**Marshall University Syllabus**

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| Course Title/Number | New Drug Development HON 480/IST 455 |
| Semester/Year | FALL SEMESTER 2015 |
| CRN | 2500 |
| Days/Time | 4-5:15 MW |
| Location | BBSC 125 |
| Instructor | Elizabeth E. Murray, Ph.D. |
| Office | 241G Byrd Biotechnology Science Center (BBSC) or 211 BBSC (lab) |
| Phone | 304-696-3515 (office) 304-617-6198 (cell) |
| E-Mail | murraye@marshall.edu |
| Office/Hours | Office hours: M-F 9-10 and by appt. I may be in BBSC 211 (lab) so call or text my cell phone (number is given in class and is listed in MU Online). Please give your name and class if you text me so I know who you are. |
| University Policies | By enrolling in this course, you agree to the University Policies listed below. Please read the full text of each policy be going to [www.marshall.edu/academic-affairs](http://www.marshall.edu/academic-affairs) and clicking on “Marshall University Policies.” Or, you can access the policies directly by going to <http://www.marshall.edu/academic-affairs/?page_id=802>  Academic Dishonesty/ Excused Absence Policy for Undergraduates/ Computing Services Acceptable Use/ Inclement Weather/ Dead Week/ Students with Disabilities/ Academic Forgiveness/ Academic Probation and Suspension/ Academic Rights and Responsibilities of Students/ Affirmative Action/ Sexual Harassment |

**Course Description:**

Students will learn key components of the drug discovery process and the steps leading to full regulatory approval and commercialization of drugs, biologics and medical devices. Case studies will be discussed.

**Desired Objectives/Outcomes:**

An interdisciplinary examination of scientific and technological issues of new drug development. New Drug Development is a complex process, involving both business and scientific decisions within a federally regulated market. Students will examine key components of the drug discovery process (including scientific basis of drug’s mechanism of action and side effects, patents and licensing) as well as the steps leading to full regulatory approval to legal permission to market the drug. The very important role of preclinical and clinical trials will be considered as well as ethical issues of human experimentation, use of advertising and cost of new drugs in the health care/insurance landscape. Student teams will present a class seminar on the discovery, development and marketing of a new drug introduction. Examples used in class will include historical as well as current examples of small molecule drugs, large molecule drugs, live and subunit vaccines including recent products of the biotechnology/molecular biology revolution. Medical devices and biological therapies will also be discussed and well as herbal remedies and supplements.

**Required Texts:**

* *Drugs: From Discovery to Approval* by Rick Ng Wiley-Blackwell; 3rd edition 2015) ISBN-10:047019510X
* *The Billion Dollar Molecule: One Company's Quest for the Perfect Drug* by Barry Werth 1995 ISBN-10:0671510576
* <http://csdd.tufts.edu/_documents/www/Centerbib_with_links_080310_PDF.pdf> is an excellent bibliography from the Tufts Center for the Study of New Drug Development on issues related to new drug development from 1976-2010.

