

## MENG3500: Medical Engineering Regulatory Requirements and Quality Systems

Callaghan

Semester 1 - 2024



THE UNIVERSITY OF  
NEWCASTLE  
AUSTRALIA

## OVERVIEW

<b>Course Description</b>	On completion of this course, students have a broad appreciation of the factors associated with the critical area of approval of medical devices prior to broad scale release. Students develop skills in product development both in terms of potential physical objects and the associated quality systems needed to ensure regulatory approvals. The course highlights how the regulated environment impacts the design, testing and delivery of medical devices. Invited speakers who currently work in the industry will present case studies on data collation and documentation methods necessary for the medical engineering field.
<b>Academic Progress Requirements</b>	Nil
<b>Contact Hours</b>	<b>Callaghan Lecture</b> Face to Face On Campus 2 hour(s) per week(s) for 13 week(s) starting Week 1  <b>Tutorial</b> Face to Face On Campus 2 hour(s) per week(s) for 12 week(s) starting Week 2
<b>Unit Weighting</b>	10
<b>Workload</b>	Students are required to spend on average 120-140 hours of effort (contact and non-contact) including assessments per 10 unit course.

# COURSE OUTLINE

# CONTACTS

<b>Course Coordinator</b>	<b>Callaghan</b> Prof Andrew Fleming Andrew.Fleming@newcastle.edu.au (02) 4921 6493 Consultation: Wednesday 2pm to 3pm in EAG29
<b>Teaching Staff</b>	Other teaching staff will be advised on the course Canvas site.
<b>School Office</b>	<b>School of Engineering</b> EAG02 EA Building Callaghan +61 2 4921 5798 9.00am-1.00pm and 2.00pm-5.00pm (Monday to Friday)

# SYLLABUS

<b>Course Content</b>	<ul style="list-style-type: none"><li>• Medical engineering regulation: history and rationale</li><li>• Best practice processes for design and manufacturing to meet regulatory requirements in medical engineering</li><li>• General standards in medical engineering</li><li>• Benefit-risk considerations</li><li>• Specific safety systems and standards</li><li>• Software development requirements in medical systems</li><li>• Quality systems in medical engineering</li><li>• Documentation for device approvals: requirements and obligations</li><li>• Post-market responsibilities</li></ul>
<b>Course Learning Outcomes</b>	<p><b>On successful completion of this course, students will be able to:</b></p> <ol style="list-style-type: none"><li>1. Describe the principles of operation of the major medical device regulatory systems in a global context</li><li>2. Apply key regulatory concepts to a medical device development process, including intended use and risk class</li><li>3. Operate within a quality management system to maintain compliance to key design, manufacturing and post-market requirements</li><li>4. Produce an industry relevant risk assessment of a medical device</li><li>5. Determine relevant standards applying to medical device development</li><li>6. Create the technical documentation required for medical device market authorisation</li></ol>
<b>Course Materials</b>	<p><b>Lecture Materials:</b></p> <ul style="list-style-type: none"><li>- Lecture notes are available on Canvas</li></ul>

# ASSESSMENTS

This course has 4 assessments. Each assessment is described in more detail in the sections below.

	Assessment Name	Due Date	Involvement	Weighting	Learning Outcomes
1	Quizzes x 2	See weekly schedule on Canvas	Individual	20%	1, 2, 3, 5
2	Assignment 1	See weekly schedule on Canvas	Group	35%	2, 4, 5, 6
3	Assignment 2	See weekly schedule on Canvas	Individual	15%	2, 4, 5, 6
4	Examination	Final Examination Period	Individual	30%	1, 2, 3, 4, 5, 6

**Late Submissions** The mark for an assessment item submitted after the designated time on the due date, without an approved extension of time, will be reduced by 10% of the possible maximum mark for that assessment item for each day or part day that the assessment item is late. Note: this applies equally to week and weekend days.

