Nanyang Technological University
Division of Chemistry and Biological Chemistry

Academic Year	AY21/22	**Semester**	1
Course Coordinator	Zheng Yiying		
Course Code	CM9202		
Course Title	Quality Assurance for Medical Products		
Pre-requisites	NIL		
Mutually Exclusive	NIL		
No of AUs	3		
Contact Hours	Lectures: 39 hours		
Proposal Date	4 January 2021		

Course Aims

This course aims to provide the application of standards and regulations to the development and commercialization of drugs, biologics and medical devices. Throughout the course, you will learn about the regulations needed to ensure the quality of drugs, biologics, and medical devices in the pharmaceutical, biotechnology, and medical device industries, and gain an understanding of the principles required for the interpretation and implementation of a quality system.

Intended Learning Outcomes (ILO)

By the end of this course, you should be able to:

1. Define quality and explain how to measure performance against quality standards
2. Compare Good Laboratory Practice (GLP) and Good Manufacturing Practices (GMP), which are industry-specific guidelines for compliance in the stages of design, testing, manufacturing and distributing medical products
3. Describe the Quality Management System (QMS) that directs and controls a pharmaceutical, biotechnology, medical device company in terms of quality
4. Administer the creation, approval, distribution, usage and updates of documents and records (documented information) used in the QMS
5. Recognise the basics of auditing for regulators
6. Apply the Statistical Process Control (SPC), which is an industry-standard methodology for measuring and controlling quality during manufacturing
7. Create the first Standard Operating Procedure (SOP) so that all the SOPs written thereafter will be in a consistent format
8. Explain Corrective and Preventive Action (CAPA) and work in a group to develop a CAPA plan
9. Define new product designs and the requisite manufacturing process by combining market requirements, technological capabilities, and resources
10. Chart the flow of goods, data, and finances related to a product from the procurement of raw materials to the delivery of the product at its destination
11. Develop streamlined industrial supply activities to maximize customer value and gain a competitive advantage in the marketplace

Course Content

Quality and Quality Metrics.

Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP).

Pharmaceutical Quality Systems: ICH Q10; ISO 9000 and Process Analytical Technology (PAT)
ICH Q10 Pharmaceutical Quality System

Quality Systems for Biologics: ICH Q5
ICH Q5A-Q5E Quality of Biotechnological Products
ICH Q5A(R1) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
ICH Q5A(R2) EWG Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
ICH Q5B Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products
ICH Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products
ICH Q5D Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products
ICH Q5E Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process

Quality Systems for Medical Devices: FDA Quality System Regulation (QSR); ISO 13485

Documentation and Records

Auditing Principles: Inspection Types, Inspection Outcomes,
Possible Issues: Facility, Equipment, Quality, Material, Production, Laboratory
FDA Inspections and Enforcement Actions: Administrative, Judicial
What to Expect from a FDA Audit
Management → Design Controls, Production and Process Controls,
Records/Documents/Change Controls, Material Controls, Facility and Equipment Controls,
Corrective and Preventive Actions (CAPA)
FDA Inspections will Follow Major GMP Quality Systems
Inspection Preparation

Statistical Process Control (SPC)

Corrective and Preventive Action (CAPA)
Three Concepts: Correction, Corrective Action, Preventive Action
Five Parts: Identification, Evaluation, Investigation, CAPA Implementation, Verification
Discussion of Group Project
CAPA Workshop

Product Realization
How Good is Good Enough: Risk Assessment, Capability Assessment, Control and Inspection Plan

Supply Chain Management: Challenges and Opportunities

Importance of Supplier Management Establishment

Assessment (includes both continuous and summative assessment)

Component	Course LO Tested	Related Programme LO or Graduate Attributes	Weighting	Team/Individual	Assessment Rubrics
1. In-class online assignment	1, 2	Competence, Creativity, Civic-mindedness	20%	Individual	Point-based marking (not rubrics based)
2. Midterm test	1, 2, 3	Competence, Creativity, Civic-mindedness	30%	Individual	Point-based marking (not rubrics based)
3. Term paper	1, 2, 3, 4, 7	Competence, Creativity, Civic-mindedness	25%	Individual	Point-based marking (not rubrics based)
4. Group research project and presentation	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	Competence, Creativity, Communication, Civic-mindedness	25%	Team	Appendix 1
Total			100%		

Formative feedback

You will be given feedback in four ways:

1. By working through examples provided during lectures
2. By response to postings on the course discussion board
3. By attending consultation hours
4. By studying the comments provided by the instructors after the grading of the in-class assignment and midterm test

Learning and Teaching approach

Lectures	Face-to-face lectures will be employed to enable you to interact directly with the instructor.

Reading and References

United States Food and Drug Administration (US FDA): https://www.fda.gov/home
Electronic Code of Federal Regulations (eCFR): https://gov.ecfr.io/cgi-bin/ECFR?page=browse
International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH): https://www.ich.org/
International Organization for Standardization (ISO): https://www.iso.org/home.html

Course Policies and Student Responsibilities

(1) General

You are expected to complete all assigned readings and activities, attend all lectures punctually, participate in discussions, and take all scheduled assignments and tests by due dates.

(2) Absenteeism

Absence from the midterm without a valid reason will affect your overall course grade. Valid reasons include falling sick supported by a medical certificate and participation in NTU's approved activities supported by an excuse letter from the relevant bodies. There will be no make-up opportunities for CA components.

All project assignments must be submitted on time. Failure to do so will affect your score.

