Welcome to the course

”Applied Pharmaceutical and Biomedical analysis”

Spring semester 2022

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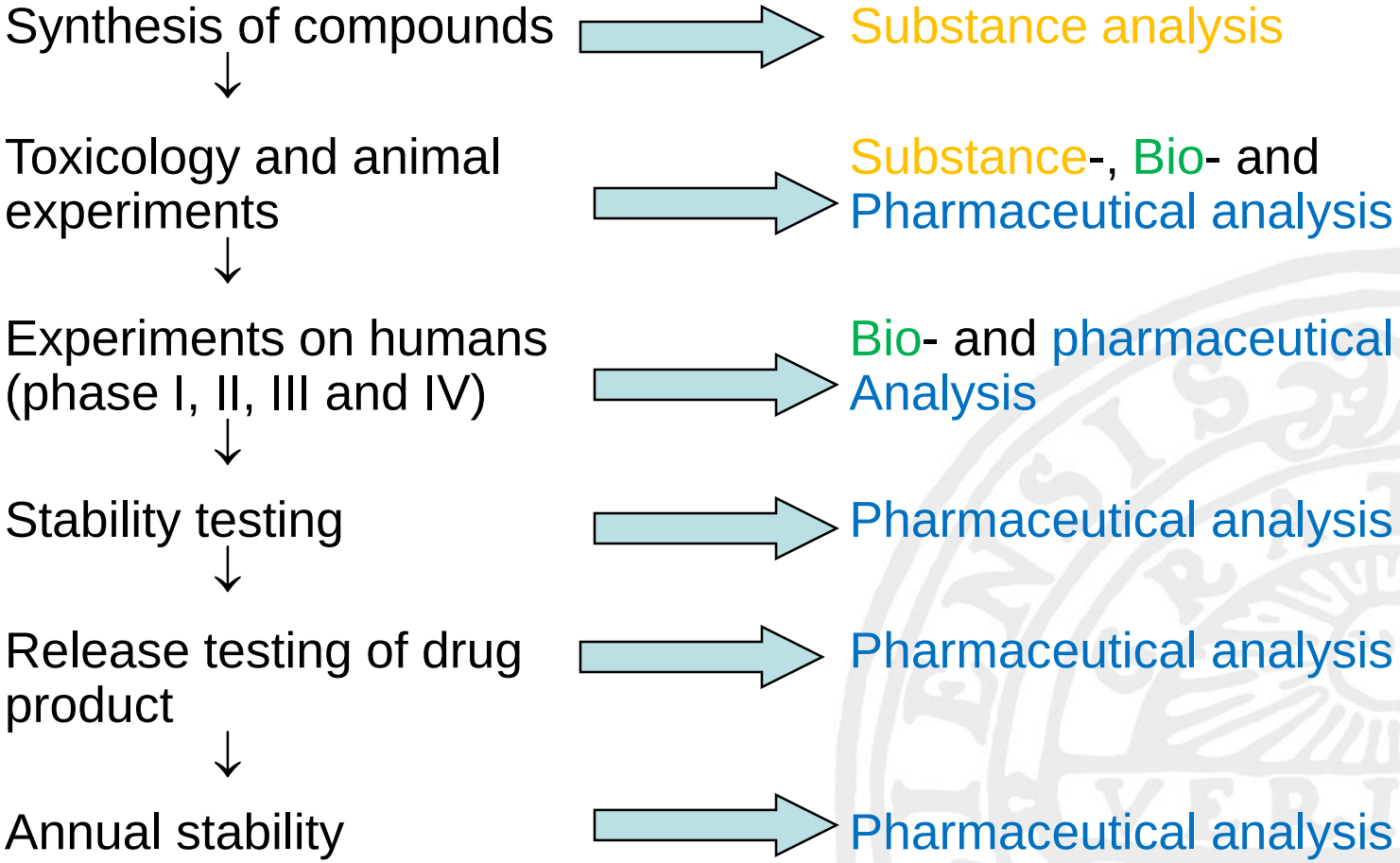
Applied Pharmaceutical and Biomedical analysis (7,5 hp)

