

| Cursus | Sem. | Type |
|--|------|------|
| Biotechnology and Bioengineering | | Obl. |
| Computational and Quantitative Biology | | Obl. |

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| Language of teaching | English |
| Credits | 2 |
| Session | |
| Exam | Written & Oral |
| Workload | 60h |
| Hours | 22 |
| Courses | 14 |
| TP | 8 |
| Number of positions | 18 |

Frequency

Only this year

Remark

Next time: Spring 2019

Summary

This course covers analytic approaches to risk assessment and governance, then develops cases on safeguard design and testing to limit risks of: gene drive disease control; biosynthesis of materials; and health data and apps to care of patients and recruit subjects for clinical trials.

Content

This course is designed to inform deliberation on responsible innovation and risk governance by students in science, engineering and management. It will provide basic training on analytic approaches to risk assessment and governance and also focus on in depth cases in rapidly changing technological fields.

Week 1: Description and evaluation of risk assessment and forecasting methods in light of contemporaneous projections of benefits and risks of past emerging technologies such as the automobile, laser, internet, and GPS.

Week 2: Description and evaluation of precautionary, permissive and adaptive approaches to risk governance in light of cases on transportation, flood control, diet standards, air standards, drug licensing and other policy areas.

Weeks 3 4 5 6: Regular class meetings on concepts and parallel working group meetings on cases.

Regular Class Meetings on Concepts

Week 3: On development and testing of technical safeguards in historical cases

Week 4: On credible knowledge assessment in areas of uncertainty and controversy

Week 5: On multi-stakeholder and regulatory engagement in evaluation of safeguards

Week 6: On legal and ethical duties of scientists, engineers and managers

Parallel Working Groups on Cases

Applications to current emerging technology cases drawn from synthetic biology, pharmaceuticals, and AI / information technology with emphasis on the design and testing of technical safeguards to mitigate risks. Students will work on one of the cases below.

* gene drive applications to control vector-borne diseases, with emphasis on safeguards to limit gene drive effects to specific geographic locales and/or specific subsets of target species.

* materials synthesis using pathways in biological chassis, with emphasis on safeguards to limit environmental effects of release by reducing gene transfer and fitness.

* health data and app use to advise and monitor patients and/or to identify, recruit and monitor subjects for clinical trials, with emphasis on safeguards protecting privacy and informed consent.

Each case will be developed by mixed teams of students.

* Scientists will focus on risk assessment under conditions of uncertainty and controversy, with

emphasis on the validity of evidence and on factors affecting the credibility of assessments.

- * Engineers will focus on design and testing of safeguards to mitigate risks, with attention to development of intrinsic technical safeguards and of credible methods of testing.
- * Managers will focus on development of nonmarket strategies to shape regulations and standards to advantage firms, with emphasis on linking R&D, regulatory affairs and marketing.

Week 7: Presentations of cases by teams to a panel of regulators, insurers, and risk governance experts. The final meeting of the seminar may be longer than 2 hours.

Note

NOTE ON DATES/TIMES OF COURSE: Tuesday 9.4.2019 to Tuesday 28.5.2019, from 4-6 PM for the regular meeting times. There will also be parallel working group meetings during weeks 3-6.

Keywords

Risk governance
Responsible research