

POSTGRADUATE EUROPEAN RADIOPHARMACY COURSE**Module 1: P H A R M A C Y****Ljubljana, August 26th – September 6th, 2019**

Programme

ETHEidgenössische Technische Hochschule Zürich
Swiss Federal Institute of Technology Zurich**Monday, August 26th, 2019**

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| 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

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| 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

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

Thursday, August 29 th, 2019

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

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Ljubljana, August 26th – September 6th, 2019

Friday, August 30th, 2019

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| 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. Rožkar</i> |
| 15.30 – 16.00 | Coffee break | |
| 16.00 – 17.00 | (In)Stability of Radiopharmaceuticals | <i>M. Krošelj</i> |

Monday, September 2nd, 2019

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| 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. Rožic Danko J. Zupan</i> |
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Ljubljana, August 26th – September 6th, 2019Tuesday, September 3rd, 2019**ETH**Eidgenössische Technische Hochschule Zürich
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| 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 D. Rosič Danko J. Zupan</i> |
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Wednesday, September 4th, 2019

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| 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 D. Rosič Danko J. Zupan</i> |
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Thursday, September 5th, 2019

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| 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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Friday, September 6th, 2019

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| 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 | <i>SOPs as a part of quality assurance documents: purpose, preparation and implementation</i> | <i>J. Omersel</i> |
| 12.30 - 14.00 | Good Manufacturing Practice of PET Radiopharmaceuticals | |
| 14.00 | Closing | <i>T. Gmeiner</i> |