Welcome to BME 1801: Medical Device Regulation: Hardware, Software, and AI Course Syllabus 2026

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Lecture: Wednesdays, 16:00 to 18:00pm. Roseburgh Building, Rm 211.

Tutorial: Tuesday 13:00-15:00 pm. Roseburgh Building, Rm 211

Professor's Office Hours: Wednesday 15:00 to 16;00pm, location TBD.

Communication: Email & through Quercus

Course Description

The goal of this course is to understand the development of software, hardware, and AI based medical devices with a strong emphasis on US-FDA medical device regulation.

The course combines foundational concepts with practical examples to prepare a student for a career in a medical device company, as a consultant, or as an entrepreneur commercializing their own technologies. A combination of case studies and success stories presented by successful medtech entrepreneurs will be used to support and reinforce the class materials.

This course is interactive and team building is critical for both the tutorials and term projects; thus, class and team participation are required. Please consider these criteria when signing up for this course.

At the conclusion of the course, the students should be able to:

1) Given a medical device, define potential indications for use/intended uses for the device and identify and justify the regulatory path for each possibility.

2) Develop a clinical and non-clinical validation plan for a medical device that would enable FDA clearance/approval.

3) Use the FDA's website to identify product codes and regulations, and the summary basis for the US market authorization of various products.

4) Use regulatory precedents and guidance documents to support and advocate to a regulatory for a device's regulatory path and proposed validation plan.

Course Overview: The weekly sessions are class-based with a tutorial period for discussion and term project work. Lecture presentations by Joel Ironstone and by guest lecturers will be provided to students.

Mark distribution (see appendix for Rubrics)

Milestone	Weight (%)
Q-Sub Written Project	**20**
Q-Sub Peer Assessment	**5**
Q-Sub Presentation to FDA Reviewer	**10**
Quizes (5x)	**25**
Tutorial attendance marks	**5**
Final Exam	**35**

Accommodations

If a student needs accommodation for quizzes, missed classes, missed tutorials or the exam, they must file a formal petition with or request assistance from the university and provide all required supporting documentation (e.g. doctor's note; accommodations for assessments aren't given for personal trips). To protect your privacy, the teaching team does not process accommodations. All processing must be done via the university.
https://lsm.utoronto.ca/ats/
https://www.viceprovoststudents.utoronto.ca/students/academic-accommodation/

Optional course textbook:

While the course will rely substantially on course notes and FDA guidance documents, the following textbook is an excellent resource for those considering a career in medical devices.:

Biodesign: The Process of Innovating Medical Technologies (2nd Edition) by Paul G. Yock et al.

Major term project (Q-Sub):

The primary project in the course will be the preparation of an FDA Pre-Submission (Q-Sub) Request. This request is the method by which medical device developers obtain feedback on their testing plans and proposed regulatory pathway from the FDA. Students will develop the indications for use of a novel medical device, develop clinical and non-clinical test plans, and propose and justify a regulatory pathway. The students will then present their proposal to a former FDA review in a simulated FDA Pre-Sub meeting.

Non-Contributing Team Member Policy

All team members must contribute equally to projects. If there is documented evidence that some members have not contributed (e.g. meeting minutes show absences, plagiarism concerns, deliverables missed, etc.), they will be docked marks after team and teaching staff consultation.

Quizzes

Each short answer/multiple choice quizzes is worth 5% of the term mark. These quizzes will be given at the start of the tutorial period and taken up later in the same tutorial period. These quizzes are designed to cement your understanding of the documents required for the term projects. All quizzes are in-person.

Final Exam

The format of the exam will be a supervised test in which the students will ** Review key concepts as well as questions from case studies presented during lecture.

Missed Assessments

Missed assessments must be formally petitioned with the university with appropriate supporting documentation. Valid petitioners will have their marks re-allocated to the final exam.

Tutorial Attendance Marks

Students receive marks for in-person work with your group on the Q-Sub project during the tutorial. In-person work in the tutorial helps the teaching team track your progress and answer questions about your projects.

