Welcome to BME 1800:

Biomedical Product Development

Course Syllabus 2026

Course Instructor: Prof. Omar F. Khan (BME)

Teaching Assistants:

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Lecture day & time: Tuesdays, 10:00 to 13:00 ET (1.5 hour lecture and 1.5 hour required tutorial)

Communication: please contact Professor Khan or the teaching staff through Quercus only (Quercus > Inbox > Compose a new message), which ensures visibility and a timely response.

Class location: Health Sciences Building, Room 108, 155 College Street, Toronto, ON M5T 1P8

Course Description

The goal of this course is for students to understand the development of biomedical products from prototype to commercial release. The course is designed to enable students to bring their own products to market or to obtain employment in the medical device industry as Product Development Engineers and to make significant contributions to the development of new medical devices that can change the standard of care.

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 important criteria when signing up for this course.

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

1. **Appreciate** the translational link between the fundamental concepts of biomedical engineering knowledge and their practical application in the development of commercial medical products and the design considerations for clinical use of such products.

2. **Understand** the theory behind the development of biomedical products from prototype to commercial release

3. **Apply** the theory to critically analyze practical product development issues

4. **Deliver** product designs through interactions and group projects

5. **Understand** the importance of milestones and **deliver** projects on schedule

The main themes of the course are:

- Developing proper requirements
- Design control
- Human factors engineering
- Regulatory requirements
- The IEC 60601 medical device standard
- The ISO 13485 standard
- Risk management
- Verification and validation
- Design transfer to manufacturing
- Quality systems

The course will emphasize the fundamental engineering principles that will help students become productive team members in an industrial environment and give them the background necessary to assume leadership roles in product development. Guest experts, case studies, and real-world examples provide an authentic learning experience.

Prerequisite course: Familiarity with engineering design principles or equivalency is a significant asset and is expected, but not a requirement. Undergraduate Engineering design experience from an accredited engineering school is an asset. Equivalency will be assessed by the course instructor and determined on an individual basis. The BME1800 course is a complementary course to BME1801 (*Biomaterial and Medical Device Product Development*) in the BME Master of Engineering professional program.

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/

Course Overview: The weekly sessions are class-based with a tutorial period for discussion and term project work. Students are required to follow relevant medical industry updates. Lecture presentations by Prof. Khan and by guest lecturers will be

supplied to students. The tutorials are meant to mirror a discussion you would have in a product development group.

Date	Lecture Topic	Tutorial
Lecture 1 Jan. 7	Introduction Design Control - Overview	Formation of teams for the term projects
Lecture 2 Jan. 14	Design Control - Concept Phase Risk Management - ISO14971	Term project #1 is defined and students start work.
Lecture 3 Jan. 21	Business Plan Dr. Eddie Eltoukhy, Partner, Pear Venture Capital Design Control - Planning Phase Design Control - Document Control	Work on Project #1
Lecture 4 Jan. 28	Human Factors and Industrial Design Design Control - Design Phase	Quiz 1 Work on Project #1
Lecture 5 Feb. 4	Design Control - Verification & Validation Phase ISO13485 Quality Standard Pre-clinical and clinical trial management Dr. Brian Wodlinger, VP, Engineering and Clinical, Exact Imaging	Work on Project #1
Lecture 6 Feb. 11	Design Control – Design Transfer Phase Regulatory Requirements Frédéric Hamelin, Manager, Quality Systems Section, Health Canada	**Project #1 is due.** Students start work on their Concept Phase Design Review
Lecture 7 Feb. 25	Students lead a 10 min Concept Phase Design Review of their work in Project #1. Time will be	

