Training Programme (essential elements)
Clinical Practical Year (CPY)
at Medical University of Vienna, Austria

CPY-Tertial C
Pharmacology and Toxicology

Valid from academic year 2015/16

Responsible for the content
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This training programme applies to the subject of "Pharmacology and Toxicology" within CPY tertial C "Electives". The training programmes for the elective subjects in CPY tertial C are each designed for a duration of 8 weeks.
3. Learning objectives (competences)

This elective builds on previously acquired knowledge in Pharmacology and Toxicology (see application requirements). Learning objectives comprise both theoretical and practical skills.

During their CPY, students train to acquire skills employed in experimental Pharmacology and Toxicology.

3.1 Competences to be achieved

A) Literature research of an issue in Pharmacology/Toxicology
   1. Discuss a finding (e.g. from the literature) related to the mode of action of an active compound / to the side effect of a drug
   2. Devise a testable hypothesis on the mode of action of a drug /active compound

B) Preparing for an experimental study
   3. Outline a step-by-step study protocol
   4. Preparation of test reagents, e.g. buffer solutions, test media
   5. Preparation of biological specimens: tissue dissection, isolation of cells, cultivation of isolated cells, isolation of subcellular particles, protein purification,
   6. Performing a biological test: amplification of complementary DNA, transfection of isolated cells with foreign DNA

C) Standardisation procedures
   7. Calibration of a quantitative measurement
   8. Measurement of electrical conductivity
   9. Determine sensitivity and specificity of a detection method

D) Biometric measurement
   10. Carry out a measurement used in Pharmacology and Toxicology (e.g. by electrical recordings, with the use of radiotracers, optical/colorimetric methods)
   11. Assess the effect of a drug/of an active test compound, assess the suitability of an experimental test system
   12. Assess the specificity of an effect with the use of inhibitors, determine concentration/time dependence of an effect

E) Documentation in Pharmacology/Toxicology
   13. Effect analysis
   14. Verbal and graphical presentation of experimental data, assessment of differences between measurements
   15. Interpretation of an experimental result in the context of relevant textbook knowledge

3.2 Optional competences

Additional learning objectives are

1. Identification of drugs and toxic compounds in body fluids
2. Assessment of time-dependent concentration profiles
4. Training progress

The goal of this training is to formulate and test a hypothesis by experiment. An expert mentor provides the student with supervision during the individual steps of the study. The student’s progress will be monitored by means of DOPS (Direct Observation of Procedural Skills), the mentor feeds back at meetings in the middle and at the end of the eight-week course.

4.1 DOPS: skills to be assessed

1. Formulating a testable hypothesis
2. Preparation of reagents
3. Tissue dissection and isolation of biological sample material
4. Carrying out a biometric measurement method
5. Carrying out a detection procedure
6. Carrying out a biological test
7. Performing a standardization procedure
8. Analysis of results

This list can be adapted to the type of experiment conducted.

5. Tasks to be carried out in the CPY-course in Pharmacology/Toxicology

In cooperation with the mentor, the student chooses the topic of the experimental study. The mentor is responsible for selecting articles from the literature relevant to the study topic. Except for the specified situation, the experimental study is part of a research project.

The experimental study is laid out in a numbered series of tasks to allow for a structured approach.

During the course the student proceeds under supervision with individual work steps, each giving a documented result (e.g. a protocol of the procedure) to be signed and acknowledged by the student’s mentor. If the outcome of an experiment was dubitable, the test plan should be reviewed and/or the student is demanded to train a necessary skill. A biometric measurement (or any type of experimental result critical in supporting or rejecting a hypothesis) must be confirmed through repeating it.
List of mandatory tasks:

<table>
<thead>
<tr>
<th>Tasks to be carried out</th>
<th>Number of times to be carried out*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and discuss an open issue in Pharmacology/Toxicology</td>
<td>One time</td>
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<tr>
<td>Devise a testable hypothesis</td>
<td>One time</td>
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<tr>
<td>Devise an experimental study</td>
<td>One time</td>
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<tr>
<td>Prepare test reagents and test substrate</td>
<td>Two times</td>
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<tr>
<td>Standardisation of a measurement</td>
<td>One time</td>
</tr>
<tr>
<td>Conducting a biometric measurement</td>
<td>Two times</td>
</tr>
<tr>
<td>Documentation of an experiment</td>
<td>One time</td>
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* Number of necessary repetitions
Appendix: Details of the tasks in the CPY-course Pharmacology and Toxicology

