האוניברסיטה העברית בירושלים
THE HEBREW UNIVERSITY OF JERUSALEM

The Hebrew University of Jerusalem

Syllabus

Pharmaceutical and biotechnology products development compliant with regulatory requirements - 71174

Last update 07-02-2021

HU Credits: *2*

Degree/Cycle: *2nd degree (Master)*

Responsible Department: *Biotechnology*

Academic year: *0*

Semester: *2nd Semester*

Teaching Languages: *Hebrew*

Campus: *Rehovot*

Course/Module Coordinator: *Tarryn Shuldiner-Harpaz*

Coordinator Email: *motneu@inter.net.il*

Coordinator Office Hours: *To be announced*

Teaching Staff:
Dr. Moshe Neuman

Course/Module description:
The course includes a comprehensive review of the regulatory requirements and strategies for the development and approval of pharmaceuticals and biotechnological products (including stem cell-based advanced therapies) for marketing in the US and EU.

Course/Module aims:
Learning the principles and practice of statistics in biological research

Learning outcomes - On successful completion of this module, students should be able to:
To provide comprehensive knowledge at the practical level of the required R&D procedures, from the pre-clinical stage throughout the clinical development, in order to support filing of registration product files for review and approval by the authorities.

Attendance requirements(%):

Teaching arrangement and method of instruction: Frontal instruction

Course/Module Content:

Required Reading:
A list of critical ICH guidelines and procedures published by the FDA in the US and EMA in the European Union will be provided

Additional Reading Material:
List of important articles will be provided

Course/Module evaluation:
End of year written/oral examination 100 %

Presentation 0 %
Participation in Tutorials 0 %
Project work 0 %
Assignments 0 %
Reports 0 %
Research project 0 %
Quizzes 0 %
Other 0 %

Additional information: