BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI
ACADEMIC-GRADUATE STUDIES AND RESEARCH DIVISION
First Semester 2023-24
Course Handout (Part II)

08-08-2023

In addition to Part-I (general handout for all courses appended to the time table), this portion gives further specific details regarding the course.

Course No. : PHA G613
Course Title : Pharmaceutical Biotechnology
Instructor-in-charge : Swati Biswas
Instructors : Asif Md. Itoo, Milan Paul

Course Desscription: Molecular biology, immunology, recombinant DNA technology and principles of biochemical engineering. Application of biotechnology in diagnosis, therapeutics and production of products of fermentation. Bioinformatic tools required to store, analyse and use biological information for therapeutic utility, immense potentiality and application f decoding the human genome

1. Scope and Objective of the course:

This course is designed to provide pharmaceutics graduate students with an understanding of the technology used in the pharmaceutical biotechnology industry to develop biologics-based medicines. The application of genetic engineering, recombinant DNA technology, hybridoma technology, drug delivery aspects of biotechnology products, and their clinical evaluation are dealt with in this course. After completing this course, students should be able to:

* Select and evaluate appropriate in-vitro and in-vivo models by which to test novel formulations or delivery methods
* understand the rationale and theory behind common techniques in the biotechnology field and use them to solve problems routinely encountered in the biotech industry.
* appreciate that modern therapeutics derived from genetic techniques are often difficult to produce and handle but are highly specific for their biological sites of activity.
* understand the concept of gene therapy, where the field is currently, and how the pharmaceutical scientist can play a significant role in the development of a product to treat a genetic disease.

Text Book (T)

Bernard R. Glick, Jack J. Pasternak, Molecular Biotechnology – Principles and Application of rDNA. 2nd edition, ASM press, Washington. 1998.

Reference Books (R):

R1: Bruce Alberts et al, Molecular Biology of the Cell, 5th edition, New York, Garland Science 2006.

R2: Daan J. A. Crommelin, Robert D. Sindelar, Pharmaceutical Biotechnology. Harwood Academic Publishers, Amsterdam, 1997.

R3: Balasubramanian D, Bryce, CFA, Dharmalingam K, Green J, Jayaraman K. Concepts in Biotechnology. University Press, Hyderabad, India, 1996

2. Course Plan:

Learning objectives	Topics to be covered	Chapter in the Text Book	No. of Lectures
Pharmaceutical Biotechnology: An introduction	) The emergence of molecular biotechnology,) commercialization,) concerns and consequences.	T1, Ch-1	1
The theoretical basis of molecular biotechnology	) Structural and functional dynamics of cells,) structure of DNA, DNA replication,) Decoding genetic information: RNA and proteins,) Transcription, translation, and their regulations) protein secretion pathways .	T1, Ch-2	5
Recombinant DNA Technology	) Principle behind recombinant DNA technology) Restriction endonucleases and other enzymes required for cloning) principle behind Gel electrophoresis, and western blot) Plasmid cloning vectors) Process of transformation and selection) Creating and screening procedures of genomic library, including DNA hybridization, immunological assays and protein activity) Vectors for cloning large pieces of DNAs.	T1, Ch-3	6
Chemical synthesis of DNA	) The phosphoramidite method) Application of synthesized DNAs.	T1, Ch-4	2
Amplification, and sequencing of DNA	) Polymerase chain reactions, real - time PCR, RT-PCR probes) PCR amplification of full length DNA) Gene synthesis by PCR) DNA sequencing techniques) Large scale DNA sequencing	T1, Ch-4	3
Manipulation of gene expression in prokaryotes/eukaryotes	) Gene expression from strong and regulatable promoters,) Fusion proteins,) increasing protein stability, overcoming oxygen limitation, and biofilm formation	T1, Ch-6, 7	6
Application of Immunological diagnostic procedures	) ELISA, hybridoma techniques	T1, Ch-7	1
Application of biotechnology in therapy	) Monoclonal antibodies, vaccines, principles behind vaccine design, sub-unit vaccines, formulation perspectives	T1, Ch-10-12, R2:Ch-4	6

Application of biotechnology in therapy	) Gene delivery, gene delivery vectors, formulation perspectives, proof of concept studies	Notes to be given in the class	3
Application of biotechnology in therapy	) siRNA, concept and mechanism of action, vectors, formulation perspectives, proof of concept studies	Notes to be given in class	3
Application of biotechnology in therapy	) miRNA, concept, principles of action, formulation perspectives, proof of concept studies	Notes to be given in class	2
	) ODNs, application in therapy	Notes to be given in class	1
Application of biotechnology in therapy and diagnosis	) Nucleic acid aptamers, concept and application in imaging and drug delivery; Nucleic acid structures: G-quadruplex, and triplex and their application	Notes to be given in class	3

3. List of Experiments for the lab:

1	Basics of cell culture, mammalian cells thawing, passaging, and seeding techniques.
2	To perform protein assay by Bradford assay method
3	To perform a cell viability assay in mammalian breast cancer cells using the MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide) method
4	To Conduct a live-dead cell assay using Calcein AM and propidium iodide (PI) staining, followed by a fluorescence microscope visualization.
5	Isolation of DNA and quantification by Nanodrop
6	DNA fragmentation assay using gel electrophoresis
7	Isolation of mRNA and quantification
8	To perform the RT-PCR (Reverse Transcription Polymerase Chain Reaction) and investigate the expression levels of specific miRNAs in mammalian cells following DNA damage-induced apoptosis.
9	To perform the Quantification of Protein Expression Levels by Western Blot Analysis.
10	Immunofluorescence assay.

4. Evaluation Scheme:

Component	Duration	Weightage (%)	Date and time	Remarks
Mid-semester Test	90 min	30	10/10 11.30 - 1.00PM	CB
Assignments/seminars		20		OB
Laboratory component		20		15 % OB+5 % CB
Comprehensive exam	180 minutes	30	09/12 FN	25 % CB + 5 % OB

*: Assignments/lab sessions/seminar will involve 3 contact hours per week for each student. Topics, mode of evaluation and number will be announced in the regular class or lab sessions. CB – closed book and OB – open book

5. **Mid-semester evaluation:** Will be announced after the 2nd test.

6. Attendance: Regularity in attendance will be one of the criteria in deciding the borderline cases at the time of final grading.

7. Grading Procedure:

a) It is not necessary that all the five grades (i.e. A to E) would be awarded.
b) In borderline cases subjective judgment will be exercised for pull-up's (max. 2%). Basic guiding factors will be regularity, consistency in performance (above average) or/and steady improvement throughout the semester.
c) **Make-up:** Make-up will be given only for **genuine** reasons. It is expected that students shall avoid misuse of this feature.

8. **Chamber consultation hours:** To be announced in the class.
9. **Notices:** Notices about this course will be displayed **only on Pharmacy Department Notice Board.**
10. **Academic Honesty and Integrity Policy**: Academic honesty and integrity are to be maintained by all the students throughout the semester, and no type of academic dishonesty is acceptable.

Instructor-in-charge

PHA G613