|  |  |
| --- | --- |
| **Course Title:** | Pharmaceutical quality control and good manufacturing practice |
| **Course Code:** | **PHCU 537** |
| **Program:** | **Pharmaceutical Sciences** |
| **Department:** | **Pharmaceutics** |
| **College:** | **College of Pharmacy** |
| **Institution:** | **Najran University** |

Table of Contents

[A. Course Identification 3](#_Toc951372)

[6. Mode of Instruction (mark all that apply) 3](#_Toc951373)

[B. Course Objectives and Learning Outcomes 3](#_Toc951374)

[1. Course Description 3](#_Toc951375)

[2. Course Main Objective 4](#_Toc951376)

[3. Course Learning Outcomes 4](#_Toc951377)

[C. Course Content 4](#_Toc951378)

[D. Teaching and Assessment 5](#_Toc951379)

[1. Alignment of Course Learning Outcomes with Teaching Strategies and Assessment Methods 5](#_Toc951380)

[2. Assessment Tasks for Students 5](#_Toc951381)

[E. Student Academic Counseling and Support 5](#_Toc951382)

[F. Learning Resources and Facilities 6](#_Toc951383)

[1.Learning Resources 6](#_Toc951384)

[2. Facilities Required 6](#_Toc951385)

[G. Course Quality Evaluation 6](#_Toc951386)

[H. Specification Approval Data 7](#_Toc951387)

# A. Course Identification

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Credit hours:** 2(2+0) | | | | | |  | | | | | | | | | | |
| **2. Course type** | | | | | | | | | | | | | | | | |
| **a.** | University | |  | College | | | | **√** | Department | | | |  | Others |  |  |
| **b.** | | Required | | | **√** | | Elective | | |  |  | | | | | |
| **3. Level/year at which this course is offered:** | | | | | | | | | | | | 10th level | | | | |
| **4. Pre-requisites for this course** (if any)**:** PHCU 535 | | | | | | | | | | | | | | | | |
| **5. Co-requisites for this course** (if any)**:** | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |

## 6. Mode of Instruction (mark all that apply)

| **No** | **Mode of Instruction** | **Contact Hours** | **Percentage** |
| --- | --- | --- | --- |
| **1** | **Traditional classroom** | 30 | 100 |
| **2** | **Blended** |  |  |
| **3** | **E-learning** |  |  |
| **4** | **Correspondence** |  |  |
| **5** | **Other** |  |  |

**7. Actual Learning Hours** (based on academic semester)

|  |  |  |
| --- | --- | --- |
| **No** | **Activity** | **Learning Hours** |
| **Contact Hours** | | |
| **1** | **Lecture** | 30 |
| **2** | **Laboratory/Studio** |  |
| **3** | **Tutorial** |  |
| **4** | **Others** (specify) |  |
|  | **Total** | 30 |
| **Other Learning Hours\*** | | |
| **1** | **Study** | 30 |
| **2** | **Assignments** | 15 |
| **3** | **Library** | 15 |
| **4** | **Projects/Research Essays/Theses** | 10 |
| **5** | **Others** (specify) | - |
|  | **Total** | 70 |

**\*** The length of time that a learner takes to complete learning activities that lead to achievement of course learning outcomes, such as study time, homework assignments, projects, preparing presentations, library times

# B. Course Objectives and Learning Outcomes

|  |
| --- |
| 1. Course Description |
| This course is designed to familiarize the students with the quality assurance and regulatory affairs which include good manufacturing practice (GMP) and quality control aspects of raw materials and finished products. The quality control includes the final testing of the product besides the in – process quality control of different dosage forms. This course also outlines the principles of self-inspection, validation, and handling of product recalls and complaints. |
| 2. Course Main Objective |
| The course provides the students with the basic concepts and guidance for manufacturing, testing, and quality assurance. |

## 3. Course Learning Outcomes

| **CLOs** | | **Aligned****PLOs** |
| --- | --- | --- |
| 1 | **Knowledge:** |  |
| 1.1 | Describe pharmaceutical industry, GMP and quality assurance. | K3 |
| 1.2 |  |  |
| 1.3 |  |  |
| 1... |  |  |
| **2** | **Skills:** |  |
| 2.1 | Design proper documentation for quality assurance. | S2 |
| 2.2 | Develop and apply good laboratory practice (GLP) and good manufacturing practice (GMP) guidelines in pharmacy practice and Pharmaceutical industry. | S2 |
| 2.3 |  |  |
| 2... |  |  |
| **3** | **Competence:** |  |
| 3.1 | Work independentlyand professionally**.** | C1 |
| 3.2 | Use of personal values and ethical principles in specialization or field of work | C2 |
| 3.3 |  |  |
| 3... |  |  |