Class & Tutorial Schedule

#	Week of	Lecture Topic	Readings	Tutorial
1	Sept 9	**Introduction to Medical Device Development** • What is and what isn't a regulated medical device • Basic Principles of Medical Device Development & Regulation. • Intended Use & Labeling • Introduction to the Medical Device Industry • Medical Device Regulatory Frameworks in US, Canada, and Europe • Case Studies; OURA, Apple AFib	FDA Guidance "Classification of Products as Drugs and Devices & Additional Product Classification Issues" https://www.fda.gov/media/80384/download FDA General Wellness guidance: https://www.fda.gov/media/90652/download Oura warning letter: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/whoop-inc-709755-07142025	None
2	Sept 16	**US FDA Pathways 1** • Review of FDA Regulations/Classification • Product Codes, regulations, and the FDA databases • Class I and 510(k) Exempt Devices • The 510(k) process & Demonstrating Substantial Equivalence • Multiple Predicates, Reference Device etc. • Borderline situations • Advocating for Substantial Equivalence • Content of a 510(k)	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications: https://www.fda.gov/media/82395/download FDA Guidance on General/Specific Intended Use: https://www.fda.gov/media/71966/download	**Quiz 1- Medical device or not** Tutorial- Navigating the FDA Databases
3	Sept 23	**US FDA Pathways 2** • The De-Novo Process (risk/benefit analysis, special controls) • The PMA Process • HDEs, breakthrough designations… • Case Studies for FDA Pathways	FDA De-Novo Guidance: https://www.fda.gov/media/72674/download FDA Breakthrough Device Guidance: https://www.fda.gov/media/162413/download	**Quiz 2- 510(k) process** Group Review of 510(k) Examples
4	Sept 30	**Guest Lecturer:** Elizabeth Munro, Founder, LMC Consulting & Co-Founder of Perimeter Medical Imaging **The Q-Sub Process and Large Project Intro** • When to have a Q-Sub • Types of Q-Subs • Structure and content	FDA Q-Sub Guidance: https://www.fda.gov/media/114034/download	Q-Sub Project: Introduction Form Q-Sub Teams Select Q-Sub Topics

		• Review of 510(k) Flow Chart • How to write a device description • How to propose non clinical, clinical testing & regulatory pathways • FDA Focus Questions • Interpreting FDA's written Response • Responding to FDA Feedback • Negotiating with FDA and next steps		
5	Oct 7	**Guest Lecturer:** Matthew Asselin, Founder, On2 Product Development **Non-Clinical Testing** • Intro to Risk analysis • The framework-Design Inputs, Outputs and Traceability • Comprehensiveness • Use of standards guidance documents, and reference devices • Testing to Requirements • Usability and Human Factors • Biocomp, Sterilization, Shelf Life, C&D…	FDA Human Factors Guidance: https://www.fda.gov/media/80481/download FDA Guidance on Biocompatibility and use of ISO 10993: https://www.fda.gov/media/142959/download	Tutorial: Reviewing Q-Sub Guidance and Structure of a Q-Sub Develop Q-Sub Outline & Device Description
6	Oct 14	**Clinical Studies of Medical Devices** • The IDE process & IDE Exemptions • The Health Canada ITA process • ISO 14155 & GCP • Clinical study designs (interventional, observational, RCTs, blinding) • Bias • Powering studies • Therapeutic vs diagnostic endpoints (ROC curves, Sens & Spec) Case Studies	FDA Guidance on reporting results from diagnostics studies: https://www.fda.gov/media/71147/download Design Considerations for Pivotal Clinical Investigations: https://www.fda.gov/media/87363/download FDA Guidance on Non-Clinical Bench Testing: https://www.fda.gov/media/113230/download	**Quiz 3 Non-Clinical Testing** Develop Q-Sub Intended & Regulatory Strategy
7	Oct 21	**Guest Lecturer: Marc Saab** Founder, BML Healthcare **Devices with Software** • SaMD • AI/ML in medical devices • Cybersecurity • CDS and non-device Software functions • Software Validation • PCCPs	FDA Guidance on Software Validation: https://www.fda.gov/media/73141/download Good Machine Learning Practice Guidance: https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles	**Quiz 4-Clinical Studies** Develop Q-Sub Non-Clinical Testing Section
-	Oct 28			
8	Nov 4	**Guest Lecturer:** Catriona Boyd Founder, illuMED Advisory **Quality Systems** • Overview of ISO13485 & QMSR • General principles		Develop Q-Sub Clinical Testing Section

