COURSE SYLLABUS

Degree Program: BS Pharmaceutical Sciences

Program Learning Outcomes:
PLO 1: Practice pharmacy in a professional, legal and ethical manner to serve the Filipino people;
PLO 2: Effectively communicate pharmaceutical product information and research outputs in the pharmaceutical sciences to key stakeholders through different types of media;
PLO 3: Conduct ethical and relevant researches that focus on design, development, and manufacture of medicines;
PLO 4: Work collaboratively with inter- and multi-professional pharmaceutical industries and other related fields;
PLO 5: Pursue life-long learning for professional development towards nation building;
PLO 6: Apply the principles of product lifecycle management in ensuring operational efficiency;
PLO 7: Evaluate the safety, efficacy, quality, and cost of pharmaceutical products; and,
PLO 8: Formulate pharmaceutical products designed to achieve optimum therapeutic outcomes.

A. Course Catalogue Description

Course Title: Biological Assays

Course Number: Pharm Sci 160	**Credit Units:** 1.0	**Number of Hours:** 1 hour	**Year Level offered:** 3rd	**Semester Offered:** 1st semester

Meeting Type/Instructional Format: Face-to-face

Course Description: Evaluation and development of biological assay

Prerequisites: Pharmacology for Pharmacy 2 (Pharm 126)

Corequisites: None

Course Stipulation (if any)

Course Goals:	This course aims to develop students' ability to select, design, and validate appropriate biological assays for specific experimental applications.

B. Relationship of Course Learning Outcomes to Program Learning Outcomes		**Program Learning Outcomes**							
Course Learning Outcomes		**PLO1**	**PLO2**	**PLO3**	**PLO4**	**PLO5**	**PLO6**	**PLO7**	**PLO8**
CLO1:	Select an appropriate method of biological assay for a given situation			R			R	R	
CLO2:	Explain the process of designing an appropriate biological assay			R	R				R
CLO3:	Identify validation parameters appropriate for a new bioassay	R				R		R	

I – Introduced D- Demonstrated

R- Reinforced

C. Course Content	
Topics	**Number of Hours**
I. Introduction to Biological Assays A. Definition and Importance of Biological Assays B. Historical Perspectives on Bioassays C. Comparison of Bioassays with Chemical Assays D. Applications for Biological Assays	2 hours
II. Classification and Types of Biological Assays A. Qualitative Bioassays: Observation-based assays B. Quantitative Bioassays: Dose-response relationship, statistical approaches C. End-point vs. Kinetic Bioassays D. Common Assay Models: Cell-based, Enzyme-based, Animal-based	2 hours
III. Selection of Appropriate Biological Assay A. Key Factors in Assay Selection • Nature of the analyte • Biological relevance • Throughput requirements	2 hours

B. Ethical and Regulatory Considerations • Good Laboratory Practices (GLP) and Compliance • Ethical Concerns in Animal-based Bioassays • Reporting and Documentation Requirements C. Choosing the right bioassay for specific applications (e.g., drug discovery, diagnostics)	
IV. Design and Development of Bioassays A. Steps in Designing a Bioassay • Defining Objectives and Hypotheses • Selection of Biological Models • Control and Reference Standards • Optimization of Assay Conditions B. Analytical Tools and Techniques in Bioassays • Role of Instrumentation in Biological Assays • Techniques: ELISA, Flow Cytometry, PCR-based Bioassays • Emerging Technologies: High-throughput Screening, Multiplex Assays, Biosensors C. Statistical Considerations in Assay Design	3 hours
V. Validation of Bioassays A. Key Validation Parameters • Accuracy, Precision, Specificity, Linearity, Robustness • Limit of Detection (LOD) and Limit of Quantitation (LOQ) B. Overview of Regulatory Guidelines for Bioassays (e.g., ICH, USP) C. Troubleshooting Assay Performance Issues	3 hours
VI. Special Topics of Bioassay A. Innovations in Biological Assay Development B. Challenges in Translating Assay Development to Industry	1 hour
VII. Designing a Capsule Proposal	3 hours
D. Course Coverage	

Week	Learning Outcomes	LLOs with CLOs	Course Topics	Essential or Key Questions	Teaching and Learning Activities	Assessment Methods and Tools	Core Readings/Learning Resources
1-2	• Explain the biological assays and its historical development • Compare and contrast bioassays with chemical assays • Describe their practical applications in research and industry	CLO1	**I. Introduction to Biological Assays** A. Definition and Importance of Biological Assays B. Historical Perspectives on Bioassays C. Comparison of Bioassays with Chemical Assays D. Application of Bioassay	• What is a biological assay? • What are some landmark developments in the field of bioassays? • What are the advantages and limitations of each type? • What are innovative or emerging applications of bioassays?	Interactive lecture with real-world examples Q & A	Short quizzes with written analysis and problem solving	Core Readings/Learning Resources
3-4	• Classify biological assays • Determine advantages and limitations of various biological assay types • Evaluate common assay models such as cell-, enzyme-, and animal-based systems.	CLO1	**II. Classification and Types of Biological Assays** A. Qualitative Bioassays: Observation-based assays B. Quantitative Bioassays: Dose-response relationship C. End-point vs. Kinetic Bioassays D. Common Assay Models: Cell-based, Enzyme-based, Animal-based	• What distinguishes quantitative bioassays from qualitative ones? • What are the advantages and limitations of qualitative and quantitative bioassays? • What are the most used models in bioassays?	Interactive Lecture with examples Video demonstrations Q & A	Short quizzes with written analysis and problem solving	

