Annexe A: New/Revised Course Content in OBTL+ Format

Course Overview

The sections shown on this interface are based on the templates UG OBTL+ or PG OBTL+

If you are revising/duplicating an existing course and do not see the pre-filled contents you expect in the subsequent sections e.g. Course Aims, Intended Learning Outcomes etc. please refer to Data Transformation Status for more information.

Expected Implementation in Academic Year	AY2023-2024
Semester/Trimester/Others (specify approx. Start/End date)	Semester 2
Course Author * Faculty proposing/revising the course	Su Luanyu, Dacia
Course Author Email	dacia.su@main.staff.ntu.edu.sg
Course Title	Global Medical Device Regulatory Overview
Course Code	BG4313
Academic Units	3
Contact Hours	39
Research Experience Components	Not Applicable

Course Requisites (if applicable)

Pre-requisites	
Co-requisites	
Pre-requisite to	
Mutually exclusive to	
Replacement course to	
Remarks (if any)	

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.

Course's Intended Learning Outcomes (ILOs)

Upon the successful completion of this course, you (student) would be able to:

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

Course Content

Medical Device Fundamentals
Regulatory Systems in Key Countries
Use of Standards in MedTech Development
Overview of Singapore's Medical Device Regulatory Framework
Regulatory related softskills

Reading and References (if applicable)

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

Planned Schedule

Week or Session	Topics or Themes	ILO	Readings	Delivery Mode	Activities
1	Introduction Topic 1 – Course Objectives & Administrative Details Topic 2 – Why Study Regulatory Systems? Topic 3 – The Need for Regulatory Systems	1			
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			
3	Singapore's Medical Device Regulatory Framework	2			
4	Singapore's Medical Device Regulatory Framework	2			
5	Singapore's Medical Device Regulatory Framework	2			

Week or Session	Topics or Themes	ILO	Readings	Delivery Mode	Activities
6	Singapore's Medical Device Regulatory Framework	3			
7	Regulatory Strategy Presentations	2			
8	Regulatory Strategy Presentations	3			
9	Regulatory Systems in Key Countries (ASEAN)	3			
10	Regulatory Systems in Key Countries(Asia)	3			
11	Regulatory Systems in Key Countries (Global)	3			
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			

Learning and Teaching Approach

Approach	How does this approach support you in achieving the learning outcomes?
Presentation	Allows students to practise their presentation and to learn from each other on strength and weaknesses

Assessment Structure

Assessment Components (includes both continuous and summative assessment)

No.	Component	ILO	Related PLO or Accreditation	Weightage	Team/Individual	Rubrics	Level of Understanding
1	Continuous Assessment (CA): Project(Group Project)	1,2 & 5	a,b,c	30	Team		
2	Continuous Assessment (CA): Presentation(Presentation on Regulatory Soft Skills)	9	i & k	20	Team		
3	Summative Assessment (EXAM): Final exam(Final Examination)	3,4,5,6,7 & 8	a,b,c,d,f & i	50	Individual		

Description of Assessment Components (if applicable)

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.

NTU Graduate Attributes/Competency Mapping

This course intends to develop the following graduate attributes and competencies (maximum 5 most relevant)

Attributes/Competency	Level
Adaptability	Advanced
Global Perspective	Basic

Course Policy

Policy (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. On the use of technological tools (such as Generative AI tools), different courses / assignments have different intended learning outcomes. Students should refer to the specific assignment instructions on their use and requirements and/or consult your instructors on how you can use these tools to help your learning. Consult your instructor(s) if you need any clarification about the requirements of academic integrity in the course.

Policy (General)

(1) 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

Policy (Absenteeism)

(2) Absenteesim

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.

