Course Documentation

School of Biosciences

Program: Chemical Engineering Technician

Academic Year: 2011-12 Fall [ ] Winter [x] Spring [ ]

Program Year: 3 **Program Semester:** 6

Course Name: Good Manufacturing Practices

Course Code: BIOS 3004 **Course Hours:** 42 **Credit Value:** 3

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Class	Lab	Field	Other	Total
			42	42

Prerequisites/Corequisites/Equivalent Courses

PR/CO/EQ	Course Code	Course Name	Conditions
PR	BIOS 2000 CHEM 3003 MATH 3000	Microbiology Analytical Instrumentation Data Analysis 2	
CO	N/A		
EQ	LTDC 7141	Good Mfg Practices - On-line	

This Course is A Prerequisite For:

Course Code	Course Name
N/A	

1. Calendar Description

This course combines Health Canada's Guidelines for Good Manufacturing Practices: Food and Drug Regulations, (as referred to Division 2, Part C of the Food and Drug Regulations) with the World Health Organization's (WHO) Basic Training Modules on GMP.

The scope of this course includes all GMP activities relating to fabricating, packaging/labelling, testing, distributing, importing and wholesaling of drugs for human or veterinary use.
Division 2 applies to drugs listed is Schedules C and D to the Act.
The course runs over a one-semester period as an online course using the WebCT format. A facilitator will monitor participants and provide expert feedback and support.

2. Course Learning Outcomes: Upon successful completion of the course, the student will be

Dean/Chair Approval:  Date: 2/9/2012

1.Understand the importance of Good Manufacturing Practices (GMPs) to the pharmaceutical industry, as well as for consumers.

2.Understand the rationale governing GMPs, including whom the regulations apply to and how the guidelines facilitate compliance by the regulated industry.

3.Discuss the requirements for the design, construction and maintenance of GMP facilities and equipment.

4.Understand the requirements for sanitation and personnel in GMP facilities.

5.Discuss the requirements for the control, selection and testing of raw, in process, finished and packaging materials.

6.Discuss key concepts of quality assurance and quality control.

7.Discuss the essentials of good documentation as part of a quality assurance program.

8.Understand the basic concepts of a drug stability program.

9.Describe the general requirements for the fabrication and packaging of sterile therapeutics.

3. Essential Employability Skills Outcomes: This course will contribute to the achievement of the following essential employability skills

[x] 1. communicate clearly, concisely and correctly in the written, spoken, and visual form that fulfills the purpose and meets the needs of the audience.

[x] 2. respond to written, spoken, or visual messages in a manner that ensures effective communication.

[ ] 3. execute mathematical operations accurately.

[ ] 4. apply a systematic approach to solve problems.

[x] 5. use a variety of thinking skills to anticipate and solve problems.

[x] 6. locate, select, organize, and document information using appropriate technology and information systems.

[x] 7. analyze, evaluate, and apply relevant information from a variety of sources.

[ ] 8. show respect for the diverse opinions, values, belief systems, and contribution of others.

[ ] 9. interact with others in groups or team in ways that contribute to effective working relationships and the achievement of goals.

[x] 10. manage the use of time and other resources to complete projects.

[x] 11. take responsibility for one's own actions, decisions, and consequences.

4. General Education:

Indicate if this course is identified as a General Education course in the program of study.

[ ] Yes [x] No

If yes, indicate which General Education theme this course addresses.

[ ] 1. Arts in Society
[ ] 2. Civic Life
[ ] 3. Social and Cultural Understanding
[ ] 4. Personal Understanding
[ ] 5. Science and Technology

5. Prior Learning Assessment and Recognition:

Students may apply to receive credit by demonstrating achievement of the course learning outcomes through previous life and work experiences.
This course is eligible for challenge through the following method(s) indicated

Challenge Exam	Portfolio	Interview	Dual Credit	Other	Not Eligible
[x]	[x]	[x]	[ ]	[ ]	[ ]

PLAR: Sue Deans / Charolyn Babichuk

6. Required Texts, Materials, Resources or Technical Materials Required

All course materials are available via LMS, the internet, the Loyalist College library and the accompanied student CD.