Date	Lecture Topic	Tutorial
	allotted for Q&A after each overview.	
Lecture 8 Mar. 4	IEC 60601 Global Medical Device Standard Garry Lee, President, Megalab Group, Inc.	Work on Project #2
Lecture 9 Mar. 11	Intellectual property and its management Nir Lifshitz, VP, Intellectual Property & Legal Affairs, Baylis Medtech	Work on Project #2
Lecture 10 Mar. 18	Quiz 2 Project #2 sprint	Work on Project #2
Lecture 11 Mar. 25	IP Enforcement Christopher A. Guerreiro, J.D., BSc (Hons.), Of Counsel, Norton Rose Fulbright Canada	Work on Project #2
Lecture 12 Apr. 1	Software Lifecycle Darcy Bachert, CEO, Prolucid Technologies	**Project #2 is due.** Discussion on learnings from the projects.
Final Exam Apr. 8	Location TBD	Arrive no later than 10:10. Exam starts at 10:15.

Optional course textbook:

Reliable Design of Medical Devices, 3rd Ed. Richard C. Fries, CRC Press.

Book description: As medical devices become even more intricate, concerns about efficacy, safety, and reliability continue to be raised. Users and patients both want the device to operate as specified, perform in a safe manner, and continue to perform over a long period of time without failure.

See http://www.amazon.ca/Reliable- Design-Medical-Devices-Third/dp/1439894914/ref=sr_1_2?ie=UTF8&qid=1370986860&sr=8-2&keywords=reliable+design+of+biomedical

Select articles and other resources will be posted on Quercus.

Major term projects:

There are two major term projects. Students will be formed into groups of 4 to 6 team members (depending on class size). Ideally, groups will be composed of students with diverse technical and medical knowledge to simulate development groups in industry. ***Students will submit a short bio online during the first class so that groups can be formed by the end of the first tutorial.*** Groups will choose a medical device to develop through the Concept and Planning phases of Design Control. You can choose any device that interests you, or suggestions will be provided. You can choose to develop a new device or to add features to an existing device that will significantly improve its value proposition. The project should require a high degree of innovation, but the complexity of the project must be balanced against the practical aspects of the workload required and the expertise available. All projects must be approved by Prof. Khan before you start.

Both projects will be submitted as a collection of documents in accordance with Design Control. For Project #1, you will submit the following documents:

- Marketing Requirements Specification
- Validation Plan
- New Technology Assessment
- Hazard Analysis
- Design and Development Plan

Templates for each document will be supplied.

Each team will conduct a Design Review of their Concept Phase as a presentation to the class and students are expected to engage in Q&A with their peers.

Design Review Presentation Format:

- 10-min Design Review followed by 10-min Q/A session
- Each team member must present some part of the Design Review
- Teach team is responsible for bringing a computer to present their work

For Project #2 you will submit:

- Updated Concept Phase documents
- Design Inputs
- Verification Plan
- Traceability Matrix

Students will work on projects in class during the tutorial time while class consultants are available, as well as outside of class time. Three tutorial sessions have been reserved for work on each project.

1. There should be a focus on the quality, thoroughness, and credibility of product development planning
2. Students must clearly make and defend development decisions (e.g. substantiate with references to any standards, studies or public reports)
3. Students should demonstrate the ability to follow the discipline of Design Control and product development standards
4. It is expected that students will research the standards that their proposed device must adhere to
5. Students must demonstrate competence in consideration of the hazards and risks associated with their proposed device, and demonstrate engineering skill and creativity in suggesting mitigations for these risks;
6. Students should demonstrate sufficient knowledge of medical practice to write effective Market Requirements Specifications for their proposed product
7. Students should demonstrate good scientific and engineering judgement in formulating plans that ensure Marketing Requirements are properly validated
8. Students should demonstrate competence in translating Marketing Requirements into Design Input requirements that are technically feasible, require a reasonable level of resources, and will satisfy the marketing requirements
9. Students should demonstrate the engineering knowledge to write verification plans that will ensure that Design Outputs satisfy the Design Input requirements accurately and thoroughly
10. Students should demonstrate good engineering judgement in formulating plans and schedules
11. Deliver projects on time to prevent schedule creep, demonstrate team organization and the ability to adhere to strict milestone schedules

