

POSTGRADUATE EUROPEAN RADIOPHARMACY COURSE

Module 1: P H A R M A C Y
Ljubljana, August 26th – September 6th, 2019



Programme - draft

Monday, August 26th, 2019

9.00	Registration	
9.30	Opening words and some information	<i>FFA T. Gmeiner</i>
10.00 – 10.15	Information on the Postgraduate Course in Radiochemistry/Radiopharmacy	<i>R. Furegati</i>
10:15 - 12.00	Pharmacopoeia	<i>T. Kroon</i>
12.00 - 13.30	Lunch break	
13.30 - 15.00	Pharmacopoeia – how to use it	<i>T. Kroon</i>
<i>15.00 – 15.30</i>	<i>Coffee break</i>	
15.30 – 16.30	Legislation in Radiopharmacy, Introduction and overview	<i>C. Decristoforo</i>
16.30 – 17.30	European Directives and GMP	<i>S. Todde</i>
17.30 – 17.45	Introduction to oral exam	<i>T. Gmeiner</i>
19.00	Town Hall - reception	

Tuesday, August 27th, 2017

9.00 – 10.00	Specific radiopharmaceutical legislation; Small Scale, non commercial preparation of radiopharmaceuticals	<i>C. Decristoforo</i>
10.00 – 11.00	Good Manufacturing Practice in the pharmaceutical industry	<i>D. Vendrig</i>
<i>11.00 – 11.30</i>	<i>Coffee break</i>	
11.30 – 12.30	Good Manufacturing Practice of Classical Radiopharmaceuticals	<i>D. Vendrig</i>
12.30 - 14.00	Lunch break	
14.00 – 15.00	Clinical Trial directives and IMPD	<i>S. Todde</i>
15.00 – 15.30	Discussion – how are you regulated?	<i>C. Decristoforo S. Todde</i>
<i>15.30 – 16.00</i>	<i>Coffee break</i>	
16.00 – 17.30	Specific examples: preclinical requirements and risk assessment	<i>C. Decristoforo S. Todde</i>
18.00	Ljubljana: Guided Walk	<i>D. Poljanšek</i>

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Wednesday, August 28th, 2019

9.00 – 10.30	Design of dosage forms	A. Zvonar Pobirk
10.30 -11.00	Coffee break	
11.00 – 12.00	Aseptic preparation	T. Gmeiner
12.00 - 13.30	Lunch break	
13.30 – 15.00	Microbiology in Pharmacy	M. Korva, M. Petrovec
15.00 - 15.30	Coffee break	
15.30 – 17.00	Microbiology in Pharmacy, continued	M. Korva, M. Petrovec

Thursday, August 29 th, 2019

9.00 – 10.30	Methods of preparation of sterile products	M. Gašperlin
10.30 – 11.00	Coffee break	
11.00 – 12.00	The role of excipients in parenteral radiopharmaceutical preparations	B. Janković
12.00 - 13.30	Lunch break	
13.30 -15.00	Water for pharmaceutical use	Š. Zupančič
15.00 – 16.00	Particulate contamination	R.Dreu
16.00 - 16.30	Coffee break	
16.30 -17.30	Pharmaceutical packaging	A.Sočan

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Friday, August 30th, 2019

9.00 -10.30	Principles of Medicinal Chemistry	<i>T. Tomašič</i>
<i>10.30 -11.00</i>	<i>Coffee break</i>	
11.00 – 12.30	Principles of Medicinal Chemistry, continued	<i>T. Tomašič</i>
12.30 - 13.30	Lunch break	
13.30 -14.30	Sterility testing and endotoxin determination: from pharmacopoeial methods to the Recombinant Factor C assay	<i>B. Janković</i>
14.30 – 15.30	Stability and shelf-life of pharmaceuticals	<i>R. Roškar</i>
15.30 – 16.00	Coffee break	
16.00 – 17.00	(In)Stability of Radiopharmaceuticals	<i>M. Krošelj</i>

Monday, September 2nd, 2019

9.00 – 10.30	Radiolabelling of blood cells	<i>T. Gmeiner</i>
<i>10.30 – 11.00</i>	Coffee break	
11.00 – 12.30	Radiolabelling of blood cells -continued	<i>T. Gmeiner</i>
12.30 - 13.30	Lunch break	
13.30 – 14.00	Introduction to practicals – all together	
14.00 – 18.00	Practicals I, II, III in groups Cell labelling, Pyrogen testing, Flow cytometry + Microscopy	<i>A. Sočan, M. Krošelj R. Rošic Danko J. Zupan</i>

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Tuesday, September 3rd, 2019

9.00 - 10.30	From gene engineering to modern biologicals	<i>B. Štrukelj</i>
10.30 – 11.00	<i>Coffee break</i>	
11.00 - 12.30	From gene engineering to modern biologicals - continued	<i>B. Štrukelj</i>
12.30- 14.00	Lunch break	
14.00 – 18.00	Practicals I, II, III in groups: Cell labelling, Pyrogen testing, Flow cytometry + Microscopy	<i>A. Sočan, M. Krošelj P. Kolenc-Peitl J. Zupan</i>

Wednesday, September 4th, 2019

9.00 - 10.30	Basic concepts of Pharmacokinetics	<i>I. Grabnar</i>
10.30 – 11.00	<i>Coffee break</i>	
11.00 - 12.30	Basic concepts of Pharmacokinetics, continued	<i>I. Grabnar</i>
12.30 - 14.00	Lunch break	
14.00 – 18.00	Practicals I, II, III in groups Cell labelling, Pyrogen testing, Flow cytometry + Microscopy	<i>A. Sočan, M. Krošelj P. Kolenc-Peitl J. Zupan</i>

Thursday, September 5th, 2019

9.00 -10.30	An overview of modern pharmaceutical analysis	<i>J. Ilaš</i>
10.30 – 11.00	<i>Coffee break</i>	
11.00 – 12.30	Pharmaceutical Analysis, continued	<i>J. Ilaš</i>
12.30 – 13.00	Break	
13.00- 18.00	Oral examination and discussion	<i>T. Gmeiner B. Štrukelj M. Krošelj R. Schibli</i>
20.00	Farewell Party	

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University of Ljubljana
Faculty of Pharmacy



Friday, September 6th, 2019

9.00 – 10.30	Registration of medicinal products and General rules for distribution	<i>S. Zalar</i>
10.30 – 11.00	<i>Coffee break</i>	
11.00 – 12.30	Quality Assurance and Preparation of Standard Operating Procedures (SOPs)	<i>J. Omersel</i>
12.30 - 14.00	Good Manufacturing Practice of PET Radiopharmaceuticals	
14.00	Closing	<i>T. Gmeiner</i>