**Instructor**

Denise Holliday

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(469) 268-1865 cell

Office: In classroom

Office Hours: By appointment

**Class Schedule**

7:00pm-8:20pm, MoWe, Room CHEM 106

**Optional Textbook and Materials**

None

**Catalog Course Description (BMEN 4312)**

Introduction to regulations and best practices recommended by the US Food and Drug Administration (FDA) that pertain to testing and marketing of biomedical devices and systems. Discussion on implementation of best practices for pre-clinical and clinical studies. Introduction to total quality engineering and total quality management as related to medical devices and systems. Building quality into design of products and systems in biomedical engineering.

Prerequisite(s): BMEN 3311, BMEN 3321; and senior classification.

**Catalog Course Description (BMEN 5100)**

Develop full understanding of US Food and Drug Administration (FDA) regulations that pertain to medical devices within the US, including requirements for manufacturers, importers, contract manufacturers and specification developers. Overview of translations between regulations and quality and industry standards and best practices. Develop an understanding of ISO 13485, the internationally-recognized standard followed by medical device companies globally. Introduction to regulations required by countries outside the USA including Canada and the European Union (EU). Introduction into requirements for clinical and pre-clinical testing. Overview of ethical and moral considerations for biomedical engineers entering into the medical device industry. Design project to include case study developing design history file documentation for the development of a medical device product to be developed.

Prerequisite(s): Graduate student in Biomedical Engineering or permission of instructor.

**Course Objectives**

1. Understanding FDA regulations for the medical device industry
2. Provide an overview of market clearance and approval for medical devices within the United States
3. Overview of clinical evaluation requirements within the US
4. Understanding quality and regulatory considerations when developing medical devices and for sustaining product engineering
5. Utilize problem-solving skills to ensure quality is integrated into medical device designs

**ABET Criteria**

Addresses the following ABET program outcomes:

1. an ability to identify, formulate, and solve complex engineering problems by applying principles of engineering, science, and mathematics
2. an ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts
3. an ability to develop and conduct appropriate experimentation, analyze and interpret data, and use engineering judgment to draw conclusions
4. an ability to acquire and apply new knowledge as needed, using appropriate learning strategies

**Disability Policy**

All reasonable accommodation will be made to facilitate special needs. If special accommodations are required, the student must first meet with the staff of the Office of Disability Accommodation (ODA), Union Suite 322, (040) 565-4323. After meeting with that office, please contact me to discuss what accommodations will be necessary. For more information, see htup://www.unt.cdu/oda

**University Policy on Academic Misconduct**

*Academic Misconduct (Sec. 3.4 from the Student Handbook):* Any act that violates the academic integrity of the institution is considered academic misconduct. The procedures used to resolve suspected acts of academic misconduct are available in the offices of Academic Deans and the Office of Campus Life. Specific examples include, but are not limited to:

*Cheating:* Copying from another student’s test paper, written assignment, other report, or computer files and listings; Using, during any academic exercise, material and/or devices not authorized by the person in charge of the test; Collaborating with or seeking aid from another student during a test or laboratory without permission; Knowingly using, buying, selling, stealing, transporting, or soliciting in its entirety or in part, the contents of a test or other assignment unauthorized for release; Substituting for another student or permitting another student to substitute for oneself.

*Plagiarism:* The appropriation, theft, purchase or obtaining by any means another’s work, and the unacknowledged submission or incorporation of that work as one’s own offered for credit. Appropriation includes the quoting or paraphrasing of another’s work without giving credit (especially online resources). Turnitin will be utilized to ensure online resources are not misappropriated.

Any work not meeting this standard will be evaluated and subject to either a re-write, if the Instructor concludes that the assignment was unintentionally plagiarized or a zero for the assignment. Egregious forms of academic conduct are subject to a formal hearing. For more information on paper writing, including how to avoid plagiarism, and how to use citations, see http://anthropology.unt.edu/resources-writingpaper.php. For information on the University’s policies regarding academic integrity and dishonesty, see the UNT Center for Student Rights and Responsibilities, http://www.unt.edu/csrr/.

