MTU BE 4775 / BE 5775

Medical Devices

Fall 2014

MWF, 12:05 – 12:55 PM, EERC 501

Michael R. Neuman (mneuman@mtu.edu)
Orhan Soykan (osoykan@mtu.edu)
Bruce H. Barkalow (bruce@bhbi.com)

Course Information

This is a one semester introductory course on medical devices.

Course consists of two main components:

(A) Lecture Component:

Part 1: Lectures 03 – 12: Introduction to various medical devices,

Part 2: Lectures 13 – 23: General issues common to many medical devices, and

Part 3: Lectures 24 – 32: Contemporary technologies and trends.

(B) Case Studies: Students will form groups and each group will study a given case.

www.biomed.mtu.edu/~osoykan/classes/be4775/be4775.htm

Part 1: Introduction to various devices

[LECTURE 02 ON 08 SEP 2014 MON	Introduction of the five case studies]
LECTURE 03 ON 10 SEP 2014 WED	Diagnostic – Imaging Systems (MRI, CT)
LECTURE 04 ON 12 SEP 2014 FRI	In vitro diagnostics (ELISA, mass spect)
LECTURE 05 ON 15 SEP 2014 MON	Extracorporeal therapueutic devices (hemodialysis, drug pumps)
LECTURE 06 ON 17 SEP 2014 WED	Implantable therapeutics (stimulators)
LECTURE 07 ON 19 SEP 2014 FRI	Recorders and monitors (Cath lab tools)
LECTURE 08 ON 22 SEP 2014 MON	Surgical tools (Endoscopes, respirators)
LECTURE 09 ON 24 SEP 2014 WED	Surgical robots (daVinci)
LECTURE 10 ON 26 SEP 2014 FRI	Radiation Systems (Gamma knive)
LECTURE 11 ON 29 SEP 2014 MON	Dental (Ultrasound) & Ophthalmic devices
LECTURE 12 ON 01 OCT 2014 WED	*Review before exam # 1*

EXAM 1 ON 03 OCT 2014 FRI

Part 2: Issues common to medical devices

LECTURE 13 ON 06 OCT 2014 MON Safety

LECTURE 14 ON 08 OCT 2014 WED Device reliability

LECTURE 15 ON 10 OCT 2014 FRI Tracebility

LECTURE 16 ON 13 OCT 2014 MON Data transmission and protection

LECTURE 17 ON 15 OCT 2014 WED Preclinical testing - Renee Gerhart

LECTURE 18 ON 17 OCT 2014 FRI Clinical trials - Luc Mongeon

LECTURE 19 ON 20 OCT 2014 MON Quality Assurance - Matt Bergan

LECTURE 20 ON 22 OCT 2014 WED Compliance - Jeff Silberberg

LECTURE 21 ON 24 OCT 2014 FRI Regulatory pathways - Janice Kruse

LECTURE 22 ON 27 OCT 2014 MON Post market surveillance - Martyn Smith

LECTURE 23 ON 29 OCT 2014 WED *Review before exam # 2*

EXAM 2 ON 31 OCT 2014 FRI

Part 3: Contemporary technologies & trends

LECTURE 24 ON 03 NOV 2014 MON	Technologies for patient isolation (electrical and optical)
LECTURE 25 ON 05 NOV 2014 WED	Technologies for sterilization (EtO and e-beam)
LECTURE 26 ON 07 NOV 2014 FRI	Artificial organs (Bionic pancreas)
LECTURE 27 ON 10 NOV 2014 MON	Software design (firmware)
LECTURE 28 ON 12 NOV 2014 WED	Electronic medical records
LECTURE 29 ON 14 NOV 2014 FRI	Remote monitoring / telehealth
LECTURE 30 ON 17 NOV 2014 MON	Current trends: Cost pressures
LECTURE 31 ON 19 NOV 2014 WED	Current trends: Intellectual property
LECTURE 32 ON 20 NOV 2014 FRI	Current trends: Affordable care act

