

BME 658 - Medical Device Design (3 ch) - Spring 2018

Section 50 - Monday 6:00-7:50 PM, Wednesday 6:00-6:50, Room FH 267

Course Description: A practical approach to learning the process and principles for medical device design. Students will learn the basic concepts of designing medical devices and through a hands-on approach. Teams of students will work together on a design project including concepts such as needs identification, FDA regulation, record-keeping, reverse engineering, human factors, prototyping, and validation.

BME 758 - Medical Devices (2 ch) - Spring 2018

Section 50 - Monday 6:00-7:50 PM, Room FH 267

Course Description: The process and principles of medical device design, including concepts such as needs identification, FDA regulation, intellectual property, record-keeping, reverse engineering, human factors, prototyping, and validation.

Blackboard Site: Accessed through CSU home page.

Instructor: Nolan B. Holland, Department of Chemical & Biomedical Engineering

Office: Fenn Hall 462

Phone: 687-2572

E-mail: n.holland1@csuohio.edu

Textbook:

Yock et al. *Biodesign: The Process of Innovating Medical Technologies, 2nd Edition*, Cambridge (2015).

References:

P. H. King, R. C. Fries & A. T. Johnson. *Design of Biomedical Devices and Systems, 3rd Edition*, CRC Press (2015).

Design Control Guidance for Medical Device Manufacturer, FDA Center for devices and Radiological Health, March 11, 1997.

Evaluation:

CHE 758 CHE 658

The final grade will be determined as follows

Quizzes	60%	40%
Homework/class participation	15%	20%
Device Paper (758)/Design Project (658)	15%	40%
Presentations	10%	
Total	100%	100%

Topics Covered

Introduction to Medical Device Design

FDA Regulation

Biomaterial Selection and Testing

Clinical Testing

User Interfaces/Human Factors

Finite Element Modeling

Intellectual Property

Entrepreneurship

Packaging/Sterilization

Legal/Ethical Issues

Device Case Studies

Note: The schedule and/or syllabus may be revised at any time by the instructor.