BIOE 4420/5420 Marketing your novel medical product: Regulatory pathways
Fall 2016
Course Syllabus

BIOE 4420/5420


Days/Times: Tuesday/Thursday 8:00 – 9:15 am

Location: Bioscience 2 Classroom

Instructor: Cristin Welle
cristin.welle@ucdenver.edu
303-724-9116
RC2 6011

Office Hours:
Tuesday 1 pm – 2 pm or by appointment

Course Description

Do you want to create a product for patients that can be used to treat or diagnose a medical condition?
If so, you’ll need to get approval from the FDA to do so! This course covers the scope of FDA regulation, the
types of regulatory pathways for approval, and the scientific data needed to support a successful approval
decision from FDA. Premarket applications will be covered in detail, along with FDA quality systems regulations,
post-market surveillance and global inspection efforts. Also covered is a comparison of US FDA regulatory
system with that of European regulatory systems. Special topics lectures will cover current events related to FDA
regulatory decisions.

Learning Objectives

This course will prepare participants to identify which medical products fall inside FDA regulation, and the
appropriate regulatory pathway for that product. Students will become familiar with the types of scientific data
needed to support common regulatory pathways. Understanding and preparing regulatory submissions will be a
critical learning objecting and evaluation criteria.

Learning Outcomes

1. Development of effective Communication in written and oral form
2. Development of effective Teamwork Strategies
3. Understanding of FDA Food and Drug Law
4. Identification of medical products and the appropriate regulatory pathways
5. Familiarity with preclinical and clinical testing paradigms
6. Understanding of current events surrounding FDA
7. Ability to draft a regulatory submission
8. Familiarity with FDA.gov

Required Text:

Canvas
It is your responsibility to be competent with the functions of Canvas.
Canvas is an online course management system that supports course information, communications, and
assignments.

Grade Breakdown:
All assignments will be submitted on Canvas unless otherwise indicated in class.

<table>
<thead>
<tr>
<th>Assignment</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Preliminary Exam</td>
<td>25%</td>
</tr>
<tr>
<td>Team Case Studies</td>
<td>10%</td>
</tr>
<tr>
<td>Current Events Presentation</td>
<td>10%</td>
</tr>
<tr>
<td>Final Project</td>
<td>25%</td>
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<tr>
<td>Final Exam</td>
<td>25%</td>
</tr>
<tr>
<td>Class Participation</td>
<td>5%</td>
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</tbody>
</table>

Late Assignments will be deducted 10% for each day late up to 3 days, after that point, LATE ASSIGNMENTS WILL NOT BE ACCEPTED. Please make sure to notify the instructor of any absence BEFORE class.

**Grade Scale**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>A</td>
<td>93.0 – 100</td>
</tr>
<tr>
<td>A-</td>
<td>90.0 – 92.9</td>
</tr>
<tr>
<td>B+</td>
<td>87.0 – 89.9</td>
</tr>
<tr>
<td>B</td>
<td>83.0 – 86.9</td>
</tr>
<tr>
<td>B-</td>
<td>80.0 – 82.9</td>
</tr>
<tr>
<td>C+</td>
<td>77.0 – 79.9</td>
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<tr>
<td>C</td>
<td>73.0 – 76.0</td>
</tr>
<tr>
<td>C-</td>
<td>70.0 – 72.9</td>
</tr>
<tr>
<td>D+</td>
<td>67.0 – 69.9</td>
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<tr>
<td>D</td>
<td>63.0 – 66.9</td>
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<tr>
<td>D-</td>
<td>60.0 – 62.9</td>
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<tr>
<td>F</td>
<td>Below 60.0</td>
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**Final Assessments**

**Team Case Studies:**
Students will participate in teams to respond to case studies for example medical products. All students are required to participate, and take responsibility for a discrete section of the case study report.

**Final Project:**
Individuals will write a mock regulatory submission. The medical product and regulatory pathway will be determined collaboratively with the instructor. The final project grade will include intermediate assignments project that will be due at timepoints throughout the semester. The completed final project will be due the week before finals.

**Current Events Presentation:**
All students will prepare a 15-minute presentation on a current event related to FDA regulation. Presentations will take place every Thursday, and students will be assigned a presentation date during the first week of class.

**Exams:**
The preliminary and final exams will test on the cumulative knowledge presented during lectures and in the weekly assigned reading.

**Class Participation:**
Students are expected to engage with the material during class. This includes asking questions during class, contributing to team presentations, and being present and on time for class.

*This course syllabus is subject to change in order to ensure that all learning objectives are sufficiently met. All students will be notified well in advance of such adjustments.*
University Policies

CU-Denver Student and Faculty Conduct:
The members of the CU-Denver community are committed to creating a place of work and study where everyone is treated with respect and courtesy. Inappropriate behavior is classified as disruption of teaching or research, abuse of property, any form of harassment, or failure to adhere to applicable laws and regulations. Individuals who fail to adhere to CU-Denver Code of Conduct are subject to disciplinary action.

