

The Hebrew University of Jerusalem

Syllabus

Regulation of the Pharmaceutical Industry - 64901

Last update 11-07-2018

HU Credits: 2

Degree/Cycle: 2nd degree (Master)

Responsible Department: School of Pharmacy

Academic year: 0

Semester: 1st Semester

Teaching Languages: Hebrew

Campus: Mt. Scopus

Course/Module Coordinator: Zohar Yahalom, Adv.

Coordinator Email: zohar@yahalomlaw.co.il

Coordinator Office Hours: Thursday, 10.00-11.00

Teaching Staff:

Zohar Yahalom

Course/Module description:

Introduction of the regulation of the pharmaceutical industry in Israel and abroad

Course/Module aims:

Acquaintance with the basic principles and terminology of pharmaceutical regulation in Israel and abroad

Learning outcomes - On successful completion of this module, students should be able to:

Analyze basic questions related to the pharmaceutical regulation

Attendance requirements(%):
required

Teaching arrangement and method of instruction: Frontal Presentation

Course/Module Content:

- 1. Regulatory definition and classification of medicinal products.*
- 2. Registration of Medicinal Product and its exemptions.*
- 3. Clinical trials.*
- 4. Regulation of pharmaceuticals' manufacturing, distribution, dispensing and importation.*
- 5. Pharmacovigilance.*
- 6. Pharmaceuticals' chain of supply.*
- 7. Drug Information and Pharmaceuticals' advertisement.*
- 8. Pricing and Reimbursement.*
- 9. Pharmaceutical Companies and HCPs interactions.*
- 10. Enforcement and surveillance in the pharmaceutical market.*

Required Reading:

*petition to the High Court
30/82,70/80.1405/14,4675/03*

Additional Reading Material:

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: