Good Practices in Experimental Sciences

Title	Good Practices in Experimental Sciences
Semester	F2024
Master programme in	Chemical Biology / Environmental Science / Molecular Health Science
Type of activity	Course
Teaching language	English
Study regulation	Read about the Master Programme and find the Study Regulations at ruc.dk
	Læs mere om uddannelsen og find din studieordning på <u>ruc.dk</u>

REGISTRATION AND STUDY ADMINISTRATIVE

Registration

Sign up for study activities at <u>stads selvbetjening</u> within the announced registration period, as you can see on the <u>Studyadministration</u> <u>homepage</u>.

When signing up for study activities, please be aware of potential conflicts between study activities or exam dates.

The planning of activities at Roskilde University is based on the recommended study programs which do not overlap. However, if you choose optional courses and/or study plans that goes beyond the recommended study programs, an overlap of lectures or exam dates may occur depending on which courses you choose.

Number of participants

ECTS

5

Responsible for the activity

Louise Torp Dalgaard (ltd@ruc.dk)

Head of study

Lotte Jelsbak (<u>ljelsbak@ruc.dk</u>)

Teachers

Study administration

INM Registration & Exams (inm-exams@ruc.dk)

Exam code(s)

U60175

ACADEMIC CONTENT

Overall objective

The overall objective of this course is to introduce the concept of Good Practices within different areas of experimental research ('GxP'), to make

students knowledgeable about how careful considerations and implementation of experimental good practices can lead to improved validity and consistency of performed research and experiments, and render data more dependable. Furthermore, the aim is to provide students with the necessary methodological and data analysis skills to be able to evaluate validity and quality of methods and data, and critically assess data and methods in general.

Detailed description of content

The overall objective of this course is to introduce the concept of Good Practices within different areas of experimental research ('GxP') in order to make students knowledgeable about how careful considerations and implementation of experimental good practices can lead to improved validity and consistency of performed research and experiments, and render data more dependable.

Furthermore, the course will equip students with the necessary methodological, statistical and data analysis skills to be able to evaluate validity and quality of methods and data, and critically assess data and methods in general.

Course material and Reading list

The course is based on notes and primary literature (please confer with Moodle upon course registration).

Overall plan and expected work effort

- Lectures 24 hours (10-12 double lectures and 2-3 double sessions of problem solving)
- Preparation time 89 hours this means that students should expect to use at least 3½ hours of preparation time for each double lecture.
- Question hour 2 hours
- Report writing 20 hours (2 reports of 10 hours each)
- In total 135 hours

Format

Evaluation and feedback

The course includes formative evaluation based on dialogue between the students and the teacher(s).

Students are expected to provide constructive critique, feedback and viewpoints during the course if it is needed for the course to have better quality. Every other year at the end of the course, there will also be an evaluation through a questionnaire in SurveyXact. The Study Board will handle all evaluations along with any comments from the course responsible teacher.

Furthermore, students can, in accordance with RUCs 'feel free to state your views' strategy through their representatives at the study board, send evaluations, comments or insights form the course to the study board during or after the course.

Programme

Part 1 has focus on good experimental practices, giving an introduction to GXP (good experimental practices, good manufacturing practices, good laboratory practices etc), and guidelines and rules concerning these. Moreover, the course will introduce students to method validation and comparison, quality control and handling of devations, as well as requirements to accreditation, as well as regulatory complience. This part will end with a report or a case based analysis.

The second part has focus on methods associated with planning experiments and analysis thereof, as well as on comparing methods, and analyzing performance. This includes introduction to statistical analysis using parametric and non-parametric methods, especially methods relevant to method comparisons. This part will end with a report or a case based analysis.

ASSESSMENT

Overall learning outcomes

After completing the course, the students will be able to:

- axplain the concepts of Good Practices (good laboratory practice, good manufacturing practice etc.)
- describe and explain how experimental methods can be validated, and how consistency and quality of results are handled under Good practice guidelines
- describe regulatory organizations governing biological and chemical compounds, and pharmacological active ingredients
- describe basic aspects of quality assurance, documentation and regulatory affairs, especially in relation to the biotechnological and pharmaceutical industry
- perform basic statistical evaluation of experimental outcomes using common spreadsheet software, including descriptive statistics, comparison of means, variance analysis, correlation analysis
- calculate and analyze performance of an experimental method or assay
- compare and evaluate performance of two methods against each other
- evaluate the performance of a new method by comparing it with a currently used method
- explain specific academic terms related to performance evaluation of methods and experiments (such as sensitivity and specificity, precision and accuracy, predictive values)
- explain how power calculations can determine sample size
- discuss and evaluate method validity and performance
- write documents describing methodological considerations
- communicate the knowledge and understanding gained from the course in a precise and scientific way.