Project Submission

- Project #1 must be submitted online by 23:59 ET on the due date
- Project #2 must be submitted online by 23:59 ET on the due date
- Late penalties are 10% per day

Mark distribution (see appendix for Rubrics)

Milestone	Weight (%)
Project #1	**20**
Project #1 presentation	**10**
Project 2	**20**
Quiz 1	**5**
Quiz 2	**5**
Guest lecture participation marks	**5**

Tutorial attendance marks	**5**
Final Exam	**30**

Project reports and presentation

Students will be assigned responsibility for one or more documents in each project by the project leader and will present their document(s) at the Design Review. Where group sizes do not correspond to the number of documents required, adjustments will be made. All team members will collaborate to provide feedback on each document and work together to ensure that the project achieves its objectives and the documents are internally consistent.

Sample Documents and Caveat

- Sample documents are provided as general guidance for formatting
- These documents are not perfect; in cases where content conflicts with lecture notes or the syllabus, the lecture notes and syllabus are correct
- Follow the official rubrics published in the syllabus only
- Please make use of the tutorial time to check in with the teaching team for questions about content

Project Mark Weighting

Project #1 written report	Weight
Market Requirements Specification	**7%**
Validation Plan	**7%**
New Technology Evaluation Report	**7%**
Hazard Analysis	**14%**
Design and Development Plan	**7%**
Project Organization and Appearance	**8%**

Project #1 design review presentation	Weight
Presented within allotted time	**2%**
Speaks to class and not reading from notes	**2%**
Each person/section of report was represented	**2%**
Concluding recommendation for each section	**2%**
Slide organization and clarity	**2%**

Project #2 written report	Weight
Updated Concept Phase Documents	**12%**

Design Inputs	**18%**
Verification Plan	**14%**
Traceability Matrix	**6%**

The 50 marks for each project will be divided to yield the final weighting.

Marks for project reports are determined according to the grading rubric in the appendix.

Team marks for Design Review presentations are determined according the grading rubric in the appendix.

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 be evaluated in two parts. In Part A they will be assessed on their overall knowledge of processes for developing proper requirements, Design Controls, Regulatory requirements, Medical Device standards, and Risk management. In Part B they will be evaluated on their practical understanding of all the knowledge acquired in the course through case study analyses related to student term projects and in-class examples.

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.

Guest Lecture Participation Marks

Actively participate in at least 5 guest lecture sessions to receive full marks. A maximum of 1 mark per guest lecture. Attending a guest lecture is not counted as participation. Asking the guest lecturer a question about their presented content and receiving an answer is required to receive a mark.

Through **Quercus**, students must send a summary of their question and the answer received from the guest lecturer to **both teaching assistants** to receive a mark (go to Inbox and compose a new message). These summaries must be received by 23:59 ET on the day of the guest lecture. Summaries that are missing or received after the deadline will not be counted.

Tutorial Attendance Marks

Attend tutorials and do not leave early. Students receive marks for in-person work with your group on your term projects during the tutorial. In-person work in the tutorial helps the teaching team track your progress and answer questions about your projects.

Framework Lectures

Introduction; Design Control - Overview
This lecture will provide an overview of medical device development in a highly regulated environment - requirements, risk management, human factors, quality systems, regulatory requirements, design control and document control. The interdependent role of Product Development within a Medical Device company is examined.

Design Controls - Concept Phase
Detailed review of Marketing Requirements, Technology Assessment, Validation Plan, Design and Development Plan, Human Factors Plan, Regulatory Plan, design reviews, and phase sign-off meetings.

Risk Management – ISO14971
ISO 14971 is the risk management standard for medical devices. Designing for patient and operator safety is more than dedication and working hard – it is a long and detailed process that results in products that are inherently safe. Detailed review of risk planning, risk assessment, risk mitigation; a case study will be discussed.

Design Control - Planning Phase
Detailed review of Functional requirements, Design Inputs, traceability matrix, verification planning.

Design Control - Document Control

change management and Document Control; Quiz #2 will cover Concept Phase and Risk Management. The remainder of the tutorial will involve continuing work on Project #1.