7. Evaluation: Students will demonstrate learning in the following ways

Assessment Description	Course Learning Outcome(s)	Assignment Weighting
Introductory Written Assignments -Navigating in LMS -Understanding how GMPs protect consumer safety.	1, 2	Total will equal 5%
Research-Based Assignments -Premises -Equipment -Materials -Quality management	3, 5	Total will equal 20%
Applied Knowledge-Based Assignments -Sanitation -Personnel -Documentation -Stability.	4, 6, 7, 8	Total will equal 30%
Unit of Unit Quizzes	3, 4, 5, 6, 7, 9	Total will equal 30%
Final exam	2 through 9	15%

8. Other:

Loyalist College has a Violence Prevention policy:

All College members have a responsibility to foster a climate of respect and safety, free from violent behavior and harassment.
- Violence (e.g. physical violence, threatening actions or harassment) is not, in any way, acceptable behavior.
- Weapons or replicas of weapons are not permitted on Loyalist College property.
- Unacceptable behavior will result in disciplinary action or appropriate sanctions.
- More information can be found in the “Student Manual”.

Students must make a reasonable effort to submit assigned work on time. Students must advise the instructor in advance if they are unable to meet scheduled deadlines. The instructor reserves the right to refuse late assignments and rescheduling of quizzes or assign late penalties.

All submitted work must be solely that of the student submitting the work. Plagiarism is an academic offense and will result in a grade of zero, at minimum. Students should familiarize themselves with Loyalist College policy concerning academic honesty as outlined in the Registrar's Handbook for students.

The passing grade for the course is 60% .

9. Curriculum, Delivery, Learning Plan and Learning Outcomes:

Course Components/Course Learning Outcomes	Related Elements of Performance	Learning Activities/Assessment/Resources
Introduction to Good Manufacturing Practices	Participants will be introduced to the acronym GMP and understand its importance to industry as well as consumers. Participants will become familiar with the regulations and responsibilities guiding the different entities for GMP production and handling of drug products.	Activities: Online notes, PowerPoint presentations and a virtual tour of the US FDA. Evaluation: Graded assignment - defining GMP entities and describing non-compliance scenarios.
The design, construction, and maintenance of pharmaceutical manufacturing facilities and equipment must meet GMP requirements.	Participants will understand how GMP facilities and equipment are designed to optimize cleaning and maintenance and to prevent contamination and mix-ups.	Activities: Class lectures, online notes, selected publications and PowerPoint presentations. Evaluation: Graded assignments - evaluation of a laboratory space and a selected piece of equipment for GMP design and suitability. Unit quizzes.
Requirements exist for ensuring that facility personnel are qualified to perform their job responsibilities.	Participants will understand the rationale involved in appropriately staffing a pharmaceutical operation.	Activities: Class lecture, online notes and PowerPoint presentations. Evaluation:

		Graded assignment - preparation of an organizational chart for key personnel in a pharmaceutical company and evaluation of managerial functions through employment advertizements. Unit quiz.
Proper sanitation is required in a pharmaceutical manufacturing environment.	Participants will rationalize the requirements of cleanliness, orderliness and control of airborne and other contaminants in order to safeguard product integrity.	Activities: Class lectures, online notes and PowerPoint presentations. Evaluation: Graded assignment - describe the sanitation requirements for personnel, premises and equipment. Unit quiz.
GMP requirements exist for handling and testing of materials used in pharmaceutical manufacturing.	Participants will recognize that each lot or batch of raw material, drug product or packaging material shall be tested against the specifications for that material.	Activities: Online notes and PowerPoint presentations. Evaluation: Graded assignment - Familiarization with the US Pharmacopeia. Unit quiz.
Every manufacturer, packager/labeler, distributor and importer shall have on his premises a quality management system that is supervised by qualified personnel.	Participants will understand the rationale for quality control and quality assurance and how they relate to GMPs.	Activities: Online notes and PowerPoint presentations. Evaluation: Graded assignment- evaluating the 'quality' expectations of staff and management in a pharmaceutical manufacturing facility. Unit quiz.
Every fabricator, packager/labeler, tester and distributor shall maintain written procedures for GMP activities and specifications for materials. Good documentation is essential for establishing that procedures have been followed and that specifications have been met.	Participants will be able to: -discuss the essentials of good documentation as part of a quality assurance program. -describe what SOPs are and the format they are kept in.	Activities: Online notes, selected publications and PowerPoint presentations. Evaluation: Graded assignments - essential elements of Standard Operating Procedures. Unit quiz.
Every manufacturer shall monitor, by means of a continuing program, the stability of the drug in the package in which it is sold.	Participants will understand the purpose and design of a written drug stability program.	Activities: Online notes and selected publications. Evaluation: Graded assignment - design of a drug stability program.
Special handling and equipment standards are essential to the manufacture and packaging of sterile therapeutics.	Participants will be able to recognize the stringent air quality, material handling, premise design and personnel training standards for sterile	Activities: Online notes and PowerPoint presentations.

	manufacturing.	Evaluation: Unit quiz.