

1st Semester Programme



Module Code	Theoretical Modules	U Assigned Prof. module (Μαθήµατος)	Theoretical modules educational goal	Code Lesson	Topics	Speaker	Date	Day	Hours
CGT 101	Introduction to C> GMP	Prof. A Spyridonidis	The students will accept a best practice approach to manufacture C>s utilizing instructions comply with cGMP guidelines. They will cover all logistics and practical aspects of GMP production.	CGT 101/T1	Welcome and syllabus	Alexandros Spyridonidis	09 March 2022	Wednesday	17:00-19:00
				CGT 101/T2	Introduction to cell and gene therapies	Eyal Neria			19:00-21:00
				CGT 101/T3	Basic principles of GMP Part 1	Gerhard Bauer	16 March 2022	Wednesday	17:00-19:00
				CGT 101/T4	Basic principles of GMP Part 2	Gerhard Bauer			19:00-21:00
				CGT 101/T5	Elements of a QA System	Vincent Vandamme			17:00-19:00
				CGT 101/T6	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	Chaya Mazouz	23 March 2022	Wednesday	19:00-21:00
				CGT 101/T7	Risk Analysis - ICH Q9 and FMEA	Chaya Mazouz	30 March 2022	Wednesday	17:00-19:00
				CGT 101/T8	The Role of the QP	Vincent Vandamme			19:00-21:00
				CGT 101/T9	POCare Manufacturing	Vered Caplan			17:00-19:00
				CGT 101/T10	The regulatory authorities (FDA, EMA) and the regulatory review pathways (IND to BLA; IMPD to MAA)	Chaya Mazouz	06 April 2022	Wednesday	19:00-21:00
				CGT 101/T11	EXAMS		13 April 2022	Wednesday	17:00-21:00
CGT 102	Biological aspects of	Ass. Prof. A. Kriebardis	The students will gain understanding about	CGT 102/T1	Cells and tissue culture basics, cells life cycle	Anastasios Kriebardis	10 March 2022	Thursday	17:00-19:00

1st Semester Programme



CGT 102	C> / Basic cell biology		different cell types, as well as basic aspects related to cell biology. The students will also learn about different methods (viral and non viral vectors) of gene therapy.	CGT 102/T2	Cells life cycle, cell death, aging and senescence, differentiation	Zoe Lygerou			19:00-21:00
				CGT 102/T3	Stem cells	Stavros Taraviras			17:00-19:00
				CGT 102/T4	Case studies of cell types (MSCs, immune cells, stem cells)	Stephen Minger	17 March 2022	Thursday	19:00-21:00
				CGT 102/T5	Response of immune system to cell therapies	Robert Zeiser			17:00-19:00
				CGT 102/T6	Cell signalling with focus on T cell signalling	Konstantina Nika	24 March 2022	Thursday	19:00-21:00
				CGT 102/T7	Viruses and viral vectors, non-viral gene therapies	Reem Miari			17:00-19:00
				CGT 102/T8	Case studies of gene therapies (viral vectors, non-viral vectors)	Ioanna Yannaki	31 March 2022	Thursday	19:00-21:00
				CGT 102/T9	EXAMS		07 April 2022	Thursday	17:00-21:00
				CGT 103	C> Regulation	Prof. A Spyridonidis	The students will gain knowledge about the US, EU and local regulations of cells and gene therapies. They will be exposed to applicable laws, regulations and guidelines for best practice	CGT 103/T1	ATMP (EU) legislation - an overview
CGT 103/T2	Case study	Gerhard Bauer	04 May 2022					Wednesday	19:00-21:00
CGT 103/T3	CGT (FDA) guidance - an overview	Chaya Mazouz							17:00-19:00
CGT 103/T4	Cell & Gene Therapy Quality/ CMC considerations	Sagi Nahum	11 May 2022					Wednesday	19:00-21:00
CGT 103/T5	SEC / ISBT 128 and other labelling systems	Miri Sani							17:00-19:00
CGT 103/T6	Hospital Exemption Use	Heiko Von Der Leyen	18 May 2022					Wednesday	19:00-21:00

				CGT 103/T7	Submitting a file for GMP Facility authorization	Vincent Vandamme		25 May 2022	Wednesday	17:00-19:00	
				CGT 103/T8	Expedited programs and orphan drug issues	Chaya Mazouz				19:00-21:00	
				CGT 103/T9	Case study	Dimitrios Mougiakakos		01 June 2022	Wednesday	17:00-19:00	
				CGT 103/T10	EXAMS					17:00-21:00	
CGT 104	Biostatistics and medical data analysis	Prof. E. Papageorgiou	The basic principles of statistical analysis will be presented and their applications to C> therapeutic products	CGT 104/T1	Population, sample, and data collection	Eftsathia Papageorgiou		05 May 2022	Thursday	17:00-19:00	
				CGT 104/T2	Descriptive statistic methodology using SPSS	Eftsathia Papageorgiou					19:00-21:00
				CGT 104/T3	Survival outcomes (Kaplan–Meier, CI, competing risks)	Eftsathia Papageorgiou		12 May 2022	Thursday	17:00-19:00	
				CGT 104/T4	Univariate comparisons	Eftsathia Papageorgiou					19:00-21:00
				CGT 104/T5	Gray’s statistic for cumulative incidence functions	Eftsathia Papageorgiou		19 May 2022	Thursday	17:00-19:00	
				CGT 104/T6	Cox regression Multivariate analysis	Eftsathia Papageorgiou					19:00-21:00
				CGT 104/T7	Data presentation of small and big data	Eftsathia Papageorgiou		26 May 2022	Thursday	17:00-19:00	
				CGT 104/T8	EXAMS						19:00-21:00