Grading Information

BE 4775 Grading:

Exam 1:	20 %	*03 OCT 2014 FRI*
Exam 2:	20 %	*31 OCT 2014 FRI*
Case Study:	15 %	
Homework:	15 %	
Final Exam:	30 %	

BE 5775 Grading:

Exam 1:	15 %
Exam 2:	15 %
Case Study:	15 %
Homework:	15 %
Final Exam:	25 %
Term paper:	20 %

BE 5775 students will be asked to prepare a term paper on the analysis of a medical device. The contents of the paper as well as the particular device to be analyzed will be chosen by the student but must be approved by one of the course instructors before the end of the third week (19 September 2014).

FDA Defines Medical Devices As:

- A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - 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 its 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."

Medical Devices

- The United States (U.S.) medical device manufacturing sector is a highly diversified industry that produces a range of products designed to diagnose and treat patients in healthcare systems worldwide.
- Medical devices differ from drugs in that they do not achieve their intended use through chemical reaction and are not metabolized in the body.
- Medical devices range in nature and complexity from simple tongue depressors and bandages to complex programmable pacemakers and sophisticated imaging systems.

Medical Device Industry in U.S.

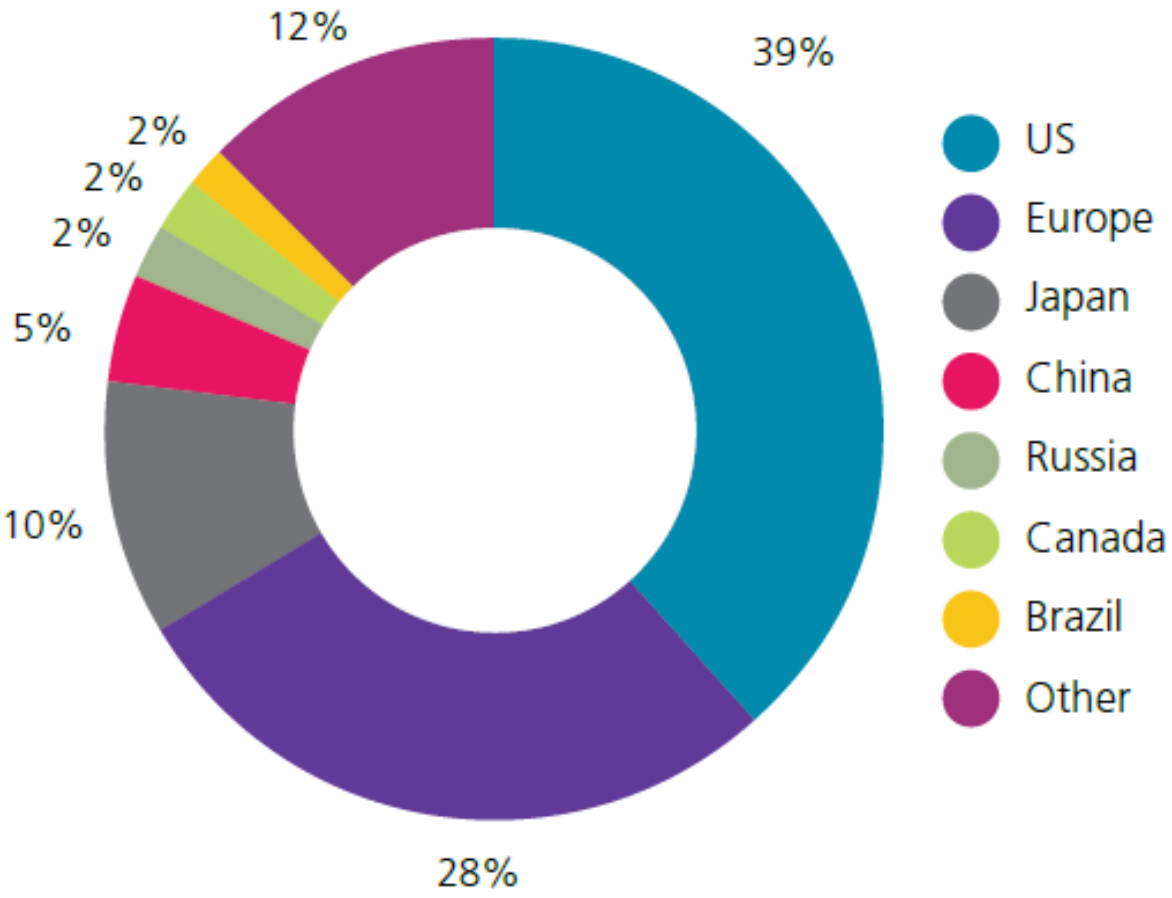
- U.S. Gross > $100 Billion, Global > $300 Billion
  - US Exports ≈ $30 Billion - US Imports ≈ $30 Billion
- Employment > 300,000 jobs in the U.S.