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
Zheng Yiying			yiying.zheng@ntu.edu.sg

Planned Weekly Schedule

Week	Topic	Course ILO	Readings/Activities
1	Quality and Quality Metrics	1	Lecture
2	GLP and GMP	2	Lecture, in-class online assignment
3	Pharmaceutical Quality Systems	3	Lecture
4	Quality Systems for Biologics	3	Lecture

5	Quality Systems for Medical Devices	3	Lecture
6	Revision and Midterm	1,2,3	Midterm test
7	Documentation and Records	4	Lecture
8	Auditing Principles	5	Lecture
9	Statistical Process Control (SPC)	6,7	Lecture, homework
10	Corrective and Preventive Action (CAPA)	8	Lecture
11	Product Realization	9	Lecture
12	Supply Chain Management	10,11	Lecture
13	Group Project Presentations	1,2,3,4,5,6, 7,8,9,10,11	Presentations

Appendix 1: Rubrics for Group research project and presentation (25%)

Grading criteria by instructor

Performance Level	Criteria
Excellent	Demonstrates complete achievement of the learning outcomes 1 – 6. Able to connect to the topics covered and how it can be used to solve the problem. Able to organize the team to present the assigned topic and answer the comments/questions after the oral presentation. Show good communication ability to lead the team members.
Good	Demonstrates complete achievement of the learning outcomes 1 – 6. Able to connect to the topics covered and how it can be used to solve the problem at hand. Able to present the assigned topic and have good communication with the team members.
Satisfactory	Demonstrates partial achievement of the learning outcomes 1 – 6. Able to apply the technique or methodology taught in class only in direct way. Able to present the assigned topic but may not be precise or concise enough.
Unsatisfactory	Demonstrates minimal achievement of the learning outcomes 1 – 6. Not able to apply the knowledge to the problems or not able to present the assigned topic well or have difficulty to maintain good communication with the team members.
Poor	Do not possess sufficient understanding of problem and lack solution for it. Not able to complete presentation and join team study.

Peer evaluation

Your instructor has no way to assess the contribution of each student to the final project. Hence, each team needs to include a contribution statement at the end of the presentation to state the individual team members' contributions.

In addition, each student is required to rate the contribution of each of the other group members with a peer assessment score out of 10. Peer assessment should consider attendance at group

meetings (3 points), contributions to the project analyses (4 points), and contribution to the preparation of the final presentation (3 points).

All peer evaluation scores will be kept strictly confidential and will not be revealed to the other group members. You are to evaluate other group members fairly and objectively, as your evaluation will affect other group members' grades (explained below). It is essential for you to submit your peer evaluation form to get marks for the final project. To account for peer evaluations, the final grades for the final project will be calculated as follows:

Based on the instructor's evaluation of the presentation, the entire group will receive the same grade, before peer evaluations are considered.

If a student receives an averaged peer evaluation rating of 8 or more, that student receives 100% of the group's grade.

If a student receives an averaged peer evaluation rating of less than 8, that student receives a percentage of the group's grade as calculated by the formulae below:

- An average rating of 7 to <8 = 90% + (average rating – 7) × 10
- An average rating of 6 to <7 = 80% + (average rating – 6) × 10
- An average rating of 5 to <6 = 70% + (average rating – 5) × 10
- An average rating of 4 to <5 = 60% + (average rating – 4) × 10
- An average rating of 3 to <4 = 50% + (average rating – 3) × 10
- An average rating of 2 to <3 = 40% + (average rating – 2) × 10

Example

Assume the group receives 20 marks from the instructor for the project. A student with an average rating of 8.90 gets 100% of 20 marks, i.e., 20 marks. An average rating of 6.29 means that a student gets 82.9% [or 80% + (6.29 – 6) × 10] of 20 marks, i.e., 16.58 marks.

An average rating <2 will be investigated by your instructor, and the student may receive 0% of group grade.

Your instructor reserves the right to review the student ratings if in doubt, including if malice or discrimination are suspected. Similarly, if one student is not listed in the contribution statement and the instructor suspects that the student did not contribute at all, that student may receive 0% of the group grade regardless of the peer evaluation score.

Here is an example of the peer evaluation score table:

Criteria	Yourself	Member 1	Member 2	Member 3	Member 4
Contributed a fair share of work (Y/N)					
Attendance at group meetings (3 points)					
Contributions to the project analyses (4 points)					
Preparation of final products (3 points)					
TOTAL					
Comments, if any					

CBC Programme Learning Outcome

The Division of Chemistry and Biological Chemistry (CBC) offers an undergraduate degree major in Chemistry that satisfies the American Chemical Society (ACS) curricular guidelines and equips students with knowledge relevant to the industry. Graduates of the Division of Chemistry and Biological Chemistry should have the following key attributes:

1. Competence

Graduates should be well-versed in the foundational and advanced concepts of chemical science, be able to evaluate chemistry-related information critically and independently, and be able to use complex reasoning to solve emergent chemical problems.

2. Creativity

Graduates should be able to synthesize and integrate multiple ideas across the curriculum, and propose innovative solutions to emergent chemistry-related problems based on their training in chemistry.

3. Communication

Graduates should be able to demonstrate clarity of thought, independent thinking, and sound scientific analysis and reasoning through written and oral reports to audiences with varying technical backgrounds. They should also be able to effectively engage other professional chemists in collaborative endeavours.

4. Character

Graduates should be able to act in responsible ways and uphold the high ethical standards that the society expects of professional chemists.

5. Civic-mindedness

Graduates should be aware of the impact of chemistry on society, and how chemistry can be applied to benefit mankind. They should also be aware of and uphold the best chemical safety practices.