Universidad Carlos III de Madrid

SUBJECT: QUALITY PROCESSES IN THE BIOMEDICAL INDUSTRY. REGULATORY BASIS		
MASTER DEGREE: MASTER IN BIOMEDICAL TECHNOLOGIES MANAGEMENT AND DEVELOPMENT	ECTS:5	QUARTER: 2

TIMETABLE FOR THE SUBJECT

WEEK	SESSION	DESCRIPTION OF EACH SESSION	GROUP (X mark)		Indicate if a different lecture room is needed (computer, audiovisual, etc.)	HOMEWORK PER WEEK		
			1	2		DESCRIPTION	ATTENDING HOURS	HOMEWORK Max. 7H/WEEK
1	1	Introduction to the general and specific quality systems of the pharmaceutical industry (GXP): ISO standards: ISO 9001: 2000 - ISO 13485 medical devices	X				1,5	6
1	2	Good Laboratory Practices (legal basis, introduction and objective, requirements of the Standard, accreditation)	X				1,5	
2	3	GCP - Good Clinical Practices (legal basis, introduction and objective, requirements of the Standard). GDP - Good Distribution Practices (legal basis, introduction and objective, requirements of the Standard, certification)	X				1,5	6
2	4	GMP - Good Manufacturing Practices (legal basis, introduction and objective - Special Features in Advanced Therapy)	X				1,5	
3	5	GMP: Quality Systems and Personal. Facilities and Equipment.	X				1,5	6
3	6	GMP: Production and Quality Control	X				1,5	
4	7	GMP: Manufacturing and analysis by contract, claims, withdrawals, audits and administrative procedure in inspections	X				1,5	6
4	8	Annexes of the GMP Guide	X				1,5	

5	9	CE labelling Requirements for regulatory purposes.	X				1,5	6
5	10	Regulatory agencies of different countries (AEMPS, MHRA, Paul Ehrlich Institute) and EMA and FDA central agencies. Regulatory aspects in Asia	X				1,5	
6	11	Clinical trial authorisation	X				1,5	6
6	12	PEI (IMPD)	X				1,5	
7	13	Drug Registry and marketing authorization	X				1,5	6
7	14	CTD. Commun Technical Document	X				1,5	
8	15 y 16	Veterinary medicaments. Clinical Trial and Marketing / CTD. Experience of EQUICORD-YMAS	X				3	6
9	17 y 18	Innovative therapeutic agents based on interference RNA (RNAi). SYLENTIS (Pharmamar Group)	X				3	6
10	19 y 20	Advanced Therapies (AEMPS)	X				3	6
11	21	R & D and Preclinical GLP in Advanced Therapy Drugs: developed from the company. Experience of CORETHERAPIX (Tigenix)	X				1,5	6
11	22	CRO and ATMPs. Biomedical research	X				1,5	
		Tutorials, handing in, assessments…						30
TOTAL HOURS							33	96