Course goals
This course will introduce the students to the multi-disciplinary nature and various applications of modern biotechnology, utilizing production and commercialization of recombinant human epidermal growth factor and basic fibroblast growth factor as examples to elucidate the technological, regulatory and legal aspects involved in the development of biopharmaceutical products.

Learning Outcomes
By the end of this course, the students are expected to be able to:

1. Understand the multi-disciplinary nature of biotechnology which involves the use of a wide spectrum of cutting-edge technologies.

2. Appreciate the wide scope of applications of biotechnology in medicine, agriculture, biomass utilization for energy generation, and environmental conservation.

3. Recognize the legal issues including various aspects of intellectual property protection and ethical concerns in biotechnology.

4. Have an enhanced understanding in the day-to-day business management and operation undertaken in a biotechnology corporation.

Course description
Since its inception in the late 1970s, modern biotechnology has evolved as a multidisciplinary field embracing recombinant DNA technology, immunology, biochemistry, microbiology, bioengineering and others. From another angle, biotechnology may be construed as a science-based industry, in which the research outcomes are transformed into commercial products for applications in many aspects of our daily life including medical and health care, agriculture and animal husbandry, environmental conservation, and energy generation. In addition to the above aforementioned aspects, the students taking the course will also be introduced to the various ethical and legal issues in biotechnology that deal with conduct of investigators and intellectual protection for research inventions, respectively. To enable the students to appreciate the lengthy stages involved in the transformation of research results into
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marketable products in the biotechnology industry, the production of recombinant human epidermal growth factor (hEGF) is employed as a model R & D process for elaboration and illustration in the course.

**Teaching approach**
This course is essentially taught in an interactive lecture format. As biotechnology covers a wide range of scientific and technological disciplines, topics of current interest in biotechnological research and development are carefully selected as teaching materials, which are prepared as notes in the form of handouts for the students taking the course. The materials distributed will then be gone through in detail in class, where the students are encouraged to ask questions and participate in discussion. To provide the students with a better appreciation of operational issues in the biotechnology industry, they are required to read original papers discussing the research and development of a successful recombinant process which has been employed cost-effectively to produce marketable active protein ingredients – hEGF and human basic fibroblast growth factor (hbFGF). In addition, the students will be introduced to the application of the recombinant hEGF as an active ingredient to various skin care and health care industries. Last but not least, the students are encouraged to contact the instructor if they have questions regarding the materials covered in class.

**Assessment scheme**
Students taking the course are expected to be assessed as summarized below:

<table>
<thead>
<tr>
<th>Components</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>A. 1st Midterm exam</td>
<td>20-25</td>
</tr>
<tr>
<td>B. 2nd Midterm exam</td>
<td>20-25</td>
</tr>
<tr>
<td>C. Final exam</td>
<td>50-60</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
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</tbody>
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**Course outline**

1. Introduction and background

2. Applications of biotechnology in: medicine, agriculture and livestock, environmental conservation, biomass utilization, and basic research

3. Microbial selection, manipulation and applications

4. Modes of expression of heterologous proteins in prokaryotic and eukaryotic systems
5. Production and utilization of hEGF and hbFGF: applications of recombinant these factors in skin care and health care products
6. An overview of production of recombinant proteins
7. Microbial growth kinetics
8. Introduction to fermentation processes
9. Various types of fermentors; optimization of important parameters
10. Procedures for registration of biopharmaceuticals
11. Legal, social and ethical aspects

Selected reference books

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