*Collusion:* The unauthorized collaboration with another in preparing work offered for credit.

**Sexual Discrimination, Harassment and Assault**

UNT is committed to providing an environment free of all forms of discrimination and sexual harassment, including sexual assault, domestic violence, dating violence, and stalking. If you (or someone you know) has experienced or experiences any of these acts of aggression, please know that you are not alone. The federal Title IX law makes it clear that violence and harassment based on sex and gender are Civil Rights offenses. UNT has staff members trained to support you in navigating campus life, accessing health and counseling services, providing academic and housing accommodations, helping with legal protective orders, and more.

**Personal Distress**

Excerpts from http://studentaffairs.unt.edu/care “The University of North Texas cares about our students' success, not only academically, but emotionally and physically…. Because of our commitment, we provide literally hundreds of departments and services across campus that respond to our students' unique needs. UNT believes it is important to foster an environment that encourages students to maintain a standard of responsibility for self-care which includes the ability to respond adequately to one's emotional, physical, and educational needs. If you are experiencing physical or emotional distress which adversely affects your ability to succeed in class, please see me as soon as possible. Together, we will point you towards the appropriate resources.

**Grade Breakdown – Undergraduate Students (BMEN 4312)**

|  |  |  |
| --- | --- | --- |
| **Type** | **Point Value Total** | **Percent** |
| Class Participation/Attendance x18 | 90 | 70% |
| Discussion Posts x13 | 130 |
| Quizzes x13 | 130 |
| Final Exam | 150 | 30% |
| **Total:** | **500** | **100%** |

**Grade Breakdown – Graduate Students (BMEN 5100)**

|  |  |  |
| --- | --- | --- |
| **Type** | **Point Value Total** | **Percent** |
| Class Participation/Attendance x18 | 90 | 50% |
| Discussion Posts x13 | 130 |
| Quizzes x13 | 130 |
| Final Exam | 150 | 50% |
| Final Project | 200 |
| **Total:** | **700** | **100%** |