GM = $155 Billion

Region	Revenue	Number of companies	Market capitalization 30 June 2012	R&D	Net income	Cash and cash equivalents	Total assets
Massachusetts	$29,570 7%	29 0%	$45,055 -22%	$2,085 3%	$1,849 338%	$3,635 2%	$69,350 10%
Minnesota	$22,391 6%	18 0%	$56,097 -8%	$2,329 3%	$3,986 4%	$3,836 -18%	$40,720 8%
Southern California	$14,478 -15%	35 -5%	$47,821 -18%	$1,540 -8%	$856 -27%	$6,327 28%	$28,647 5%
New Jersey	$11,919 7%	12 -20%	$26,552 -13%	$731 7%	$1,634 -13%	$2,350 -8%	$15,962 12%
Northern California	$10,609 9%	31 0%	$48,054 17%	$1,106 9%	$1,038 4%	$4,260 -3%	$15,805 10%
Pennsylvania	$9,572 29%	9 0%	$10,168 37%	$379 34%	$1,535 26%	$3,421 22%	$19,086 46%
Michigan	$8,411 13%	3 0%	$21,184 -8%	$480 21%	$1,278 1%	$3,436 -22%	$12,513 13%
Indiana	$6,409 6%	4 0%	$13,577 -12%	$327 9%	$891 23%	$1,467 29%	$10,456 8%
New York	$2,913 8%	23 -4%	$4,761 -15%	$215 10%	$84 -14%	$696 26%	$4,556 5%
Texas	$2,379 -43%	10 -9%	$5,149 -41%	$120 -43%	$129 -72%	$556 -23%	$3,066 -47%

