DCOM 492/592
Topics- Comparative Development and Commercialization of Medical Devices in the United States and Europe
Summer 2018

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Office Hours: TBD or by appointment
Class meets: TBD

Course Description

Durable medical equipment (DME) are medically necessary devices prescribed by a health care provider to aid in, contribute to, provide monitoring of, or treatment for a medical condition. As such, health care providers must possess knowledge of DMEs. The process through which a piece of medical equipment becomes available for commercial use entails several steps from design to development to distribution. The complexity of this process increases if the DME is manufactured outside of the United States. This international course will explore the process of developing a DME through on-site discussion and facility exploration of a DME research lab, development company, and manufacturing facilities located at multiple locations in Europe. The course will be divided into three section: development, design, and distribution of DMEs. First, the process through which a medical device is developed will be explored, including initial and clinical trials and the mechanisms of product refinement. Second, the process for developing candidacy and fitting criteria will be discussed with particular reference to the US Food and Drug Administration (FDA) labeling and approval processes. Finally, the medical and legal requirements for commercialization will be investigated in respect to both DMEs manufactured within the US and for DMEs manufactured outside of the US. This course will also focus on the differentiation of the three categories of FDA approval classes as well as the difference between these classes and over-the-counter medical equipment.

Learning Objectives

Through this course, students will:

- Gain factual knowledge (terminology, classifications, methods, trends)
- Learn fundamental principles, generalizations, or theories
- Develop specific skills, competencies, and points of view needed by professionals in the field most closely related to this course.

Upon completion of this course, students will demonstrate knowledge of and be able to:

- discuss DME concept development and refinement
- describe how a durable medical product becomes commercially available
- define and differentiate the FDA approval process for durable medical equipment manufactured within and outside of the US
- compare and contrast the DME approval process within the US to international approval processes
- discuss how differences in DME approval processes around the world impact global health care and global standards of practice
- discuss the impact of DME development, design, and distribution on a medical professional's clinical practice patterns (undergraduate)
- discuss the impact of DME development, design, and distribution on their future clinical practice patterns, decisions processes, and prescriptions/recommendations (graduate)
- Students will demonstrate awareness of multiple perspectives of DME within the global community
- Students will investigate and analyze contemporary issues, phenomena, and ideas with global impact, considering their effect on the individuals, communities, and social or natural environments involved.

Readings

Readings will be provided by the instructor prior to commencement of the course.

Grading

Grades will be based on performance on multiple writing projects and course participation. Satisfactory completion of writing projects will require evidence of integrative, reflective, and comprehensive thought expressed through a well-written document. Final course grade determination and assignment details are as follows:

Undergraduate	
DME project:	30%
Daily journal entries:	10%
Participation/attendance:	30%
Reflection paper:	25%
Debriefing discussion:	5%
Total:	100%

Graduate	
DME project:	30%
Daily journal entries:	10%
Participation/attendance:	30%
Reflection paper (2):	25%
Debriefing discussion:	5%
Total:	100%

Letter grades will be assigned as follows:
A – 100-93%
B – 92-85%
C – 84-77%
D – 76-69%
F – below 69%

*Please note that students at both the graduate level and undergraduate level will be expected to complete the same assignments. These two levels of courses will be differentiated by the grading rubric used for each assignment. Graduate students will be held to a higher level of integrative and application-based thought than will undergraduate students.

DME project: Students will be required to develop a DME proposal portfolio. The portfolio will present a medical condition/challenge that could be resolved/mitigated through use of a DME that has been identified by the student, rational for developing a DME including a SWOT analysis, general design of a clinical trial to evaluate the proposed DME, determination and justification of FDA DME category and resulting approval process. Those students who are enrolled in the course for graduate credit must include target clinical population and the impact on the patient's care including future goals and how the device will be used in their daily life/functioning. Further information will be provided about this project during the initial preparatory meeting for this course.

Daily journal entries and directed reflections: Students will be required to complete daily journal entries to encourage daily reflective thought on experiences, knowledge, and integration with course content. The content and length of these journal entries is not specified by the instructors, however, journal entries are expected to be presented in an understandable manner. Please note that although journal entries should include some written content, they may also include doodles, mind-maps, or other visual references that the student feels are representative of their thoughts of the day. Instructors will provide questions to be used for the directed portion of the reflections. These questions should be incorporated into at least one-half of the journal entries. The questions will be provided by the instructor ahead of time. The questions will differ between undergraduate and graduate level students. Those students enrolled in the course for graduate credit will be asked to address additional questions related to applications/implications in the current U.S. health care environment.