Design Controls - Design Phase

Detailed review of Design phase deliverables including the Device Master Record and Design History File.

Design Control - Verification and Validation Phases

Detailed review of Verification and Validation phase, including bench, standards, preclinical and biocompatibility testing, and clinical trial design and management.

Business Plan

Discuss how companies evaluate a new technology's market potential, viability, and strategic partnership opportunities.

Regulatory Requirements

Medical device regulations and actual practice in Canada. The session will focus on describing differences between medical device classifications, familiarizing students with investigational device testing, the submission structure, and managing panel meetings. As well, the mechanics of preparing a submission will be presented and discussed. During the tutorial, we discuss a summary of requirements in Europe. These jurisdictions will be put into context with the US FDA system that students will have been familiarized with in BME1801.

Pre-clinical and clinical trial management

This session covers clinical studies and trials, Good Clinical Practice, hospital Investigational Review Boards, and the support requirements from Product Development.

Human Factors and Industrial Design

Getting from Good to Great. Human factor design is now a mandatory requirement in medical device development. Human factors and their implementation will be presented and discussed.

ISO 13485 Quality Standard

ISO 13485 is an International Standards Organization standard which requires an organization to design a quality management system that establishes and maintains the effectiveness of its processes. The culture of a successful medical device company is totally focused on its quality system. It affects all departments of the company and forms the basis of all activities, including product development. The content of this standard will be reviewed and discussed.

IEC 60601 Global Medical Device Standard

IEC 60601 is a family of technical standards for the development of medical devices.

The primary standard governing safe medical device design is IEC 60601-1. Topics including leakage current, defibrillator safety, electromagnetic radiation and mechanical strength. The specific requirements for many classes of devices will be presented and discussed.

Software Lifecycle

Software is a key part of most medical devices and is governed by IEC 62304. The Agile software development process will be presented.

Intellectual property and its management

This lecture will focus on the strategy of intellectual property management within a typical medical device company. This lecture will not cover patent search strategies since the students will have been introduced to this in BME1801.

Intellectual property enforcement

This lecture will focus on what a company does to stop those infringing on their patents. It also explores ways in which companies can examine existing IP to avoid infringement and enforcement issues.

Design Control - Design Transfer Phase

This lecture describes process development, method transfer, scale-up and quality assurance/quality control considerations when transitioning from discovery to production.

Appendix A – Rubric for the Term Projects

Project #1 - Submitted documents – Team Marks See Appendix B for a detailed rubric for each document					
	1	**2**	**3**	**4**	**Total**
Content	Student/Team omits or provides insufficient content on the topic	Student/Team addresses the topic, but the content provided is unclear or superficial	Student/Team provides a reasonable level of detail and explains the content well	Content on the topic is excellent and presented clearly and with the appropriate level of detail.	
Marketing Requirement Specification	Lacking or incomplete requirements that would not enable progress to the next level of Design Control. Requirements are not testable or traceable.	Minimal set of requirements with evidence of testability and traceability	Requirements that would likely pass a Design Review and allow the team to progress to the next step of Design Control	Excellent requirements including mandatory and optional that are comprehensive, testable and traceable.	/7
Hazard Analysis	Insufficient risk enumeration or mitigation for the considered design. Serious safety concerns.	Some evidence of serious consideration of potential risks and mitigations for the considered design, but remaining safety concerns	Reasonable level of risk planning and analysis for the considered design, supported with some level of detail	Comprehensive, thorough and well considered risk assessment and effective mitigations supported by an appropriate level of detail.	/14
Design and Development Plan	Plan does not show an understanding of the Design Control process. Resource requirements, budgets, and schedules lack credibility for the development of a commercial device.	Plan shows a basic understanding of Design Control. Details of plan execution show serious consideration but are incomplete.	Reasonably detailed and feasible plan that would likely pass a Design Review	Plan is fully compliant with Design Control. Details of plan execution are feasible within a commercial environment.	/7
Validation plan	Plan does not show an understanding of the validation process. Validation does not address or satisfy Marketing Requirements.	Validation procedures address Marketing Requirements but are incomplete or are not sufficient to demonstrate safety and efficacy.	Reasonably detailed validation plan that would likely pass a Design Review	Plans that call for the appropriate level of resources, would likely enable progress to the next level of Design Control, and would likely be acceptable to Regulatory agencies.	/7
New Technology Evaluation	Technologies are not characterized to the level needed to start development under Design Control. The evaluation fails to prove the case to continue the project.	Technologies have been characterized but there are serious concerns regarding technical or scientific viability.	Technologies have been well characterized and evaluated, but with some open questions remaining. Project can start development	Technologies have achieved proof of concept and evaluation is comprehensive. Project can start development under Design Control.	/7

