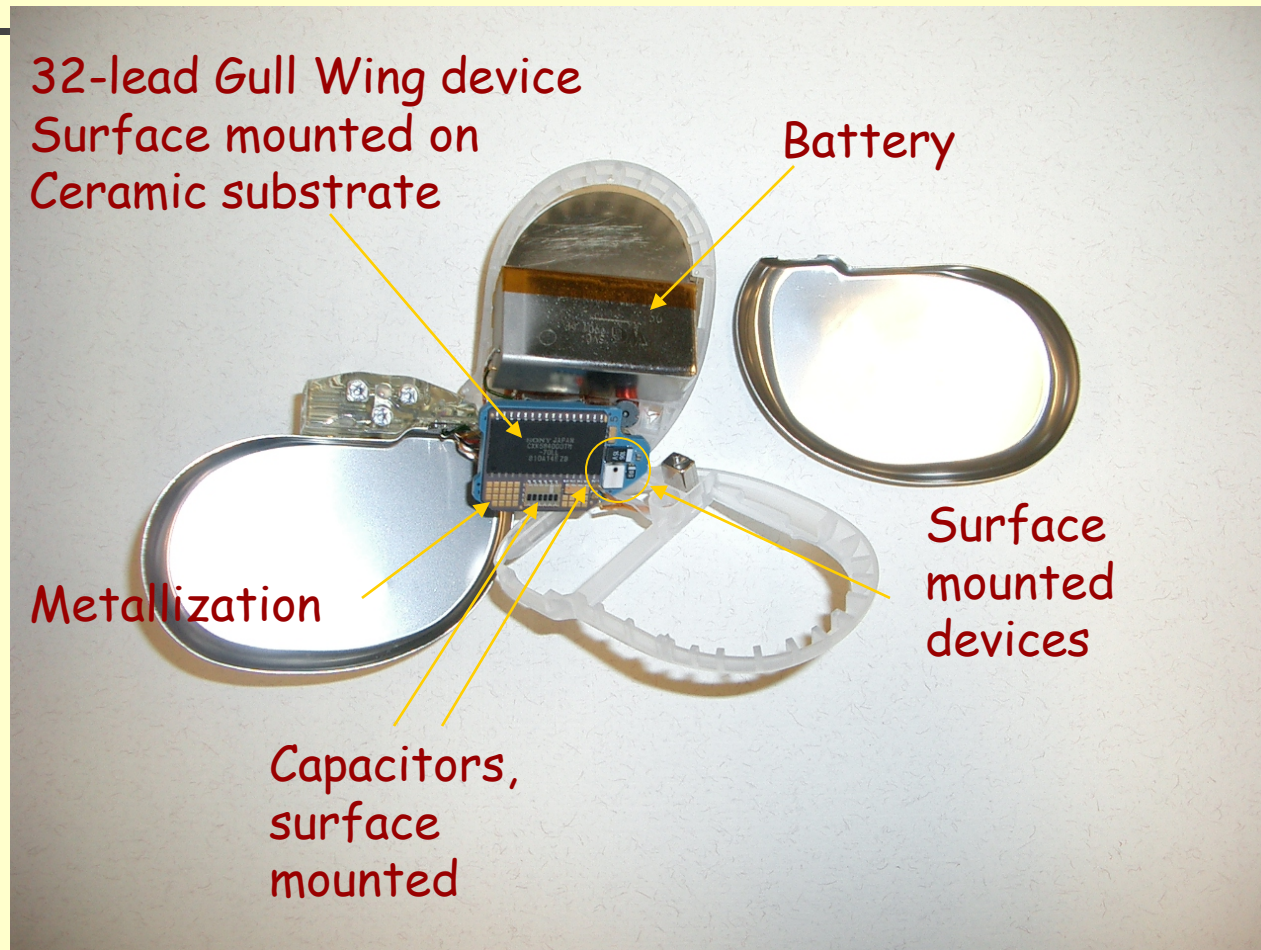
Electrode (Pt-Ir)
with polyurethane
or silicone insulation