Form of examination

The course is passed through active, regular attendance and satisfactory participation.

Active participation is defined as:

The student must participate in course related activities (e.g. workshops, seminars, field excursions, process study groups, working conferences, supervision groups, feedback sessions).

Regular attendance is defined as:

- The student must be present for minimum 75 percent of the lessons.

Satisfactory participation is defined as:

- e.g. oral presentations (individually or in a group), peer reviews, mini projects, test, planning of a course session .

Assessment: Pass/Fail.

Form of Re-

Students that have not participated satisfactory must hand in renewed written products.

Students that have only met the requirement of regular attendance between 50% and 75% must hand in an additional written product.

Type of examination in special cases

Examination and assessment criteria

The course is passed through active, regular attendance and satisfactory participation.

Active participation and regular attendance is defined as participation in 75% of the lectures and problem-solving sessions, as well as the handing-in and approval of two case-reports; one for each part of the course.

Assessment: Pass/Fail.

Assessment criteria for reports:

The student can explain the concepts of Good Practices (good laboratory practice, good manufacturing practice etc.)

The student is able to describe and explain how experimental methods can be validated, and how consistency and quality of results are handled under Good practice guidelines

The student can describe regulatory organizations governing biological and chemical compounds, and pharmacological active ingredients, as well as describe basic aspects of quality assurance, documentation and regulatory affairs

Moreover, the student will be able to perform basic statistical evaluation of experimental outcomes using common spread-sheet software, including descriptive statistics, comparison of means, variance analysis, correlation analysis

The student can calculate and analyze performance of an experimental method or assay, as well as compare and evaluate performance of two methods against each other, or a new method with a current method.

The student can explain specific academic terms related to performance evaluation of methods and experiments (such as sensitivity and specificity, precision and accuracy, predictive values). In addition, the student is able to explain how power calculations can determine sample size

The student can combine the above mentioned considerations and write documents describing method performance, and can communicate the knowledge and understanding gained from the course in a precise and scientific way.

Exam code(s)

 $Exam\,code(s): U60175$

Course days:

Hold: 1

Good Practices in Experimental Sciences (MHS, CB)

time 05-02-2024 12:15 til 05-02-2024 16:00

00 02 202 110.00

location 27.1-089 - teorirum 27 (66)

Teacher Louise Torp Dalgaard (Itd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB) - Note: Building 21

time 08-02-2024 08:15 til

08-02-2024 12:00

forberedelsesnorm ikke valgt forberedelsesnorm D-VIP ikke valgt

location 21.1-031 - undervisningslokale (56)

Teacher Louise Torp Dalgaard (ltd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time 12-02-2024 12:15 til

12-02-2024 14:00

location 27.1-089 - teorirum 27 (66)

Teacher Louise Torp Dalgaard (Itd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB) - Note: Building 21

time 15-02-2024 10:15 til

15-02-2024 12:00

location 21.1-031 - undervisningslokale (56)

Teacher René Jørgensen (renejoe@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time 19-02-2024 12:15 til

19-02-2024 14:00

location 27.1-089 - teorirum 27 (66)

Teacher René Jørgensen (renejoe@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB) - Note: Building 21

time 22-02-2024 10:15 til

22-02-2024 12:00

location 21.1-031 - undervisningslokale (56)

Teacher René Jørgensen (renejoe@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB) - Note: Building 11

time 26-02-2024 12:15 til

26-02-2024 14:00

forberedelsesnorm ikke valgt forberedelsesnorm D-VIP ikke valgt

location 11.2-047 - gl. natfagsal (65)

Teacher Louise Torp Dalgaard (Itd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time 29-02-2024 10:15 til

29-02-2024 12:00

location 27.1-089 - teorirum 27 (66)

Teacher David Møbjerg Kristensen (davidmk@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time 04-03-2024 12:15 til

04-03-2024 14:00

location 27.1-089 - teorirum 27 (66)

Teacher David Møbjerg Kristensen (davidmk@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB) - Note: Building 21

time 07-03-2024 10:15 til

07-03-2024 12:00

location 21.1-031 - undervisningslokale (56)

Teacher David Møbjerg Kristensen (davidmk@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time 11-03-2024 12:15 til

11-03-2024 14:00

location 27.1-089 - teorirum 27 (66)

Teacher David Møbjerg Kristensen (davidmk@ruc.dk)