Universitat Autònoma de Barcelona

2022/2023

Biotechnological Vaccines and Drugs

Code: 100973
ECTS Credits: 6

Degree	Type	Year	Semester
2500253 Biotechnology	OT	4	1

Contact

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Use of Languages

Principal working language: catalan (cat)
Some groups entirely in English: No
Some groups entirely in Catalan: Yes
Some groups entirely in Spanish: No

Teachers

Jaume Piñol Ribas

Prerequisites

There are no official prerequisites but knowledge of Biochemistry and Molecular Biology, Genetics, Microbiology, Cell Biology, Recombinant DNA Methods, Genomics and Proteomics, and Bioinformatics are assumed.

Objectives and Contextualisation

The first biotechnological drugs were simply "substitution molecules". These drugs were substances from human or animal organisms (hormones, etc.), which were available in very limited quantities, and that the recombinant DNA techniques allowed to obtain in large amounts. The current paradigm of the application of biotechnology to the design of vaccines and drugs is based on the prior identification of vaccine targets (genes / proteins related to pathogenicity, virulence or immunogenicity) and pharmacological targets (enzymes, receptors , whole metabolic pathways related to pathology, etc.) an then obtain the corresponding vaccine or drug by a rational design. The different "omics" (genomics, transcriptomics, proteomics, interactions, metabolomics, systems biology ...) represent key methodologies to identify the targets. In fact, these methods have allowed the emergence of so-called "reverse vaccination" (where a "silico" genome can be obtained by obtaining a vaccine) and the rational design of drugs from the three-dimensional structure of proteins. "Omics" have also generated new concepts in drug design such as "druggable genome / proteome / targetome" or "diseasome".

This course is aimed to describe the main procedures to identify vaccine and therapeutic targets. Methods and strategies to develop vaccines and to design organic molecules to modulate the biological activity of a therapeutic target will also presented.

Competences

- Act with ethical responsibility and respect for fundamental rights and duties, diversity and democratic values.

- Apply the principal techniques for the use of biological systems: recombinant DNA and cloning, cell cultures, manipulation of viruses, bacteria and animal and plant cells, immunological techniques, microscopy techniques, recombinant proteins and methods of separation and characterisation of biomolecules.
- Comply with ethical principles and legislation in the manipulation of biological systems.
- Design continuation experiments for problem solving.
- Display an integrated vision of an R&D&I process, from the discovery of the basic knowledge and the development of applications to market launch, and apply the main concepts of organisation and management to a biotechnological process.
- Identify the structural and functional elements of viruses and other useful microorganisms for the design of new strategies for molecular diagnosis of infectious diseases.
- Interpret experimental results and identify consistent and inconsistent elements.
- Learn new knowledge and techniques autonomously.
- Make an oral, written and visual presentation of one's work to a professional or non-professional audience in English or in one's own language.
- Obtain information from databases and use the software necessary to establish correlations between the structure, function and evolution of macromolecules.
- Read specialised texts both in English and one's own language.
- Reason in a critical manner
- Search for and manage information from various sources.
- Search for, obtain and interpret information from the principal databases on biology, bibliography and patents and use basic bioinformatic tools.
- Take account of social, economic and environmental impacts when operating within one's own area of knowledge.
- Take sex- or gender-based inequalities into consideration when operating within one's own area of knowledge.
- Think in an integrated manner and approach problems from different perspectives.
- Understand the legislation that regulates intellectual property in the area of knowledge and application of biotechnology.
- Use ICT for communication, information searching, data processing and calculations.
- Work individually and in teams

Learning Outcomes

1. Act with ethical responsibility and respect for fundamental rights and duties, diversity and democratic values.
2. Apply pathogenomic information in order to identify target genes and proteins for the design of vaccines and antiviral compounds and for diagnosis.
3. Describe the criteria and general requirements for applying for patents and registration of vaccines and drugs.
4. Describe the numerous, and costly, steps for developing and registering a drug or vaccine.
5. Design continuation experiments for problem solving.
6. Interpret experimental results and identify consistent and inconsistent elements.
7. Know and comply with the principles of bioethics and professional codes of conduct in R&D and in pre-clinical and clinical trials.
8. Learn new knowledge and techniques autonomously.
9. Make an oral, written and visual presentation of one's work to a professional or non-professional audience in English or in one's own language.
10. Read specialised texts both in English and one's own language.
11. Reason in a critical manner
12. Search for and manage information from various sources.
13. Take account of social, economic and environmental impacts when operating within one's own area of knowledge.
14. Take sex- or gender-based inequalities into consideration when operating within one's own area of knowledge.
15. Think in an integrated manner and approach problems from different perspectives.
16. Use ICT for communication, information searching, data processing and calculations.

