BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI
Second Semester 2019-2020
Course Handout (Part II)

23-11-2019

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 : Nirmal J
Instructors : RaghuramanManimaran

Course Description :

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, analyze 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 anunderstanding about the technology used in pharmaceutical biotechnology industry to develop biologics based medicines. The application of genetic engineering, recombinant DNA technology, hybridoma technology, biologicals formulation and characterization,drug delivery aspects of biologics products are dealt with in this course.

Learning Outcomes (course benefits): Students who have undergone the course are expected to

- Understand the rationale and theory behind common techniques used in the pharmaceutical biotechnology field and use them to solve problems routinely encountered in the biotech industry
- Understand the formulation considerations and characterization of biological products like monoclonal antibodies, vaccines and peptides
- Select appropriate excipients and containers for biologics formulation
- Understand the fate of biologics in the body after administration
- Understand the role of delivery system in biologics to treat various diseases.

2. Text Books (T)

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

Reference Books (R):

1. Wei Wang and Manmohan Singh, Biological drug products - development and strategies, Wiley and sons, 2014
2. Bruce Alberts et al, Molecular Biology of the Cell, 5th edition, New York, Garland Science 2006.
3. Stefan Deubel and Janice M Reichert, Handbook of therapeutic antibodies, 2nd edition, Volume 1 to 4, Wiley Blackwell, 2014
4. Daan J. A. Crommelin, Robert D. Sindelar, Pharmaceutical Biotechnology. Harwood Academic Publishers, Amsterdam, 1997.
5. Balasubramanian D, Bryce, CFA, Dharmalingam K, Green J, Jayaraman K. Concepts in Biotechnology. University Press, Hyderabad, India, 1996.

3. Course Plan:

a) Lectures:

Lect. No	Learning objectives	Topics to be covered	Chapter in the Text Book/Ref Book
1	Pharmaceutical biotechnology: An overview	Emergence of molecular biotechnology, commercialization, concerns and consequences	T1, Ch-1
2-5	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	R2, Ch-1, 2 & 3
6-9	Recombinant DNA Technology	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,	T1, Ch-3

		including DNA hybridization, immunological assays and protein activity, Vectors for cloning large pieces of DNAs.	
10-14	Monoclonal antibodies and biosimilars	Principle behind the Monoclonal antibodies and biosimilar Formulation considerations Stability issues	R3, Ch-2 R1, Ch-11 Notes to be given in class
15-18	Vaccine formulation	Principle behind the vaccine Formulation considerations Stability issues	T1, Ch-7 R1, Ch-13 & 14
19-22	Peptide formulations	Principle behind the peptide Formulation considerations Stability issues	R1, Ch-11
23-26	Characterization of biologicals products	Structural characterization Physicochemical properties Biophysical characterization Aggregates and particulates	R1, Ch-10
27-30	Biologics manufacturing	Upstream and downstream process	T1, Ch-9
31-32	Packaging of biologicals	Conventional delivery packaging Emerging containers and devices for biologics delivery	R1, Ch-20
33-37	Pharmacokinetics of biologicals: Brief overview	Routes of delivery for biologics Absorption, distribution, and elimination of biologics	R1, Ch-22 Notes to be given in class
38-42	Novel delivery systems for biologics	Implants, liposomes, nanoparticles, hydrogels, microspheres etc..	R1, Ch-21 Notes to be given in class

4. Evaluation Scheme:

Component	**Duration**	**Weightage (%)**	**Date and time**	**Remarks**
Mid-semester Test	90 min	20	2/3 , 01:30-03:00 PM	CB
Seminars/ Assignments		25		OB
Laboratory component		20		15 % OB+5 % CB
Comprehensive	180 min	35	02/05 FN	35% CB

exam				

*: Assignments/seminar topics/lab sessions, 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 Mid-term test.
   a) **Grading Procedure:** 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.
6. **Make-up:**Prior approval or intimation to take a make-up is mandatory. It is solely at the discretion of the instructor-in-charge, depending upon the genuineness of the circumstances, to allow or disallow a student to appear for a make-up evaluation component.
7. **Chamber consultation hours:** To be announced in the class.
8. **Notices:** Notices pertaining to this course will be displayed on Department Notice Board.
9. **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