## Assessment 1 - Quizzes x 2

**Assessment Type** Quiz  
**Purpose** To provide students with feedback on student learning and stimulate discussion with lecturers and tutors.  
**Description** Each quiz contributes 10% to the final mark.  
**Weighting** 20%  
**Length** 1 hour  
**Due Date** See weekly schedule on Canvas  
**Submission Method** Online  
**Assessment Criteria** Refer to the quiz description in Canvas for detailed assessment criteria  
**Return Method** Online  
**Feedback Provided** Online - One week after quiz.  
**Opportunity to Reattempt** Students WILL NOT be given the opportunity to reattempt this assessment.

## Assessment 2 - Assignment 1

**Assessment Type** Written Assignment  
**Purpose** To apply course material to practical applications.  
**Description** Independent research is conducted then presented in a professional report format. Refer to Canvas for a detailed description.  
**Weighting** 35%  
**Due Date** See weekly schedule on Canvas  
**Submission Method** Online  
**Assessment Criteria** Refer to the assignment description in Canvas for detailed assessment criteria  
**Return Method** Online  
**Feedback Provided** Online - One week after due date.  
**Opportunity to Reattempt** Students WILL NOT be given the opportunity to reattempt this assessment.

## Assessment 3 - Assignment 2

**Assessment Type** Written Assignment  
**Purpose** To apply course material to practical applications.  
**Description** Independent research is conducted then presented in a professional report format. Refer to Canvas for a detailed description.  
**Weighting** 15%  
**Due Date** See weekly schedule on Canvas  
**Submission Method** Online  
**Assessment Criteria** Refer to the assignment description in Canvas for detailed assessment criteria  
**Return Method** Online  
**Feedback Provided**  
**Opportunity to Reattempt** Students WILL NOT be given the opportunity to reattempt this assessment.

## Assessment 4 - Examination

<b>Assessment Type</b>	Formal Examination
<b>Purpose</b>	To test knowledge of the course material and ability to describe, analyse and hypothesise from this material.
<b>Description</b>	Formal examination covering all course material.
<b>Weighting</b>	30%
<b>Length</b>	2 hours
<b>Due Date</b>	Final Examination Period
<b>Submission Method</b>	Formal Exam
<b>Assessment Criteria</b>	Correct understanding and application of course content.
<b>Return Method</b>	Not Returned
<b>Feedback Provided</b>	No Feedback
<b>Opportunity to Reattempt</b>	Students WILL NOT be given the opportunity to reattempt this assessment.

## ADDITIONAL INFORMATION

### Grading Scheme

This course is graded as follows:

Range of Marks	Grade	Description
85-100	High Distinction (HD)	Outstanding standard indicating comprehensive knowledge and understanding of the relevant materials; demonstration of an outstanding level of academic achievement; mastery of skills*; and achievement of all assessment objectives.
75-84	Distinction (D)	Excellent standard indicating a very high level of knowledge and understanding of the relevant materials; demonstration of a very high level of academic ability; sound development of skills*; and achievement of all assessment objectives.
65-74	Credit (C)	Good standard indicating a high level of knowledge and understanding of the relevant materials; demonstration of a high level of academic achievement; reasonable development of skills*; and achievement of all learning outcomes.
50-64	Pass (P)	Satisfactory standard indicating an adequate knowledge and understanding of the relevant materials; demonstration of an adequate level of academic achievement; satisfactory development of skills*; and achievement of all learning outcomes.
0-49	Fail (FF)	Failure to satisfactorily achieve learning outcomes. If all compulsory course components are not completed the mark will be zero. A fail grade may also be awarded following disciplinary action.

\*Skills are those identified for the purposes of assessment task(s).

### Communication Methods

Communication methods used in this course include:

- Canvas Course Site: Students will receive communications via the posting of content or announcements on the Canvas course site.

### Course Evaluation

Each year feedback is sought from students and other stakeholders about the courses offered in the University for the purposes of identifying areas of excellence and potential improvement.

