

# FHK3008 Clinical Innovation and Design for PhD students 9.0 credits

Klinisk innovation och design för doktorander

This is a translation of the Swedish, legally binding, course syllabus.

If the course is discontinued, students may request to be examined during the following two academic years

## **Establishment**

Course syllabus for FHK3008 valid from Autumn 2015

# **Grading scale**

## **Education cycle**

Third cycle

# Specific prerequisites

Enrolled as PhD student at KTH, KI, SU, or SSE. Short written explanation why you think this course is interesting for your PhD education, and what you can contribute to an interdiciplinary team.

# Language of instruction

The language of instruction is specified in the course offering information in the course catalogue.

## Intended learning outcomes

The students learn how to use the BioDesign process to create innovations within health and healthcare.

After a finished course, the student should be able to:

- 1. describe the different parts of in the Biodesign process
- 2. describe how to perform the different steps in Sweden and Europe
- 3. argue why the steps are and why they happen in that order as they do
- 4. apply the Biodesign method: based on an observed need from reality (which is given to them) students should be able to validate and develop a solution and write a business plan.
- 5. select the appropriate criteria in order to perform necessary validation, solution generation and solution validation.
- 6. generate a business plan in such a way that it can persuade a venture capitalist to invest in their solution.
- 7. understand how the Biodesign process can be used in their own current and future research

## Course contents

The course consists of:

- Evening Seminars
- Individual work
- Group project
- Feedback from experts

## Disposition

In this course, the students work with real clinical needs in order to find solutions to the needs and ways to commercialize their solutions that may be new products or services. This process is integrated in the course of all operations:

Twelve evening seminars with exercises and guest lecturers to practice and understand different steps if the Biodesign process:

### **Identify:**

- Sem. 1-2, Needs Identification: find strategic focus, observation, need description
- Sem. 3-4, Need Validation: examine disease state fundamentals, treatment options, stakeholder analysis, market analysis, needs selection.

#### **Inventing:**

- Sem. 5-6, Concept generation: brainstorming, concept screening
- Sem. 7-8, Concept Selection: IP rights, regulatory, reimbursement, business model, prototyping, concept

## **Implement:**

- Sem. 9-10, Development strategy: IP, R&D, clinical, regulatory and sales strategy, reimbursement strategy, marketing and stakeholder strategy, competitive advantage, and business strategy
- Sem. 11-12 Integration: Development, financing, business plan, funding, licensing

#### **Feedback sessions:**

- At 3 times each group gets a one-hour feedback session with an expert.
- In the final report, experts from medtech/venture capital will attend.

#### **Individual work:**

- Preparation for the seminars
- Development of Poster after the seminar 4, which describes the needs that the students have researched.
- Written reflection on how the Biodesign process can be used in their own current and future research

### **Group work:**

- takes place in interdisciplinary teams and you choose yourselves what you focus and put your time in, for example, prototyping, patienting, patient surveys, economic calculations, seeking funding, etc.
- results in the business plan as you build up during the course of different stages and ends with oral presentation for experts/venture capitalists.

## Course literature

Zenios, Makower and Yock, "Biodesign. The Process of Innovating Medical Technologies" ISBN 0521517427

## **Examination**

Based on recommendation from KTH's coordinator for disabilities, the examiner will decide how to adapt an examination for students with documented disability.

The examiner may apply another examination format when re-examining individual students.

- Group project with Presentation, 3,5 ETCS
- Presentation, 2,5 ETCS
- Seminars, 2,5 ETCS
- Written assignment, 0,5 ETCS

# Other requirements for final grade

#### Part 1:

- Active participation in seminars 2.5 ETCS
- Poster presentation 2.5 ETCS. Approved poster presentation required to participate in Part 2 of the course.

#### Part 2:

- Group work with oral presentation 3.5 ETCS
- Written assignment, 0.5 ETCS

## Ethical approach

- All members of a group are responsible for the group's work.
- In any assessment, every student shall honestly disclose any help received and sources used.
- In an oral assessment, every student shall be able to present and answer questions about the entire assignment and solution.