**Schedule and Grading**

|  |  |  |  |
| --- | --- | --- | --- |
| **Week** | **Date** | **Topic** | **Activity** |
| 1 | Mon. 8/18 | Class Introductions/ Syllabus Overview  [An Introduction to FDA’s Regulation of Medical Devices](http://fda.yorkcast.com/webcast/Play/884aea9662174dea8ef4df68988b86981d)  [Is My Product a Medical Device?](http://fda.yorkcast.com/webcast/Play/e0eec5f6ee3d4947a70fcedef32993f71d)  Discussion Post #1 Assigned | In Person |
| Wed. 8/20 | ISO 13485 and FDA 21 CFR Part 820 Summary  [Overview of the Quality System](http://fda.yorkcast.com/webcast/Play/4abbbeeb0f76423998cab8c782c3e4181d)  [Overview of the Quality Management System Regulation](https://youtu.be/Na-OF3OkqEg)  Quiz #1 Assigned | Remote |
| 2 | Mon. 8/25 | **Discussion Post #1 Due**  ISO 13485:2016 Clause 4  [Documents, Change Control, and Records](http://fda.yorkcast.com/webcast/Play/3833c9464d2148fd8f258238725f9f871d)  Discussion Post #2 Assigned | Does Not Meet |
| Wed. 8/27 | **Quiz #1 Due**  ISO 13485:2016 Clause 4  Quiz #2 Assigned  Discussion Post #3 Assigned | Remote |
| 3 | Mon. 9/1 | **NO CLASS – Labor Day**  **Discussion Post #2 Due** | |
| Wed. 9/3 | **Quiz #2 Due**  ISO 13485:2016 Clause 5  [Management Controls](http://fda.yorkcast.com/webcast/Play/5812f1d8ab474dafb200cd55bfbaac361d)  Quiz #3 Assigned | In Person |
| 4 | Mon. 9/8 | **Discussion Post #3 Due**  ISO 13485:2016 Clause 6.1, 6.2  Discussion Post #4 Assigned | In Person |
| Wed. 9/10 | **Quiz #3 Due**  ISO 13485:2016 Clause 6.3, 6.4  [Production and Process Controls](http://fda.yorkcast.com/webcast/Play/c996037bfee443e4904ff2080833603a1d)  Quiz #4 Assigned | Remote |
| 5 | Mon. 9/15 | **Discussion Post #4 Due**  ISO 13485:2016 Clause 7.1  [Risk Basics for Medical Devices](https://fda.yorkcast.com/webcast/Play/69a2920f1a284ac2be3b33f1aa5497b81d)  [Application of Risk Management Principles for Medical Devices](https://fda.yorkcast.com/webcast/Play/2f3dce7e06d140c4a769666418af58e91d)  Discussion Post #5 Assigned | In Person |
| Wed. 9/17 | **Quiz #4 Due**  ISO 13485:2016 Clause 7.1  Quiz #5 Assigned | Remote |
| 6 | Mon. 9/22 | **Discussion Post #5 Due**  ISO 13485:2016 Clause 7.2  Discussion Post #6 Assigned | Does Not Meet |
| Wed. 9/24 | **Quiz #5 Due**  ISO 13485:2016 Clause 7.3  [Design Controls](http://fda.yorkcast.com/webcast/Play/a12e1a3b9faa40ae96225b236de6d1a51d)  Quiz #6 Assigned | Remote |
| 7 | Mon. 9/29 | **Discussion Post #6 Due**  ISO 13485:2016 Clause 7.3  Discussion Post #7 Assigned | Does Not Meet |
| Wed. 10/1 | **Quiz #6 Due**  ISO 13485:2016 Clause 7.4  [Purchasing Controls](http://fda.yorkcast.com/webcast/Play/083de1ef7cfb40169e2451492a32ed1e1d)  Quiz #7 Assigned | In Person |
| 8 | Mon. 10/6 | **Discussion Post #7 Due**  ISO 13485:2016 Clause 7.5  [Production and Process Controls, Part 2](http://fda.yorkcast.com/webcast/Play/a2350a316b774c918baa21230d36b6dd1d)  [Process Validation](http://fda.yorkcast.com/webcast/Play/090c4052bc2b4f90ba94245204e745061d)  [Unique Device Identification (UDI) System Regulatory Overview](http://fda.yorkcast.com/webcast/Play/455307461f76415ead204eeb03dedad61d)  21 CFR Part 801, 830  Discussion Post #8 Assigned | In Person |
| Wed. 10/8 | **Quiz #7 Due**  ISO 13485:2016 Clause 7.5  Quiz #8 Assigned | Remote |
| 9 | Mon. 10/13 | **Discussion Post #8 Due**  ISO 13485:2016 Clause 7.6  Discussion Post #9 Assigned | Does Not Meet |
| Wed. 10/15 | **Quiz #8 Due**  ISO 13485:2016 Clause 8.1, 8.2  21 CFR Part 803  [Complaint Files](http://fda.yorkcast.com/webcast/Play/1980e8ad35064bc5b0f8cbc75b99793d1d)  [Overview of Medical Device Reporting](http://fda.yorkcast.com/webcast/Play/7885da0375b648bfb080f8c54d4c88561d)  Quiz #9 Assigned | In Person |
| 10 | Mon. 10/20 | **Discussion Post #9 Due**  ISO 13485:2016 Clause 8.1, 8.2  Discussion Post #10 Assigned | In Person |
| Wed. 10/22 | **Quiz #9 Due**  ISO 13485:2016 Clause 8.3  21 CFR Part 806  [Nonconforming Product](http://fda.yorkcast.com/webcast/Play/1c9f57f8b762476bbb692fdf6d23851d1d)  [Introduction to Medical Device Recalls](https://fda.mediasite.com/mediasite/Play/1d5699afd25c4667bd51121d63ec714c1d)  [Recall Module 21 CFR Part 806: Medical Devices; Reports of Corrections and Removals](http://fda.yorkcast.com/webcast/Viewer/?peid=895f808c834f49bfbc230df241fe64501d)  Quiz #10 Assigned | Remote |
| 11 | Mon. 10/27 | **Discussion Post #10 Due**  ISO 13485:2016 Clause 8.3  21 CFR Part 806  Discussion Post #11 Assigned | Does Not Meet |
| Wed. 10/29 | **Quiz #10 Due**  ISO 13485:2016 Clause 8.4  [Corrective and Preventive Actions](http://fda.yorkcast.com/webcast/Play/c78cfebf72774163a59f8f6f197435451d)  Quiz #11 Assigned | Does Not Meet |
| 12 | Mon. 11/3 | **Discussion Post #11 Due**  FDA Submissions  [How is My Medical Device Classified?](http://fda.yorkcast.com/webcast/Play/17792840509f49f0875806b6e9a1be471d)  [Case Study: How is My Medical Device Classified?](http://fda.yorkcast.com/webcast/Play/b2ac233bb624462b9750bf0552018daa1d)  Discussion Post #12 Assigned | Does Not Meet |
| Wed. 11/5 | **Quiz #11 Due**  FDA Submission  Quiz #12 Assigned | Does Not Meet |
| 13 | Mon. 11/10 | **Discussion Post #12 Due**  Establishment Registration and Listing  21 CFR Part 807  Discussion Post #13 Assigned | In Person |
| Wed. 11/12 | **Quiz #12 Due**  MDSAP Program  Quiz #13 Assigned | Remote |
| 14 | Mon. 11/17 | **Discussion Post #13 Due**  Changes to 21 CFR Part 820  [Navigating the Quality Management System Regulation](https://youtu.be/CMnJw6G4hKo) | Remote |
| Wed. 11/19 | Advanced Topics Overview  **Quiz #13 Due** | Remote |
| **Thanksgiving Break (no classes) November 24-30, 2025** | | | |
| 15 | Mon. 12/1 | Final Review and Q&A | In Person |
| Wed. 12/3 | **Final Project Due – Graduate Students Only**  Final Review and Q&A | In Person |
| - | Mon. 12/8 | **Final Exam** | Does Not Meet |

