



# **I. Pharmaceutical Immunology Section-Wagner**

## GOALS FOR THE COURSE

The emphasis in this course will be on basic biological mechanisms of the immune system that should be understood in order to appreciate therapeutic methods and to understand and anticipate potential complications. You should also understand how to find the latest information pertaining to vaccination via the internet. At the conclusion of this course each student should be able to:

1. Describe the mechanism of antibody and cell-mediated immunity
2. Be able to explain the mechanisms by which vaccines based on AMI and CMI work
3. Define the mechanisms responsible for hypersensitivity to allergens and how they are related to drug immunopathologies.
4. Describe the possible mechanisms responsible for immune related diseases
5. Characterize transplant rejection and mechanisms for prevention

## EVALUATION REQUIREMENTS

### **Exams**

There will be two 1 hr exams (100 pts). These exams will cover only material covered during lectures and in-class discussions. 15% of the exam will be based on questions from the internet quizzes. Exams will typically be composed of multiple choice, short answer and essay questions. Students getting D's and F's will have an opportunity to take a comprehensive Final Exam (essay-type) during Finals Week with the possibility of raising their grade to a C. All exams and will be returned to your college mailbox. You can have them returned to you in person by writing this request on the front page of your exam or assignment.

### **Internet Quizzes**

There will be five quizzes (10 pts each) that will be given during the instruction period. The quizzes will be posted on the course WebVista site. The quizzes are open book, but are to be completed on an individual basis as specified by the honor code. You will be given a window of 48 hrs to complete them starting at noon on the quiz date.

#1	Jan. 31	#2	Feb. 7	#3	Feb. 21
#4	Feb. 28	#5	March 6		

## INSTRUCTION

### **1) Lectures**

Material for the class will be covered by in class lectures. The lectures will be based on the class handout and selected textbook readings. The assigned readings should be completed before class.

## 2) **In-Class Discussion Questions**

The class will be divided at random into groups of three students and assigned a number and folder. On selected days, a discussion question on material that has been covered in class will be handed out in a folder. The groups will be given time to answer the questions, followed by a general class discussion of the answers. All students are expected to participate.

## **II. Recombinant DNA-Derived Drugs Section-Anderson/Shier/L. Traynor**

### COURSE REQUIREMENTS:

Attend class sessions, take exams, study the relevant sections of the Lesson Plan in advance of class sessions, participate in class discussions, contribute to an active learning group project on a recombinant DNA-derived drug.

### COURSE OBJECTIVES:

The objective of this course will be to understand DNA technology as it relates to drug therapy which can be used in the Pharmaceutical Care of a patient. The emphasis will be on understanding the science that underlies recombinant DNA-derived drugs, as well as an introduction to some approved recombinant DNA-derived drugs. At the conclusion of this course each student should be able to:

1. Describe how recombinant DNA techniques can be used in the production of drugs and for the diagnosis of disease.
2. Describe currently available drugs derived from recombinant DNA techniques, and those likely to be available in the foreseeable future
3. Understand therapeutic applications of recombinant DNA-derived drugs which may be encountered in subsequent courses.
4. Understand experimental therapeutic approaches using DNA technology, such as gene therapy, which may be encountered in future practice.

### COURSE EVALUATION:

Students will have an opportunity to evaluate the course on a date to be scheduled during the last week of the course at the beginning of the class.

**(1) Written Examinations.** You are required to complete two scheduled in class examinations (1 hr) worth 100 points each. The dates of these exams are announced in the course outline below, and they will cover only the lectures specified.

**(2) Active Learning Group Presentations.** You will be participating in an active learning exercise in which you will collaborate with classmates to research and prepare a presentation to the rest of the class on assigned medications. It will be worth 50 points. The goals for this class exercise are to:

1. Introduce you to classes of drugs generated by recombinant DNA-related technology.
2. Provide you with an active learning exercise designed to enhance your understanding of the scientific methods used to design these classes of drugs.
3. Foster collaborative work.

4. Provide you an opportunity to teach your classmates important concepts behind the therapeutic applications of specific classes of recombinant DNA derived drugs. The class will be held responsible for the information presented by these student groups. Test questions for your exams will be derived from these presentations.