Honor Code:
www.ucdenver.edu/academics/colleges/Engineering/student-services/policies-forms/Pages/default.aspx

Student Code of Conduct:
www.ucdenver.edu/life/services/standards/students/pages/default.aspx

Academic Freedom:
www.ucdenver.edu/policy/pages/academic-Freedom.aspx

Family Educational Rights and Privacy Act (FERPA):
www.ucdenver.edu/student-services/resources/registrar/students/policies/Pages/StudentPrivacy.aspx

Campus Closure:
If the campus is unexpectedly closed, any exams, activity or deadline will automatically be rescheduled for the next lecture period.

Incomplete grades: CLAS Policy on Incomplete Grades.
The following college policy on the awarding of Incomplete grades (I) was approved by the faculty, and was formerly printed in the Schedule of Courses. The CLAS Course Completion agreement is available in the CLAS Advising Office. Incomplete Grades are not granted for low academic performance. To be eligible for an incomplete grade, students must (1) successfully complete 75 percent of the course, (2) have special circumstances (verification may be required) that preclude the student from attending class and completing graded assignments, and (3) make arrangements to complete missing assignments with the original instructor. A CLAS Course Completion agreement is strongly suggested. Students who must retake the course are not eligible for an incomplete grade. Students with poor academic performance are not eligible for an incomplete grade. Student making up an incomplete grade should not re-register for the course. When an instructor determines that an incomplete grade is justifiable, students are encouraged to submit a CLAS Course Completion Agreement, which is available from the CLAS Advising Office. This contract documents completed and missing assignments, current course grade, and conditions necessary to obtain a letter grade for the course. If this contract has not been fulfilled within one calendar year (12 months), the grade will be converted automatically either into an “F”.

Weekly schedule:

