NANYANG TECHNOLOGICAL UNIVERSITY SINGAPORE

COURSE CONTENT

Academic Year	2022/2023	**Semester**	2
Course Coordinator	Jack Wong		
Course Code	BG4313		
Course Title	Global Medical Device Regulatory Overview		
Pre-requisites	Nil		
No of AUs	3		
Contact Hours	*39 hours lecture, 0 hours tutorial*		
Proposal Date	*28 Jan 2021*		

Course Aims

Knowledge of medical device regulatory affairs (MDRA) is critical for the development, commercialization, and distribution of safe and effective healthcare products. This course aims to provide you with an overview of medical device regulatory systems globally.

Intended Learning Outcomes (ILO)

At the end of this course, you will be able to:

1. Describe common regulatory systems for Medical Devices and rationale for regulatory policies.
2. Outline the engineering activities, resources, and tests required as part of a high-level R&D plan.
3. Determine the risks and opportunities associated with different regulatory strategies

Course Content

Medical Device Fundamentals
Regulatory Affairs and Medical Innovations
Regulatory Systems in Key Countries
Use of Standards in MedTech Development
Overview of Singapore's Medical Device Regulatory Framework
Regulatory related soft skills

Assessment (includes both continuous and summative assessment)

Component	Course LO Tested	Related Programme LO or Graduate Attributes	Weighting	Team /Individual	Assessment rubrics
a. CA1 - Group Project (30%)	2	d, j	30%	Team	Appendix 1 to 3
b. CA2 - Presentation on Regulatory Strategy (20%)	3	c, f, i, j, k	20%	Team	Appendix 1 to 3
c. Final Examinations (50%) (2hrs Open Book)	1, 2, 3	b, c, f	50%	Individual	Exam
Total			100%		

Mapping of Course ILOs to EAB Graduate Attributes

Course Intended Learning Outcomes	Cat	EAB's 12 Graduate Attributes*											
		(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)
	Core	š	◐	◐	◐		◐		š	š	š	Š	
Describe common regulatory systems for Medical Devices and rationale for regulatory policies.												f	
Outline the engineering activities, resources, and tests required as part of a high-level R&D plan.												a, b, d, f, k	
Understand the risks and opportunities associated with different regulatory strategies.												a, b, c, f, h, k	

Legend:
- ● Fully consistent (contributes to more than 75% of Intended Learning Outcomes)
- ◐ Partially consistent (contributes to about 50% of Intended Learning Outcomes)
- š Weakly consistent (contributes to about 25% of Intended Learning Outcomes)
- Blank Not related to Student Learning Outcomes

Formative feedback

i. Term papers will be graded with comments uploaded onto NTULearn
ii. Practical reports will be graded with comments uploaded onto NTULearn
iii. Immediate feedback will be provided at the end of presentations.

Learning and Teaching approach

Approach	How does this approach support students in achieving the learning outcomes?
Lecture	Didactic lectures will be supplemented by real life examples; guest speakers invited from industry to provide case studies.

Reading and References

Handbook of Medical Device Regulatory Affairs in Asia Paperback by Jack Wong (Editor), Raymond Tong (Editor)
ISBN-13: 978-9814411219 ISBN-10: 9814411213 Edition: 2nd

Course Policies and Student Responsibilities

General: Students are expected to complete all online activities and take all scheduled assignments and tests by due dates. Students are expected to take responsibility to follow up with course notes, assignments and course related announcements. Students are expected to participate in all tutorial discussions and activities.

Continuous assessments: Students are required to attend all continuous assessments.
Absenteeism: Continuous assessments make up a significant portion of students' course grade. Absence from continuous assessments without officially approved leave will result in no marks and affect students' overall course grade.

Academic Integrity

Good academic work depends on honesty and ethical behaviour. The quality of your work as a student relies on adhering to the principles of academic integrity and to the NTU Honour Code, a set of values shared by the whole university community. Truth, Trust and Justice are at the core of NTU's shared values.

As a student, it is important that you recognize your responsibilities in understanding and applying the principles of academic integrity in all the work you do at NTU. Not knowing what is involved in maintaining academic integrity does not excuse academic dishonesty. You need to actively equip yourself with strategies to avoid all forms of academic dishonesty, including plagiarism, academic fraud, collusion and cheating. If you are uncertain of the definitions of any of these terms, you should go to the academic integrity website for more information. Consult your instructor(s) if you need any clarification about the requirements of academic integrity in the course.