			under Design Control.		
Project Integration and Appearance	There should be internal consistency between documents, demonstrating good communication within the team. This applies to both the appearance and content of the documents. Templates will be provided for all documents.				/8
				Total Points:	/50

Project 1 Design Review Presentation			
Content	Below expectation	Achieved expectation	Total
All team members present within allotted time	Deviation from allocated time > 1 minute	Deviation from allocated time < 1 minute	/2
All team members speak to class and not reading from notes	Reads from script; not everyone participates in questions and answers; a team member speaks over others	Speaks without a script; makes eye contact with class; every member contributed verbally to questions	/2
Each section of report was represented	Skipped section	All sections presented	/2
Concluding recommendation for each section	No recommendation given	States their opinion on whether the project proceeds	/2
Slide organization, clarity and answering questions	Difficult to follow; not used to clarify points; a few students dominate the question session and speaks over everyone else	Clear, legible, and supports what is presented orally; students don't block others from answering questions	/2
		Total Points:	/10

Project #2 - Submitted documents – Team Marks See Appendix B for a detailed rubric for each document					
Revisions to Project #1 documents	No revisions made	Revisions were attempted but some major deficiencies were not understood or were not addressed	Majority of revisions are appropriate, with special attention to risk management	Project #1 documents are revised appropriately and are now excellent	/12
Design Inputs	Lacking or incomplete requirements that would not enable	Minimal set of requirements with evidence of	Requirements that would likely pass a Design Review and allow the team to	Excellent requirements including mandatory and	/18

	progress to the next level of Design Control. Requirements are not testable or traceable.	testability and traceability.	progress to the next step of Design Control.	optional that are comprehensive, testable, and traceable.	
Verification plan	Plan does not show an understanding of the verification process. Verification does not address or satisfy Design Inputs and Risk Mitigations.	Verification procedures address Design Inputs and Risk Mitigations but are incomplete or are not sufficient to prove conformance.	Reasonably detailed Verification plan that would likely pass a Design Review	Plans that call for the appropriate level of resources, would likely enable progress to the next level of Design Control, and would likely be acceptable to Regulatory agencies.	/14
Traceability Matrix	Some Marketing Requirement Specification (MRS) elements are not covered by Design Inputs, risk mitigations are not traced, and errors are present in the table.	MRS requirements and risk mitigations are traced but the table contains omissions or serious errors	MRS requirements and risk mitigations are traced, but some errors in the table	All requirements, including risk mitigations are fully traceable in both MRS and Design Inputs, and are easy to follow	/6
				Total Points:	/50