Policy (Others, if applicable)

Continuous assessments: Students are required to attend all continuous assessments

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Last Updated By: Song Juha (Assoc Prof)

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ppendix 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%)				

Mapping of Course ILOs to EAB Graduate Attributes

Course Code & Title	BG4313 Global Medical Device Regulatory Overview
Course Type	UNDERGRADUATE

Overview											
(a)	◑	(b)	○	(c)	○	(d)	◑	(e)		(f)	◑
(g)		(h)		(i)○	◑	(j)		(k)	○		

Legend:
- ●   Fully consistent (contributes to more than 75% of Student Learning Outcome)
- ◑   Partially consistent (contributes to about 50% of Student Learning Outcome)
- ○   Weakly consistent (contributes to about 25% of Student Learning Outcome)
- Blank   Not related to Student Learning Outcome

Course ILOs		EAB Graduate Attributes
1)	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	a,c
2)	Singapore's Medical Device Regulatory Framework Topic 1 - Determine the Evaluation Routes. Topic 2 - Prepare for Submissions- Required Documents, Registration Fees & Approval Timelines	b,c
3)	Singapore's Medical Device Regulatory Framework Topic 1 - Telehealth Products Topic 2 - Softwares	a,f
4)	Singapore's Medical Device Regulatory Framework Topic 1 - Dealers Licensing Topic 2 - GDPMDS, ISO 13485 & MDSAP	c,i
5)	Singapore's Medical Device Regulatory Framework Topic 1 – Post Submissions	a,b
6)	Regulatory Systems in ASEAN	d,f
7)	Regulatory Systems in Asia	d,f
8)	Regulatory Systems in Global	d,f
9)	Regulatory related soft skills Topic 1 – Job interview Topic 2 – Project Management skill Topic 3 – Stakeholder Management skill	i,k

EAB Graduate Attributes

a) **Engineering Knowledge**: Apply the knowledge of mathematics, natural science, computing and engineering fundamentals, and an engineering specialisation as specified in WK1 to WK4 respectively 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 with holistic considerations for sustainable development. (WK1 to WK4)

c) **Design / Development of Solutions**: Design creative solutions for complex engineering problems and design systems, components or processes that meet identified needs with appropriate consideration for public health and safety, whole-life cost, net zero carbon as well as resource, cultural, societal, and environmental considerations as required. (WK5)

d) **Investigation**: Conduct investigations of complex problems using research-based knowledge (WK8) 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 problems, with an understanding of the limitations. (WK2 and WK6)

f) **The Engineer and the World**: When solving complex engineering problems, analyse and evaluate sustainable development impacts to: society, the economy, sustainability, health and safety, legal frameworks and the environment (WK1, WK5, and WK7).

g) **Ethics**: Apply ethical principles and commit to professional ethics and responsibilities and norms of engineering practice and adhere to relevant national and international laws. Demonstrate an understanding of the need for diversity and inclusion (WK9).

h) **Individual and Collaborative Team Work**: Function effectively as an individual, and as a member or leader in diverse and inclusive teams and in multidisciplinary, face-to-face, remote and distributed settings (WK9).

i) **Communication**: Communicate effectively and inclusively 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, taking into account cultural, language, and learning differences.

j) **Project Management and Finance**: Demonstrate knowledge and understanding of engineering 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.

k) **Life-long Learning**: Recognise the need for, and have the preparation and ability to (i) engage in independent and life-long learning, and (ii) adapt to new and emerging technologies, and (iii) think critically, in the broadest context of technological change (WK8).

No	Knowledge Profile
WK1	A systematic, theory-based understanding of the natural sciences applicable to the discipline and awareness of relevant social sciences
WK2	Conceptually-based mathematics, numerical analysis, data analysis, statistics and formal aspects of computer and information science to support detailed analysis and modelling applicable to the discipline
WK3	A systematic, theory-based formulation of engineering fundamentals required in the engineering discipline
WK4	Engineering specialist knowledge that provides theoretical frameworks and bodies of knowledge for the accepted practice areas in the engineering discipline; much is at the forefront of the discipline
WK5	Knowledge including efficient resource use, environmental impacts, whole-life cost, re-use of resources, net zero carbon, and similar concepts that supports engineering design and operations in a practice area
WK6	Knowledge of engineering practice (technology) in the practice areas in the engineering discipline
WK7	Knowledge of the role of engineering in society and identified issues in engineering practice in the discipline such as the professional responsibility of an engineer to public safety and sustainable development.
WK8	Engagement with selected knowledge in the current research literature of the discipline, awareness of the power of critical thinking and creative approaches to evaluate emerging issues
WK9	Knowledge of professional ethics, responsibilities, and norms of engineering practice. Awareness of the need for diversity by reason of ethnicity, gender, age, physical ability etc with mutual understanding and respect, and of inclusive attitudes

Reference: EAB Accreditation Manual