### **Twin Cities Students:**

Members of the Twin Cities class will be assigned to one of 16 active learning groups of 6 or 7 students each. Each group will be assigned one of eight sets of recombinant DNA-derived drugs as given below, and they will be asked to prepare a 20-25 minute PowerPoint presentation on the assigned group of drugs. Examples of earlier student presentations will be posted on the class website, and additional instructions will be provided during the first Biotechnology lecture. You may also view a BREEZE presentation prepared by Dr. Traynor on the class website for more information about this active learning exercise. The 6 or 7 students in section A will work together on a joint set of PowerPoint presentation materials, and the 6 or 7 students on section B will work together on second, different set of presentation materials on the same assigned subject. An electronic copy of a rough draft of each presentation must be turned in to Dr. Shier two weeks before the scheduled date of the presentation. Dr. Shier will meet with all the members of the Group (A and B). Each person will present part of their subgroups presentation. The Group (A and B) and Dr. Shier will together select the best presentation or the best combination of the two presentations, and a presenter of the final combined presentation. The presenter, with help from the two sections (A and B), will have one week to finalize the combined presentation. All members of the Group (A and B) should be present to assist with the question period, if needed. The presentation will be subjectively graded by Dr. Shier out of a possible 50 points, with 25 points for the PowerPoint materials, and 25 points for the presentation and question-answer period. Thus, everybody in Group 1, for example, will get the same grade. In previous years all grades ranged from 45 to 50.

### **Duluth Students:**

1. Members of the Duluth class will be divided into 8 groups.
2. Each student is required to view a Breeze presentation on the class website that introduces the requirements and tips for completing this active learning exercise.
3. Each group will prepare and present a 20 minute, in-class oral presentation on assigned therapeutic agents. The presentation will focus on the following questions:
  - What molecular approaches were used in the design of these agents?
  - Describe the biological mechanism of action for these agents.
  - What is the biological basis for the common side effects encountered with these agents?
  - What special considerations are used in the preparation and administration of these agents and what is the rationale for those special considerations?
4. Each group will select 1 or 2 members of their group to present their material. However, the entire group must contribute to the presentation content.
5. Each person will receive up to a maximum of 50 points for their work on the project. In previous years the grades ranged from 45 to 50.
  - Up to 30 points will be awarded for the quality of the work the group did on the presentation as a whole. Due to this, all members of the group will receive the same grade for these 30 points. These 30 points will be awarded subjectively by Dr. Traynor.

- Up to 20 points will be awarded for the quality of each individual's work on the presentation. These 20 points will also be awarded subjectively by Dr. Traynor, however, Dr. Traynor will rely heavily on peer evaluations of other participants in the groups. At the conclusion of the presentation, each member of the groups will be asked to privately assess the quality of work performed by their peers. These evaluations will be kept confidential to only be seen by Dr. Traynor. Dr. Traynor will be happy to meet with any student who has concerns with their assigned grade, but will only discuss the global thoughts of the group on their individual performance to keep the evaluation process confidential. Failure to turn in a peer evaluation will result in a 0 for your 20 points.
6. Each group will schedule time to meet with Dr. Traynor outside of class once before their presentation.
- Presentations must be emailed to Dr. Traynor **at least** one week before the presentation. Failure to email a complete rough draft of the PowerPoint presentation to Dr. Traynor will result in an automatic 5 point deduction from the grade that would have otherwise been assigned to your group.
  - The meeting will consist of Dr. Traynor reviewing the PowerPoint presentation and commenting on the content before it is presented. Failure to schedule this second meeting with Dr. Traynor a minimum of two days prior to the presentation will result in an automatic 5 point deduction from the grade that would have otherwise been assigned to your group. This second review is critical to ensure the quality of the material presented to the class and assure your classmates have a good learning experience.

#### Active Learning Group Drug Assignments:

Each group must cover each of the drugs that has been assigned to your group. There may be overlap between your assigned drugs in terms of mechanism of action, side effects, etc. In that case, do not repeat information for each drug, but rather attempt to present it only once.

- Groups 1A and 1B: Insulins: Humulin R, Humulin N, insulin glargine; insulin detemir, insulin aspart; lispro insulin.
- Groups 2A and 2B: Cytokine-based Drugs: Epoetin alfa, darbepoetin, filgrastim, pegfilgrastim, sargramostim
- Groups 3A and 3B: Immunosuppressives: Muromonab-CD3, daclizumab, basiliximab, omalizumab
- Groups 4A and 4B: Genetic Deficiency Replacement Therapies: recombinant Factor VIII, rVIIa, dornase alfa, nutropin, imiglucerase
- Groups 5A and 5B: Clot-Busters: Alteplase, reteplase, tenecteplase, lepirudin, abciximab.
- Groups 6A and 6B: TNF $\alpha$ -Blockers and Other Anti-inflammatory Agents: Infliximab, adalimumab, etanercept, abatacept.
- Groups 7A and 7B: Anti-Cancer Drugs: Rituximab, trastuzumab, bevacizumab, gemtuzumab, ozogamicin, denileukin diftitox.
- Groups 8A and 8B: Anti-Infectives/Others: Palivizumab, drotrecogin alfa, peginterferon alfa-2b, hepatitis B vaccines, ranibizumab