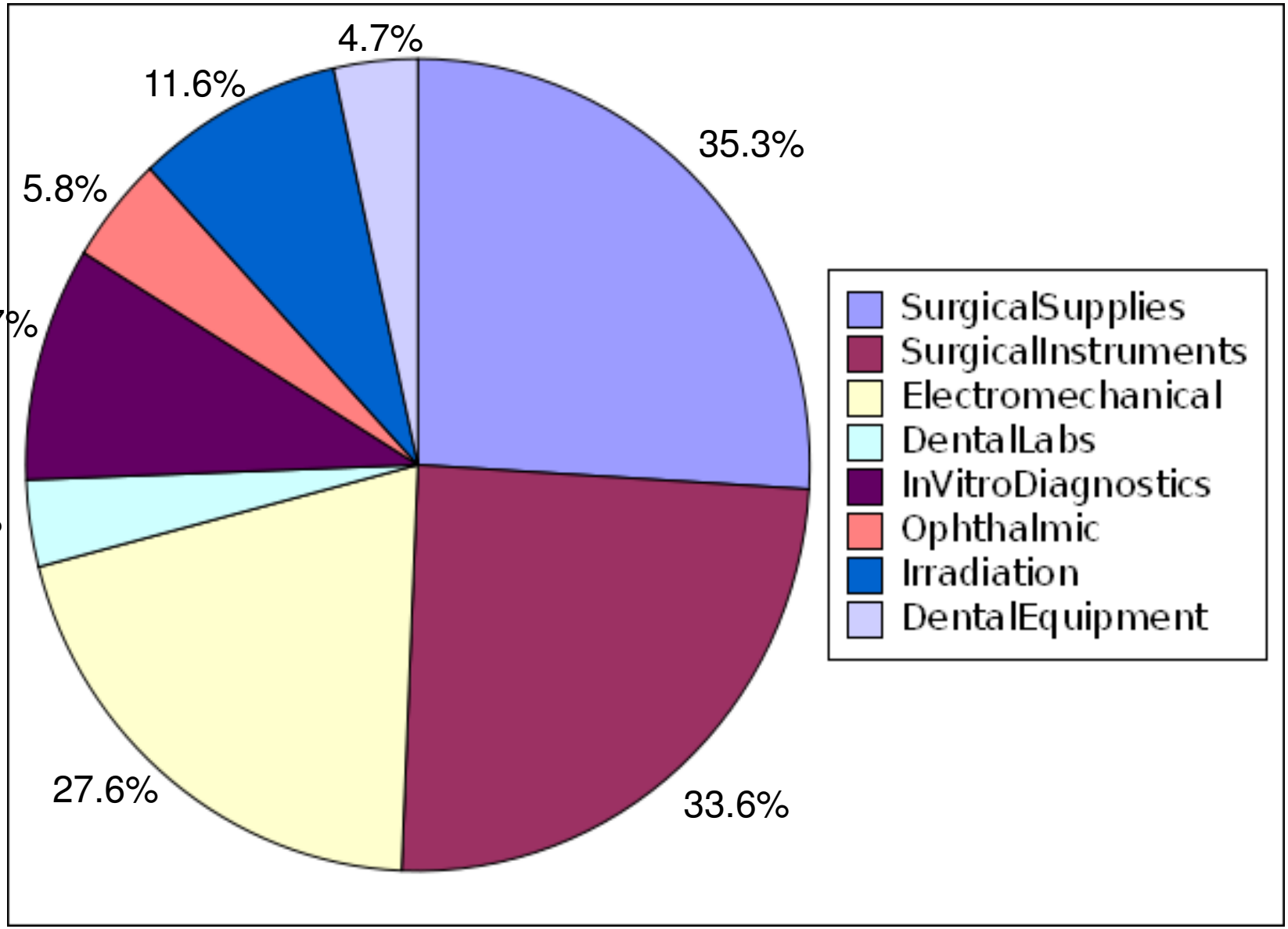
MEDICAL DEVICE INDUSTRY IS PROFITABLE BUT SMALL !

US + EU + JP = 3/4



World medical technology market by region based on manufacturer prices. Data as of CY 2012.

Size of Medical Device Sectors



Employment in Medical Device Industry

Exhibit 3: Ten States with Largest MTI Employment

State	Employees (1000s)
California	84.0
Minnesota	26.9
Massachusetts	23.9
Pennsylvania	22.2
Florida	21.7
New Jersey	20.5
Indiana	19.9
New York	19.6
Texas	16.6
Wisconsin	14.4

Exhibit 4: Ten States with Highest Percentage MTI Employment

State	Percent State Employment
Minnesota	1.06%
Utah	0.93%
Delaware	0.79%
Massachusetts	0.78%
Indiana	0.75%
New Hampshire	0.66%
California	0.61%
Nebraska	0.60%
Wisconsin	0.58%
New Jersey	0.56%

Top 25 Employers in Minnesota

1. State of Minnesota
2. U.S. Federal Government
3. Mayo Clinic
4. Target Corporation
5. University of Minnesota
6. Allina Health
7. Wal-Mart Stores
8. Wells Fargo
9. Fairview Hospitals
10. United Health
11. Minnesota State Colleges
12. 3M Company
13. Health Parners
14. U.S. Bancorp
15. Essentia Health
16. Delta Air Lines
17. Park Nicollet Health
18. Supervalu
19. Hormel Foods
20. Thompson-Reuters
21. **Medtronic**
22. Best Buy
23. Hennepin County
24. Health East
25. CentraCare