### Oral Interviews (Vivas)

As part of the evaluation process of any assessment item in this course an oral examination (viva) may be conducted. The purpose of the oral examination is to verify the authorship of the material submitted in response to the assessment task. The oral examination will be conducted in accordance with the principles set out in the [Oral Examination \(viva\) Procedure](#). In cases where the oral examination reveals the assessment item may not be the student's own work the case will be dealt with under the [Student Conduct Rule](#).

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<b>Academic Misconduct</b>	All students are required to meet the academic integrity standards of the University. These standards reinforce the importance of integrity and honesty in an academic environment. Academic Integrity policies apply to all students of the University in all modes of study and in all locations. For the Student Academic Integrity Policy, refer to <a href="https://policies.newcastle.edu.au/document/view-current.php?id=35">https://policies.newcastle.edu.au/document/view-current.php?id=35</a> .
<b>Adverse Circumstances</b>	<p>The University acknowledges the right of students to seek consideration for the impact of allowable adverse circumstances that may affect their performance in assessment item(s). Applications for special consideration due to adverse circumstances will be made using the online Adverse Circumstances system where:</p> <ol style="list-style-type: none"><li>1. the assessment item is a major assessment item; or</li><li>2. the assessment item is a minor assessment item and the Course Co-ordinator has specified in the Course Outline that students may apply the online Adverse Circumstances system;</li><li>3. you are requesting a change of placement; or</li><li>4. the course has a compulsory attendance requirement.</li></ol> <p>Before applying you must refer to the Adverse Circumstance Affecting Assessment Items Procedure available at: <a href="https://policies.newcastle.edu.au/document/view-current.php?id=236">https://policies.newcastle.edu.au/document/view-current.php?id=236</a></p>
<b>Important Policy Information</b>	<p>The Help button in the Canvas Navigation menu contains helpful information for using the Learning Management System. Students should familiarise themselves with the policies and procedures at <a href="https://www.newcastle.edu.au/current-students/respect-at-uni/policies-and-procedures">https://www.newcastle.edu.au/current-students/respect-at-uni/policies-and-procedures</a> that support a safe and respectful environment at the University.</p>

*This course outline was approved by the Head of School on 12.02.2024. No alteration of this course outline is permitted without Head of School approval. If a change is approved, students will be notified and an amended course outline will be provided in the same manner as the original.*

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### Graduate Profile Statements – MENG3500 – S1 2024

This course builds students' capacity in the following University of Newcastle Bachelor of Engineering Graduate Profile Statements (based on 2011 Engineers Australia revised Stage 1 Competency Standards for Professional Engineers):

UON Att.	University of Newcastle Bachelor of Engineering Graduate Profile Statements/ Engineers Australia Stage 1 competency statements	Taught	Practised	Assessed	Skill Level (1-4)
	<b>Professional Attributes</b>				
11	3.1. Ethical conduct and professional accountability	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3
12	3.2. Effective oral and written communication in professional and lay domains.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3
13	3.3. Creative, innovative and pro-active demeanour.				
14	3.4. Professional use and management of information.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3
15	3.5. Orderly management of self, and professional conduct.				
16	3.6. Effective team membership and team leadership.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3
	<b>Engineering Ability</b>				
7	2.1. Application of established engineering methods to complex engineering problem solving.				
8	2.2. Fluent application of engineering techniques, tools and resources.				
9	2.3. Application of systematic engineering synthesis and design processes.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3
10	2.4. Application of systematic approaches to the conduct and management of engineering projects.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4
	<b>Knowledge Base</b>				
1	1.1. Comprehensive, theory based understanding of the underpinning natural and physical sciences and the engineering fundamentals applicable to the engineering discipline.				
2	1.2. Conceptual understanding of the, mathematics, numerical analysis, statistics, and computer and information sciences which underpin the engineering discipline.				
3	1.3. In-depth understanding of specialist bodies of knowledge within the engineering discipline.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2
4	1.4. Discernment of knowledge development and research directions within the engineering discipline.				
5	1.5. Knowledge of contextual factors impacting the engineering discipline.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2
6	1.6. Understanding of the scope, principles, norms, accountabilities and bounds of contemporary engineering practice in the specific discipline.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4