**Course Requirements**

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| 1. Participation is critical for seminar classes. The instructor will assess participation in a number of ways including daily attendance. You cannot participate if you miss class. Instructor may call on you, request answers to questions in the group or break the group into smaller groups for discussion and presentation. Instructor also encourages students to ask questions about the reading and topic for discussion and to bring in relevant topics from the news. 2. Reading quizzes/online chapter discussions will be given to assess that students are keeping up with reading. A reading quiz will be given as per the schedule. 3. There are two book report assignments. One will be on the book we read together in class, *The Billion Dollar Molecule*. The second will be on a book selected with input from Dr. Murray who will provide a bibliography of additional books on drug development. There will also be a short presentation to the class of the summary of the individual book report 4. Students will take the CITI informed consent course and review Marshall University’s informed consent and conflict of interest documentation. Students will also take a short AICUC training. After completion, we will discuss the process of using animals and human patients and volunteers in development of new drugs, biologics, instruments and other medical procedures and the ethical challenges to new drug testing. 5. Each student will be assigned a drug “package insert” and then be asked to summarize the indications for the prescription, dosage, side-effects, interactions with other drugs in classes “round robin” throughout semester as those topics are discussed. Each student will discuss how their drug is advertised to the public or physicians. 6. Each student will be assigned an herbal remedy from the National Center for Alternative and Complementary Medicine and be asked to summarize the results briefly and discuss them in a class “round robin.” 7. Group Teaching of class seminar on development and introduction of a new drug/biological/instrument. Total points 400 pts  * Oral team proposal (4 weeks before group presents) 25 pts * Written team proposal including annotated bibliography (3 weeks before group presents) 25 pts * Discussion with instructor and plan (2 weeks before group presents) 25 pts * Group teaching of class 200 pts * Team record of group process (week after group presents) to include meeting minutes, PowerPoint slides etc. 25 pts * Individual evaluation of group process and product (week after class taught) 25 pts * Group Research Bibliography 75 points  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Evaluation of Learner Outcomes**: Major assignments will be evaluated using a three-part approach:   * **Content, the substance of what you say or write.** This includes the topic, focus, how well the paper or presentation answers the assignment, the use and integration of supporting materials, understanding of principles and their application. Outside references should be properly cited. * **Organization, how you arrange what you say or write.** This includes effective introductions and conclusions, paragraphing, main points being clearly indicated and arranged and transitions logically connecting those points. Written work should be neat, succinct, clear, and use the appropriate terms. * **Delivery/Style, how you present the information in a speech or paper.** * For oral assignments, delivery will include both verbal aspects (vocal rate, clarity and variety, use of pauses, absence of distractions) and nonverbal aspects (professional manner, dress, eye contact, posture, use of gestures and movement and effective use of visuals).For written assignments, style will include sentence structure, use of language, proper grammar, spelling, syntax and preparation of paper. * All written course assignments (e.g., Course Project) should be typed in Times New Roman, 12-point font, double-spaced, with 1-inch margins and use APA format. In-class assignments are to be neatly written, signed by all group members, and submitted at the end of the class period. Team assignments will be given a team grade, but students will also be able to assess teamwork of the group.   **Point Breakdown:**   |  |  |  | | --- | --- | --- | | **Assignment** | **Points** | **Due Date** | | Reading Quizzes/On-Line Discussions | 100 | Weekly | | Round Robin on drug commercials | 50 | 9/2 | | Round Robin on package inserts | 50 | 9/14 | | Round Robin on Herbal Remedies | 25 | 9/30 | | CITI Course and AICUC training | 25 | 10/14 | | Attendance/Participation | 100 | Weekly | | Book report on Billion Dollar Molecule | 100 | 10/28 | | Group Teaching of class seminar on development and introduction of a new drug/biological/instrument. | 400 | 12/2 | | Book Report on Student selected book | 100 | 11/9-11/30 | | Book report class presentation | 50 | 12/2 |   Final Grade scale:  A = 901-1000 pts Excellent work, goes significantly beyond class requirements.  B = 801-900 pts Very good work, meets or exceeds all class requirements.  C = 701-800 pts Average work, meets class requirements.  D = 601-700 pts Below average work, fails to meet one or more class requirements.  F = 600 pts or less Unacceptable work, fails to meet the minimum class standards. | | |  | | | **Attendance Policy**  **Classroom Expectations**  Please be considerate of the other students in the class. It is up to you whether or not you choose to attend class and if you choose to pay attention. It is unfair, however, for you to negatively impact the ability of others students to learn. Please take care that your actions are considerate and do not detract from the learning environment. Once class has begun, please refrain from sending text messages, reading newspapers, or otherwise distracting from the class discussion.  **It is also expected that the opinions and backgrounds of all class members will be welcomed and respected.** All students are encouraged to participate in class discussion, but please address others with respect**.**  **Accessing Course Information**  Power-point slides, assignments, and other necessary class information will be posted on Blackboard. The website for Blackboard is marshall-bb.blackboard.com. It is imperative that you have access to Blackboard and that you check your MU email regularly**.**  **Academic Integrity**  Please be aware that academic integrity is taken very seriously at this university and in this class. Any type of cheating or plagiarism will not be tolerated. Plagiarism includes citing anyone else’s words or ideas in your own writing without giving credit. Additionally, self-plagiarism will not be tolerated in this course. This includes turning in assignments that have previously been used for another class or purpose. All assignments must be completed specifically for this course. More information regarding plagiarism is provided in the Marshall University handbook. However, if you have a question about any academic integrity issues, please contact me.  **By enrolling in this course, you agree to the University Policies listed below. Please read the full text of each policy by going to** [**www.marshall.edu/academic-affairs**](http://www.marshall.edu/academic-affairs) **and clicking on “Marshall University Policies.” Or, you can access the policies directly by going to** [**http://www.marshall.edu/academic-affairs/?page\_id=802**](http://www.marshall.edu/academic-affairs/?page_id=802)  Academic Dishonesty/ Excused Absence Policy for Undergraduates/ Computing Services Acceptable Use/ Inclement Weather/ Dead Week/ Students with Disabilities/ Academic Forgiveness/ Academic Probation and Suspension/ Academic Rights and Responsibilities of Students/ Affirmative Action/ Sexual Harassment | |

