Syllabus

Regulatory and Quality Issues in Medical Device Development; 3 credits

Monday/Wednesday 3:30-4:45pm; MoSE rm 1224

Instructor Information

Instructor	Email	Office Hours & Meeting Link
Rebeccah Brown	rjcbrown@gatech.edu It is preferred if you send messages to me via Canvas Inbox	By appointment
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General Information

Description

This course equips students with practical, industry-aligned knowledge of the regulatory and quality systems essential to bringing medical devices to market and maintaining compliance. Focusing on the Total Product Life Cycle (TPLC), the curriculum bridges engineering design with regulatory strategy, from early concept and risk management to premarket authorization, commercialization, and post-market surveillance.

The first portion of the course covers Regulatory Foundations, Quality Management Systems (harmonizing FDA QMSR and ISO 13485), and Quality by Design (QdB) incorporating ISO 14971 risk management, the essential bedrocks of medical device quality. The middle portion of the course guides students through design verification, validation, pre-market clinical strategies (including Investigational Device Exemptions), and the primary pre-market clearance and approval pathways (510(k), De Novo, and PMA) using modern tools like the FDA eSTAR template. The final portion transitions to manufacturing design transfer, process validation, post-market surveillance (complaint handling, MDRs, recalls, and CAPAs), and emerging regulatory frontiers including AI/ML, Software as a Medical Device (SaMD), PCCPs, and cybersecurity.

Instructors integrate real-world medical device development experience and regulatory casework throughout the lectures. Students apply these theoretical principles to a medical device through a series of collaborative team project milestones. Rather than passive learning, project teams complete four structured Team Activities acting as realistic regulatory and quality exercises in medical device development: pitching a product definition and classification strategy, constructing a hazard analysis/FMEA and traceability matrix, executing a technical gap

analysis on an eSTAR submission dossier, and managing a simulated post-market safety failure and CAPA response.

Pre- &/or Co-Requisites
Pre-Requisite is BME 2310 Intro to BME Design.

Course Goals and Learning Outcomes
At the end of this course, students will have developed a comprehensive understanding of U.S. regulatory and quality frameworks governing medical devices, including the roles of the FDA.

Specifically, students will be able to:

- **Analyze regulatory requirements** across the product lifecycle, from initial product definition and classification through post-market surveillance and enforcement actions.
- **Evaluate submission strategies and regulatory pathways**, including 510(k), De Novo, Premarket Approval (PMA), and special designations (Breakthrough, STeP, HUD, Custom Devices), incorporating risk-benefit analyses and coverage alignment.
- **Apply risk management principles** (ISO 14971) and structured risk analysis tools (such as dFMEA and pFMEA) to identify, prioritize, and mitigate risks in device design and manufacturing.
- **Design and assess Quality Management Systems (QMS)** that comply with FDA QMSR and ISO 13485:2016 standards, implementing robust design controls, verification and validation (V&V) protocols, and document control.
- **Integrate clinical trial strategies** (Investigational Device Exemptions, clinical trial endpoints) and post-market safety procedures (complaint handling, MDR reportability, HHE, and recalls) into a cohesive compliance program.
- **Synthesize ethical reasoning and emerging trends** (AI/ML, Software as a Medical Device, PCCPs, and cybersecurity) to navigate the dynamic global regulatory ecosystem responsibly.

Course Modality Information and Attendance Policy

Class attendance is required unless permission is received ahead of time to miss a class.

Calendar – Schedule of Topics

Module 1: Regulatory Foundations & Quality Management Systems		
Mon, Aug 24	Introduction to Device Regulation & FDA Organizational Architecture	Regulatory hierarchy mapping (Statute -> CFR -> Guidance -> Standard) and agency jurisdiction mapping across FDA Centers (CDRH/CDER/CBER) and OII

