



UNIVERSITÀ DEGLI STUDI DI PALERMO

DEPARTMENT	Scienze e Tecnologie Biologiche, Chimiche e Farmaceutiche
ACADEMIC YEAR	2021/2022
BACHELOR'S DEGREE (BSC)	BIOTECHNOLOGIES
SUBJECT	BIOTECHNOLOGIES LAW
TYPE OF EDUCATIONAL ACTIVITY	B
AMBIT	50079-Discipline per la regolamentazione, economia e bioetica
CODE	17541
SCIENTIFIC SECTOR(S)	IUS/02
HEAD PROFESSOR(S)	VANNI DI SAN Professore Associato Univ. di PALERMO VINCENZO DOMITILLA
OTHER PROFESSOR(S)	
CREDITS	6
INDIVIDUAL STUDY (Hrs)	102
COURSE ACTIVITY (Hrs)	48
PROPAEDEUTICAL SUBJECTS	
MUTUALIZATION	
YEAR	1
TERM (SEMESTER)	2° semester
ATTENDANCE	Not mandatory
EVALUATION	Out of 30
TEACHER OFFICE HOURS	VANNI DI SAN VINCENZO DOMITILLA Monday 10:00 12:00 Stanza sita al piano terra, attigua alla sala lettura dell'ex dipartimento di diritto privato generale. Tuesday 10:00 12:00 Stanza sita al piano terra, attigua alla sala lettura dell'ex dipartimento di diritto privato generale.

DOCENTE: Prof.ssa DOMITILLA VANNI DI SAN VINCENZO

PREREQUISITES	Adequate historical, institutional, economic and legal knowledge of the Italian and European legal system.
LEARNING OUTCOMES	<p>Knowledge and understanding</p> <p>Acquisition of advanced tools for understanding the evolution of biotechnology law. Ability to use the specific language of this discipline and to master the system of sources, the main institutions and legal concepts of private law with reference to the comparative methodology in the biotechnology field,</p> <p>Ability to apply knowledge and understanding</p> <p>Ability to independently recognize and organize the constituent and founding elements of the biotechnology law of each legal system including the legal system of the European Union, in light of the comparison with common law systems.</p> <p>Autonomy of judgment</p> <p>Be able to evaluate the implications deriving from differences and equality between legal systems. Being able to assess the impact of the system of sources and the political, social and economic evolution of each legal system on the different biotechnology statutes and human rights.</p> <p>Communication skills</p> <p>Ability to expose the results of the studies carried out even to a non-expert public. Being able to support the importance and highlight the differences between operational legal rules and "declaimed" rules. Ability to master the linguistic-conceptual differences of legal terms.</p> <p>Learning skills</p> <p>Ability to update by consulting the scientific publications of the sector, the main judicial decisions as well as domestic, European and international legislation, essentially using the texts in the original language and in detail in English and French. Ability to follow, using the knowledge acquired in the course, both first level masters, in-depth courses and specialized seminars in the field of biotechnology law.</p>
ASSESSMENT METHODS	<p>A paper and an oral examination aimed at ascertaining the level of knowledge of the subject matters. The evaluation will unfold as follows: Excellent (30 - 30 cum laude): good knowledge of the topics, excellent property of language, excellent capacity of analysis ; the student is able to apply theoretical knowledge to real cases which are proposed to be analysed; Very good (26 - 29): good knowledge of the topics, good properties of language, good analytical capacity; the student is able to apply theoretical knowledge to real cases which are proposed to be analysed; Good (24 - 25): Basic knowledge of the main topics, good property of language, the student shows limited ability' to apply theoretical knowledge to real cases which are proposed to be analysed; Satisfactory (21 - 23): the student does not show that complete command of the main teaching topics, although showing to know the basic knowledge; he/she shows satisfactory property of language albeit with a poor ability' to adequately apply theoretical knowledge to real cases which are proposed to be analysed; Sufficient (18 - 20): The threshold of sufficiency will be achieved when the student shows knowledge and understanding of the topics at least in general terms and has minimum application competencies for the resolution of concrete cases; below this threshold, the examination will be considered insufficient.</p>
EDUCATIONAL OBJECTIVES	Acquisition of advanced tools for understanding the evolution of biotechnology law. Ability to use the specific language of this discipline and to master the system of sources, the main legal institutions and concepts of private law with reference to the comparative methodology in the biotechnology field, Knowledge of the fundamentals of legal rules referable to research, experimentation and application of biotechnology.
TEACHING METHODS	Frontal lessons
SUGGESTED BIBLIOGRAPHY	<p>L'indicazione delle letture di base e di approfondimento è meramente esemplificativa ed è data ai soli fini di un possibile ausilio e supporto alle lezioni la cui frequenza è, naturalmente, insostituibile.</p> <p>Conseguentemente possono essere utilizzati dagli studenti altri testi, anche diversi da quelli indicati, che trattino e sviluppino gli argomenti del programma del corso.</p> <p>Si segnala come lettura di base preliminare:</p> <ul style="list-style-type: none"> - G. Giaimo, La volontà e il corpo, Giappichelli 2019, ISBN 9788892119468. <p>Si consiglia inoltre per l'approfondimento la lettura di:</p> <ul style="list-style-type: none"> - V. D'antonio, Invenzioni biotecnologiche e modelli giuridici: Europa e Stati Uniti, Jovene 2004, ISBN 9788824315319; nonché del testo in lingua inglese: - R.Hardcastle, Law and the Human Body. Property Rights, Ownership and Control, Oxford and Portland, Oregon 2009, ISBN 9781841136011.

SYLLABUS

Hrs	Frontal teaching
4	An introduction to biotechnology law: the regulatory international framework

SYLLABUS

Hrs	Frontal teaching
6	-Biotechnology law in National and European law: a comparison between different legal systems
4	-Regulatory, constitutional, European and international sources with particular regard to biotechnology
4	-Legal protection of biotechnological inventions, related international agreements, the European rules and the Directive 98/44/EC
4	-D.lgs. n. 131/2010 (amendments to the C.P.I.) and biotechnological inventions
10	Analysis of some problems derived by globalisation and related rules: biodiversity, bioethics, biolaw, biobanks and privacy. The assisted reproduction. New drugs, Environmental Protection, Environmental and Plant Biotechnology.
8	Analysis of the principles governing contracts and liability in the law of biotechnology. Brief overview of the main technology transfer and licensing agreements - Medical liability
4	Legislation on risk prevention at the workplace and responsibilities
4	-Civil/administrative/criminal liability