**Course Specification**

*For Guidance on the completion of this template, please refer to of Handbook 2 Internal Quality Assurance Arrangements*

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| Institution: **King Saud University**   |
| College/Department : **College of Pharmacy/ Department of Pharmaceutics/ Microbiology and Immunology** |

**A. Course Identification and General Information**

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| 1. Course title and code: **Pharmaceutical Biotechnology (PHT 426)** |
| 2. Credit hours: **2** **(2+0)** |
| 3. Program(s) in which the course is offered. (If general elective available in many programs indicate this rather than list programs)**Doctor of Pharmacy** |
| 4. Name of faculty member responsible for the course |
| 5. Level/year at which this course is offered:  **Level 8** |
| 6. Pre-requisites for this course (if any)Previous course requirement: **PHT 416, PHT 417**  |
| 7. Co-requisites for this course (if any)  |
| 8. Location if not on main campus |

**B. Objectives**

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| 1. Summary of the main learning outcomes for students enrolled in the course. * Make the student aware with the different biotechnological procedures through which the scientists and researchers are able to produce or improve the biologically active compounds. Not only in the field of pharmaceutics / Microbiology, but in the different fields of science as well.
* Many valuable procedures will be discussed in this course including microbial biotransformation, fermentation.
* Under standing of molecular-biological procedures such as DNA recombination, gene delivery and therapy, stem cell and immune system based procedures.
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| 2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web based reference material, changes in content as a result of new research in the field)* This course will be well maintained through periodic updating based on the recent developments in the field of biotechnology either through the internet and the online sources or through recent publications.
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**C. Course Description** (Note: General description in the form to be used for the Bulletin or Handbook should be attached)

The student 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 produced pharmaceutical, with special emphasis on their clinical use and application, including advantages and current limitation. Their application in both drug and vaccine therapy will be covered using case studies.

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| 1. Topics to be covered. |
| Topic | Detail | No of Weeks | Contact Hours |
| Principles of biotechnology and Types of Biotechnology |   .5 | 1 |
| The structure of microbes |  | .5 | 1 |
| Fermentation- technologies | Solid substrate fermentationLiquid fermentationBatch fermentation Feed-batch processContinuous fermentation Downstream processing | 1.5 | 3 |
| Monoclonal antibodies | Antibodies structureDevelopment of antibody-based therapeutics Applications of monoclonal antibodiesVaccine preparations | 1.5 | 3 |
| Microbial products | Single cell proteinBiological fuelsHormones productionEnzymes productionEthanol, Methanol productionBiogas (methane) productionAntibiotics ProductionPenicillin Production | 1.5 | 3 |
| Biodegradation and bioremediation |  | .5 | 1 |
| Bioterrorism/Biodefenses |  | .5 | 1 |
| Bioethics/Biosafety |  | .5 | 1 |
| Advanced drug delivery |  | .5 | 1 |
| The role of Genomics and Proteomics in biotechnology |  | .5 | 1 |
| Recombinant DNA | DNA Structure Central DogmaDNA ReplicationProtein SynthesisTranscriptionTranslationRecombination MethodsCloningVectorPlasmidRestriction EnzymesLigationTransformationApplications | 1.5 | 3 |
|  DNA Methodology | Gel ElectrophoresisPolymerase Chain ReactionRT-PCRSanger’s MethodDNA Large and mini-PreparationsSouthern Blot Analysis Northern Blot AnalysisWestern Blot AnalysisDNA SequencingApplications | 2.5 | 5 |
|  Gene Delivery and Gene Therapy  | Chemical MethodsBiological MethodsPhysical MethodsApplications | 1 | 2 |
|  Stem Cell- Based Researches | Transgenic AnimalsKnockout AnimalsApplications | 1 | 2 |

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| 2. Course components (total contact hours per semester):  |
| Lecture:28 | Tutorial:  | Practical/Fieldwork/Internship: | Other: |

