TOR VERGATA
UNIVERSITY OF ROME

Degree Course in
Pharmacy

COURSE PROGRAM 2020-2021

COURSE	THE AUTHORIZATION OF MEDICINAL PRODUCTS IN THE EU			
OPTIONAL COURSE	PROFESSOR	SSD	CFU	HOURS
	John Joseph Bprh	BIO/14	5	40

PROFESSOR	John Joseph Borg
ATTENDANCE	Mandatory
OFFICE HOURS	To be agreed
E-Mail/Contact	cyberjob@hotmail.it

PROGRAM	1. Part 1 EU Directives and Regulations on Medicinal products General Aspects of the EU legislation – covering Named patient basis/compassionate use/public health authorisations, industrial manufacturing, national marketing authorisations, decentralised and mutual recognition, referral procedures, arbitration at the European Medicines Agency, CHMP. 2. Part 2 EU Directives and Regulations on Medicinal products Pharmacovigilance regulations and obligations 3. Part 3 EU Directives and Regulations on Medicinal products Risk Management Plans and Advertising of Medicinal products issues and case examples 4. The EU regulatory Framework on Biosimilars General aspects on Biosimilars/Quality-clinical programs and regulatory updates. 5. How to assess a medicinal product including an OTC. 6. General aspects on what assessors do when evaluating risk/benefit of medicines and OTC 7. Part 1 the well established use licensing of medicinal products Extrapolation of literature data to support a marketing authorisation 8. Does the Regulator face ethical issues Updates on the clinical trial regulation and a case example of ECMO. 9. Part I pre-clinical data required to support a medicine's safety - Ion channel of excitable membranes General aspects of receptors and electrophysiology 10. Part 2 – pre-clinical data required to support a medicine's safety - Applying basic concepts to understand clinical relevance 11. Part 3 - pre-clinical data required to support a medicine's safety – ICHS7A & ICHS7B explained General discussion on how industry assesses cardiac safety of medicines in development. 12. Part 4 - pre-clinical data required to support a medicine's safety – juvenile toxicology studies 13. Part 5 - pre-clinical data required to support a medicine's safety – Non-Clinical Investigation of the Dependence Potential of Medicinal Products 14. Part 6 - data required to support a medicine's safety – Biotech products 15. Part 7- data required to support a medicine's safety – anticancer/DSMBs/Extrapolation of

	Animal data. 16. Licensing of Generics - Understanding Bioequivalence studies and the analytical method part 1 17. Licensing of Generics - Understanding Bioequivalence studies and the analytical method part 2 2
EXAM METHOD	Written test
MODALITA' D'ESAME	Prova Scritta
EVALUATION	18/30
VALUTAZIONE	18/30