

**BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI**  
**Second Semester 2021-2022**  
**Course Handout (Part II)**

01-01-  
2022

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 : Raghuraman Manimaran, Manisha Malani, Shubham Prakash  
Debaje

**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, analyse and use biological information for therapeutic utility, immense potentiality and application of decoding the human genome

**1. Scope and Objective of the course:**

This course is designed to provide pharmaceuticals graduate students with an understanding 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. 2<sup>nd</sup> 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, 5<sup>th</sup> 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:**

<b>Lect. No</b>	<b>Learning objectives</b>	<b>Topics to be covered</b>	<b>Chapter in the Text Book/Ref Book</b>
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 etc..	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, 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	T1, Ch-3

		cloning large pieces of DNAs.	
10-14	Monoclonal antibodies (Biologics)	Principle behind the Monoclonal antibodies Formulation considerations Stability issues	R3, Ch-2 R1, Ch-11 Notes to be given in class
15-18	Vaccine formulation (Biologics)	Principle behind the vaccine Formulation considerations Stability issues	T1, Ch-7 R1, Ch-13 & 14
19-23	Characterization of biologics products	Structural characterization Physicochemical properties Biophysical characterization Aggregates and particulates	R1, Ch-10
24-27	Biologics manufacturing	Upstream and downstream process	T1, Ch-9
28-31	Biological barriers to biologics delivery	Routes of delivery for biologics Absorption, distribution, and elimination of biologics	R1, Ch-22 Notes to be given in class
32-35	Novel delivery systems for biologics	Implants, liposomes, nanoparticles, hydrogels, microspheres etc..	R1, Ch-21 Notes to be given in class
36-40	Packaging of biologics	Conventional delivery packaging Emerging containers and devices for biologics delivery	R1, Ch-20

#### 4. Evaluation Scheme:

Component	Duration	Weightage (%)	Date and time	Remarks
Mid-semester Test	90 min	30	As per Timetable	As announced in the timetable (100% CB if conducted offline/ 100% OB if conducted online or hybrid mode)
Seminars/ Assignments		20		OB
Laboratory component		15		OB
Comprehensive exam	120 min	35	As per Timetable	As announced in the timetable (95% CB if

				conducted offline/ 100% OB if conducted online or hybrid mode)
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\*: 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**