		• Key Processes (Document Controls, Design Controls, Design Transfer, Production Controls, CAPA) • What devices need a QMS and when • What goes into a DHF, DMR, and DHR		
9	Nov 11	**Guest Lecturer:** Charusheila Ramkumar CSO, CNTRL+ **In-Vito Diagnostic Devices & Combination products** • What is an IVD • Types of IVDs • LDTs • CLIA and test complexity • IVD Validation • Combination products classification and PMOA, RFDs		**Quiz 5:** **QMS** Develop FDA Focus Questions & Prepare for presentation
10	Nov 18	**Guest Reviewer:** Megan Shackelfor, Former FDA Lead Reviewer & Founder Shackelford Consulting Services **Q-Sub Project Presentations**		Preparation for Team Presentations
11	Nov 25	**Guest Lecturer:** Stefano Picone, Former CFO Conavi, Fractional CFO to medtech start-ups **The Business of Medtech**		Package Q-Sub & Submit
12	Dec 2	**Lessons from the Canadian medtech ecosystem** **Guest Speakers:** Darren Kraemer Founder of Attodyne and LMI Liam Kaufman Founder of Winterlight Labs (Acquired by Cambridge Cognition) John Dillon Founder of Molli (Acquired by Stryker)		Exam Prep

Appendix A – Rubric for the Q-SUB written Report

Element	1	2	3	4	Pts
Q-Sub Content & Organization	Missing major Q-Sub elements; purpose and requested feedback unclear.	Most sections present, but purpose, context, or organization is incomplete.	Complete and well organized; purpose, future submission, and requested feedback are clear.	Concise, reviewer-focused, and structured so FDA can quickly understand the device, strategy, evidence plan, and questions.	**/5**
Device Description & Intended Use	Device, operation, or intended use is unclear or inconsistent.	Basic description provided, but important technology, users, workflow, population, or use setting is missing.	Clearly describes function, principle of operation, key characteristics, intended users, population, and proposed indications. Clearly articulates how the device will modify the clinical workflow	Provides exactly the technical and clinical context needed to evaluate the regulatory and testing strategy; figures are used effectively.	**/10**
Regulatory Strategy	Pathway unsupported; predicates/precedents absent or inappropriate; no link to testing.	Pathway and possible predicates identified, but comparison and justification are superficial.	Pathway is justified; appropriate predicate/reference/analogous devices are compared in a table; key differences are identified and linked to the validation plan. If De-Novo is proposed risks and benefits are evaluated in light of other cleared devices.	Strong argument from intended use → pathway → predicate/precedent → important differences → evidence needed. Table explicitly cross-references the non-clinical/clinical test that addresses each difference or novel risk and benefit	**/10**
Non-Clinical Testing & Validation	Major testing missing or listed without methods or acceptance criteria.	Major tests identified, but rationale, methods, worst-case configuration, sample size and acceptance criteria are incomplete or ambiguous	Appropriate testing is proposed and linked to risks/differences. Key tests include method, standard/guidance, test article, sample size/replicates, and acceptance criteria.	Complete Integrated plan showing sample size, detailed test method & acceptance criterion. Worst-case selection, controls, sample size, and criteria are scientifically justified.	**/10**
Clinical Testing, Endpoints & Sample Size	Study is absent when needed or cannot support the intended use; endpoints/sample size poorly defined.	Basic study design exists, but population, comparator, endpoints, sample size, or statistical rationale is incomplete.	Study design is appropriate population, comparator, follow-up, primary/secondary endpoints, sample-size rationale, and analysis approach.	Study directly supports the proposed claim. Endpoints and success criteria are defined; sample size is derived from valid power calculation and corrects for multiplicity analysis population, and key bias controls are justified.	**/10**

Element	1	2	3	4	Pts
FDA Focus Questions	Questions are vague, ask FDA to design the program, or ask whether the device will be cleared/approved.	Relevant questions, but too open-ended, poorly prioritized, or unsupported by a sponsor proposal.	Focused questions address defined uncertainties; each is preceded by the sponsor's proposal and rationale.	High-value questions follow: issue → sponsor proposal → evidence/rationale → specific FDA question. Questions are answerable and target decisions that materially reduce development risk.	**/5**
Integration & Internal Consistency	Sections conflict; intended use, predicates, testing, clinical evidence, and questions do not align.	Overall strategy is visible, but important inconsistencies or unexplained gaps remain.	Sections form a coherent development program with reasonable cross-references.	Entire Q-Sub reads as one regulatory argument; material differences drive evidence, and remaining uncertainty drives FDA questions.	**/5**
Professional Quality & Evidence	Poor writing/formatting; regulatory assertions unsupported.	Understandable, but inconsistent and incompletely sourced.	Professional writing using relevant FDA guidance, standards, literature, and prior FDA decisions.	Could credibly be provided to FDA with limited editing; concise, well referenced, and easy to review.	**/10**
				Total	**/65**

Appendix B – Rubric for FDA Q-Sub Presentation

Reviewer role. Evaluate the team as you would a sponsor presenting a Pre-Submission to FDA. Focus on the quality of the proposal, regulatory reasoning, validation strategy, presentation, and responses to reviewer questions.