Wed, Aug 26	Intended Use, Device Risk Classification, & Labeling Foundations	Intended Use vs. Indications for Use breakdown, ProCode database queries, 21 CFR device classification, and core labeling constraint mapping
Mon, Aug 31	Quality Management Systems: FDA QMSR Harmonization & ISO 13485	FDA QMSR and ISO 13485:2016 scope, purpose, and structure
Wed, Sep 02	Quality System Failures & Root-Cause Case Studies	Root-cause teardown of major public health failures and identification of underlying QMS breakdowns
Mon, Sep 07	**Labor Day**	
Wed, Sep 09	**Team Activity 1**: Product Definition, Classification, & Regulatory Strategy	Student teams pitch assigned device product profiles, Intended Use statements, proposed risk classifications, ProCodes, and core consensus standards with peer/instructor feedback
Module 2: Quality by Design (QdB) & Risk Management		
Mon, Sep 14	Design Controls Architecture & Translating User Needs to Design Inputs	QdB and Design Controls overview; practical exercise translating qualitative user needs into quantifiable, testable design inputs.
Wed, Sep 16	Risk Management Principles (ISO 14971)	Fundamentals of ISO 14971 and mapping risk-based and data-driven decision-making across TPLC
Mon, Sep 21	Risk Analysis Tools: dFMEA & pFMEA	Hands-on construction of dFMEA/pFMEA tables, calculating risk priority metrics, and applying the three-tier risk mitigation hierarchy
Wed, Sep 23	Design Outputs, V&V Planning, & Traceability Matrix	Mapping design outputs to inputs and structuring a closed-loop Traceability Matrix (User Needs -> Inputs -> Outputs -> V&V), linked to consensus standards
Mon, Sep 28	**Team Activity 2**: Risk Analysis & Traceability Matrix Construction	Team working session creating the preliminary ISO 14971 Hazard Analysis/FMEA and Traceability Matrix for their project device
Wed, Sep 30	**Exam 1**	Covers Module 1 and Module 2
Mon, Oct 05	**Fall Break**	
Module 3: Design Verification, Validation, & Pre-Market Clinical Strategy		
Wed, Oct 07	Early Agency Interactions: FDA Q-Subs, TAP Pilot, & Coverage Alignment	The mechanics of meeting with the FDA; Pre-Sub strategy, drafting FDA feedback requests, TAP Pilot enrollment benefits, and early FDA/CMS alignment via the RAPID coverage pathway framework
Mon, Oct 12	Design Verification and Design Validation Execution	Design control recap (V&V placement), developing and executing non-clinical V&V protocols, and bridging to clinical trials as design validation

Wed, Oct 14	Investigational Device Exemptions (IDE) & Clinical Trials	SR vs. NSR determinations, IRB oversight, GCP compliance; designing IDE clinical trial protocols, primary safety and efficacy endpoints, sample size rationale, and secondary reimbursement/coverage alignment
Mon, Oct 19	Design Reviews, Change Control, & DDF Lifecycle Maintenance	Simulated design review meeting resolving V&V failures, evaluating engineering change orders (ECOs), and maintaining DDF integrity
Module 4: Premarket Regulatory Submissions		
Wed, Oct 21	Premarket Dossier Architecture, eSTAR, & Special Program Designations	Common submission mechanics, MDUFA fees, and eSTAR template structure; evaluating special status program criteria (Breakthrough, STeP, HUD, Custom Devices)
Mon, Oct 26	Class II & Moderate-Risk Pathways: 510(k), De Novo, & Dual 510(k)/CLIA	510(k) predicate selection, reference devices, and SE arguments; De Novo risk-benefit and Special Controls; Dual 510(k)/CLIA Waiver joint applications
Wed, Oct 28	Premarket Approval (PMA): High-Risk Devices & Clinical Evidence	PMA dossier structure, review mechanics, MDUFA timelines, and post-approval requirements; evaluating clinical trial evidence standards and mock FDA Advisory Panel reviews
Mon, Nov 02	Global Market Access: EU MDR/IVDR & International Harmonization	Comparative analysis of US FDA clearance vs. EU CE marking under MDR/IVDR, Notified Body review requirements, and IMDRF/MDSAP audit frameworks
Wed, Nov 04	**Team Activity 3**: FDA eSTAR Walkthrough & Submission Strategy	Demonstration of FDA's interactive eSTAR template and PreSTAR tool, followed by a team-based "FDA Technical Screener" gap analysis on a flawed submission dossier
Mon, Nov 09	**Exam 2**	Covers Module 3 and 4
Module 5: Manufacturing Transfer & Post-Market Surveillance		
Wed, Nov 11	Design Transfer to Manufacturing & Process Validation	Mapping design transfer requirements from DDF to Medical Device File (MDF), structuring IQ/OQ/PQ process validation protocols, and establishing production controls
Mon, Nov 16	Complaint Handling, MDRs, & Recalls	Triage of post-market adverse events, executing 15/30-day MDR reportability determinations, conducting Health Hazard Evaluations, and determining recall classification
Wed, Nov 18	OOS Investigations, Root Cause Analysis, CAPA	Investigating out-of-specification (OOS) manufacturing and field events using 5 Whys and Fishbone analyses to design and execute a CAPA plan

Mon, Nov 23	FDA Inspections & Enforcement Actions	Preparation for FDA facility inspections under CP 7382.850, analyzing Form FDA 483 inspectional observations, and drafting effective corrective action responses
Wed, Nov 25	**No class**	
Mon, Nov 30	Advertisement, Promotion & Off-Label Rules	Overview of advertising and promotional regulations, fair balance standards, and off-label enforcement; simulated Promotional Review Committee / MLR review process for commercial collateral
Wed, Dec 02	**Team Activity 4**: Post-Market Event Triage, Risk Analysis, & CAPA Execution	Teams receive a simulated post-market failure scenario for their project device, perform an HHE, determine MDR reportability, and formulate a CAPA response
Module 6: Emerging Regulatory Horizons & Industry Innovation		
Mon, Dec 07	Emerging Trends in QA/RA & Course Synthesis	Exploring regulatory frameworks for AI/ML, SaMD, PCCPs, and cybersecurity, followed by a TPLC course synthesis, career path overview, and final exam prep
TBD	**Final Exam**	Covers Module 1-6

Course Requirements & Grading

Course requirements are split into two major categories: 1) Exams and Final (**60% of grade**), and 2) Team Activities (**40% of grade**). Note that Team Activities will consist of multiple components, however it is the submitted presentation that will be graded for each team for each activity.

