

PHA 5172 BIOTECHNOLOGY & INDUSTRY (Research and Practice)

Course SYLLABUS, Fall, 2005

Course Objectives:

With focuses on both product development & pharmaceutical patient care, students will:

1. *Elucidate* the **scientific principles** in biotechnology.
2. *Explain* the components of, and challenges in, **development and launch of drugs and biologicals** in the pharmaceutical and biotechnology industry.
3. *Elaborate* about **approved products**, e.g., indications, impact on disease therapy, & product limitations and about **pipeline products**, e.g., development challenges.
4. *Envisage* the **usage** of biological products, including their daily use by and impact on health care systems, providers, patients, and pharmaceutical companies.

Course Professor: Ronald P. Evens, Pharm.D., Clinical Professor
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Teaching Methods:

1. *Overall goals* are to **learn** about biotechnology, have **fun**, make it **practical and usable**, include **real-life examples**, and **apply** it to healthcare and drug development.
2. *Lectures, discussions, presentations, and tests* are employed in assimilation of materials.
3. *Copies of slides* for all lectures/discussions are provided to the students.
4. A *book* is used for optional readings: Pharmaceutical Biotechnology for Pharmacists and Pharmaceutical Scientists 2nd Ed., Editors - Crommelin D & Sindelar R.
5. *Student presentations* (1 per student) will cover biological products.

Grading Practices:

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| 1. Midterm Exam: | 40 points |
| Brief Essay questions; Answer 8 out of 12 (Topics for Sessions #1-7) | |
| 2. Final Exam: Brief Essay questions; Answer 10 out of 15. | 50 points |
| 3. Student Presentation & Paper (Topic will be approved biological): | 50 points |
| - #1 per student (20 minutes each; 33% of total grade) | |
| 4. Class Participation: | 10 points |
| Total: | 150 points |

Bonus: Extra Credit is possible for 2nd paper (25 points)

Class Times: Thursdays, 10:40 AM to 12:35 PM
Class Bldg & Room: MSB Auditorium 2nd Floor

PHA 5172 BIOTECHNOLOGY (Industry Research and Pharmacy Practice)

Lecture Schedule (Thursdays) and Topics (Fall, 2005):

Section A. The Science of Biotechnology: (Weeks 1-6)

- Aug. 25 (1) Course Introduction and Biological Basis of Biotechnology
- Sep. 1 (2) The Industry and Product Discovery
- Sep. 8 (3) Core Technologies: rDNA and Monoclonal Antibodies (Mabs)
- Sep. 15 (4) Genetic Technologies: e.g., PCR, Genomics, Gene therapy, Proteomics, Antisense, Pharmacogenomics
- Sep. 22 (5) Discovery with Mediators, Cell processes, and Development Advances: e.g., Molecular engineering, Cell therapies
- Sep. 29 (6) Product Formulations, Manufacturing & Drug Delivery

Section B. The Biological Products, Approved and Pipeline: (Weeks 7, 9, 10)

- Oct. 6 (7) Approved Biologicals: Hormone, Enzyme, Growth Factor, Mab, Interferons, Etc.; Diseases & Indications for Approved Biologicals
- Oct. 10 **Midterm Exam: 5-7 PM**, Covers Sessions #1-7

Section C. Usage and Development Challenges for Industry: (Weeks 8, 11-15)

- Oct. 13 (8) Pipeline and Product Development (Clinical Research 1)
- Oct. 20 & 27 (9 & 10) **Student Presentations, Gainesville, 10:35AM, Oct 20, 27; Jacksonville Oct. 31, 1PM; St. Pete 1PM & Orlando, Oct. 28, 5PM**
- Nov. 3 (11) Pipeline and Product Development (Clinical Research 2)
- Nov. 10 (12) Health Care and New Product Launches
- Nov. 17 (13) Pharmacoeconomics: Studies & Issues in Development & Healthcare
- Nov. 24 (14) No Class: THANKSGIVING HOLIDAY
- Dec. 1 (15) Patients, Companies & Pharmacy Issues
- Exam Week **Final Exam** (Date TBD)