Study Plan No.	**2021/2022**		**University Specialization**		**Bachelor of Pharmacy**	
Course No.	**0201559**		**Course Name**		**Gene and Protein Therapy**	
Credit Hours	**3**		**Prerequisite *Co-requisite**		**Pharmaceutical Biotechnology**	
Course Type	☐ Mandatory University Requirement	☐ University Elective Requirement	☐ Faculty Mandatory Requirement	☐ Support course family requirements	☐ Mandatory Requirement	☑ **Elective Requirement**
Teaching Style	☐ Full Online Learning		☑ **Blended Learning**		☐ Traditional Learning	
Teaching Model	☐ 1 Synchronous: 1 Asynchronous		☑ **1 Face to Face: 1 Asynchronous**		☐ 2 Traditional	

Faculty Member and Study Divisions Information *(to be filled in each semester by the subject instructor)*

Name	Academic rank	Office No.	Phone No.	E-mail	
Office Hours (Days/Time)	**Sunday, Tuesday, Thursday ()**		**Monday, Wednesday ()**		
Division number	**Time**	**Place**	**Number of Students**	**Teaching Style**	**Approved Model**
				Blended Learning	**1 Face to Face: 1 Asynchronous**

Brief Description

Gene and Protein Therapy introduces modern gene-, protein-, RNA- and cell-based treatments, outlining viral, non-viral and genome-editing delivery methods for inherited and acquired diseases. The course details therapeutic proteins such as hormones, enzymes and monoclonal antibodies, alongside stem-cell and adoptive immune-cell therapies, illustrating their mechanisms, formulations and clinical uses in cancer, autoimmune and rare disorders. Ethical, economic and regulatory considerations governing advanced therapy medicinal products are woven throughout to prepare students for evidence-based professional decision-making.

Learning Resources

Course Book Information (Title, author, date of issue, publisher ... etc)	Crommelin DJA, Sindelar RD, Meibohm B, eds. Pharmaceutical Biotechnology: Fundamentals and Applications. 6th ed. Springer; 2024			
Supportive Learning Resources (Books, databases, periodicals, software, applications, others)	1. Lu Y, Gorovits B. Drug Development for Gene Therapy: Translational Biomarkers, Bioanalysis, and Companion Diagnostics. Wiley; 2024. 2. Galli MC, ed. Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective. Springer; 2023. 3. Singh DB, Tripathi T, eds. Protein-Based Therapeutics. Springer; 2023. 4. Kokate C. Textbook of Pharmaceutical Biotechnology. CBS Publishers; 2022.			
Supporting Websites	-			
The Physical Environment for Teaching	☑ **Classroom**	☐ Labs	☑ **Virtual Educational Platform**	☐ Others

Necessary Equipment and Software	Moodle
Supporting People with Special Needs	-
For Technical Support	E-Learning & Open Educational Resources Center Email: elearning@zuj.edu.jo; Phone: +962 6 429 1511 ext. 425/362

Course learning outcomes *(K= Knowledge, S= Skills, C= Competencies)*

No.	Course Learning Outcomes	The Associated Program Learning Output Code
Knowledge **The student should be able to:**		
K1	Explain contemporary gene-therapy strategies used to correct monogenic disorders.	**MK2**
K2	Compare cellular and stem-cell therapies for tissue regeneration	**MK2**
K3	Evaluate therapeutic proteins and monoclonal antibodies for targeted disease management.	**MK2**
K4	Appraise ethical and regulatory frameworks governing advanced biotherapeutics in Jordan and globally.	**MK2**
Skills **The student should be able to:**		
S1	Interpret clinical and safety data for novel genes, protein, and cell therapies.	**MS4**
S2	Design a theoretical delivery protocol for proteins, genes, or cell therapy.	**MS4**
Competencies **The student should be able to:**		
C1	Select the most appropriate gene-, protein-, or cell-based therapy for a given clinical vignette.	**MC3**
C2	Identify key contraindications and safety precautions when recommending advanced biotherapeutics.	**MC3**

Mechanisms for Direct Evaluation of Learning Outcomes

Type of Assessment / Learning Style	Fully Electronic Learning	Blended Learning	Traditional Learning (Theory Learning)	Traditional Learning (Practical Learning)
Midterm Exam	30%	**30%**	30%	0%
Participation / Practical Applications	0	**0%**	20%	25%
Asynchronous Interactive Activities	20%	**30%**	0	0
Final Exam	50%	**40%**	50%	50%

Note 1: *Asynchronous interactive activities are activities, tasks, projects, assignments, research, studies, projects, and work within student groups ... etc, which the student carries out on his own, through the virtual platform without a direct encounter with the subject teacher.*

Note 2: *According to the Regulations of granting Master's degree at Al-Zaytoonah University of Jordan, 40% of final evaluation goes for the final exam, and 60% for the semester work (examinations, reports, research or any scientific activity assigned to the student).*