LEARNING OUTCOMES, PRACTICE and EVALUATION

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| **Course Student Learning Outcomes** | **How Practiced in this Course** | **How Assessed in this Course** |
| Students will analyze how new drugs and devices are taken from the laboratory to the marketplace in the U.S. and globally, including scientific methods of drug target identification and development | Students will read two texts, Ng (2015) and Werth (1995), view films and have in class lectures, guest speakers, student presented seminars and class discussions. | Attendance, participation in class discussions; round-robin assignment on package inserts, team seminar on a new drug introduction, book reviews on Werth (1995) and a second, student selected book; reading quizzes on Ng and Werth and discussions online. |
| Students will demonstrate knowledge of the current and historical FDA approval process for Drugs, Biologics and Medical Devices as well as key differences globally. | Students will read two texts, Ng (2015) and Werth (1995), view films on FDA, present round robin assignments and have in class presentations on history of drug development and its regulation. | Attendance and participation in class discussions; round-robin assignment on package inserts, herbal remedies, book reviews, team seminar on a new drug introduction, book reviews on Werth (1995) and another book; reading quizzes on Ng and Werth. |
| Students will demonstrate knowledge of ethical issues in new drug development and human and animal experimentation. | Students will take the CITI class on human experimentation and discuss Marshall University Informed consent and conflict of interest paperwork. Students will take a short IACUC online class on using animals in research. | Certifications from online classes and participation in class discussions. |
| Students will analyze the balance between medical benefit, medical risk, economic reward, and economic risk in the decision making process as it relates to drugs and devices in development | In class presentation on business aspects of new drug introduction, guest lectures, Round Robin assignment on drug commercials, selected readings from business and trade publications on economics of selected new drug introductions. | Attendance and participation in class discussions; round-robin assignment on drug commercials, package inserts, herbal remedies, book reviews, team seminar on a new drug introduction, book reviews on Werth (1995) and another book. |

**Course Schedule**

**Fall 2015 – Semester Schedule :** This schedule and the topics may change during the course of the semester. The reading assignments may be supplemented with other readings.

**I hope to have some guest lecturers-I will post revised schedules in MU Online.**

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| **Date** | **Topic** | **Reading due** | **Assignments Due** |
| **August 24** | Introduction to Class | 1 Introduction  History of Drug Discovery and Development |  |
| **August 26** | History of Drug Development |  |  |
| **August 31** | How Do companies decide to develop a drug? | 2 Drug Discovery: Targets and Receptors | Quiz 1 |
| **September 2** | Drug Discovery |  | Round Robin on drug commercials |
| **September 7** | Labor Day | 3 Drug Discovery: Small Molecule Drugs |  |
| **September 9** | Drug Discovery |  | Quiz 2 |
| **September 14** | Drug Discovery | 4 Drug Discovery: Large Molecule Drugs | Round Robin on package inserts |
| **September 16** | FDA Video |  | Quiz 3 |
| **September 21** | Preclinical studies | 5 Drug Development and Preclinical Studies Regulatory Applications |  |
| **September 23** | Vaccine Development |  | Quiz 4 |
| **September 28** | Regulation of Nutraceuticals | 6 Clinical Trials |  |
| **September 30** | Round Robin on Herbal Remedies |  | Quiz 5 |
| **October 5** | Regulation of tests and medical equipment | 7 Regulatory Authorities |  |
| **October 7** | Working in a regulated environment |  | Quiz 6 |
| **October 12** | Death of a Wonder Drug film and Vioxx | 8 Regulatory Applications |  |
| **October 14** | Animal and Human Experimentation |  | Quiz 7 |
| **October 19** | cGMPs | 9 Good Manufacturing Practice Regulatory Requirements |  |
| **October 21** | Birth Control Pills |  | Quiz 8 |
| **October 26** | HIV Medications | 10 Good Manufacturing Practice: Drug Manufacturing |  |
| **October 28** | Rituximab |  | Quiz 9  Book review on Billion Dollar Molecule |
| **November 2** |  | 11 Future Perspectives |  |
| **November 4** |  |  | Group 1 |
| **November 9** |  |  | Group 2 |
| **November 11** |  |  | Group 3 |
| **November 16** |  |  | Group 4 |
| **November 23** | **Thanksgiving Break**  **Quiz 10 on Future of Drug Development** | | |
| **November 25** |
| **November 30** |  |  | Group 5 |
| **December 2** |  | Class presentation of Book Reports | Final Book Review due |