### **III. Grading and Exam Policies**

All exams must be answered in pen. Grades will be assigned at the end of the term and will be based on the total number of points out of a maximum of 500 points for the combined sections. As would be the case for a combined 3 cr. course, you will receive the grade you have obtained at the end of the semester for both courses. The assignment of grades will be according to the below definitions. To pass the class you must obtain 60% (300 pts) of the total points.

<b>Grade</b>	<b>Percent</b>
A	>93
A-	90-92
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
D	60-69
F	>60

Students getting a D or F on the combined grade will have an opportunity to take a comprehensive Final Exam (essay-type) during Finals Week with the possibility of raising their grade to a C-. Incomplete grades will be given only by prior arrangement approved by the course director.

#### REGRADE POLICY

All exams submitted for regrade must have a written explanation attached detailing the need for the exam to be regraded. The request must be submitted to the instructor within one week of receiving the graded exam. No changes will be made in the final grade without the consent of Dr. Wagner, Dr. Shier or Dr. Grant. Regraded exams may also result in further point deductions if overlooked grading errors are found.

#### MAKE-UP EXAM POLICY

Under no circumstances will make-up exams be scheduled for unexcused absences. Excused absences include 1) illness verified by a physician's letter, 2) serious family emergency, and 3) a University-sponsored event, verified by a note from the leader of the sponsoring institution. Notification of the course director must occur in advance of the regularly scheduled exam.

#### HONOR CODE

Each student is bound by the following specific provisions as part of the Code: Academic misconduct is any unauthorized act which may give a student an unfair advantage over other students, including but not limited to: falsification, plagiarism, misuse of test materials, receiving unauthorized assistance and giving unauthorized assistance. Specifically, each student will be required to do their own work on all quizzes, tests and written assignments. For internet quizzes, students are not allowed to discuss the quiz with other students during the time the quiz is given.

For written assignments, students are allowed to discuss the assignment with other students, but all written material must be their own work and not the result of group discussions.

### DISABILITY ACCOMMODATIONS

Any student with a documented disability (e.g. physical learning, psychiatric, vision, hearing, etc.) who needs to arrange reasonable accommodations must contact the Course Director (625-2614) and Disability Services (626-1333) at the beginning of the semester. All discussions will remain confidential.

## I. Pharmaceutical Immunology Section-Wagner

LECTURE	COURSE OUTLINE	HANDOUT/READINGS
1 Wagner	OVERVIEW OF THE IMMUNE SYSTEM A. What is Immunity? B. What are the key concepts	Chapter 1
2 Wagner	THE BODY'S DEFENSE MECHANISMS A. Acquired Immunity vs Innate or Natural Immunity B. Innate or Natural Immunity C. Host Defense Mechanisms that Constitute Innate Immunity	Chapter 2/Chap. 1, pgs 1-11, Chap. 8, pgs 227-233, 236-244 Chap. 1 Questions 1-3, 5 Chap. 8, Questions 1-3, 11
3-4 Wagner	MOLECULAR COMPONENTS OF THE IMMUNE SYSTEM A. Antigens B. Antibodies	Chapter 3/Chap. 2, pgs 37-63 Chap. 2 Questions 1-10, 13
5 Wagner	ANTIBODIES AND PASSIVE IMMUNIZATION A. Vaccines B. Mechanism of Action of Passive Immunization and Risks C. Current Antibody Based Therapeutics	Chapter 3/Chap. 2. Pgs 37-52 Chap. 2 Questions 1-4
6-7 Wagner	THE GENERATION OF ANTIBODY-MEDIATED IMMUNE (AMI) RESPONSES A. Immunological Responsiveness B. Clonal Selection Model for Stimulating Antibody Synthesis C. Mechanisms of Cell-Cell Cooperation D. T-Independent AMI	Chapter 4/ Chap 6, pgs145-159; Chap.7, pgs 181-194 Chap. 6, Questions 2, 5, 9, 13; Chap. 7 Questions 1-4,
8-10 Wagner	THE GENERATION OF CELL-MEDIATED IMMUNE (CMI) RESPONSES A. Development of Cell-Mediated Immunity B. Phases of Cytotoxic Response C. Antibody-dependent cell mediated Cytotoxicity D. Vaccines that use AMI and CMI	Chapter 5 Chap. 6, pgs 159-175 Chap. 6 Questions 7, 8