Appendix B - Detailed Rubric for Documents

Project #1

Marketing Requirement Specification

Section	Marking Guide	Mark
Product Description	The system is described in enough detail to give the reader a complete understanding of the project. If this is an improvement to an existing device, students refer the reader to the MRS for the original device and then concentrate on the market requirements of the improvement and not the original product. The value proposition of the product or of the improvement are clear, compelling, and short. There are objectives regarding schedule and regulatory clearance. Sources of MRS requirements are stated.	1
Proposed Intended Use	The Intended Use should be clinical and consistent with the regulatory classification.	1
Standards List	All references and standards listed must are the correct version. There are 13485, 60601-1 (if electrical or mechanical),60601-1-2 (if electrical), 60601-1-6, FDA, Health Canada, Europe, 14971, 62304 and HIPAA and PIPEDA (if any software or firmware), 10993, ISTA 2 or 3 (if there is a device to be shipped), 14155 (if a clinical evaluation is required), 15223. There are standards that are specific to the project – one of the 60601-2 series, 60601-1-11 (home health care), ISO11135 or other sterilization standard if needed, wireless standards, etc. Anything with a battery needs one of the battery standards (IEC 60086-4 Ed. 5.0 b:2019). Anything with alarms needs the alarm standard (IEC 60601-1-8:2006). Does not list unneeded standards, which lead to unnecessary validation costs. Military standards are not listed unless there is a very good reason.	2
Product Requirements	MRS requirements are qualitative in nature, not technical, with some small exceptions. They are all from the User's point of view. Requirements are numbered. MRS #1 describes the clinical benefit or use of the product so that it is addressable in the Validation Plan. MRS is organized in a logical fashion – by function or by module, or any other logical sequence. Requirements are thorough – they must completely describe the product in terms of function, accuracy, appearance, usability, environment, patient characteristics, etc. All requirements are testable. Use of "shall", "should", and "may" must be appropriate. Requirements are practical and achievable. Requirements include price and shelf life.	3
	Total	**7**

New Technology Evaluation Report

Section	Marking Guide	Mark
Alignment with Corporate Objectives	Any reasonable corporate objective is acceptable – increase sales, capture a larger market share, increase profitability, be seen as an innovator, etc. The objective has something to do with making money. If the project is an improvement to an existing device, all sections should address the improvement or innovation instead of the total device.	1
Scientific Proof of Concept	Separate science from technology. Are there scientific questions that need to be answered before the engineering work can be done? For example, is the mechanism of action of a drug or material thoroughly understood? Is there good science behind the expected clinical efficacy? Since you have not had the opportunity to actually perform any experiments, state what needs to be done to achieve scientific validity and what the acceptance criteria are. If there is no science to complete, you should state that.	4 (both)

Technical Feasibility	The technologies that present the highest risk to the success of this project are fully characterized and shown to be feasible. The research and testing needed to demonstrate proof of concept is described. The potential for generating Intellectual Property (patents) is described. The engineering skills required to develop this technology are described along with a recommendation to either perform this development internally or subcontract the development. Other major risks, including availability of components or materials are discussed.	
Economic Viability	Estimate the cost of goods for the finished device and compare that with the price requirement from the MRS. Is there sufficient margin and/or return on investment? Is the market large enough? Is there reimbursement?	1
Overall Evaluation	Clearly articulates why the team is ready to proceed to the planning phase.	1
	Total	**7**

Hazard Analysis

Section	Marking Guide	Mark
Hazard Identification	If this is an improvement to an existing device, students refer the reader to the Hazard Analysis for the original device and then concentrate on the hazards of the improvement and not the original product. Sources of hazard identification are shown. Preferably, answers to Annex C questions and comments from Annex E (2012 edition) are shown Alternatively, Tables C1 and C2 from the 2019 edition are used. State other sources, which could include expert opinion, recalls, literature, etc. There must be traceability between the answers to the Annex or Tables to your hazard table. That is often done by numbering the hazards using the question numbers in the table, but any logical method is acceptable. The answers to the questions or tables need to make sense considering the risks of your product. You must have a statement of Essential Performance. You must identify hazards associated with unintentional and intentional misuse. Hazards must be listed before any mitigation.	5
Hazard Analysis	The assigned Probability and Severity ratings are reasonable. Any ratings that are not obvious include justification. Hazards that are potentially life-threatening have a severity of 5.	2
Mitigations	Mitigations are reasonable and practical. All hazards are mitigated as far as possible. Mitigations are examined for any new risks that are introduced. Mitigations are by design where possible. Labeling and training are not used to reduce the Hazard Risk Index.	4
Residual Risk	The revised Severity and Probability settings are reasonable and not simply designed to reduce all risks into the acceptable range. Generally, mitigations reduce the probability but not the severity. If you reduce severity, provide a rationale unless it is obvious. Labeling and training cannot be used to reduce HRI.	1.5
Risk/Benefit Analysis	There is a statement of risk/benefit. In the unlikely case that all residual risks are low, then a statement to that effect in included. In all other cases, a reasonable argument is provided as to why the benefit of your device outweighs the residual risks. Use objective evidence where possible.	1.5
	Total*	**14**