Assignment	Date	Weight (Percentage, points, etc)
Team Activity 1	Sept 9	10%
Team Activity 2	Sept 28	10%
Exam 1	Sept 30	15%
Team Activity 3	Nov 4	10%
Exam 2	Nov 9	15%
Team Activity 4	Dec 2	10%
Final Exam	TBD	30%

Grading Scale

Your final grade will be assigned as a letter grade according to the following scale:

A 90-100%
B 80-89%
C 70-79%

D 60-69%
F 0-59%

According to policy, grades at Georgia Tech are interpreted as follows:
A Excellent (4 quality points per credit hour)
B Good (3 quality points per credit hour)
C Satisfactory (2 quality points per credit hour)
D Passing (1 quality point per credit hour)
F Failure (0 quality points per credit hour)

See http://registrar.gatech.edu/info/grading-system for more information about the grading system at Georgia Tech.

Course Materials

Course Website and Other Classroom Management Tools

All course material will be available on Canvas. All communication if possible should be done through Canvas via email. Required written assignments will be submitted on Canvas.

Course Text

There is no course text. Most of the material comes from the FDA website: fda.gov. Learning the FDA website is a critical skill for medical device development to access regulatory requirements, guidance documents, etc. Lecture notes will be posted to Canvas in PDF. In addition, all required readings as well as relevant current events, news etc. related to FDA will be posted on Canvas.

Course Expectations & Guidelines

Academic Integrity

Georgia Tech aims to cultivate a community based on trust, academic integrity, and honor. Students are expected to act according to the highest ethical standards. For information on Georgia Tech's Academic Honor Code, please visit:

http://www.catalog.gatech.edu/policies/honor-code/

or

http://www.catalog.gatech.edu/rules/18/.

Any student suspected of cheating or plagiarizing on an exam, or assignment will be reported to the Office of Student Integrity, who will investigate the incident and identify the appropriate penalty for violations.

Use of AI such as Chat GPT for Assignments

The use of AI is not allowed for exams and will be seen as a violation for this course for the honor code. However, you may use AI systems as a resources to help research medical devices, safety issues, design requirements, etc. If you do use AI to assist in development of your Team Activity assignments, this should be referenced as a resource.

Collaboration & Group Work

A large segment of the class will be project group work, for the team activities. You will work with your project teams on all aspects of the project. Within group work, it is important that all students are responsible and contribute to the final work product. All team members will receive the same grade for team activities and deliverables.

Accommodations for Students with Disabilities

If you are a student with learning needs that require special accommodation, contact the Office of Disability Services at (404)894-2563 or http://disabilityservices.gatech.edu, as soon as possible, to make an appointment to discuss your special needs and to obtain an accommodations letter. Please also e-mail one of the instructors as soon as possible in order to set up a time to discuss your learning needs.

Extensions, Late Assignments, & Re-Scheduled/Missed Exams

If you develop COVID illness or other circumstances that prevent you from participating in exams or team activities, please let an instructor know as soon as possible. Exams will be rescheduled.

Student-Faculty Expectations Agreement

At Georgia Tech we believe that it is important to strive for an atmosphere of mutual respect, acknowledgement, and responsibility between faculty members and the student body. See https://catalog.gatech.edu/rules/22/ for an articulation of some basic expectation that you can have of your instructors and that your instructors have of you. In the end, simple respect for knowledge, hard work, and cordial interactions will help build the environment we seek. Therefore, we encourage you to remain committed to the ideals of Georgia Tech while in this class.

Campus Resources for Students

Please see the following website for access to resources that cover these aspects of student life: https://students.gatech.edu. This site includes mental health resources, career development resources, Office of Disability Services, Student diversity resources, Victim advocacy resources, Campus Recreation and the Georgia Tech Police Department. Also, please feel free to approach and contact an instructor concerning any issues related to the course or related to life at Georgia Tech outside the course!

Additional Syllabus Components

The goal of this course is to cover as many aspects of the FDA regulatory process related to medical device development as possible. Of course, without developing a physical device, it will not be possible to replicate the complete process. However, we will discuss all the processes for quality control and regulatory approval that you would need to go through to get a medical device approved. You may have taken courses such as capstone design that will cover some aspects of design control in a few lectures. The goal of this course is to cover these topics in depth, including reviewing FDA guidance documents and fully utilizing the FDA website. It is important to note that if you work in medical devices, you WILL encounter these issues in your career, as the FDA regulates all aspects of medical devices (in addition to drugs and biologics) and a company cannot advertise or sell a medical product in the US without FDA regulatory oversight. FDA-regulated food, tobacco, and medical products account for more than **$4.1 TRILLION dollars** of the US economy (21 cents of every dollar spent by US consumers).