

Good Practices in Experimental Sciences

Title	Good Practices in Experimental Sciences
Semester	F2023
Master programme in	Chemical Biology / 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 ruc.dk

REGISTRATION AND STUDY ADMINISTRATIVE

Registration	<p>Sign up for study activities at stads selvbetjening within the announced registration period, as you can see on the Studyadministration homepage.</p> <p>When signing up for study activities, please be aware of potential conflicts between study activities or exam dates.</p> <p>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.</p>
Number of participants	
ECTS	5
Responsible for the activity	Louise Torp Dalgaard (ltd@ruc.dk)
Head of study	Lotte Jelsbak (ljelsbak@ruc.dk)
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
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	<p>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.</p>
Detailed description of content	<p>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.</p> <p>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.</p>
Course material and Reading list	<p>The course is based on notes and primary literature, and on a statistical introductory book (to be determined, please confer with Moodle upon course registration).</p>
Overall plan and expected work effort	<ul style="list-style-type: none"> • 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) <p>- In total 135 hours</p>
Format	
Evaluation and feedback	<p>The course includes formative evaluation based on dialogue between the students and the teacher(s).</p> <p>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.</p> <p>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 from the course to the study board during or after the course.</p>
Programme	<p>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 deviations, as well as requirements to accreditation, as well as regulatory compliance. This part will end with a report or a case based analysis.</p>

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:

- explain 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-examination

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 03-02-2023 10:15 til
03-02-2023 12:00

location 11.2-047 - gl. natfagsal (65)

Teacher Louise Torp Dalgaard (ltd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB) - Please note building 15

time 06-02-2023 12:15 til
06-02-2023 14:00

forberedelsesnorm ikke valgt

forberedelsesnorm D-VIP ikke valgt

location 15.0-003 - auditorie 15 (68)

Teacher René Jørgensen (renejoe@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time 09-02-2023 14:15 til
09-02-2023 16:00

forberedelsesnorm ikke valgt

forberedelsesnorm D-VIP ikke valgt

location 11.1-047 - studiesal (40)

Teacher David Møbjerg Kristensen (davidmb@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time 13-02-2023 12:15 til
13-02-2023 14:00

forberedelsesnorm ikke valgt

forberedelsesnorm D-VIP ikke valgt

location 11.2-047 - gl. natfagsal (65)

Teacher David Møbjerg Kristensen (davidmb@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	17-02-2023 10:15 til 17-02-2023 12:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.2-047 - gl. natfagsal (65)
Teacher	David Møbjerg Kristensen (davidmb@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	20-02-2023 12:15 til 20-02-2023 14:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.2-047 - gl. natfagsal (65)
Teacher	René Jørgensen (renejoe@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	23-02-2023 14:15 til 23-02-2023 16:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.1-047 - studiesal (40)
Teacher	René Jørgensen (renejoe@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	27-02-2023 12:15 til 27-02-2023 14:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.2-047 - gl. natfagsal (65)
Teacher	Louise Torp Dalgaard (ltd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	08-03-2023 14:15 til 08-03-2023 16:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.1-047 - studiesal (40)
Teacher	David Møbjerg Kristensen (davidmb@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	10-03-2023 10:15 til 10-03-2023 12:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.1-047 - studiesal (40)
Teacher	Louise Torp Dalgaard (ltd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	13-03-2023 12:15 til 13-03-2023 14:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.2-047 - gl. natfagsal (65)
Teacher	Louise Torp Dalgaard (ltd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	17-03-2023 10:15 til 17-03-2023 12:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.1-047 - studiesal (40)
Teacher	Louise Torp Dalgaard (ltd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	20-03-2023 12:15 til 20-03-2023 14:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.2-047 - gl. natfagsal (65)
Teacher	Louise Torp Dalgaard (ltd@ruc.dk)

Good Practices in Experimental Sciences (MHS, CB)

time	24-03-2023 10:15 til 24-03-2023 12:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt
location	11.1-047 - studiesal (40)
Teacher	Louise Torp Dalgaard (ltd@ruc.dk)

Good Practices in Experimental Sciences - Hand-in of written products (reexam) (MHS, CB)

time	12-04-2023 10:00 til 12-04-2023 10:00
forberedelsesnorm	ikke valgt
forberedelsesnorm D-VIP	ikke valgt