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| **Course Designation** | PHT 437 | صيد 473 | **رقم المقرر ورمزه** |
| **Course Name** | Pharmaceutical Biotechnology –II | التقنية الحيوية الصيدالنية 2- | **إسم المقرر** |
| **No. of Credits** | 2 | 2 | **عدد الوحدات الدراسية المعتمدة** |
| **Level** | Industrial Pharmacy Track | مسار الصيدلة الصناعية | **المستوى** |
| **Prerequisites** | PHL 213, PHL 224,  PHT 313, PHT 425 | دوي، 224 ، دوي 213  صيد 425 صيد، 313 | **متطلب سابق** |
| **Credit Distribution** | ( Lecture): (2+0) | )0+2( **:**(نظري( | **توزيع المقرر (نظري+عملي+تمارين)** |
| **وصف المقرر:**  التقنية الحيوية الصيدالنية هي علم في األحياء التطبيقية والذي يشمل استخدام الكائنات الحية والعمليات الحيوية في الهندسة والتقنية والطب وغير ذلك من المجاالت المستفيدة من المنتجات الحيوية لإلنتاج الدوائي بالتقنية الحيوية. يغطي هذا المقرر الخلفية العلمية النظرية والجوانب التطبيقية لألدوية المنتجة حيويا مع التركيز على توسيع نطاق تصنيعها الصيدالني. ويركز كذلك على روافد هذا المجال من العلوم الصيدالنية وكذلك القضايا المتعلقة بالممارسة الصيدالنية في هذا الجانب. إن مجال التقنية الحيوية الصيدالنية سريع التطور والنمو. وقد نتج عن ذلك حشد كبير من األدوية البروتينية األصل والمنتجة بتقنيات التوليف لعالج العديد من األمراض المستعصية كالسرطان والعدوى الفيروسية وأمراض القلب واألمراض الوراثية. كما أننا سنتطرق في هذا المقرر إلى تقنيات حديثة  سلسلة تفاعالت البلمرة وكيمياء االندماج والعالج الجيني. | | | |
| **Course Description:**  Pharmaceutical biotechnology is a field of applied biology that involves the use of living organisms and bioprocesses in engineering, technology, medicine and other fields requiring bioproducts for the biotechnological manufacturing of pharmaceutical products. It provides extensive coverage of both the basic science and the applications of biotechnology-produced pharmaceuticals, with special emphasis on their clinical use. There is a strong focus on those issues that are related to the pharmaceutical profession and the pharmaceutical sciences. The field of pharmaceutical biotechnology is a rapidly evolving subject. A whole new arsenal of protein pharmaceuticals is being produced by recombinant techniques for a spectrum of serious diseases such as cancer, viral infections, cardiovascular and hereditary disorders. In addition, we are confronted with new technologies such as polymerase chain reactions, combinatorial chemistry and gene therapy. | | | |
| **Textbooks:** |  |  | **الكتب المقررة:** |
| **1.** Rodney J.Y. Ho and Milo Gibaldi, Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs, 1st edition, John Wiley & Sons, Inc., Hoboken, NJ, 2003. | | | |
| **اعتمد بموافقة مجلس الكلية بجلسته**  **بتاريخ**  **توقيع رئيس القسم:**  **توقيع عميد الكلية:** | | | |

## LECTURES’ OUTLINE: PHT 437 (Pharmaceutical Biotechnology-II) 2+0

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| --- | --- | --- |
| **Week** | **Lecture number** | **Topic** |
| 1 | 1 | Protein Production   * Background * Protein Pharmaceuticals * Synthetic peptides * Protein expression systems (bacteria, yeast, and mammalian cells) * Fermentation * Purification |
| 2 |
| 2 | 3 | Protein Formulation   * Protein stability * Denaturation * Aggregation * Precipitation * Adsorption * Chemical modification * Enzymatic proteolysis * Protein storage * Refrigeration * Packaging * Additives * Freeze drying * Site-directed mutagenesis * Improvements for in vivo use * Oral protein delivery |
| 4 |
| 3 | 5 |
| 6 |
| 4 | 7 |
| 8 |
| 5 | 9 |
| 10 |
| 6 | 11 | Nanobiotechnology   * Introduction to nanotechnology * Nanobiotechnology and nanomedicine * Advanced drug delivery systems * Novel nanobiotech products * Drug Targeting |
| 12 |
| 7 | 13 |
| 14 |
| 8 | 15 |
| 16 |
| 9 | 17 | Stem-Cell Technology   * Background and significance * Transgenic animals * Knockout animals * Stem-cell research applications * Pharmacogenomics |
| 18 |
| 10 | 19 |
| 20 |
| 11 | 21 | Biotechnology-derived Pharmaceutical Products   * Insulin * EPO * Growth Hormone * mAb * Cytokines |
| 22 |
| 12 | 23 |
| 24 |
| 13 | 25 | Regulatory and Ethical Issues   * Regulation and approval * Medico-legal and bio-ethical concerns |
| 26 |
| 14 | 27 | Exams |
| 28 |

COURSE EVALUATION:

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| --- | --- |
| First midterm exam Second midterm exam Quizzes | 25  25  10 |
| Total | 60 |
| Final examination: | 40 |
| Total marks 100 | |