Reflection Paper: (1) Students will be required to complete a written comparative discussion of the United States approval system for DMEs to an international approval system. Travel to Europe presents the opportunity for comparison between the US DME approval process and an international DME approval process. These two processes are different from one another which leads to a discrepancy between DME available within the US to outside of the US. The reflection paper should present the differences and the potential impact these differences have on the medical system in the United States. Examples of questions that should be included in the paper are: Do differences in approval process contribute to initial trial of DMEs outside of the US rather than inside of the US? Is the oversight of the US approval process more restrictive than international systems? If so, is does the restrictive nature slow medical advances in the US in comparison to the rest of the world? What is the impact of this on the cost of production and as a result, the overall cost to the consumer? What are some benefits and challenges of the US approval process? Further information will be provided about this project during the initial preparatory meeting for this course.
(2) Students enrolled in the course for graduate credit will be required to complete a second paper reflecting on the application and impact of the experiences gained through this course on future of practice in the health care

environment. Further information will be provided about this project during the initial preparatory meeting for this course.

Debriefing discussion: Students will be required to actively participate in and provide an oral presentation during a post-trip debriefing discussion. During this presentation, students will be asked to present a summary of their DME project, journal entries, and reflection paper. This presentation should be cohesive and fluid, meaning that the three separate projects summarized should be presented in a manner than ties the three together into a meaningful personal or professional insight. Further information will be provided about this project during the initial preparatory meeting for this course. Those students enrolled in this course for graduate credit should ensure that they incorporate the additional directed reflection questions and second reflection paper in this presentation.

Other Stuff

Attendance Policy: Although attendance will not be taken during each class period, students should be aware that the majority of the lecture material has been developed from sources in addition to the required readings, and examinations will cover material presented in lectures and not in the readings. Therefore, consistent class attendance will be necessary for successful completion of this course. **You will be held responsible for material in your absence.**

Freedom in Learning: Under Board of Regents and University policy student academic performance may be evaluated solely on an academic basis, not on opinions or conduct in matters unrelated to academic standards. Students should be free to take reasoned exception to the data or views offered in any course of study and to reserve judgment about matters of opinion, but they are responsible for learning the content of any course of study for which they are enrolled. Students who believe that an academic evaluation reflects prejudiced or capricious consideration of student opinions or conduct unrelated to academic standards should contact the dean of the college or school that offers the class to initiate a review of the evaluation.

Diversity and Inclusive Excellence: The University of South Dakota strives to foster a globally inclusive learning environment where opportunities are provided for diversity to be recognized and respected.

Disability Accommodation: Any student who feels s/he may need academic accommodations or access accommodations based on the impact of a documented disability should contact and register with Disability Services during the first week of class or as soon as possible after the diagnosis of a disability. Disability Services is the official office to assist students through the process of disability verification and coordination of appropriate and reasonable accommodations. Students currently registered with Disability Services must obtain a new accommodation memo each semester.

Please note, if your home institution is not the University of South Dakota but one of the other South Dakota Board of Regents institutions (e.g., SDSU, SDSMT, BHSU, NSU, DSU), you should work with the disability services coordinator at your home institution.

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Academic Integrity: The College of Arts and Sciences considers plagiarism, cheating, and other forms of academic dishonesty inimical to the objectives of higher education. The College supports the imposition of penalties on students who engage in academic dishonesty, as defined in the "Conduct" section of the University of South Dakota Student Handbook.

No credit can be given for a dishonest assignment. A student found to have engaged in any form of academic dishonesty may, at the discretion of the instructor, be:

a. Given a zero for that assignment.
b. Allowed to rewrite and resubmit the assignment for credit.
c. Assigned a reduced grade for the course.
d. Dropped from the course.
e. Failed in the course.

Proficiency Expectations and Remediation: For students entering the professions of speech-language pathology and audiology, the ultimate goal is not merely to earn a passing grade in a course or on an examination or assignment. Rather, it is to demonstrate the acquisition of knowledge and skills relative to certification standards in the profession(s). As such, students are required to demonstrate adequate proficiency in essential knowledge and skill areas, as determined by the academic instructor. If student performance for one or more specific knowledge/skill area is below expectations, instructors may require remediation and implement strategies that may include, but are not limited to, the following:

- Rewriting/resubmitting incorrect/incomplete test answer(s)
- Providing oral explanations of content material
- Redoing all or part of academic projects
- Completing directed readings
- Viewing supplemental videos
- Other targeted activities

These additional remediation activities will not alter the grade earned on a particular examination or assignment; however, they will ensure that each student has demonstrated acquisition of each of the knowledge and/or skill areas targeted in the course.

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Tentative Course Schedule

Date	Topic	Assignment/Reading/contact hours
TBD	Global Learning Orientation	2 hours
TBD	Pre-trip session 1: Syllabus review	1 hour
TBD	Pre-trip session 2: Project planning	2 hours
TBD	Pre-trip session 3: Travel prep	1 hour
TBD	On-site tour/discussion: FDA Category 3: Research and Development, Manufacturing, Marketing	~18 hours
TBD	On-site tour/discussion: FDA Category 1 &2: Research and Development, Manufacturing, Marketing	~12 hours
TBD	In-country discussions	~7 hours
TBD	Post-trip debriefing	2 hours