# C. Course Content (Theoretical)

|  |  |  |
| --- | --- | --- |
| **No** | **List of Topics** | **Contact Hours** |
| 1 | Introduction to pharmaceutical industry and GMP | 2 |
| 2 | Therapeutic goods regulators | 2 |
| 3 | Production: premises and equipment | 2 |
| 4 | Air cleanliness levels | 1 |
| 5 | Prevention of cross contamination | 1 |
| 6 | Processing operation and packaging operation | 2 |
| 7 | Quality control: documentation, specifications, sampling, testing, and ongoing stability program | 6 |
| 8 | Sampling Training and personnel hygiene | 4 |
| 9 | Quality assurance: self-inspection | 4 |
| 10 | Validation | 4 |
| 11 | Product complaints and recall | 2 |
| **Total** | | 30 |

# D. Teaching and Assessment

## 1. Alignment of Course Learning Outcomes with Teaching Strategies and Assessment Methods

| **Code** | **Course Learning Outcomes** | **Teaching Strategies** | **Assessment Methods** |
| --- | --- | --- | --- |
| **1.0** | **Knowledge** | | |
| 1.1 | Describe pharmaceutical industry, GMP and quality assurance. | Lectures | 1. MCQ  2. Assignment |
| 1.2 |  |  |  |
| … |  |  |  |
| **2.0** | **Skills** | | |
| 2.1 | Design proper documentation for quality assurance. | 1. Lectures  2. Problem solving exercises.  3. Case Study | 1. Written exam.  2. Observation card |
| 2.2 | Develop and apply good laboratory practice (GLP) and good manufacturing practice (GMP) guidelines in pharmacy practice and Pharmaceutical industry. | 1. Lectures  2. Problem solving exercises.  3. Case Study | 1. Written exam.  2. Observation card |
| … |  |  |  |
| **3.0** | **Competence** | | |
| 3.1 | Work independentlyand professionally**.** | Group discussions | 1. Oral presentation  2. Observation card |
| 3.2 | Use of personal values and ethical principles in specialization or field of work | Group discussions | 1. Oral presentation  2. Observation card |
| … |  |  |  |

## 2. Assessment Tasks for Students

| **#** | **Assessment task\*** | **Week Due** | **Percentage of Total Assessment Score** |
| --- | --- | --- | --- |
| **1** | Midterm Theoretical Exam 1 | 6 | 20 |
| **2** | Midterm Theoretical Exam 2 | 11 | 20 |
| **3** | Assignments and oral presentation | 12 | 5 |
| **4** | Observation card | 14 | 5 |
| **5** | Final Written Exam | 15 | 50 |
| **6** | Total |  | 100 |
|  |  |  |  |
|  |  |  |  |

**\*Assessment task** (i.e., written test, oral test, oral presentation, group project, essay, etc.)

# E. Student Academic Counseling and Support

|  |
| --- |
| **Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice :** |
| Office hour : (8 hour per week + appointment with student)  Help session : (Problem solving): As required per week |

# F. Learning Resources and Facilities

## 1.Learning Resources

|  |  |
| --- | --- |
| **Required Textbooks** | Electronic FDF book: The encyclopedia or pharmaceutical technology, third edition, James Swarbrrick.  Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Vol. 2, Good manufacturing practices and inspection. —2nd ed. 2007. WHO  Guide to Good Manufacturing Practice for Medicinal Products, Version 3. Drug Sector Saudi Food & Drug Authority |
| **Essential References Materials** | Good Manufacturing Practices for Pharmaceuticals, Sixth Edition edited by Joseph D. Nally, Informa Healthcare. |
| **Electronic Materials** | <https://sdl.edu.sa/SDLPorta1/en/Publishers.aspx>  <http://dlaf.nu,edu.sa/en/e-libraries>  <http://www.nu.edu.sa/en/web/deanship-of-libraries-affairs/85>  <http://Iib.nu.edu.sa/DigitalLibbrary.aspx> |
| **Other Learning Materials** |  |

## 2. Facilities Required

| **Item** | **Resources** |
| --- | --- |
| **Accommodation**  (Classrooms, laboratories, demonstration rooms/labs, etc.) | A lecture hall containing at least 25 seats for student |
| **Technology Resources**  (AV, data show, Smart Board, software, etc.) | Projector for power point presentations with internet. |
| **Other Resources**  (Specify, e.g. if specific laboratory equipment is required, list requirements or attach a list) |  |

# G. Course Quality Evaluation

| **Evaluation**  **Areas/Issues** | **Evaluators** | **Evaluation Methods** |
| --- | --- | --- |
| Effectiveness of teaching and assessment | Head of the department | Direct |
| Quality of learning resources | Students | Direct |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Evaluation areas** (e.g., Effectiveness of teaching and assessment, Extent of achievement of course learning outcomes, Quality of learning resources, etc.)

**Evaluators** (Students, Faculty, Program Leaders, Peer Reviewer, Others (specify)

**Assessment Methods** (Direct, Indirect)

# H. Specification Approval Data

|  |  |
| --- | --- |
| **Council / Committee** | Pharmaceutics department committee |
| **Reference No.** | Department meeting No.1 |
| **Date** | 10/9/2019 |