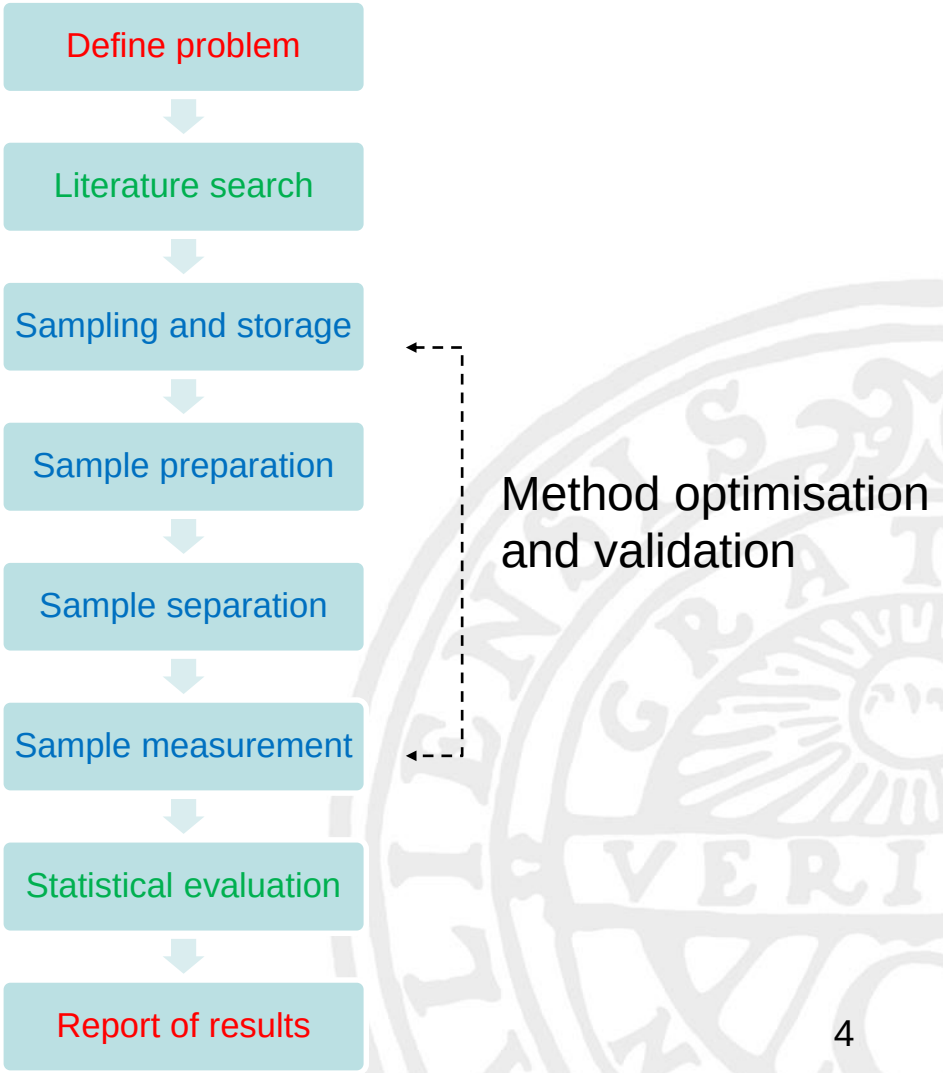
- The course is focused on applied drug analysis
- Discussion seminars and the study visit elucidate common issues concerning analytical method development and validation
- The main part of the course is devoted to a specific case project (a method development laboratory practical) that will be solved individually under supervision by a tutor

Analytical chemistry in drug development

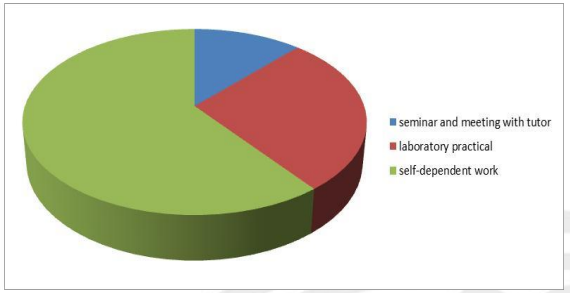


Anders Karlsson/JO
2005-09-29

Method development and validation



Applied Pharmaceutical and Biomedical analysis, 7,5 hp



- Lectures (3 hours)
- Seminars (5 x 2-4 hours)
- Laboratory practical (9 days)

- Mandatory attendance at all moments related to the laboratory practical (tutor meetings, laboratory practical sessions and the examination seminar) as well as the discussion seminars

Staff

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Course administrators:
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Teachers

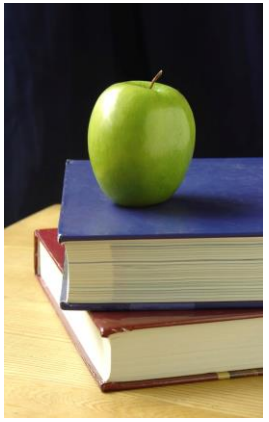
From UU: (www.ilk.uu.se)

- Mikael Engskog
- Jakob Haglöf
- Mikael Hedeland

External:

- *Cari Sänger van de Griend (consultant)*
- *Anders Karlsson (AstraZeneca)*

Course literature



- **The main part of the literature** consists of scientific publications (reviews). The course literature list is found on ”Studium”.