* The Hazard Analysis is worth 14 marks because it is the most complex document and needs participation from the whole group.

Validation Plan

Section	Marking Guide	Mark
Purpose/Scope	Identify the amount of clinical testing that needs to be done. If you believe that clinical trials are not required, provide justification. If your device is Class III, almost any significant improvement will require a new clinical trial. If your device is Class I or II, then you need to argue that the safety and clinical efficacy of your device or improvement can be assessed without a trial. All projects need a usability trial. If you need a clinical trial, then you should estimate the size. I am not expecting a statistical analysis, but you should quote trial sizes from predicate devices or competitors. There should be a statement of the scientific hypothesis for the study using terms like superiority or non-inferiority.	2
References and Standards	At a minimum you need to list clinical trial and usability standards - ISO 14155:2011 and IEC 62366-1:2015 and/or IEC60601-1-6:2010. There should be no standards listed that do not apply to your device.	0.2
Responsibilities	Qualified personnel are used to execute the plan and their responsibilities should match the work to be done.	0.2
System Description	The major parts in this section are Intended Use and Workflow. The scope of the validation plan should match the intended use. The workflow description should be comprehensive enough to guide a usability study.	1
Validation Testing	The testing plan is laid out in detail. If there is a clinical trial, then it includes the number of sites and number of patients, and primary and secondary endpoints. The inclusion and exclusion criteria ensures that recruitment will be fast (enough patients are included) but the risk of failure is low (enough patients with co-morbidities are excluded). The timelines projected are reasonable. There is a plan for usability testing.	1.5
Validation Reports	The validation report includes a Case Report form. There is a table of MRS requirements – each requirement should have a validation test and acceptance criteria. Acceptance criteria is quantitative, such as a score of 7 or above on a usability test questionnaire, or a sensitivity exceeding 80%, or fewer than 5 adverse events. Address validation and not verification – tests must be performed in a clinical setting and not on the bench. For example, battery life is validated by observing that the battery life is sufficient for the duration of the clinical case.	2
Reportable Events	See the sample document	0.1
	Total	**7**

Design and Development Plan

Section	Marking Guide	Mark
Scope	Describe the purpose and scope of the project	0.2
Design Process	Break down the project into tasks which are assigned either internally or to subcontractors. These tasks are logical and comprehensive. You should show engineering judgement as to the difficulty and complexity of each task and whether it can be accomplished in the required time span without seeking outside expertise. This section provides an indication of the size and complexity of the project. You should indicate if you are using a waterfall, agile, or other iterative process.	1
Project Deliverables	Deliverables include documents, prototypes, and tooling that will form the DMR. The deliverables are appropriate for the project.	0.5
Regulations and Standards	This list is comprehensive. It can include all the standards listed in the MRS and may also include other standards specifically related to the development process or manufacturing process. Ensure that all the standards listed are appropriate to the project.	0.2
Resource Requirements	This is a list of everyone who is working on the project, both internal and subcontractors. Qualified personnel should be used to execute the plan and their responsibilities match the work to be done.	1
Project Budget and Timelines	Divide the project into tasks and subtasks and make educated guesses about the resources and time required for each task. Show dependencies within the schedule when certain tasks cannot proceed until other tasks have been finished. Show the design phases – Planning, Design, Validation &Verification, and Design Transfer within the schedule, and within the Design Phase show any iterations described in the Design Process section. The schedule does not place the company in more than two design phases at once and ensures that the design is completely frozen (Design Phase complete) before the Validation & Verification phase is started. The budget should be derived from the schedule making reasonable assumptions for salaries, overheads, equipment required, and subcontractor costs.	2.5
Project Risks	Students should demonstrate that they understand the difference between project risks and product risks. At a minimum, project risks include financing, staff turnover, obsolescence of parts, and remaining technology risks.	1
Remaining sections	See the sample document	0.6
	Total	**7**