5-6	• Analyze key factors influencing bioassay selection • Evaluate ethical and regulatory considerations • Plan an appropriate biological assay for specific applications such as drug discovery, diagnostics, or research studies	CLO1	**III. Selection of Appropriate Biological Assay** A. Key Factors in Assay Selection • Nature of the analyte • Biological relevance • Throughput requirements B. Ethical and Regulatory Considerations • Good Laboratory Practices (GLP) and Compliance • Ethical Concerns in Animal-based Bioassays • Reporting and Documentation Requirements C. Choosing the right bioassay for specific applications (e.g., drug discovery, diagnostics)	• What factors influence the selection of a biological assay? • What are the key ethical concerns in performing biological assays, especially animal-based studies? • What factors determine the suitability of a bioassay for a particular purpose?	Interactive lecture with real-world examples Q & A Guided reading Case studies and Group activities	Short quizzes with written analysis and problem solving Case study report	Core Readings/Learning Resources
7-9	• Design appropriate biological assays tailored for certain applications • Analyze various analytical techniques appropriate for bioassays	CLO2	**IV. Design and Development of Bioassays** A. Steps in Designing a Bioassay • Defining Objectives and Hypotheses • Selection of Biological Models • Control and Reference Standards	• What are the critical steps in designing a biological assay? • How do you choose appropriate biological models for a given assay? • How to choose the most appropriate main analytical technique in a	Interactive lecture with real-world examples Q & A Problem Solving Exercises and Group activities	Short quizzes with written analysis and problem solving Capsule Proposal	

	• Applying statistical considerations		• Optimization of Assay Conditions B. Analytical Tools and Techniques in Bioassays • Role of Instrumentation in Biological Assays • Techniques: ELISA, Flow Cytometry, PCR-based Bioassays • Emerging Technologies: High-throughput Screening, Multiplex Assays, Biosensors C. Statistical Considerations in Assay Design	particular biological assays? • What statistical parameters are important in bioassay design?			
10-12	• Evaluate key validation parameters aligned with existing regulatory guidelines	CLO3	**V. Validation of Bioassays** A. Key Validation Parameters • Accuracy, Precision, Specificity, Linearity, Robustness • Limit of Detection (LOD) and Limit of Quantitation (LOQ) B. Overview of Regulatory Guidelines for Bioassays (e.g., ICH, USP) C. Troubleshooting Assay Performance Issues	• What are the essential validation parameters for a biological assay? • How are these parameters measured and interpreted in each bioassay?	Interactive Lectures with real-world examples and regulatory expectations Q&A Problem Solving Exercises and Group activities	Short quizzes with written analysis and problem solving Capsule Proposal	

13	• Analyze recent innovations in bioassay development	CLO1, CLO2 CLO3	**VI. Special Topics of Bioassay** A. Innovations in Biological Assay Development B. Challenges in Translating Assay Development to Industry	• What are the recent innovations in biological assay design and methodology?	Interactive Lectures with real-world examples and regulatory expectations Q&A Problem Solving Exercises and Group activities	Journal Reporting	
14-16	• Design a capsule proposal that applies bioassay concepts to address a specific research question	CLO1, CLO2 CLO3	Designing a Capsule Proposal			Capsule Proposal	

E. Course Requirements

1	Attend at **least 80%** of the total lecture hours with active participation
2	Complete assignments, oral reports, and other assignments
3	Submit a capsule research proposal demonstrating understanding of bioassay concepts
4	Participate in peer evaluations to provide constructive feedback and reflect on teamwork skills

F. Assessment Plan (formative and summative evaluation)

COURSE ASSESSMENT PLAN			
Assessment Component	**Course Learning Outcomes**		
	CLO1	CLO2	CLO3
Capsule Proposal (40%)	Rubric	Rubric	Rubric

Quizzes (20%)	MCQs with Problem Solving	MCQs with Problem Solving	MCQs with Problem Solving
Oral Report (15%)	Rubric	Rubric	Rubric
Attendance (10%)			
Peer Evaluation (15%)	Rating Scale	Rating Scale	Rating Scale

G. References

1	Atta-ur-Rahman, M. Iqbalt Choudhary, Thomsen WJ. (2001). Bioassay Techniques for Drug Development. Boca Raton: Taylor and Francis.
2	Azadeh, M., Good, J., Gunsior, M. et al. Best Practices for Development and Validation of Enzymatic Activity Assays to Support Drug Development for Inborn Errors of Metabolism and Biomarker Assessment. AAPS J 26, 97 (2024). https://doi.org/10.1208/s12248-024-00966-y
3	Hader, D-P, Erzinger,, GS. (2017). Bioassays: Advanced Methods and Applications. Netherlands: Elsevier.
4	Sabotič, Jerica & Bayram, Engin & Ezra, David & Gaudencio, Susana & Haznedaroglu, Berat & Janež, Nika & Ktari, Leila & Luganini, Anna & Mandalakis, Manolis & Safarik, Ivo & Simes, Dina & Strode, Evita & Toruńska-Sitarz, Anna & Varamogianni-Mamatsi, Despoina & Varese, Giovanna & Vasquez, Marlen. (2024). A guide to the use of bioassays in exploration of natural resources. Biotechnology Advances. 71. 108307. 10.1016/j.biotechadv.2024.108307.
5	United States Pharmacopeial Convention. The United States Pharmacopeia Revision and National Formulary.
6	Wu G. (2010). Assay Development: Fundamentals and Practices. Hoboken, NJ: Wiley.

H. List of Faculty

1	Paolo Robert P. Bueno, RChT, PhD
2	Edwin C. Ruamero, RPh, MPH