Source: Biomedical Engineering Handbook, CRC Press, p 1287

Defibrillator: electronic components



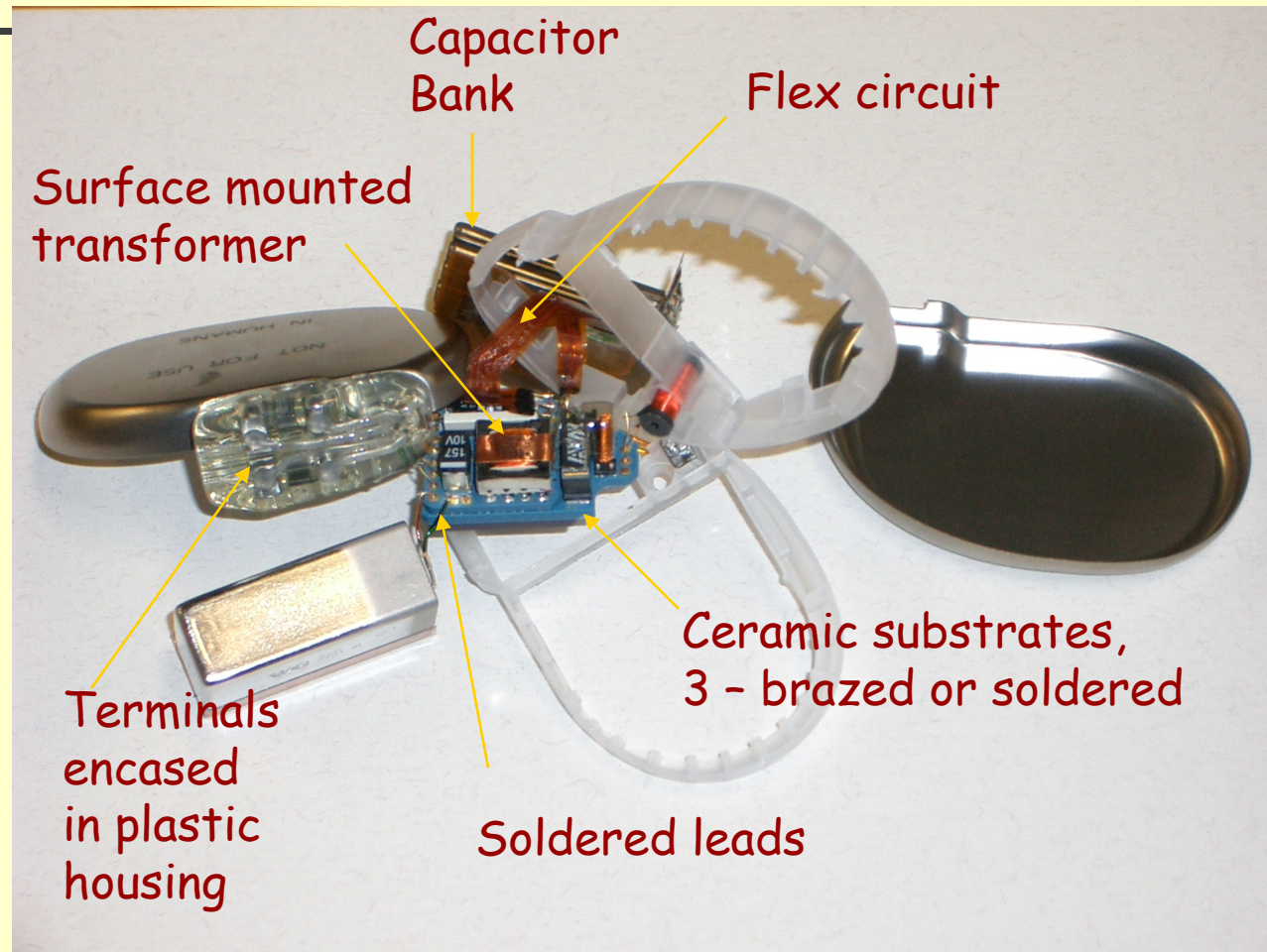
San José State
UNIVERSITY



Defibrillators: more components



San José State
UNIVERSITY





Some advancements/efforts

- Robotic surgical systems
- Drug delivery to targeted areas
- Patient-centric devices
- Artificial bone, muscles, ligaments
- Embedded chips for health monitoring
- Mobile health applications
- Many others



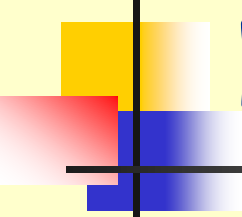
Nanotechnology in Medicine

- Targeted drug delivery/smart drugs
- Cancer treatment
- Cholesterol treatment
- Scaffolding in nerve regeneration
- Nano-sized ZrO_2 for dental fillings and prosthetics
- Magnetic nanoparticles (ferrofluids) conjugated to antibodies directed against rare cells, e.g., circulating tumor cells
- Enhancement of imaging
- Antibacterial coatings - Ag nanoparticles