Research and discuss an open issue in Pharmacology/Toxicology and devise a testable hypothesis

Procedure:
   a) Perform a literature research on an open question related to one of the following: the mode of action of a drug, the side effect of a drug or a pharmacokinetic issue. Textbooks, scientific literature and SmPC (the official label of the properties of a drug) are basis for the research.
   b) Formulate a hypothesis amenable to experimental testing
   c) Describe and discuss applicable experimental methods

Portfolio documentation (list, use keywords):
   • Discussion of the selected finding
   • Formulation of a testable hypothesis
   • Presentation of the selected experimental method

Signature of mentor

Time frame: 3 days
Preparation for an experimental study
(Devise an experimental study, and prepare test reagents and test substrate)

Procedure:
   a) Devise an experimental protocol
   b) Describe experimental methods in a step-by-step manner
   c) Preparation of test reagents
   d) Preparation of the test substrate

Portfolio documentation (list, use keywords):
   • Study outline with experimental work plan
   • Experimental methods (assay protocols) in preparation of the biometric measurement

Signature of mentor

Time frame: 2 weeks

<table>
<thead>
<tr>
<th>Preparing for a biometric measurement</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of assay reagents</td>
<td>Concentration and volume calculations</td>
</tr>
<tr>
<td></td>
<td>Setting the pH value of buffer solutions</td>
</tr>
<tr>
<td>Preparation of sample material</td>
<td>Anatomical dissection, tissue fractionation</td>
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<td>Sedimentation method: isolation of defined cell components</td>
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<tr>
<td>Cultivation of cells</td>
<td>Determination of cell numbers and proliferation rate</td>
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<td>Transfection of cells with foreign DNA</td>
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<tr>
<td>Isolation of biomolecules</td>
<td>Chromatography, electrophoresis: Collection of protein or nucleic acid fractions</td>
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<tr>
<td>Carrying out a biological test</td>
<td>Amplification of complementary DNA and restriction analysis</td>
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</tbody>
</table>
Standardisation of a measurement method, determination of assay sensitivity

Procedure:

a) Carry out a measurement method typically employed in Pharmacology/Toxicology
b) Determine sensitivity using available standard samples
c) Adjust measurement method to the standards and optimize the conditions of the method
d) Maintenance (appropriate disposal of chemicals, return of technical equipment in order, replenishing of consumed materials etc.)

Portfolio documentation (list, use keywords):

- Description of measurement/ assay protocol
- Presentation of original data obtained by recording/measurement
- Graphical depiction and analysis of standardisation/sensitivity determination

Signature of mentor

Time frame: 2 weeks

Measurement methods typical employed in experimental Pharmacology/Toxicology

- Enzymatic/colorimetric measurement
- Physical measurement
- Microscopic analysis
- Fluorescence-based recording
- Electrical recording
- Radiotracer method
- Histological tissue staining
- Identification of cell structures using isolation method
- Methods in molecular biology

Examples of standardisation methods

- Calibration of a method to determine concentration
- Calibration of a method to determine molecular mass
- Determination of the specific activity of an enzymatic measurement method / radiotracer method
- Determination of electrical conductivity
- Determination of the sensitivity of a detection method
Conducting a biometric measurement (to assess a pharmacological effect)

Procedure:
1. Carry out measurement under mentor’s guidance
2. Repeat measurement on own initiative

   a) Investigate effect of a drug/active compound, assess specificity of effect
   b) Verify suitability of assay substrate
   c) Quantitate effect size
   d) Assess concentration dependence of the effect
   e) Explore the effect with the use of specific inhibitors/antagonists

Portfolio documentation (list, in keywords):
- Assay protocol of biometric measurements (guided, repeated) with description of
  - Method
  - Test substrate
  - Test conditions (medium, buffer, temperature etc.)
  - Test compound/drug (solvent, concentration)
  - Control conditions (active standard, blanks)
  - Result of assessment: Original data

Signature of mentor

Time frame: 3 weeks
Documentation of an experiment

Procedure:
   a) Pharmacological analysis of effect parameters
   b) Discussion of differences between measurements
   c) Discussion of assay quality

Portfolio documentation:
   - Written summary of the experimental measurement method
   - Written and graphical presentation of the results
   - Evaluation of the result based on textbook knowledge

Signature of mentor

Time frame: 1 week