<table>
<thead>
<tr>
<th>Week</th>
<th>Topics</th>
<th>Assigned readings and resources</th>
<th>Assignments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8/23, 8/25</td>
<td>1. Chapters 1 (p 1-16)</td>
<td>Class Participation</td>
</tr>
<tr>
<td></td>
<td>Module 1 – Introduction to FDA</td>
<td>2. Introduction to FDA (Optional: <a href="https://collaboration.fda.gov/p4l6o3xe097/">https://collaboration.fda.gov/p4l6o3xe097/</a>)</td>
<td>[<a href="http://www.fda.gov/AboutFDA/Transparency/Basics/ucm2021108.htm">http://www.fda.gov/AboutFDA/Transparency/Basics/ucm2021108.htm</a> ]</td>
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<td>3. FDA Mission statement (<a href="http://www.fda.gov/AboutFDA/WhatWeDo/default.htm">http://www.fda.gov/AboutFDA/WhatWeDo/default.htm</a> )</td>
<td>[<a href="http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm">http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm</a> ]</td>
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<td></td>
<td>5. Food and Drug Law (<a href="http://www.fda.gov/AboutFDA/WhatWeDo/default.htm">http://www.fda.gov/AboutFDA/WhatWeDo/default.htm</a> )</td>
<td>[<a href="https://collaboration.fda.gov/p2kvfswj4wj/">https://collaboration.fda.gov/p2kvfswj4wj/</a> ]</td>
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<td>6. Medical Products and Tobacco (Optional: [<a href="http://www.fda.gov/AboutFDA/WhatWeDo/default.htm">http://www.fda.gov/AboutFDA/WhatWeDo/default.htm</a> ] )</td>
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<td>7. Food Safety, Veterinary Medicine and Global Regulatory Operations (CFSAN [<a href="http://www.fda.gov/AboutFDA/WhatWeDo/default.htm">http://www.fda.gov/AboutFDA/WhatWeDo/default.htm</a> ] )</td>
<td>[<a href="http://www.fda.gov/AboutFDA/WhatWeDo/default.htm">http://www.fda.gov/AboutFDA/WhatWeDo/default.htm</a> ]</td>
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<td>[<a href="http://www.fda.gov/AboutFDA/WhatWeDo/default.htm">http://www.fda.gov/AboutFDA/WhatWeDo/default.htm</a> ]</td>
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FDA in the News
<table>
<thead>
<tr>
<th>Module</th>
<th>Dates</th>
<th>Sub-Modules</th>
<th>Topics</th>
</tr>
</thead>
</table>
| 2 | 8/30, 9/1 | Module 2 – FDA’s Regulatory Framework | 1. Chapter 1 (p17 – 35)  
2. CDER (FDA’s Role in Public Health: Drug Efficacy, Safety, Quality, and Beyond: Course Introduction)  
3. CDRH (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm)  
4. CBER (About CBER: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CFD/ucm133072.htm)  
5. Guidance documents and Standards (http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm285282.htm)  
| 3 | 9/6, 9/8 | Module 3 – Medical device regulation | 1. Chapter 5 (p128 – 136; 146-155)  
The basics of Medical Device Approval and Post-Marketing (Last 11 minutes: https://collaboration.fda.gov/p8wspxcdqbd/)  
(Part of this material is available through https://fda.yorkcast.com/webcast/Play/040308365ec8405bad39b060d6e8561bdc1d)  
2. Medical device classification  
5. Optional: (Dhruva and Redberg, 2012; Welle and Krauthamer, 2012) |
| 4 | 9/13, 9/15 | Module 4 – Medical device regulation | 1. Chapter 5 (p137 – 146; 155 - 164)  
2. PMA (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm)  
3. HDE  
4. Expedited access  
5. Preclinical testing  
7. Quality Systems Regulation  
8. Risk and Benefit in Regulatory Decisions |
| 5 | 9/20, 9/22 | Module 5 – CDRH Case Studies and Medical Devices Database | 1. Chapter 5 (p165 – 167)  
2. National Medical Device Curriculum (http://www.fda.gov/Training/CourseMaterialsforEducators/NationalMedicalDeviceCurriculum/ucm404245.htm)  
5. In vitro diagnostics  
6. Post-Market Surveillance  
7. Medical Device Reporting |
| 6 | 9/27, 9/29 | Module 6 – Regulation of New | 1. Chapters 2 and 3 (FDA’s Role in Public Health: Drug Efficacy, Safety, Quality, and Beyond: CDER product development and review)  
2. Class Participation  
FDA in the News |
<table>
<thead>
<tr>
<th>Module</th>
<th>Date</th>
<th>Title</th>
<th>Topics</th>
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</thead>
</table>
| 7      | 10/4, 10/6 | Module 7 – CDER Regulatory Process | 1. Chapter 7  
2. Drug databases  
3. Post Market and Safety  
4. Promotions and Advertising  
5. Preclinical and clinical data requirements – CMC, toxicology, PK |
| 8      | 10/11, 10/13 | Module 8 – CDER Case study | 1. CDER Case Studies  
http://www.fda.gov/Training/ForHealthProfessionals/ucm464124.htm |
| 9      | 10/18, 10/20 | Module 9 – Regulation of Biologics | 1. Chapters 13  
2. CBER’s Regulation of Biologics  
3. BLA applications  
4. Biosimilars  
6. Blood Regulation (Optional: https://collaboration.fda.gov/p6ooqyna7uu/)  
7. Vaccine Regulation  
(http://www.fda.gov/BiologicsBloodVaccines/Vaccines/default.htm) |
| 10     | 10/25, 10/27 | Module 10 – CBER Regulatory Process | 1. CBER Case Studies  
2. (Bailey et al., 2015; Knoepfler, 2015; Witten et al., 2015; Baylor, 2016)  
3. Priority voucher program  
4. Preclinical considerations  
5. Product development and biotechnology manufacturing  
6. Postmarket, Databases and Security  
(http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/Phase4Trials/default.htm) |
| 11     | 11/1, 11/3 | Module 11 – Combination Products  
FDA Research | 1. Chapter 14  
2. OCP  
(http://www.fda.gov/CombinationProducts/AboutCombinationProducts/default.htm)  
3. Clinical trials basics |
| 12     | 11/8, 11/10 | Module 11 – Good Laboratory | 1. Chapter 9  
2. GMP  
(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRecheck/default.htm) |
|---|---|---|

<table>
<thead>
<tr>
<th>13</th>
<th>11/15, 11/17</th>
<th>FDA vs. European regulation Centers for Medicare &amp; Medicaid Services Regulatory affairs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. (Kramer et al., 2012a, 2012b, 2014; Zuckerman et al., 2012; Campillo-Artero, 2013; Sorenson and Drummond, 2014; Salmikangas et al., 2015; Daller, 2016)</td>
<td>2. Chapter 11</td>
<td></td>
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<table>
<thead>
<tr>
<th>14</th>
<th>11/22, 11/24</th>
<th>Fall Break</th>
</tr>
</thead>
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<table>
<thead>
<tr>
<th>15</th>
<th>11/29, 12/1</th>
<th>FDA Inspections and Enforcement</th>
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<tbody>
<tr>
<td>5. OCI Most wanted (<a href="http://www.fda.gov/ICECI/CriminalInvestigations/OCIsMostWantedFugitives/default.htm">http://www.fda.gov/ICECI/CriminalInvestigations/OCIsMostWantedFugitives/default.htm</a>)</td>
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<thead>
<tr>
<th>16</th>
<th>12/6, 12/8</th>
<th>Special topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Bioprinting</td>
<td>2. Brain Computer Interfaces</td>
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<thead>
<tr>
<th>17</th>
<th>Finals Week</th>
<th>Final Exam</th>
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</thead>
</table>

Class Participation
Final Project – Non-clinical testing plan
FDA in the News
Final Project – Clinical testing plan
FDA in the News
Final Exam