Challenges/Issues

- Bench to bedside
 - Regulatory pathway
 - Reimbursement
- Manufacturing on a commercial scale
- Cost effectiveness
- Education/training of workforce - not just PhD-type researchers



Nanotech @ SJSU

- Biomedical, Chemical & Materials Engineering Department

- MatE 265: Fundamentals of Nanomaterials

Instructor: Michael Oye (Michael.Oye@sjsu.edu)

- BME 256: Biomedical Applications of Nanoplatforms

Instructor: Folarin Erogbogbo(folarin.erogbogbo@sjsu.edu)



Fundamentals of Nanomaterials

- Graduate level; advanced survey of different aspects of active research in nanotechnology
- Fundamentals of physics, chemistry, biology, and material science of materials at the nanoscale (<100 nm)
- Fabrication and characterization techniques unique to reduced size and dimension of nanomaterials
- Applications of nanomaterials, including, such as:
 - Nano-grained structural materials to nano particles composites
 - Nano logic memory devices and microelectronics
 - Nano-bio materials in drug delivery and biomedical applications
 - and others...



Biomedical Applications of Nanoplatforms

- Survey of constraints placed on design of theranostic nanoplatforms by physiological parameters of tissues involved in particular diseases
- Biomedical applications of nanoplatforms in the development of three cutting edge sub fields:
 - Therapeutics (e.g., gold nanorods for photoablation in cancer therapy)
 - Prosthesis and implants (e.g., Improving Tribological Characteristics of Hip Prostheses Using Biocompatible Nanocoatings)
 - Diagnosis and screening (e.g., array of nano-cantilevers as a bio-assay for cancer diagnosis)



Foothill College

- AS degree / concentration in nanoscience
- CA State approved certificate in Nanoscience
- Educational emphasis in integrated materials engineering and characterization tools for process optimization
- Application emphasis on thin films clean energy, biomedical device and biomaterials, and biomimetic design
- Funded by NSF-DUE 0903316 (2009-2013)
- Faculty: Robert Cormia and Jamie Orr, both research faculty at NASA-ASL
- Collaboration with SJSU and UCSC, as well as commercial analytical labs

Five courses:

NANO10 - Nanoscience

NANO52 - Nanostructures

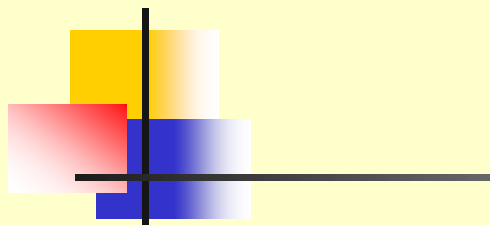
NANO54 - Nanofabrication

NANO51 - Nanotechnology applications

NANO53 - Nanocharacterization

NANO62 (Fall 2014) - Nanomaterials
Engineering

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SJSUBMES

Biomedical Engineering Society

Save the date!
Wednesday
March 26th, 2014
5th Annual
Bay Area
Biomedical Device
Conference



For information on Guest Speakers, Sponsors and
other resources, please visit:
www.biomedconference.org

