Course Code: CM9031
Course Title: Chemistry in Pharmaceutical Manufacturing

Pre-requisites: CM3061 Chemistry and Biological Chemistry Laboratory 3 & CM3062 Chemistry and Biological Chemistry Laboratory 4 or by permission
Mutually exclusive: CM9082 Drug Design and Synthesis
No of AUs: 3 AU
Contact Hours: 2 hours lecture + 3 hours lab sessions per week

Course Aims
Pharmaceutical manufacturing is a significant and critical component of Singapore’s manufacturing industry. As such, any chemistry graduate aspiring to enter this industry as a career, must have a good knowledge and understanding of all aspects of this sector. The lectures are intended to provide you with an overall understanding of the process of drug discovery, development and in-depth exposure to the manufacturing aspect. Analytical chemistry is a crucial segment of quality control in drug manufacturing and the lab component is designed to supplement the lectures by providing you with hands-on training on advanced analytical and characterization skills relevant to pharma-needs. This course aims to equip you with an awareness of the overall Drug Discovery and Development process. Additionally, it will give you an in depth understanding of the Development aspect, which includes Chemical Development, Manufacturing and Formulation, Chemistry, Manufacturing & Controls (CMC), traditional batch method and emerging technologies such as flow chemistry, and an understanding of the critical role of analytical methods across these activities (e.g. PAC/PAT).

Intended Learning Outcomes (ILO)
By the end of this course, you (as a student) would be able to:

1. Describe process Chemistry; explain the transition from Pre-development synthetic routes to Development phase
2. Describe the various manufacturing techniques involved in the production of Active Pharmaceutical Ingredient (API) on Kilo/Ton scale
3. Describe formulation; list the various techniques involved in the conversion of API to Drug Product (e.g. powder to tablet)
4. Describe flow Chemistry technique; compare with traditional batch method
5. Explore and evaluate continuous manufacturing
6. Explore and evaluate additive manufacturing (‘3D printing’) of tablets
7. Carry out analytical experiments using HPLC and GC; especially in the context of process analytical chemistry/technology (PAC/PAT); collect, interpret and report the data.

Course Content

Drug Discovery and Development Process
Target Identification and Validation; Hit and Lead Identification; Medicinal Chemistry/Optimization; Translation to Clinical Development; Development; Approval and Marketing of drug.
Chemical Development, Manufacturing and Formulation

Conversion of preclinical synthetic route to development scale; process chemistry; production of API on kilo and ton scale; CMC and the regulated process of manufacture; GMP; formulation of API to drug product; batch method of synthesis; flow chemistry; continuous manufacturing; additive manufacturing.

Analytical methods in pharmaceutical manufacturing activities

Application of HPLC and GC; Process Analytical Testing (PAT); Process Analytical Chemistry (PAC)

Formative feedback

Feedback given after each midterm on the common mistakes and level of difficulty of the problems.

Reading and References

3) Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form (Ed., M. Gibson, CRC Press, 9781420073171
4) Relevant scientific literature

Course Policies and Student Responsibilities

Absence Due to Medical or Other Reasons

If you are sick and unable to attend your class (particularly the mid-terms), you have to:

1. Send an email to the instructor regarding the absence and request for a replacement class.
2. Submit the original Medical Certificate* to administrator.
3. Attend the assigned replacement class (subject to availability).

* The medical certificate mentioned above should be issued in Singapore by a medical practitioner registered with the Singapore Medical Association.

Academic Integrity

Good academic work depends on honesty and ethical behavior. The quality of your work as a student relies on adhering to the principles of academic integrity and to the NTU Honor 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.
# Planned Weekly Schedule

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<td>Weekly 3 hours of lab</td>
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<td>Lab reports</td>
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MT*  Mid-term - to be conducted off regular curriculum time (in the evenings or Saturdays)
#  Pre/Post-lecture online assignments; Post Lecture tutorial lessons
PR – short progress report of project synopsis to tutors