**11. Exam, Lectures 1-10, 100 points (1 hr), February 15**

**LECTURE****COURSE OUTLINE****HANDOUT/READINGS**

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12-13	IMMUNOCYTE DEVELOPMENT	Chapter 6/
Wagner	A. Cells of the Immune System	Chap 1 pg. 11-15; Chap. 8 pg. 239-242
	B. Hematopoiesis	
	C. Therapeutic Cytokines	Chap 1. Question 6
14	TISSUES OF THE IMMUNE RESPONSE	Chapter 7/
Wagner	A. Primary Lymphoid Organs	Chap. 1 pgs 15-20; Chap. 4 pgs 99-115;
	B. Secondary Lymphoid Organs	Chap. 5 pgs 125-138
		Chap. 1 Question 7; Chap. 5 Questions 3, 5
15-19	HYPERSENSITIVITY AND ALLERGIC REACTIONS	Chapter 8/
Wagner	A. Mechanisms for the Development of Autoimmunity	Chap. 7 pgs 202-222
	B. TYPE II-Cytotoxic Antibody Hypersensitivity	Chap. 10, pgs 311-339
	C. TYPE III-Immune Complex Mediated Hypersensitivity	
	D. TYPE IV-Delayed-Type Hypersensitivity	
	E. Therapeutics Based on Type IV Hypersensitivity	
	E. Drug Induced Immunopathology	Chap 7 Questions 11; Chap 10 Question 1-10
20-22	IMMUNOSUPPRESSION: THERAPEUTIC, CONGENITAL AND	Chapter 9/
Wagner	ACQUIRED	Chap. 9 pgs 279-307
	A. Mechanisms of Graft Rejection	
	B. Techniques for the Prevention of Graft Rejection	
	C. Congenital Immunodeficiency Diseases	
	Acquired Immunodeficiency Diseases: AIDS	Chap 9 Questions 1-5, 9-11, 13

**23. Exam Lectures 12-22, 125 points (1 hr), March 14**

**Phar 6158**  
**Recombinant DNA-derived Drugs**  
**1 Credit, Spring 2008**

**LECTURE SCHEDULE**

DATE	LECTURE	TOPIC	LECTURER
M, Mar 24	1	Introduction to recombinant DNA (rDNA) drugs	Shier
W, Mar 26	2	Recombinant DNA toolkit I	Anderson
F, Mar 28	3	Recombinant DNA toolkit II	Anderson
M, Mar 31	4	DNA cloning	Anderson
W, Apr 2	5	Modification and mutation of cloned genes	Anderson
F, Apr 4	6	Monoclonal antibody production	Anderson
M, Apr 7	7	Uses of monoclonal antibodies	Anderson
W, Apr 9	8	Humanized monoclonal antibodies	Shier
F, Apr 11	9	Recombinant DNA-based diagnostics	Shier
M, Apr 14	10	Novel therapies	Shier
W, Apr 16	11	<b>Written Exam to end of Lecture 8, 100 points (1 hr), April 16</b>	
F, Apr 18	12	Biological response modifiers, Part 1	Shier
M, Apr 21	13	Biological response modifiers, Part 2	Shier
W, Apr 23	14	Pharmacogenomics	Guest lecturer: Dr. William Oetting
F, Apr 25	15	Recombinant DNA-derived vaccines	Shier
M, Apr 28	16	Student Presentations: Group 1: Insulins	L.Traynor/Shier
		Group 2: Cytokine-based drugs	
W, Apr 30	17	Student Presentations: Group 3: Immunosuppressives	L.Traynor/Shier
		Group 4: Replacement therapies	
F, May 2	---	Pharmacy Day 2008	
M, May 5	18	Student Presentations: Group 5: Clot-busters	L.Traynor/Shier
		Group 6: TNF $\alpha$ -blockers & other anti-inflams	
W, May 7	19	Student Presentations: Group 7: Anti-cancer drugs	L.Traynor/Shier
		Group 8: Anti-infectives	
F, May 9	20	<b>Written Exam on Lectures 9 to end, 100 points (1 hr), May 9</b>	