Questions?
conferencevp@sjsubmes.org

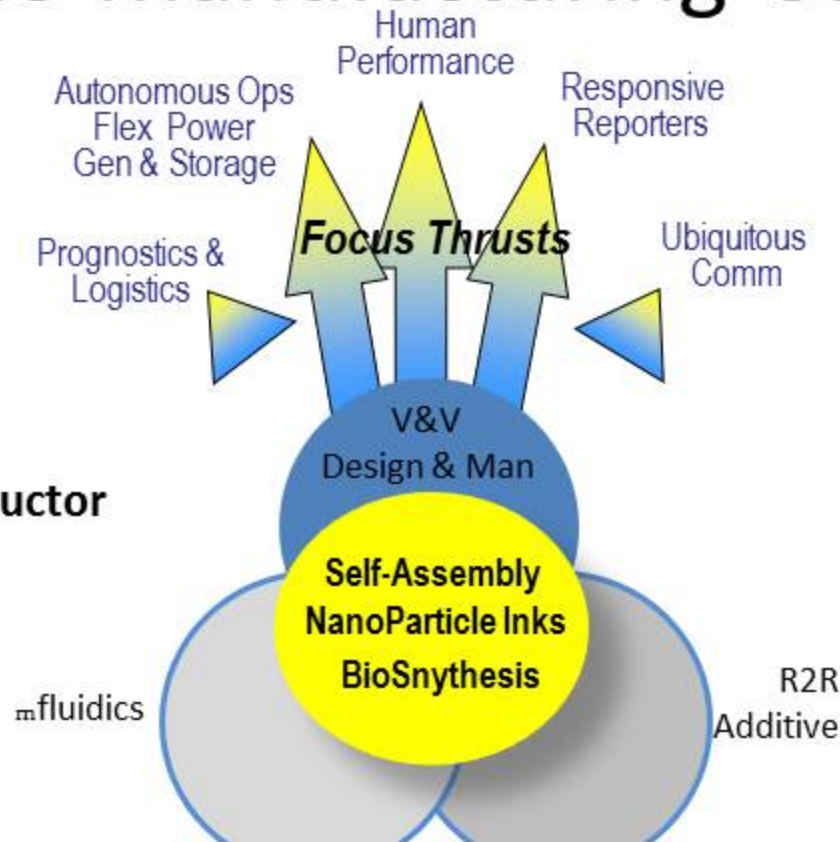


BioMed Conference @ SJSU

- Parallel Session 1: Applications of Nanotechnologies in Medicine
 - David Deamer, Ph.D., UCSC - Nanopore Analysis of Nucleic Acids: From an Idea to a Working Instrument
 - Vinod Labhasetwar, Ph.D., Cleveland Clinic - Biophysics of Cell Membrane Lipids in Cancer Drug Resistance:
 - Implications for Drug Transport and Drug Delivery with Nanoparticles
 - Joseph Sly, Ph.D., IBM Almaden Research Center - Topic TBD

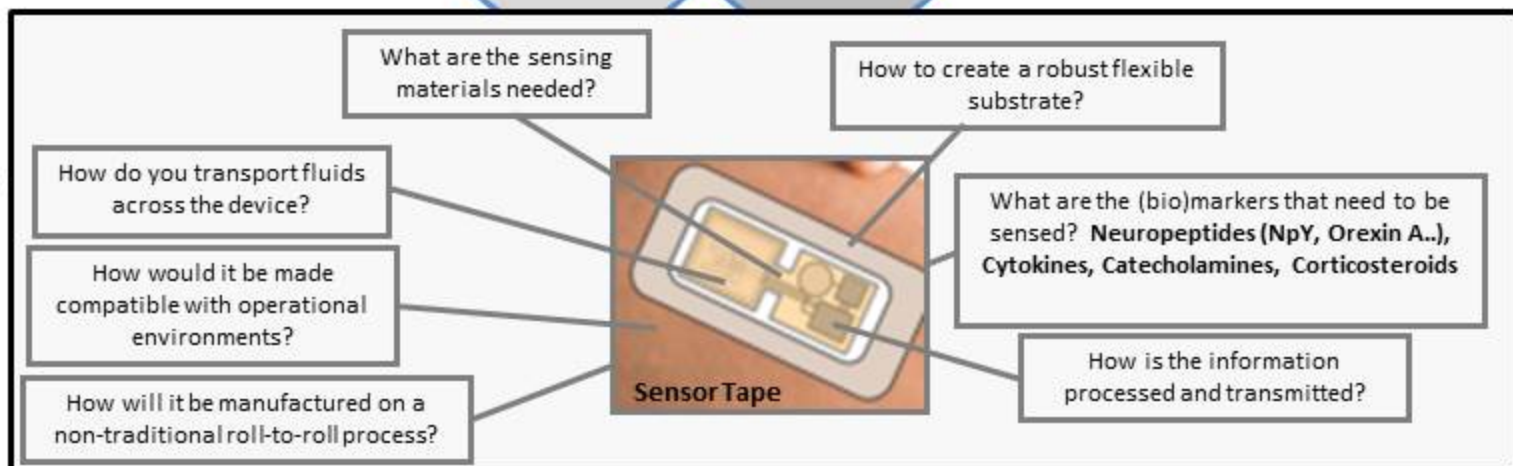
Nano-Bio Manufacturing Consortium

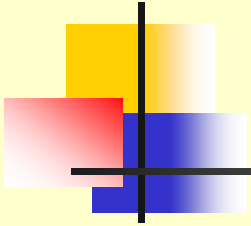
GE
DuPont Industrial
BioSciences
DuPont Teijin
PARC
Brewer Science
Soligie
American Semiconductor
MC10
Lockheed Martin
UES



UMASS
Univ of Cincinnati
UC San Diego
Cornell University
Univ of Binghamton
North Eastern University
John Hopkins University
Arizona Center of
Integrated Medicine
Arizona State Univ.

Tech Challenges





Thank You
Very Much