Performance levels: 1 = weak/unsupported 2 = partially developed 3 = solid and reviewable 4 = strong, persuasive, FDA-ready

Element	1	2	3	4	Pts
Team Introduction & Roles	Team is not introduced or roles are unclear.	Team is introduced, but roles/responsibilities are vague.	Brief, clear introduction identifies team members and relevant roles.	Professional opening establishes who is presenting, each member's role, and how responsibilities relate to the Q-Sub.	**/3**
Device & Intended Use	Device/use unclear; key clinical context missing.	Basic description, but important workflow, population, user, or technology details are missing.	Clear device, intended use, indications, users, workflow, and key technology.	Concise and complete; gives the reviewer exactly the context needed to assess the proposed strategy.	**/4**
Regulatory Strategy & Predicate / Precedent	Pathway unsupported; predicate/precedent inappropriate or absent.	Pathway identified but rationale or comparison is superficial.	Pathway is well justified; appropriate predicates/precedents are compared and key differences identified.	Persuasive regulatory argument. Material differences are explicitly linked to the proposed validation plan.	**/8**
Clinical & Non-Clinical Validation Plan	Major evidence needs are missing or poorly matched to the device/claims; methods, endpoints, sample size, or criteria are unclear.	Overall plan is reasonable, but important methods, endpoints, sample-size rationale, comparators, worst-case selection, or acceptance criteria are incomplete.	Clinical and non-clinical evidence is appropriate and linked to risks, claims, and predicate differences. Key methods, endpoints, sample size/replicates, comparators, and acceptance criteria are described.	Integrated evidence plan showing why each study/test is needed. Methods, endpoints, sample size, worst-case selection, comparators, success criteria, and acceptance criteria are scientifically and regulatorily justified.	**/12**
Presentation Clarity & Integration	Presentation is difficult to follow, overly detailed, or internally inconsistent.	Generally understandable, but organization, transitions, or links between sections are weak.	Clear and professional; device, regulatory strategy, and validation plan form a coherent story.	Highly concise and reviewer-focused; the logic from device/claims to regulatory strategy to validation evidence is easy to follow.	**/5**
Time Management	Substantially exceeds time or fails to cover major material.	Pacing is uneven; important content is rushed or excessive time is spent on lower-value material.	Finishes within the allotted time with appropriate pacing and coverage.	Uses time strategically, emphasizing decision-critical material while leaving adequate time for reviewer questions and discussion.	**/3**
Responses to Reviewer Questions	Unable to answer key questions or answers contradict the proposed strategy.	Answers show partial understanding but are vague, speculative, or inadequately supported.	Answers are clear, technically sound, and generally supported by the team's rationale/evidence.	Answers are concise, credible, and demonstrate command of trade-offs, uncertainty, and regulatory reasoning; the team directly answers and appropriately acknowledges what is not known.	**/15**
				TOTAL	**/50**

Appendix C – Rubric for FDA Q-Sub Peer Assessment

Assess each team member based on their contribution to the project. Use the 1–4 rubric below.

Criterion	1 – Limited	2 – Developing	3 – Strong	4 – Excellent
Technical Knowledge	Limited understanding of the device, technology, or evidence.	Understands assigned area but has gaps in broader technical issues.	Good command of the device and technical issues; contributes sound analysis.	Deep understanding; integrates technical issues across the project and helps resolve difficult problems.
Work Ethic & Reliability	Frequently unprepared, late, or dependent on others to complete assigned work.	Completes some assigned work, but effort, timeliness, or quality is inconsistent.	Reliable and prepared; completes assigned work on time and to a good standard.	Consistently takes ownership, delivers high-quality work, and helps the team meet deadlines.
Facility with FDA Regulations	Limited understanding of FDA pathway, guidance, or Q-Sub expectations.	Basic familiarity but requires help applying FDA requirements to the project.	Applies FDA regulations/guidance appropriately to regulatory strategy and testing.	Strong regulatory judgment; effectively uses FDA precedent, guidance, and requirements to shape the project.