- Some of the reprints are found in the “Course materials section” on Studium and **you are supposed to download** (and print if you like) **the rest of the literature** on the literature list.

Discussion seminars

- **Seminar 1:** Regulatory aspects on Pharmaceutical analysis
- **Seminar 2:** Method development in separation science (CE and HPLC) applied to the analysis of pharmaceutical compounds in formulations and biological materials.
- **Seminar 3:** The links of the bioanalytical chain – from sampling to analytical result. Pitfalls and possibilities. The importance of validation.
- **Seminar 4:** Maintaining the integrity of data – Quality Assurance in Bioanalysis *GLP = Good Laboratory Practice or just Great Loads of Paper?*
- **Seminar 5:** Critical reviews of scientific articles

Detailed goals with the seminars

SEMINAR 1

- Understand the framework of the global regulatory system in the pharmaceutical area
- Understand and be able to perform and report laboratory work according to the regulatory guidelines in the field of analytical pharmaceutical chemistry regarding pharmaceutical products.

SEMINAR 2

- Practice knowledge, creativity and a critical mind in formulating the development of analytical methods intended for pharmaceutical and biomedical analysis of pharmaceutical compounds.

Detailed goals with the seminars

SEMINAR 3

- Understand the role of bioanalysis in drug development.
- Understand the validation parameters described in the EMA guideline including how to perform a validation study and how to evaluate the results in relation to the EMA criteria.
- Understand the concept of analytical batch acceptance and the EMA criteria.
- Have a basic knowledge of how to handle different types of practical problems that may occur in all different parts of a bioanalytical study from sample transport to report.

Detailed goals with the seminars

SEMINAR 4

- Understand the scope of GLP with focus on bioanalysis
- Have a basic knowledge of the GLP terminology.
- Understand the concept of sample integrity and traceability.
- Have a basic knowledge of the different steps in a GLP study from study plan to archiving.

Detailed goals with the seminars

SEMINAR 5

- Practice critical reading of scientific papers and orally present well founded arguments on selected papers.
- Discuss the general outline and the information that should be included in a well performed original scientific paper.

Laboratory practical

- Literature search and development of a plan for the practical laboratory work.
- Two individual meetings with the tutor. The draft of the proposal is discussed (and revised after the meeting)
- Risk evaluation of the laboratory project (chemicals and methodological risks)
- Individual laboratory work. Method development according to the proposal (and modification of the proposal if necessary)
- NOTE: A risk evaluation of the laboratory project as well as a (by the tutor) approved proposal is **compulsory** prior to the start of laboratory work.

Laboratory practical

Date and time for deadlines

- **Meeting 1:** A detailed suggestion of a plan for the practical laboratory work is to be uploaded on Studium at the latest 12:00 January 19th
- **Meeting 2**: A revised proposal and risk assessment is to be uploaded at Studium at the latest 09:00 January 25th
- **Written report:** A written report (see the Laboratory instruction) is to be uploaded to Studium at the latest one day before the examination seminar. February 15th, 12:00
- **Final report:** The revised report should be approved by the tutor and passed plagiarism control (”Urkund”) at the latest February 23th

Presentation of the laboratory results

- A laboratory report written as a scientific original paper (se the laboratory instruction)
- Oral presentation and defence of the results
- Opposition and constructive feedback on another student's oral and written reports.

- **Read the laboratory instruction!**

Detailed goals with the laboratory practical

- Be able to search for relevant scientific literature and compile to a laboratory plan for the laboratory practical part.
- Knowledge in how a risk assessment is performed.
- Knowledge in how to document the laboratory work.
- Practice self-dependent work at lab (following and revising the compiled laboratory plan).
- Be able to present the obtained results written (in the form of an original research paper) and orally.
- Be able to defend the obtained results orally and act as an opponent to another students written and oral presentation.

Laboratory practical

Allocation of tasks

1. Read the project descriptions in the laboratory instruction

2. Choose the project you wish to work with and rank these (1, 2, 3) in your email

3. Specify which technique you prefer to work with (CE, LC)

Course evaluation

Please remember to fill out the course evaluation form after the course!

A link will be sent to you by e-mail and a link will be placed on the course page in Studentportalen.

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Do you have any questions?