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| 3. Additional private study/learning hours expected for students per week. (This should be an average: for the semester not a specific requirement in each week) **6 hours per week (homework, quizzes and other assignments).** |
| 4. Development of Learning Outcomes in Domains of Learning For each of the domains of learning shown below indicate:* A brief summary of the knowledge or skill the course is intended to develop.
* A description of the teaching strategies to be used in the course to develop that knowledge or skill.
* The methods of student assessment to be used in the course to evaluate learning outcomes in the domain concerned.
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| **a. Knowledge**  |
| (i) Description of the knowledge to be acquired* Awarness about the different biotechnological procedures through which the scientists and researchers are able to produce or improve the biologically active compounds. Not only in the field of pharmaceutics, but in the different field of science as well.
* Ability to understand valuable procedures course including microbial biotransformation, fermentation, and plant tissue culturing.
* Understanding of molecular-biological procedures such as DNA recombination, gene delivery and therapy, stem cell and immune system based procedures.
* Understanding of technology related issues and terms:
* Gain a much deeper appreciation for this remarkable field to the students’ clinical practice.
* Understand the clinical applications of biotechnology and biotechnology related products.
* Knowledge of the production of biotech compounds
* Understanding the biophysical and biochemical analyses of recombinant proteins
* comprehension Gene therapy and Vaccines
* knowledge the formulation of biotech, including biopharmaceutical considerations
* how to Dispense biotechnology products
* Understanding of the Pharmacokinetic and pharmacodynamic of peptides and proteins drugs.
* Learning of the benefits of applying the principal of pharmacogenomics in drug therapy and vaccination.
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| (ii) Teaching strategies to be used to develop that knowledge* **lectures**
* **assignments.**
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| (iii) Methods of assessment of knowledge acquired* **Majors, quizzes and final exams.**
* **Homework assignments.**
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| **b. Cognitive Skills** |
| (i) Cognitive skills to be developed* Emphasize on the principle on which each technique is based.
* How to link between different procedures.
* How to get benefit from any method to perform any future experiments**.**
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| (ii) Teaching strategies to be used to develop these cognitive skills* **lectures**
* Homework assignments on data collection and new approaches.
* Oral presentations.
* Active learning, feedback examinations
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| (iii) Methods of assessment of students cognitive skills * During lecture discussions.
* Home works.
* Midterm and final exams.
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| **c. Interpersonal Skills and Responsibility**  |
| (i) Description of the interpersonal skills and capacity to carry responsibility to be developed * **Work effectively both individually and in teams in both classroom and laboratory.**
* **Understand the interrelationships among technology, and global society, and of the societal implications of new developments in science.**
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| (ii) Teaching strategies to be used to develop these skills and abilities* **Working independently and in groups towards some assignments. Collect literature reports , summarize, analyse and interpret the main findings.**
* **Manage resources, time and other members of the group.**
* **Communicate results of work to others through written reports and oral presentations.**
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| (iii) Methods of assessment of students interpersonal skills and capacity to carry responsibility* **Individual performance within a group.**
* **Written presentations.**
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| **d. Communication, Information Technology and Numerical Skills**  |
| (i) Description of the skills to be developed in this domain.* **How to think and understand the principles of new technology.**
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| (ii) Teaching strategies to be used to develop these skills* **Seiners**
* **Usage of computer and the online resources**.
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| (iii) Methods of assessment of students numerical and communication skills * **Performance in the problem solving assigned in the homework.**
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| **e. Psychomotor Skills (if applicable)** |
| (i) Description of the psychomotor skills to be developed and the level of performance required **Not applicable** |
| (ii) Teaching strategies to be used to develop these skills **Not applicable** |
| (iii) Methods of assessment of students psychomotor skills **Not applicable** |

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| 5. Schedule of Assessment Tasks for Students During the Semester |
| Assessment  | Assessment task (eg. essay, test, group project, examination etc.) | Week due | Proportion of Final Assessment |
| 1 | **Major Exam I** | **Week 7** | **30%** |
| 2 | **Major Exam II** | **Week 14** | **30%** |
| 3 | **Final Exam**  | **Week 16** | **40%** |

**D. Student Support**

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| 1. Arrangements for availability of faculty for individual student consultations and academic advice. (include amount of time faculty are available each week)* **Office hours (6 hours per week + appointments).**
* **Help session (problem solving): 1 hour per week.**
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##### E. Learning Resources

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| Title of the book | Author's name | Publisher's name | Date of publication |
| Biotechnology: Science for the New Millennium,  | Ellyn Daugherty | Paradigm Pub Intl | 2007  |
| Pharmaceutical Biotechnology: Fundamentals and Applications,  | Daan J. A. Crommelin, Robert D. Sindelar, and Bernd Meibohm | Informa Healthcare | 2007  |

**F. Facilities Required**

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| Indicate requirements for the course including size of classrooms and laboratories (ie number of seats in classrooms and laboratories, extent of computer access etc.) |
| 1. Accommodation (Lecture rooms, laboratories, etc.)* **A classroom containing at least 100 seats.**
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| 2. Computing resources* **Internet access.**
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| 3. Other resources (specify --eg. If specific laboratory equipment is required, list requirements or attach list) **Access to many of the online resources.** |

**G. Course Evaluation and Improvement Processes**

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| 1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching* **Course evaluation by students.**
* **Feedback examinations**
* **Faculty – students general gatherings.**
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| 2. Other Strategies for Evaluation of Teaching by the Instructor or by the Department* **Peer consultation on teaching.**
* **Departmental council discussions.**
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| 3. Processes for Improvement of Teaching* **Attending workshops presented by experts on the teaching methodologies.**
* **Periodical departmental revisions on its methods of teaching.**
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| 4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent faculty member of a sample of student work, periodic exchange and remarking of a sample of assignments with a faculty member in another institution)* **Comparing of the student's exams results**
* **Assigning group of faculty members teaching the same course to grade same questions for various students.**
* **Faculties from other institutions are invited to review the accuracy of the grading policy.**
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| 5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement.* **The course material and learning outcome are periodically reviewed and the changes to be taken are in the departmental and higher councils.**
* **Revision of the student's exams results by the college counilo**
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