## Form (H)

**Short course description**

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| Course title: Pharmaceutical Biotechnology-II | Course number and code: PHT 437 |
| Previous course requirement: Biochemistry-I, Biochemistry-II, General Immunology, Pharmaceutical Biotechnology-I | Language of the course: English |
| Course level: Graduation Tracks: Industrial Pharmacy Tack | Effective hours: 2 (2 lectures) |

Course description

# وصف المقرر :

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| The course should provide students with an introductory course to familiarize themselves with technology related issues and terms. The student’s basic biochemistry and pharmacy education will be expanded with current concepts in biochemistry, molecular biology, analytical techniques, drug development, delivery and formulation relevant to the use and development of biotechnology-derived products, including protein and nucleic-based pharmaceuticals. The course provides extensive coverage of both basic science and applications of biotechnology-produced pharmaceutical, with special emphasis on their clinical use and applications. This course was designed to comprehend the basic and applications of biotechnology-based pharmaceutical, provides a much deeper appreciation for this remarkable field to the students’ clinical practice and the biophysical and biochemical analyses of recombinant proteins. | مجالي الكيمياء الحيوية المتصلة بموضوع التقنية الحيوية. وستستغل فيه من شأن هذا المقرر أن يعرف الطالب بالتقنيات األحياء الجزيئي والتحليل اآللي والتطوير الدوائي والعلوم الصيدالنية لتوسيع أفقه في مجاالت علم خلفية الطالب العلمية في ضا شامال للعلوم األساسية الحيوية كالبروتينات واألحماض النووية. كما يقدم والمواضيع المتصلة بآليات تشكيل وإيصال األدوية ومنتجاتها العالجية، بالتركيز على استخداماتها والتطبيقية في مجال التقنية الحيوية الصيدالنية هذا المقرر استعرا التي أحدثها هذا المجال في وتطبيقات التقنية الحيوية الصيدالنية وليقدر بشكل السريرية. صمم هذا المقرر ليشمل أساسات الجوانب التطبيقية العالجية وخصوصا للبروتينات عميق التطورات الهائلة  التوليفية. |

Course objectives

# أهداف المقرر

1. Gain a much deeper appreciation for this remarkable field to the students’ clinical practice;
2. Understand the clinical applications of biotechnology and biotechnology related products;
3. Discuss the production of biotech compounds;
4. Understand the biophysical and biochemical analyses of recombinant proteins;
5. Understand the fermentation technologies;
6. Understand recombinant DNA technology;
7. Discuss gene therapy and vaccines;
8. Describe the formulation of biotech, including biopharmaceutical considerations;
9. Dispense biotechnology products;
10. Understand the pharmacokinetic and pharmacodynamic of peptides and proteins drugs;
11. Gain knowledge concerning stem cell-based research;
12. Understand monoclonal antibodies technology.

Learning outcomes (understanding, knowledge, and intellectual and scientific skills) After studying this course, the student is expected to be able to:

1. Describe principles of pharmaceutical biotechnology.
2. Understand technology related issues and terms.
3. Comprehend the basic and applications of biotechnology-based pharmaceutical.
4. Understand the product development process .
5. Understand the Food and Drug Administration (FDA).
6. Understand the workings of the pharmaceutical, biotechnology and biodevice industries.
7. Appreciate the subjective and interpretative aspects of the regulations, and think critically about the interaction between regulatory and development processes.
8. Describe the tools necessary for Molecular Analysis.
9. Understand the basic principles of Gene Drug Therapy.
10. Understand the vaccines and their different therapeutic applications.

Textbook adopted and supporting references

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| --- | --- | --- | --- |
| Title of the book | Author's name | Publisher's name | Date of publication |
| Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs. John Wiley & Sons, Inc., Hoboken, NJ, 2003. | Rodney J.Y. Ho and Milo Gibaldi | John Wiley & Sons, Inc., Hoboken, NJ, USA, 2003. | 1st Edition, 2003 |

## This course will enable the successful candidate to:

1. Describe principles of pharmaceutical biotechnology.
2. Understand technology related issues and terms.
3. Comprehend the basic and applications of biotechnology-based pharmaceutical.
4. Understand the product development process.
5. Understand the Food and Drug Administration (FDA).
6. Understand the workings of the pharmaceutical, biotechnology and biodevice industries.
7. Appreciate the subjective and interpretative aspects of the regulations, and think critically about the interaction between regulatory and development processes.
8. Describe the tools necessary for Molecular Analysis.
9. Understand the basic principles of Gene Drug Therapy.
10. Understand the vaccines and their different therapeutic applications.

## The goals of this course are to provide students with:

* 1. An understanding of the fundamental pharmaceutical biotechnology concepts which transform proteins and chemical compounds into safe and effective drugs for use in humans;
  2. Skills in application of pharmaceutical biotechnology in gene therapy and in formulation of vaccines and their different therapeutic applications.

## Student learning goals:

1. To define the basic pharmaceutical biotechnology principles and the role of drug delivery in translating a compound/protein into drugs
2. Report on new biotechnology updates in therapy

3- Apply the Food and Drug Administration (FDA) guidelines and strategies

1. To learn about gene and cell therapeutics some of which are now approved for human use; to discuss animal cloning research as they relate to potential human therapeutic products; and to discuss new vaccine designs, adjuvant use, and vaccine delivery systems which are in development to improve safety and efficacy.
2. Comprehend the basic and applications of biotechnology-based pharmaceutical.
3. Describe the formulation of biotech, including biopharmaceutical considerations.