17. Use bioinformatic databases, algorithms and programmes to identify targets for therapy, vaccination and diagnosis
18. Use bioinformatic databases, algorithms and programmes to identify targets for therapy, vaccination and diagnosis.
19. Use techniques for identifying, cloning and expressing target genes and proteins used in the design of vaccines and biodrugs.
20. Work individually and in teams

Content

Topic 1. Introduction to vaccines. Definition. History and generations of vaccines. General characteristics, advantages and problems. Economic and social interest.

Topic 2. Infectious diseases. Zoonosis. R0 index. Pathogens. Pathogenicity and virulence factors. Mechanisms of genetic diversity and virulence.

Topic 3. Identification and characterization of vaccine antigens. Types of antigens. Pathogenomics and applications of "omics": transcriptomics, proteomics, surfomics, immunomics, protectomics, antigenomics. Functional analysis of the activation of virulence genes. Reverse and structural vaccinology. Vaccines and immune response. Techniques for the analysis of the immune response.

Topic 4. Adjuvants. Definition. History. Properties and main classes. modes of action. New adjuvants. Nanovaccines. Other components and administration routes of vaccines.

Topic 5. Vaccine types. Classic vaccines: inactivated; auto-vaccines; attenuated. Modern vaccines: subunits and conjugated; peptide; recombinant live; DNA and RNA vaccines; anti-idiotype vaccines; structural vaccines; therapeutic vaccines; carbohydrate-based vaccines. VIOLIN database (The Vaccine Investigation and Online Information Network).

Topic 6. Vaccine development. Concepts of Safety, Immunogenicity, Efficacy and Effectiveness. Side effects. Development phases (Phase 0, I, II, III and IV). Vaccine production. Quality control. GLP and GMP regulations.

Topic 7. Drugs and Biopharmaceuticals. Concept and history of biopharmaceuticals. Different generations of biotechnological drugs. New paradigms for drug development. Pharmacoeconomics. Analysis and validation of the purity of biopharmaceuticals. Key concepts of pharmacological analysis: Pharmacokinetics, Pharmacodynamics and ADME. Key parameters in pharmacology. Biotransformation. Toxicity. Phases of the development of a drug: preclinical and clinical stages.

Topic 8. Drug discovery. Therapeutic targets. Estimates on therapeutic targets from genomics and proteomics. Classification of therapeutic targets. Systems biology and network pharmacology. Concept of pharmacophore. Strategies for the identification of new therapeutic targets. Drugs and novelty.

Topic 9. Drug development. Methods and rationale to validate pharmacological targets. Validation of hits and leads. Lipinsky rules. Methods for obtaining and improving leads: combinatorial chemistry, fragment analysis and click chemistry. Techniques to identify interactions between hits and targets: SPR-Biacore, NMR, mass spectrometry, double and triple hybrid, protein complementation assay. Structure-Function relationships. SAR and QSAR: descriptors and equations. Rational design of new drugs and structure-based drug design. Some examples of rational design. Design of anti-interaction drugs. Tools for attenuation of HERG polypharmacology.

Topic 10. Discovery and development of antimicrobial drugs. Specificities and problems when developing new antimicrobial drugs. Pharmacoeconomics of antimicrobials. Main pharmaceutical targets. Strategies for the development of antimicrobials: specialized libraries, rational design, "iChips", silent operons, polyketides, antimicrobial peptides synthesized by ribosomal and non-ribosomal pathways, virulence factors and quorum sensing. New strategies for phage based therapies.

Topic 11. Biopharmaceuticals of first and second generation. Biopharmaceuticals against a pharmacological target: monoclonalantibodies, peptides and antisense and interference RNAs. Biopharmaceuticals in replacement therapies: hormones, growth factors, cytokines and interleukins, regulatory microRNAs.

