# MTU BE 4775 / BE 5775 - Medical Devices - Fall 2014

#### **Instructors:**

Michael R. Neuman (<u>mneuman@mtu.edu</u>), M&M Building Room 401 Orhan Soykan (<u>osoykan@mtu.edu</u>), M&M Building Room 403 Bruce H. Barkalow (bruce@bhbi.com)

### MWF, 12:05 - 12:55 PM, EERC Room 501

#### **Course Outline:**

This is a one semester introductory course on medical devices. Course consists of two main components:

#### A. Lecture Component:

- I. Part 1: Lectures 03 12: Introduction to various medical devices,
- II. Part 2: Lectures 13 23: General issues common to many medical devices, and
- III. Part 3: Lectures 24 32: Contemporary technologies and trends.
- B. Case Studies: Students will form groups and each group will study a given case.

#### Note to students who are signed up to BE 5775:

BE 5775 students will be asked to prepare a term paper and give a presentation 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).

**BE 5775 Grading:** 

## BE 4775 Grading:

# Exam 1: 20 % Exam 1: 15 % Exam 2: 20 % Exam 2: 15 % Case Study: 15 % Case Study: 15 % Homework: 15 % Homework: 15 % Final Exam: 30 % Final Exam: 20 % Term paper: 20 %

Week 01 LECTURE 01 ON 03 SEP 2014 WED Course Outline, Expectations, Structure Week 02 LECTURE 02 ON 08 SEP 2014 MON Introduction of the five case studies Diagnostic Devices - Imaging Systems (MRI, CT) LECTURE 03 ON 10 SEP 2014 WED LECTURE 04 ON 12 SEP 2014 FRI In vitro diagnostics (ELISA, mass spect) Week 03 LECTURE 05 ON 15 SEP 2014 MON Extracorporeal therapueutic devices (hemodialysis, drug pumps) LECTURE 06 ON 17 SEP 2014 WED Implantable therapueutic devices (stimulators) LECTURE 07 ON 19 SEP 2014 FRI Recorders and monitors (Cath lab tools) Week 04 LECTURE 08 ON 22 SEP 2014 MON Surgical tools (Endoscopes, respirators) Surgical robots (daVinci) LECTURE 09 ON 24 SEP 2014 WED LECTURE 10 ON 26 SEP 2014 FRI Radiation Systems (Gamma knife) Week 05 Dental (Ultrasound) and Ophthalmic devices LECTURE 11 ON 29 SEP 2014 MON Review before exam # 1 LECTURE 12 ON 01 OCT 2014 WED EXAM 1 ON 03 OCT 2014 FRI Week 06 LECTURE 13 ON 06 OCT 2014 MON Safety Device reliability LECTURE 14 ON 08 OCT 2014 WED LECTURE 15 ON 10 OCT 2014 FRI Tracebility Week 07 LECTURE 16 ON 13 OCT 2014 MON Data transmission (compression) and protection (coding) Preclinical testing (animal studies) - Guest lecturer: Renee Gerhart LECTURE 17 ON 15 OCT 2014 WED LECTURE 18 ON 17 OCT 2014 FRI Clinical trials (Prospective & Retrospective) - Guest lecturer: Luc Mongeon Week 08 LECTURE 19 ON 20 OCT 2014 MON Quality Assurance - Guest lecturer: Matt Bergan LECTURE 20 ON 22 OCT 2014 WED Compliance with Standards - Guest lecturer: Dan Bloomberg LECTURE 21 ON 24 OCT 2014 FRI Regulatory pathways - Guest lecturer: Janice Kruse Week 09 LECTURE 22 ON 27 OCT 2014 MON Post market surveillance - Guest lecturer: Martyn Smith LECTURE 23 ON 29 OCT 2014 WED Review before exam # 2 EXAM 2 ON 31 OCT 2014 FRI Week 10

Week 10
LECTURE 24 ON 03 NOV 2014 MON
LECTURE 25 ON 05 NOV 2014 WED
LECTURE 26 ON 07 NOV 2014 FRI

Technologies for patient isolation (electrical and optical)
Technologies for sterilization (EtO and e-beam)
Artificial organs (Bionic pancreas)

Week 11
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

Week 12

LECTURE 30 ON 17 NOV 2014 MON
LECTURE 31 ON 19 NOV 2014 WED
LECTURE 32 ON 20 NOV 2014 FRI
Current trends: Cost pressures
Current trends: Intellectual property
Current trends: Affordable care act

#### Thanksgiving Recess

Week 13

01 DEC 2014 MON Graduate Student Presentation of Medical Device # 1
03 DEC 2014 WED Graduate Student Presentation of Medical Device # 2
05 DEC 2014 FRI Graduate Student Presentation of Medical Device # 3

Week 14

08 DEC 2014 MON Graduate Student Presentation of Medical Device # 4
10 DEC 2014 WED Graduate Student Presentation of Medical Device # 5

12 DEC 2014 FRI Review before the final exam

Final Exam (Comprehensive)