Project #2

Revisions to Project #1 documents (12 marks)

Section	Marking Guide	Mark
Response to the marking and the comments made to Assignment #1 documents	Revise your Assignment #1 documents to correct the deficiencies that were pointed out (in the event that the original document was awarded a perfect mark and there were no comments, then you get full marks without making changes).	6
	Documents must show a revision history with a good summary of changes.	2
Revisions made as a result of Planning Phase activities	At a minimum, the Hazard Analysis must show new risks and hazards that were identified. For each document, the revisions made should be reasonable and thorough.	4
	Total	**12**

Design Inputs (18 marks)

Section	Marking Guide	Mark
Document organization	Projects have several Design Input documents, which usually include: • Electrical • Mechanical • Packaging and Labeling (including IFU, labels on the device, labels on the packaging) • User Interface • Risk Mitigations Almost every project has additional Design Inputs to cover important technical aspects of the project, for example: • Disposables • Software and/or firmware • Cables • Environmental • Human Factors Design Inputs are comprehensive enough to fully implement Marketing Requirements.	4
MRS Requirements translated into Technical Requirements	Technical requirements show proper engineering knowledge and judgement. They are quantitative and practical and include reasonable tolerances or ranges. For example, how long a battery shall last should be translated into the size and capacity of the battery. They must be testable. Design Input documents must cover every aspect of your project, including power supplies, inputs and outputs, display, packaging and labeling, user manual, shipping labels, etc.	10
Risk Mitigations translated into Technical Requirements	See above.	4
	Total	**18**

Verification plan (12 marks)

Section	Marking Guide	Mark
Purpose/Scope	This section states that the objective of verification is to prove that Design Outputs conform to Design Inputs.	1
References and Standards	At a minimum you need to list the standards that are used for verification, for example IEC 60601-1 and IEC 60601-1-2. All standards have dates or version numbers. All standards listed apply to your device.	1
Responsibilities	Qualified personnel are used to execute the plan and their responsibilities match the work to be done. Staff responsibilities relate to the verification activities – who is responsible for carrying out the tests, who approves the reports, etc. Subcontractors such as testing agencies are included.	1
Device Description	This section describes the technical aspects of the device, including a full description of the different technologies that need to be verified and a list of the subassemblies.	2
Verification Testing	This document is organized to follow the Design Input documents – either by subassembly or by technology. Each Design Input has an appropriate verification test. Some requirements can be verified by referring to standards that are tested at 3rd party test labs, and some can be verified by inspection or by inspection of a Certificate of Compliance (CofC) if the supplier is certified. However, many if not most requirements must be verified through testing. Verification of dimensions and weights involving tight tolerances should include a quantity of parts to be inspected in order to confirm tolerances. All bench tests must properly verify the requirement and must have success criteria. Sample preparation and test procedures are either described in detail or referred to a separate document including the document name and number.	7
Verification Plan Schedule	The schedule gives an overview of the entire procedure, and includes both internal bench testing, preclinical testing, and testing at 3rd party labs.	2
	Total	14

Traceability Matrix (6 marks)

Section	Marking Guide	Mark
Overall	The Traceability Matrix ensures all Design Inputs and are traceable to the MRS requirements and both Design Inputs and Risk Mitigations are traceable to their verification procedures. Ensure that all MRS requirements are traced to at least one Design Input. Do not fill in the column for Design Outputs until the end of the Design Phase.	6
	Total	6