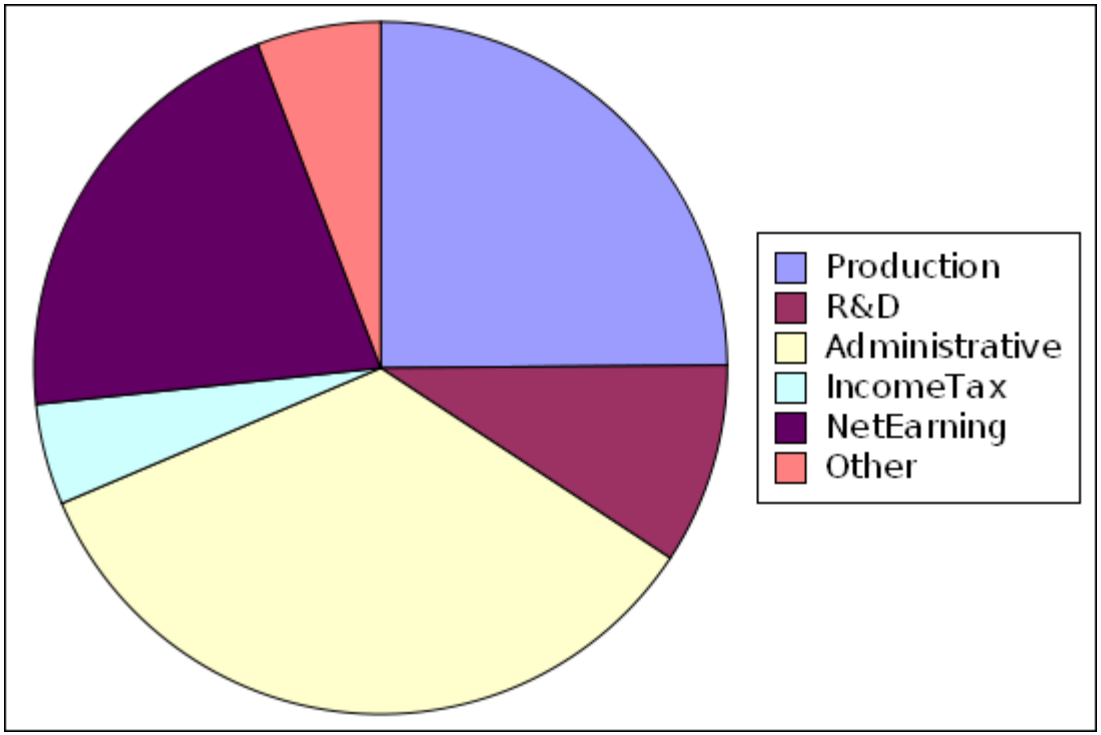
Comes in all sizes

- > 5,000 medical device companies in the U.S.
- Most are small and medium-sized enterprises.
- 3/4 of companies < 20 employees.
- Only 15% have > 100 employees.
- Increasingly outsourcing to:
  - Specialty firms,
  - Domestic and international suppliers,
  - Partners in Asia.

How is the money spent

SAMPLE ANNUAL BUDGET.

NetSales	16,590
Production	4,126
R&D	1,557
Administrative	5,698
Other	958
IncomeTax	784
NetEarning	3,467



IN MILLIONS OF DOLLARS.

How to succeed in this class

- Attend the lectures – No recordings will be made
- Take notes – There is no text book
- Keep up – Material is new to most students
- Ask questions – Best way to learn
- Start working on the case study now
- Work with the instructors on the term paper
- Your best friend is: www.google.com

www.biomed.mtu.edu/~osoykan/classes/be4775/be4775.htm