



Course syllabus

Kvalitet och produktsäkerhet Quality and Product Safety

KMBF10, 7,5 credits, G2 (First Cycle)

Valid for: 2023/24

Faculty: Faculty of Engineering, LTH

Decided by: PLED B/K

Date of Decision: 2023-04-18

General Information

Elective Compulsory for: MLIV1, MLAK1, MLSA1

Elective for: B4-l, B4-mb, B4-lm, B4-pt, K4-l, MBIO1, R4

Language of instruction: The course will be given in English

Aim

The course aims to introduce and train the students in different quality assurance methods such as HACCP, GMP and hygienic process design as well as standardised management systems such as ISO 9000, 14000 and FSSC 22000.

Learning outcomes

Knowledge and understanding

For a passing grade the student must

- comprehend the principles for industrial quality assurance and product safety
- know to the most common quality assurance methods and quality management systems

Competences and skills

For a passing grade the student must

- be able to both in written form and as an oral presentation present a risk- and quality assessment of a process in accordance with the guidelines for different quality assurance methods and quality management systems

Judgement and approach

For a passing grade the student must

- show an understanding for the need of quality assurance methods and quality management systems in order to ensure that processes and products meet the authorities', society's and companies' requirements on product quality, safety, effectiveness, sustainability and environmental consideration

Contents

- tools for quality assurance and product safety in primarily pharmaceutical and food industries, but also packaging and medical device industries are included
- the course is given in close collaboration with representatives from the mentioned industry branches. The lectures include hygienic process design, aseptic processing, clean rooms, methods for cleaning and disinfection in food and pharmaceutical industries, CIP- and SIP- procedures, good hygienic practice (GHP), HACCP, good manufacturing practice (GMP and cGMP) and validation, legislation, ISO 9000 (quality management), ISO 14000 (environmental management), ISO 22000/FSSC 22000 (food safety management), ISO14971 (risk management) and ISO13485 (medical device).

Examination details

Grading scale: TH - (U,3,4,5) - (Fail, Three, Four, Five)

Assessment: Written report and oral presentation including opposition on project assignment. Written examination. The final grade is based on the total amount of points from the written report, oral presentation, oral opposition on project assignment and written examination.

The examiner, in consultation with Disability Support Services, may deviate from the regular form of examination in order to provide a permanently disabled student with a form of examination equivalent to that of a student without a disability.

Parts

Code: 0119. **Name:** Project.

Credits: 5. **Grading scale:** UG. **Assessment:** Written report, oral presentation and opposition. Grades pass or fail.

Code: 0219. **Name:** Written Examination.

Credits: 2,5. **Grading scale:** UG. **Assessment:** Written examination with grades pass or fail.

Admission

The number of participants is limited to: No

The course overlaps following course/s: KMB031

Reading list

- Adams, M.R., Moss, M.O. and McClure P.J.: Food Microbiology, Fourth Edition. The Royal Society of Chemistry, 2016, ISBN: 978-1-84973-960-3.
- Compendium.
- Hand-outs from lectures.
- Relevant information from scientific literature and official websites.

Contact and other information

Course coordinator: Jenny Schelin, jenny.schelin@tmb.lth.se

Course homepage: <http://www.tmb.lth.se>