



# HL2034 Clinical Innovation and Design 9.0 credits

## Klinisk innovation och design

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 HL2034 valid from Autumn 2014

## Grading scale

A, B, C, D, E, FX, F

## Education cycle

Second cycle

## Main field of study

Medical Engineering

## Specific prerequisites

Eligible students should have completed a minimum of 180 credits. The course is interdisciplinary and we welcome a mix of students from different fields: technology, medicine, management, economy, design or other subjects viewed as relevant by the course organizer.

Proficiency in English corresponding to English A/English 6 is required.

# Language of instruction

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

# Intended learning outcomes

The students will gain knowledge and practical experience on how to use the BioDesign process from Stanford to create innovation in healthcare.

After taking the course the student should be able to:

1. describe the different steps in the BioDesign process
2. describe how to execute the steps in Sweden and Europe
3. discuss why the steps are performed and in which order they should be conducted
4. apply the BioDesign method: Start with a need (provided from observations in healthcare)
5. choose suitable criteria to conduct need validation, concept generation, and concept validation
6. generate a business plan

# Course contents

The course consists of:

Twelve evening seminars, following the steps of the Biodesign process:

## IDENTIFY

- Sem. 1-2: Needs Finding: Strategic Focus, Observation and Problem Identification, Need Statement Development
- Sem. 3-4: Need validation: Disease State Fundamentals, Treatment Options, Stakeholder Analysis, Market Analysis, Needs Filtering

## INVENT

- Sem. 5-6: Concept Generation: Ideation and Brainstorming, Concept Screening
- Sem. 7-8: Concept Selection: Intellectual Property Basics, Regulatory Basics, Reimbursement Basics, Business Models, Prototyping, Concept Selection

## IMPLEMENT

- Sem. 9-10: Development Strategy for: IP, R&D, Clinical, Regulatory, Sales
- Sem 11-12: Integration: Operating Plan and Financial Model, Business Plan Development, Funding Sources, Licensing

Feedback meetings:

After the seminars 4, 6, 8, and 10, each group gets an hour of feedback meeting with an expert.

Individual work:

- Preparations for seminars
- Making and presenting a poster after seminar 4

Group project:

- Generation of business plan and presentation

## Course literature

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

## Examination

- PRO1 - Group project and presentation, 4.0 credits, grading scale: A, B, C, D, E, FX, F
- RED1 - Presentation, 2.5 credits, grading scale: A, B, C, D, E, FX, F
- SEM1 - Seminars, 2.5 credits, grading scale: P, F

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.

Part 1:

- Active participation in seminars, 2,5 credits
- Poster presentation, 2,5 credits. The poster presentation needs to be passed to be able to participate in part 2 of the course.

Part 2:

- Group project with oral presentation, 4 credits

## 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.