

ETLS 520 -- Design and Manufacturing in the Medical Device Industry

Fall 2009

- Instructor:** Robert M. Johnson:
Biography: [Robert M. Johnson](#)
(651) 962-5758 (UST)
(651) 962-6419 (Fax)
rmjoh37@aol.com (E-Mail)
- Michael Shoup
Biography: [Michael Shoup](#)
(651) 486-4074 (Office)
(651) 481-7677 (Fax)
mshoup@surmodics.com
- Time:** Section 01, Monday 6:00 – 9:00 p.m.
- Location:** St. Paul Campus, OSS 127
- Required Text:** Reading materials and FDA's *Quality Systems Manual* (QS Manual) will be distributed the first day of class; additional reading materials will be distributed throughout the semester. There will be a small charge for these applied to the student's bill.
- Course Description:** This course is designed to provide an introductory overview of the medical device industry, and its unique design and manufacturing challenges. The course first examines the industry itself, reviewing basic industry statistics, current trends, and the many types of products that make up the medical device industry. It then helps students understand the fundamental systems that are used in the design, development, and manufacture of medical devices and how these relate to regulations governing the development and manufacturing processes. Finally the course explores in detail some of the unique aspects of manufacturing a medical product such as special material and process selection considerations, clean rooms, sterile packaging, sterilization processes, clinical testing, lot traceability and manufacturing controls.
- Course Objectives:**
- To provide the student with an understanding of the unique requirements and challenges in medical device design and manufacturing
 - To familiarize the student with the special "language" of medical device manufacturing, which can be confusing to those just entering the industry
 - To provide the student with a basic understanding of the size and scope of the medical device industry and current trends affecting it
- Learning Outcomes:** Upon successful completion of course, the students will be able to demonstrate a basic understanding of taking a medical device through the following phases of production:
- Development cycle (SE1, SE6, SE12)

- Understanding product requirements (SE2)
- Developing clinical, regulatory, reimbursement marketing and intellectual property strategies ((SE6)
- Materials selection - sterilization - aging (SE4)
- Process selection (SE5)
- Sterility, packaging, and cleanrooms (SE4)
- Testing and validation (SE6)
- Manufacturing strategy development and supplier selection (SE9)

The student will also have basic knowledge of the medical device industry and its history.

Course Methodology:

The course makes extensive use of outside reading assignments, videos, guest experts, and tours of local device manufacturers to provide practical illustrations of these topics.

Reading materials will be provided. Students are expected to read the materials provided under each "Session Tab" before that session. Students are also expected to read designated chapters from the QS Manual before that session. Additional materials may handed out during each session, such as additional reading materials, lecture notes, and discussion questions for the group work at the end of each session.

Major Assignments:

Students will also select a term project that allows them to apply what they have learned to a real or hypothetical medical device product. This device will be used as the basis for group discussions, presentations, and the term paper.

Grading Policy:

Final Exam	25%
Tour Assignments	15%
Class Presentations	25%
Term Project Final Report. .	30%
Team Participation	5%

Academic Integrity:

All students are expected to understand and follow the University of St Thomas policies on Academic Integrity. These are described at:
<http://www.stthomas.edu/engineering/graduate/policies>

Exams: Exams are one of the instruments used to evaluate the knowledge gained by an individual student of the class subject matter, and the progress towards meeting the outcomes of the class and the degree. To this end all exams (in class or take home) are intended to represent the effort of the individual and not a group effort unless specifically stated otherwise.

Students with Disabilities

Qualified students with documented disabilities who may need classroom accommodations should make an appointment with the Enhancement Program – Disability Services office during the first two weeks of the semester. Appointments can be made by calling 651-962-6315 or in person in O’Shaughnessy Educational Center, room 119.

Attendance Policy:

Students are expected to attend all class sessions. Circumstances which prevent attendance will be honored up to two instances. Absences in excess of two times may result in a lower grade for the course. Contact the instructor when a special situation arises. All absences require that the instructor be informed in advance.

ETLS 520 Design and Manufacturing in the Medical Device Industry					
Fall Semester 2009					
Date/Session	Topic	Subtopics	QS Manual	Instr.	Proj. Work
MONDAY 09/14/09 #1	Introduction to the Medical Device Industry	-Basic industry statistics - global and regional -Current trends and issues -Legal environment -History of medical manufacturing in Minnesota -Class I, II, III -Disposable, reusable, implantable -Hospital, health care professional, consumer/patient -Where do new product ideas come from?		Bob	Form project teams Each team selects project category
09/21/09 #2	Knowing the Customer	-Knowing who the customer is -Getting product input and feedback from customers -Developing design input specifications -Marketing tools and techniques		Guest speaker: John Foster	Team presentation on Session #2 (if seven presentations are needed)
09/28/09 #3	The Medical Device Product Development Cycle	-Typical steps in developing a medical device -Concurrent and serial development models -Documenting your development process -Regulations governing the development process -How to apply the regulations to your product/company	Chapter 3	Mike	Each team selects project device
10/05/09 #4	Clinical Studies, Regulatory Strategy and Reimbursement	-Clinical studies to verify designs -Developing the appropriate regulatory strategy -Obtaining reimbursement		Guest speaker: Lisa Wipperman-Heine	Team presentation on Session #3
10/12/09 #5	1. Process Selection 2. Risk Management	1. Manufacturing process review 2. Failure Modes and Effects Analysis (FMEA)		1. Bob 2. Mike	Team presentation on Session #5 SMC tour assignment due
10/19/09 #6	Material Selection	-Biocompatibility/toxicology -Effects of sterilization on finished product -Effects of storage and aging -Equipment selection		Guest speaker: Renate Johnson	Team presentation on Session #4

Date/Session	Topic	Subtopics	QS Manual	Instr.	Proj. Work
10/26/08 #7	Tour - Scientific Molding Corporation				Tour Questions
11/02/09 #8	Testing and Validation	-Test method and spec development -Design verification and validation -Process validation	Chapter 4	Mike	Team presentation on Session #6 Tour assignment
11/09/09 #9	Tour - HCMC Hospital			Dr. Bill West	Tour Questions
11/16/09 #10	Packaging Sterilization	- Sterile packaging forms and materials - Types of sterilization used for single-use products - Types of sterilization used for reprocessed/reusable products	Chapter 13	Guest speaker: Charlie Jones	Team presentation on Session #8 Tour assignment
11/23/09 #11	Manufacturing Scale-Up	-Developing a manufacturing strategy -Cleanrooms -Quality systems -Supplier selection and validation -Combination products	Chapter 8 (p. 1-22) Chapter 10 (p. 1-23)	Mike	Team presentation on Session #10
11/30/09 #12	Tour - Starkey Labs, SurModics				Term Papers Due
12/07/09 #13	1. MN Bio 2. Review			1. Guest Speaker: Dale Wahlstrom 2. Bob	Starkey Labs, SurModics tour assignments due
12/14/09 #14	1. Final Exam 2. Term Paper Questions 3. Course Evaluations				Term papers returned