Schedule of Simultaneous / Face-to-Face Encounters and their Topics

Week	Subject	Learning Style*	Reference ** (Pages in Course Book)
1	From Recombinant Proteins to Advanced-Therapy Medicinal Products (ATMPs)	**Lecture**	Crommelin 6e Ch 1 *The Biopharmaceutical Revolution*
2	Viral Vectors: Adeno-Associated Virus (AAV) & Lentivirus (*Zolgensma* case)	**Lecture**	Crommelin 6e Ch 10 *Gene-Delivery Systems*
3	Non-Viral & Lipid-Nanoparticle (LNP) Delivery	**Lecture**	Crommelin 6e Ch 11 *Non-Viral Carriers*
4	Classic Recombinant Proteins (insulin, EPO) & PK/PD	**Lecture**	Singh & Tripathi 2023 Ch 2 *Therapeutic Proteins: Production & Formulation*
5	Engineered Antibodies & Novel Formats (bispecifics, ADCs, nanobodies)	**Lecture**	Singh & Tripathi 2023 Ch 6–7 *Antibody Engineering*
6	RNA Medicines (mRNA 2.0, siRNA, ASO)	**Lecture**	Lu & Gorovits 2024 Ch 2 *RNA-Based Therapeutics*
7	Gene-Editing Platforms (CRISPR-Cas9, base- & prime-editing)	**Lecture**	Crommelin 6e Ch 12 *Genome Editing Technologies*
8	Adoptive Cell Therapies (CAR-T, CAR-NK, TCR-T)	**Lecture**	Crommelin 6e Ch 15 *Cell-Based Immunotherapies*
9	Stem-Cell & Regenerative Approaches (iPSC, MSC, gene-edited HSC)	**Lecture**	Galli 2023 Ch 6 *Stem-Cell-Derived ATMPs*
10	In-Vivo vs Ex-Vivo Paradigms & Good Manufacturing Practice (GMP)	**Lecture**	Lu & Gorovits 2024 Ch 5 *CMC & GMP for Gene Therapy*
11	Safety & Risk Management (cytokine-release syndrome (CRS), off-target edits, REMS)	**Lecture**	Galli 2023 Ch 9 *Risk-Benefit & Pharmacovigilance*
12	Regulation & Ethics (EMA, FDA, Jordan JFDA)	**Lecture**	Galli 2023 Ch 1–3 *Global ATMP Regulation*
13	Pharmacoeconomics & Market Access (value-based pricing; *Hemgenix* case)	**Lecture**	Crommelin 6e Ch 18 *Health-Economics of Biologics*
14	Future Horizons & Capstone Presentations (epigenome editing, programmable RNA)	**Lecture**	Kokate 2022 Ch 14 *Emerging Gene-Therapy Modalities* (supplementary)
15	New updated topics.	**Lecture**	Crommelin 6e Ch 1 *The Biopharmaceutical Revolution*
16	Final Exam	-	Crommelin 6e Ch 10 *Gene-Delivery Systems*

** Learning styles: Lecture, flipped learning, learning through projects, learning through problem solving, participatory learning ... etc.*
*** Reference: Pages in a book, database, recorded lecture, content on the e-learning platform, video, website ... etc.*

Schedule of Asynchronous Interactive Activities *(in the case of e-learning and blended learning)*

Week	Task / Activity	Reference	Expected Results
2	Video: "Why do we need ATMPs?" → discussion-board timeline	Video on the E-learning platform	**Online quiz**
3	Video: AAV manufacturing workflow → safety-data worksheet	Video on the E-learning platform	**Online quiz**
4	Video: "How LNPs escape the endosome" → LNP-design storyboard	Video on the E-learning platform	**Online quiz**
5	Video: long-acting insulin case → 10-item PK/PD quiz	Video on the E-learning platform	**Online quiz**
6	Video: "How an ADC delivers its payload" → LMS MCQs	Video on the E-learning platform	**Online quiz**
7	Video: Inclisiran MoA → Phase III data spreadsheet	Video on the E-learning platform	**Online quiz**
8	Video: base-editing animation → article critique	Video on the E-learning platform	**Online quiz**
9	**Midterm Exam**		
10	Video: iPSC reprogramming steps → Padlet concept map	Video on the E-learning platform	**Online quiz**
11	Video: virtual tour of a GMP viral-vector suite → process-flow chart	Video on the E-learning platform	**Online quiz**
12	Video: CRS pathophysiology → interactive "red-flag" e-case	Video on the E-learning platform	**Online quiz**
13	Video: "How an ATMP dossier moves through the EMA" → forum debate	Video on the E-learning platform	**Online quiz**
14	Video: payer view on gene-therapy pricing → budget-impact sheet	Video on the E-learning platform	**Online quiz**
15	Pre-watch video: "Three signals shaping gene therapy in 2030" → oral/poster defense	Video on the E-learning platform	**Online quiz**
16	**Final Exam**		