Humanization, industrial production and stabilization of monoclonal antibodies. Drug-Antibody conjugates. Main monoclonal antibodies used in therapy. Design and modifications of interference RNAs.

Methodology

The course consists of theoretical lectures and laboratory practices.

Theoretical lectures:
The teacher will develop the contents of each topic with the support of powerpoint presentations that will be posted on Virtual Campus (Moodle classroom). These presentations constitute the most important piece of the study material and it is strongly recommended that students attend lectures with a printed form of them. The use of specialized bibliography is also encouraged.

Laboratory practices:
Three sessions (4 hours each), in which some basic proteomic techniques, applied to the design of vaccines and drugs, are illustrated and performed. The assistance to the practical sessions is required.

Annotation: Within the schedule set by the centre or degree programme, 15 minutes of one class will be reserved for students to evaluate their lecturers and their courses or modules through questionnaires.

Activities

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Laboratory practices	12	0.48	1, 14, 13, 16, 2, 12, 3, 4, 5, 9, 6, 10, 15, 11, 7, 20, 17, 18, 19
Theoretical lectures	40	1.6	1, 14, 13, 16, 2, 12, 3, 4, 5, 9, 6, 10, 15, 11, 7, 20, 17, 18, 19
Type: Autonomous			
Study, recommended readings	94	3.76	1, 14, 13, 8, 16, 2, 12, 3, 4, 5, 6, 10, 15, 11, 7, 20, 17, 18, 19

Assessment

The theoretical contents will be assessed continuously through two partial exams (multiple choice test) corresponding to the Vaccine and Drugs parts of the course, respectively. The weight of each exam on the global score is a 40%. A score equal or greater than 4.0 in the partial exam allows to pass the corresponding part of the subject.

Laboratory practices will be evaluated by means of an individual exam consisting of two or three questions related to the work carried out in the lab (weight 15%), plus the student's attitude and performance during the practical sessions (weight 5%). As described for theory exams, a score equal or greater than 4.0 allows to pass this part of the subject.

Those students who have not passed either theory and practices exams as a result of the continuous evaluation must attend a final exam in order to reassess any of the parts previously scored below 4.0. Moreover, the access to the final exam will only be allowed to the students who have previously been evaluated in a set of activities whose weight equals to a minimum of two thirds of the total grade of the subject.

On the other hand, those students who have passed the subject per course as a result of the continuous evaluation can also go to the final exam to improve their grades in any of the previous exams. In this case, the score obtained in the former exam will be preserved if greater.

The students will obtain the qualification of "Not Evaluable" if the number of their assessment activities is less than 67% of the programmed ones for the subject.

To pass the course a global score equal or greater than 5.0 must be attained.

Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
Laboratory practices exam	20%	2	0.08	14, 13, 8, 3, 5, 6, 10, 15, 11, 20, 17, 19
Partial Exam 1 (part: Vaccines)	40%	1	0.04	1, 14, 13, 8, 16, 2, 12, 3, 4, 5, 9, 6, 10, 15, 11, 7, 20, 17, 18, 19
Partial Exam 2 (part: Drugs)	40%	1	0.04	1, 14, 13, 16, 2, 12, 3, 4, 5, 9, 6, 10, 11, 7, 17, 18, 19

Bibliography

- "Plotkin's Vaccines". 7th Ed. S. A. Plotkin, W. A. Orenstein, P. A. Offit, K. M. Edwards. Elsevier, 2018.
- "Vaccine delivery technology: Methods and Protocols" (Methods in Molecular Biology, vol. 2183). B. A. Pfeifer & A. Hill editors. Humana Press, 2021.
- "Vaccine Design". F. Bagnoli & R. Rappuoli eds. Caister Academic Press, 2015.
- "Basic Principles of Drug Discovery and Development". 2nd Ed. B. E. Blass. Academic Press, 2021.
- "Textbook of Drug Design and Discovery". 5th Ed. K. Stromgaard, P. Krogsgaard-Larsen, U Madsen editors. CRC Press, 2018.
- "Drugs: From Discovery to Approval". 3rd Ed. N. G. Rick. Wiley Blackwell, 2015.
- "A Practical Guide to Rational Drug Design". 1st Ed. S. Hongmao. Woodhead Publishing, 2015.

Software

No specific software is used in the subject's teaching.