1. **Prerequisites**

- Fundamentals in Drug Development
- Overview to Drug Development

2. **Course Details**

- **Course Name (Hebrew)**: עקרונות בסיסים בפיתוח תרופות
- **Course Name (English)**: Fundamentals in Drug Development
- **Teaching Methods**: Lecture, Seminar, Tutorial
- **Course Language**: Hebrew

3. **Course Content**

- The ‘Fundamentals in Drug Development’ course will cover the main aspects of the drug development and drug discovery processes and will expose students to the essential activities in the pharmaceutical development.
- Lectures will be given by guest-lecturers from Teva and the BLAVATNIK CENTER for Drug Discovery, Tel Aviv University.

4. **Course Schedule**

<table>
<thead>
<tr>
<th>Lesson</th>
<th>Lecturer</th>
<th>Subject</th>
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<td>1</td>
<td>Dr. Eliyahu Barovitch</td>
<td>Overview to Drug Development</td>
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<td>2</td>
<td>Dr. Avi Roth</td>
<td>Medicinal Chemistry and Natural Products</td>
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<td>3</td>
<td>Prof. Uri Shapira</td>
<td>Clinical Pharmacology</td>
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<td>4</td>
<td>Dr. Yoel Dov</td>
<td>Planning of Clinical Trials</td>
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<td>5</td>
<td>Dr. Alona Shivers</td>
<td>Intellectual Property in Drug Development</td>
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<td>6</td>
<td>Dr. Arior Aronov</td>
<td>Pre Clinical Pharmacology</td>
</tr>
<tr>
<td>7</td>
<td>Dr. Aviram Dvir</td>
<td>Pharmacovigilance</td>
</tr>
</tbody>
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5. **Additional Learning Resources**

- Lectures will be given by guest-lecturers from Teva and the BLAVATNIK CENTER for Drug Discovery, Tel Aviv University.

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Sagol School of Neuroscience, Ramat Aviv, 69978 Tel Aviv, Israel. Tel. 972-3-6409081, FAX. 972-3-6409136
<table>
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<tr>
<th>Course</th>
<th>Instructor</th>
<th>Credits</th>
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<td>Generics and NTEs</td>
<td>ד&quot;ר מירית ארגוב</td>
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<td>Computer-Aided Drug Design</td>
<td>ד&quot;ר חמוטל אנגל, ד&quot;ר אדוה יחזקאל</td>
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<td>Chemistry Manufacturing and Control (CMC)</td>
<td>ד&quot;ר מנסטרה אופר</td>
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<td>Personalized medicine and pharmacogenomics</td>
<td>ד&quot;ר דפנה ליבנפלד</td>
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<td>Technology Transfer and IP Commercialization</td>
<td>אפרת שולח, ד&quot;ר ש MICRO</td>
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<tr>
<td>Academia-Industry partnership + Visit at Teva Factory – Kfar Saba</td>
<td>ד&quot;ר הלה ברש</td>
<td>13</td>
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</tbody>
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6. חומר קריאה

- [http://www.fda.gov/ForPatients/Approvals/Drugs/default.htm](http://www.fda.gov/ForPatients/Approvals/Drugs/default.htm)
- [http://www.fdareview.org/index.shtml](http://www.fdareview.org/index.shtml)

- Pharmacovigilance from A to Z, Barton L. Cobert, MD; Pierre Biron, MD.
- MHRA – Good Pharmacovigilance Practice Guide

**Operational activities of the Clinical Trials/Data Management and Clinical Programming**


**Medical Monitoring during clinical study**

- FDA Guidance for Industry - Establishment and Operation of Clinical Trial Data Monitoring Committees, March 2006
Regulatory Affairs

- Communication from the Commission 2010/C 82/01 — Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1), March 2010
- United States Code Title 21, Part 312, Investigational New Drug Application, April 2012
- FDA Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants, May 2009
- European Commission: Notice to Applicants Vol. 2A: Procedures for marketing authorisation, June 2013
- The CDER Handbook, produced by the Department of Health and Human Services, Food and Drug Administration, March 1998
- Beishon M., Approval rating: how do the EMA and FDA compare?, 12 | CancerWorld | January-February 2014
- Navigating the Regulatory Landscape for Healthcare Product Development: Key principles and best practices, MaRS Discovery District, October 2012

Introduction to nonclinical safety testing

- ICH M3(R2) guideline. 11 June 2009.
8. המגלה מסף הלמידיות בקורסים

9. האם הקורסים יינטויו בכל שנה או אחר López?

10. הרכבה הציון הסופי

מעבר לאמריקאים (100%)