Course Instructors

Instructor	Office Location	Phone	Email
Adjunct AP Jack Wong	NIL	NIL	jack.wong@ntu.edu.sg

Planned Weekly Schedule

Week	Topic	Course LO	Readings/ Activities
1	**Introduction** Topic 1 – Course Objectives & Administrative Details Topic 2 – Why Study Regulatory Systems? Topic 3 – The Need for Regulatory Systems	1	Cover by Jack
2	**Medical Device Fundamentals** Topic 1 – What is a Medical Device? Topic 2 – Classification of Medical Devices Topic 3 – Quality Management Systems Topic 4 – Regulation of Medical Devices	1	Cover by Jack
3	**Regulatory Affairs and Medical Innovations** Topic 1 - Regulatory affairs and a Start-up's journey Topic 2 - Regulatory systems: Evolution towards innovation	2	Intended to invite SME management to share
4	**Regulatory Affairs and Medical Innovations** Topic 3 - Developing an R&D strategy Topic 4 - Developing a regulatory strategy	2	Intended to invite SME management to share
5	**Regulatory Affairs and Medical Innovations** Topic 5 - Developing a clinical strategy Topic 6 - From regulatory to reimbursements	2	Intended to invite SME management to share
6	**Regulatory Systems in Key Countries (Part I)** Topic 1 – Regulatory Systems in US Topic 2 – Regulatory Systems in EU	3	Cover by Jack

7	**Use of Standards in Medical Innovations** Topic 1 – ISO 13478 Topic 2 – ISO 14971	2	Intended to invite Notified body to share
8	**Overview of Singapore's Medical Device Regulatory Framework** Topic 1 – Introduction (ILT) Topic 2 – Regulatory Philosophy Topic 3 – Principles of Regulation Topic 4 – Risks (ILT) Topic 5 – Overview of HSA Topic 6 – Regulatory Framework and Approach	3	Covered by HSA (Chris)
9	**Regulatory Requirements for Medical Device Registration** Topic 1 – Introduction Topic 2 – Regulatory Approach Topic 3 – Risk-based Approach Topic 4 – Scope of Technical Review Requirements Topic 5 – Medical Device Combinations	3	Covered by HSA (Chris)
10	**Practical Session on real submission in Singapore**	3	Covered by consultant
11	**Regulatory Systems in Key Countries (Part II)** Topic 1 – Regulatory Systems in Asia Topic 2 – Introduction to ISO 13485	3	Cover by Jack
12	**Regulatory related soft skills** Topic 1 – Job interview Topic 2 – Project Management skill Topic 3 – Stakeholder Management skill	2	Cover by Jack and guest speakers
13	**Regulatory Strategy Presentation**	3	

Appendix 1: Assessment Criteria

You will be required to prepare an essay to discuss the latest regulatory changes in the field. The grading will be based on the ICE approach as follows:

Ideas represent the building blocks of learning. They are the fundamental, discrete pieces of information that make up the basics of new learning. Some teachers describe Ideas as being only information, something students acquire then possess. They include facts, definitions, vocabulary, steps in a process and discrete skills. Any reiteration, or recall of information from a textbook, notes or lecture can be said to be a demonstration of Ideas level learning.

Connections are of two kinds: those made at the content level and those that may be said to be personal meaning-making. Connections at the content level are demonstrated when students are able to articulate relationships among discrete Ideas. When you are able to describe cause-and-effect relationships, articulate the relationship between or among concepts, or when you are able to successfully blend two or more discrete skills into a fluid, efficient movement, they are demonstrating Connections at the content level. Connections at the more personal, meaning-making level are demonstrated when students are able to relate their new learning to what they already know. It is during this phase of personal meaning-making that learning appears to take on a new dimension in that it seems to become more easily retrievable and longer-term than learning at the Ideas level.

At the **Extensions** stage, new learning is created from old so that you are able to use it in novel and creative ways that may well be quite far removed from the original learning context. The learning becomes internalized to such a degree that it helps students answer extrapolative questions, articulate implications, and anticipate outcomes. Extensions are referred to by some as the AHA! phase of learning and by others as the “so what?” phase. The “so what” question is the one that is often left unasked: So, now that you know what you know, what difference does it make to the way you see the world and to what you can do? Students reaching Extensions are able to answer those questions.

From “Young, S. Fostaty. "Teaching, learning, and assessment in higher education: Using ICE to improve student learning." Proceedings of the Improving Student Learning Symposium. 2005.

Grading rubrics:

Content Area	**Ideas**	**Connections**	**Extensions**	**Totals**
Understanding of the US FDA context	20	10		30
Understanding of the chosen Asian country regulatory authority	20	10		30
Highlighted key similarities and differences in systems		10	10	20
Desirable improvements for an “ideal” system			10	10
Mechanics (paper organisation, ease of reading)				10
				100

Appendix 2

Criteria	Unsatisfactory: <40%	Borderline: 40% to 49%	Satisfactory: 50% to 69%	Very good: 70% to 89%	Exemplary: >90%
Knowledge Understanding the relevance of cell viability assays in the context of biocompatibility testing	Lacks understanding of theories, concepts, and terms governing biocompatibility testing	Partial understanding of theories, concepts, and terms governing biocompatibility testing	Good understanding of theories, concepts, and terms governing biocompatibility testing	Good and comprehensive understanding of the theories, concepts, and terms understanding of theories, concepts, and terms governing biocompatibility testing	Very good and comprehensive understanding of theories, concepts, and terms governing biocompatibility testing
Analysis The ability to analyze and present cell compatibility results	Unable to apply the theories and concepts to interpret cell viability assays	Can apply the theories and concepts to interpret cell viability assays	Can apply the theories and concepts to interpret cell viability assays and provide some conclusions on biocompatibility	Can apply the theories and concepts to interpret cell viability assays and to arrive at correct conclusions on biocompatiblity	Can apply the theories and concepts to interpret cell viability assays and to arrive at correct conclusions on biocompatibility, with good presentation of data

Appendix 3

Component	Score			
	0	**1**	**2**	**3**
Description of product (20%)	Identified product is not a medical device	Identified product is a device, but description or justification missing	Correctly identified product, but description or justification unclear	Full description and clear justification of product as a combination device
Identified documentation (20%)	Appropriate trials and / or safety requirements not identified	Appropriate trials and / or safety requirements inadequately identified	Trials and safety requirements correctly identified, but inadequately described	Trials and safety requirements correctly identified and well-described
Description of registration strategy (30%)	Strategy not presented	Strategy presented was unsound and / or impractical	Strategy presented was clear and practical	Strategy presented demonstrated was innovative and demonstrated clear mastery of regulatory principles
Organization (10%)	Audience cannot understand presentation because there is no sequence of information.	Audience has difficulty following presentation because student jumps around.	Student presents information in logical sequence which audience can follow.	Student presents information in logical, interesting sequence which audience can follow.
Keeping to time (5%)	Failed to keep to stipulated time	N.A.	N.A.	Kept to stipulated time
Bonus discretionary Score (5%) Peer Review (10%)				

Appendix 4: The EAB (Engineering Accreditation Board) Accreditation SLOs (Student Learning Outcomes)

a) **Engineering knowledge:** Apply the knowledge of mathematics, natural science, engineering fundamentals, and an engineering specialisation to the solution of complex engineering problems.

b) **Problem Analysis:** Identify, formulate, research literature, and analyse complex engineering problems reaching substantiated conclusions using first principles of mathematics, natural sciences, and engineering sciences.

c) **Design/development of Solutions:** Design solutions for complex engineering problems and design system components or processes that meet the specified needs with appropriate consideration for public health and safety, cultural, societal, and environmental considerations.

d) **Investigation:** Conduct investigations of complex problems using research-based knowledge and research methods including design of experiments, analysis and interpretation of data, and synthesis of the information to provide valid conclusions.

e) **Modern Tool Usage:** Create, select, and apply appropriate techniques, resources, and modern engineering and IT tools including prediction and modelling to complex engineering activities with an understanding of the limitations.

f) **The engineer and Society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety, legal, and cultural issues and the consequent responsibilities relevant to the professional engineering practice.

g) **Environment and Sustainability:** Understand the impact of the professional engineering solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for the sustainable development.

h) **Ethics:** Apply ethical principles and commit to professional ethics and responsibilities and norms of the engineering practice.

i) **Individual and Teamwork:** Function effectively as an individual, and as a member or leader in diverse teams and in multidisciplinary settings.

j) **Communication:** Communicate effectively on complex engineering activities with the engineering community and with society at large, such as, being able to comprehend and write effective reports and design documentation, make effective presentations, and give and receive clear instructions.

k) **Project Management and Finance:** Demonstrate knowledge and understanding of the engineering and management principles and economic decision-making, and apply these to one's own work, as a member and leader in a team, to manage projects and in multidisciplinary environments.

l) **Life-long Learning:** Recognise the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change.