Good laboratory and manufacturing practice in industrial biotechnology

STRUCTURA

Programul de studii	MASTER_Biotechnology and Entrepreneurship
Anul de studii	I
Semestrul	2
Regimul disciplinei	DOS
Numărul total de ore pe săptămână	Curs - 1 ora; L/S/P- 1 ora
Numărul total de ore conform planului de învățământ	Curs - 14 ore; L/S/P- 14 ore
Numărul de credite transferabile	5

OBIECTIVELE DISCIPLINEI

- Concepts related to quality assurance, good manufacturing practice and quality control, interdependent and fundamental in their importance in the manufacture and control of biotechnological products
- Applying the knowledge gained in the production and analysis of biotech products

CONȚINUTUL DISCIPLINEI*

CURS	Nr. ore
1. General GMP requirements on biotech products manufacturing	1
2. General requirements on quality control	1
3. Quality management in production activities	1
4. Requirements on personnel training, infrastructure and environmental conditions within the manufacturing facilities.	1
5. Management of production activities and quality control	1
6. Materials management	1
7. Production and technological processes control	1
8. Requirements on packaging, labeling, storage and distribution	1
9. Laboratory control	1
10. Validation of technological process	1
11. Changes' management	1
12. Materials rejection	1
13. Handling complaints and withdrawal of non-compliant products	1
14. Elaboration of the CTD documentation for obtaining the marketing authorization of biotechnological products	1

**Se vor specifica pe scurt conținutul disciplinei la curs si Lucrări practice L/S/P (denumire capitol și conținut capitol)*

LUCRĂRI PRACTICE L/S/P	Nr. ore
1. Labeling of a functional product made within the faculty	2
2. The packaging of a functional product made within the faculty	4
3. Microbiological control of a functional product made within the faculty	2
4. Elaboration of the documentation for obtaining the marketing authorization	n

BIBLIOGRAFIE

1.DirectiveUE/ICH: 75/319/EEC(Medicinal Product Directive);2001/83/EC si amendamente (Medicines for Human use);2003/94/EC (GMP Directive)

2. Vanessa Grant, Tim Stiles Good Clinical, Laboratory Practice(GCLP), Research Quality Association, 2012

3. Slomiany Ph.D., Mark Gregory The Indispensable Guide to Good Laboratory Practice (GLP): Second Edition 2nd Edition, CreateSpace Independent Publishing Platform, 2009.

4. Susan Mahler Zneimer, GUIDELINES FOR GOOD CLINICAL LABORATORY PRACTICE, WileyOnline Library , 2016

EVALUARE

Tip de activitate	Criterii de evaluare	Metode de evaluare	Pondere din nota finală %
Curs	Individual performance (level of acquired theoretical knowledge) Peer performance in a study case	Online multiple-choice evaluation test Online evaluation of reports (study case)	50% 50%
L/P/S	.....	.....	.....
Alte activități			

Titularul activităților de curs: Prof. dr. Emanuel Vamanu

Titularul activităților de lucrări practice L/S/P: Prof. dr. Emanuel Vamanu