**Class Participation/Attendance**

You are expected to be in class (either in person or online) on the days we meet IN PERSON and REMOTE. If you cannot attend a class, you must notify me through Canvas or by email at least 2 hours prior to class start time. For classes indicated as REMOTE, class will still meet at the scheduled time but will be hosted online. A Microsoft Teams Meeting invite will be available on Canvas prior to the session.

For classes indicated as DOES NOT MEET, course materials for the week will be available in Canvas including a pre-recorded lesson, activity or assignment, and there will be no class.

**Discussion Posts**

Discussion posts will be available on Monday of each week through Canvas and are due the following Monday. You will be graded based on how well you address the discussion topic, including opinions and out-of-the-box thinking. Your posts must include appropriate citations. Discussion posts are **due at midnight** on the following Monday.

**Quizzes**

There will be one quiz due at the end of each week and will cover information for that specific topic. They are open book and open note and are **due at midnight** on the following Wednesday.

**Late Submissions**

Late submissions will be deducted one (1) point per day late.

**Final Exam**

The final exam will be available on Canvas on Monday, December 8, 2025 from 7pm-9pm. The exam is open book and open note but will be **timed**. The final exam will be comprehensive and will cover all course materials from Week 1-13.

**Final Project – Graduate Students Only**

Requirements for the final project will be discussed during the first week of class.