1. Annotation

Course Description

The course aims to provide students with an understanding of applications and practices of biomedical science in an industrial healthcare. To put it simple, we will discuss where and how Skoltech biomedical graduates may employ their skills beyond academy science. To achieve this goal the course will decompose the industry into the value chain of independent but interconnected entities and then make deep investigation of motives, profits, and costs of any segment/entity of this value chain. The incomplete list of such entities will include: R&D-driven startups, CROs, CMOs, regulators, integrated pharma, marketing agents, distributors, retail, hospitals, doctors. The emphasis will be made on the value chain groups that are immersed into the challenge of transforming high technologies into the tangible patient benefit, from hardcore drug development to all kinds of medical devices and services. Such challenges will be taught through development of the group project that will be developed through the stages of Problem statement (indication, regulation, POC and QC), preclinical design, clinical design, manufacturing/delivery design and final integrative presentation.

Course Prerequisites / Recommendations

There are no formal requirements to BMEI enrollment, however, fundamental biomedical training is required and will be tested in the 1st class. The BMEI course is heavily rooted into the biomedical sciences: students must have at least some relevant training to enroll.

2. Structure and Content
<table>
<thead>
<tr>
<th>Topic</th>
<th>Summary of Topic</th>
<th>Lectures (# of hours)</th>
<th>Seminars (# of hours)</th>
<th>Labs (# of hours)</th>
</tr>
</thead>
</table>
| Industries relying on biomedical science | 1) List of all industries relying on BMS  
2) Non-bio industries relying on bio-science  
3) Key difference of biomedical industries: doctors and regulators asking for three stacks of paper:  
- science reports and IP documentation  
- preclin/clin documentation  
- manuf and QC documentation | 1 | 4 |
| Value chain of Biomed industries | 1) Concept of the value chain: motives, costs, competition  
2) Why Skoltech student cares about the value chain?  
3) Components of biomed value chain: lab research, clinical, manufacturing, regulators, production, marketing  
4) Agents: CDO, CRO, CMO  
5) Choose your favorite value chain segment and propose a project for it | 1 | 4 |
| Lab research & IP: crucial beginning of R&D | 1) Designing your experiment  
2) Reporting and archiving your experiment  
3) Patenting and protecting your invention  
4) Balancing disclosure and confidentiality | 1 | 4 |
| Preclinical and Clinical research: the desert of project death | 1) in vitro preclinical  
2) in vivo preclinical  
3) Human clinical trials  
4) Design, protocol, PI  
5) Start and manage CRO | 1 | 4 |
| Manufacturing: can not survive without it | 1) Concept of GMP: full traceability and fraud-proof  
2) Manufacturing protocol: challenge without a hero  
3) QC protocol: surprise to the lab warrior  
4) Start and manage CMO | 1 | 4 |
| REGULATORS & DOCTORS: protectors, supporters, attackers | 1) Concept of Caregiver: gentle balance between saving lives, poisoning people, and robbing people  
2) How you save lifes  
3) How you protect patients  
4) How you make the trains running | 1 | 4 |
| INTEGRATED BUSINESS CASE OF BIOMED innovative project | Present your project and obtain 360 feedback | 1 | 4 |

3. Assignments
<table>
<thead>
<tr>
<th>Assignment Type</th>
<th>Assignment Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team Project</td>
<td>BMEI TEAM PROJECT: Problem statement: Indication, regulation, POC, DP, QC</td>
</tr>
<tr>
<td>Team Project</td>
<td>BMEI TEAM PROJECT: three claims of the patent</td>
</tr>
<tr>
<td>Team Project</td>
<td>BMEI TEAM PROJECT: Preclinical Design</td>
</tr>
<tr>
<td>Team Project</td>
<td>BMEI TEAM PROJECT: Clinical design, manufacturing/delivery scheme</td>
</tr>
<tr>
<td>Final Project</td>
<td>Final Integrated Project presentation</td>
</tr>
</tbody>
</table>

### 4. Grading

**Type of Assessment**
- Graded

**Grade Structure**

<table>
<thead>
<tr>
<th>Activity Type</th>
<th>Activity weight, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team Project</td>
<td>15</td>
</tr>
<tr>
<td>Team Project</td>
<td>15</td>
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<tr>
<td>Team Project</td>
<td>15</td>
</tr>
<tr>
<td>Team Project</td>
<td>15</td>
</tr>
<tr>
<td>Final Project</td>
<td>30</td>
</tr>
<tr>
<td>Class participation</td>
<td>10</td>
</tr>
</tbody>
</table>

**Grading Scale**

- A: 76
- B: 66
- C: 56
- D: 46
- E: 36
- F: 0

**Attendance Requirements**
- Mandatory

### 5. Basic Information

**Maximum Number of Students**
<table>
<thead>
<tr>
<th>Maximum Number of Students</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall:</td>
</tr>
<tr>
<td>Per Group (for seminars and labs):</td>
</tr>
<tr>
<td>50</td>
</tr>
<tr>
<td>50</td>
</tr>
</tbody>
</table>

**Course Stream**

Entrepreneurship and Innovation (E&I)

**Course Term (in context of Academic Year)**

Term 2

**Course Delivery Frequency**

Every year

**Students of Which Programs do You Recommend to Consider this Course as an Elective?**

<table>
<thead>
<tr>
<th>Masters Programs</th>
<th>PhD Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Master Programs</td>
<td>All PhD Programs</td>
</tr>
</tbody>
</table>

**Course Tags**

Biotechnology  
Programming  
Engineering  
E&I

### 6. Textbooks and Internet Resources

<table>
<thead>
<tr>
<th>Web-resources (links)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>google.com</td>
<td>just go for it!</td>
</tr>
</tbody>
</table>

### 7. Facilities

### 8. Learning Outcomes
**Knowledge**

- Awareness of the fundamentals of the biomedical technological innovation process and methodology
- Ability to identify problems, articulate problems, analyze problems, and identify appropriate and feasible solutions to problems related to the biomedical innovation
- Confidence to learn quickly under pressure, with help from others and with whatever resources are at hand
- Experience in working together in teams with people from other fields and backgrounds to carry out challenging projects
- A positive and self-reliant aptitude for taking initiative and getting things done
- Ability to contextualize science and technology in a real-world context
- Experience in iterating prototypes in the technological innovation process
- Ability to identify appropriate actions and information to evaluate the robustness of innovation prototypes
- Experience in effectively communicating with others individually and in groups

**Skill**

- Approach the world with positive “can-do” attitude
- Understand and respect your end user need
- Define the impact of your innovation
- Design and prototype the product
- Plan and manage your project
- Communicate and present your product and project
- Confidently practice teamwork and leadership
- Define milestones and goals
- Carry out marketing activities
- Understand and build relationships

**Experience**

- Living through the biomedical innovation process
- Practicing teamwork and leadership
- Operating under aggressive timelines
- Learning “what you need, when you need it”
- Identifying and solving problems
- Designing to achieve impact
- Planning and running negotiations, marketing and sales
- Building prototypes
- Presenting and communicating

**9. Assessment Criteria**

**Input or Upload Example(s) of Assignment 1:**

**Select Assignment 1 Type**

Project
4 (four) midterm grades will be given for the presentations of the crucial components of the BMEI team project:
1) Problem statement: Indication, regulation, POC, DP, QC
2) three claims of the patent
3) Preclinical Design
4) Clinical design, manufacturing/delivery scheme

Assessment Criteria for Assignment 1
- well-rounded structure
- clarity of presentation
- depth of analysis and argument
- depth of prior art study and scenario planning

Input or Upload Example(s) of Assignment 2:
Select Assignment 2 Type
Final Project
Input Example(s) of Assignment 2 (preferable)
The final project of this course should provide the comprehensive scheme of the biomedical E&I project developed along the key topics discussed in class:
1) Problem statement, solution statement, underlying technology
2) Experimental design for prototype validation (POC)
3) Design of preclinical and clinical studies
4) IP strategy and 3 claims of the patent
5) Manufacturing strategy
6) Clinical trial/validation strategy
7) Value delivery model
These topics should be well-developed through the study of the prior art and planning the future action. Sufficient reasoning and references should be provided.

Assessment Criteria for Assignment 2
- well-rounded structure
- clarity of presentation
- depth of analysis and argument
- depth of prior art study and scenario planning

Input or Upload Example(s) of Assignment 3:
Select Assignment 3 Type
Other
Input Example(s) of Assignment 3 (preferable)
Class participation is crucial for the BMEI class because innovation skills can not be learned by book. They must be discussed and absorbed from the discussion.

Assessment Criteria for Assignment 3
- thoughtful participation in class discussion
- efficient participation in team presentation

Input or Upload Example(s) of Assignment 4:

Input or Upload Example(s) of Assignment 5:

10. Additional Notes