* **Dr. Murray’s class schedule Fall 2015**

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| **Time** | **Monday** | **Tuesday** | **Wednesday** | **Thursday** | **Friday** |
| **8** |  |  |  |  |  |
| **9** | **office** | **office** | **office** | **office** | **office** |
| **10** | **Lab** | **Lab** | **Lab** | **Lab** | **Lab** |
| **11** |  |  |  |  |  |
| **12** |  | **IST 120**  **12:30-1:45** | **Armstead Research Meeting** | **IST 120**  **12:30-1:45** | **Faculty Meeting** |
| **1** | **IST 340** | **IST 340** | **IST 340** |
| **2** | **1-2:45** | **IST 120** | **1-2:45** | **IST 120** | **1-2:45** |
| **3** |  | **2-3:20** |  | **2-3:20** |  |
| **4** | **HON 480** |  | **HON 480** |  |  |
| **5** | **4-5:15** |  | **4-5:15** |  |  |
| **6** |  |  |  |  |  |

New Drug Discovery Book Review Assignment Sheet:

Each student will select a book from a preapproved reading list. Another book may be selected after consultation with instructor.

Book reviews vary widely. A review does not simply summarize book material, and should not be substituted for the original book. The purpose of a book review is to make known what a work purports to do and be. Essential components to be taken into account include concerns of subject matter and style.

To be successful, your book review must:

* Be at least three pages long, TYPED
* Incorporate at least TWO (2) quotations from the work you are reading
* Review and quotations must be properly formatted, including a works cited page with at least ONE entry, according to MLA Style.
* Do more than simply summarize-provide some kind of personal analysis of the work

A review is a critical essay, a report and an analysis. Whether favorable or unfavorable in its assessment, it should seem authoritative. The reviewer's competence must be convincing and satisfying. As with any form of writing, the writer of a book review is convincing through thorough study and understanding of the material, and opinions supported by sound reasoning; the reviewer achieves reader satisfaction upon by giving justice to the subject, the book being reviewed, and connecting it with vital human concerns.

A review may be limited in its scope due to length requirements, whether those are set by an instructor or an editor. How thoroughly and with respect to what aspects a book is reviewed also depends on instructor or editor preferences, or simply the attitudes and qualifications of the reviewer.

Readers sometimes confuse book reviews with book reports, but the two are not identical. Book reports commonly describe what happens in a work; their focus is primarily on giving an account of the major plot, characters, and/or main idea of the work. Most often, book reports are a K-12 assignment and range from 250 to 500 words. By contrast, book reviews are most often a college assignment, but they also appear in many professional works: magazines, newspapers, and academic journals.

**Essential Objectives**

A book review should address three issues:

1. Contents, or what is said in the book.

2. Style, or how it is said.

3. Assessment, or analysis of how true and significant the book is.

The most essential preparation for review writing is of course a complete, thoughtful reading of the book. After reading, the reviewer should have a sound, integrated idea of the book contents, and begin to develop attitudes toward style, purpose, and value. As the reviewer forms ideas for the review, certain influences and motives should be considered:

* The reviewer's own particular interests and purposes: Does the reviewer want to remain primarily a fact-finding reporter? Or are there more specialized ideas and principles of art and ideology the reviewer wants to advance? We are interested in what the book tells us about starting and funding a successful business, usually with technology involved.
* Contemporary social, economic, political, and aesthetic issues: Do one or more of these affect the aim or emphasis of the book review? How does the incorporation and interpretation of these issues in the book review further discussion of the book's contents and style? Especially, how ethical were these business founders and what aspects of their story did you want to emulate or avoid in your own enterprise.
* Required treatment and length requirements: What requirements for the review, emphasis and length, have been set by the instructor or editor?

**Before You Read**

Before you begin to read, consider the elements you will need to include in your review. The following items may help:

* Genre: What type of book is this: fiction, nonfiction, etc.
* Who is the intended audience for this work? What is the purpose of the work?
* Title: Where does the title fit in? How is it applied in the work? Does it adequately encapsulate the message of the text? Is it interesting? Uninteresting?

**As You Read**

As you read, determine how you will structure the summary portion or background structure of your review. Be ready to take notes on the book’s key points, characters, and/or themes.

* Subjects of biography/autobiography and other individuals described in the book? Who are the principle subjects? How do they affect the story? Do you empathize with them?
* Themes/Motifs/Style: What themes or motifs stand out? How do they contribute to the work? Are they effective or not? How would you describe this author’s particular style?
* Is it accessible to all readers or just some?
* Key Ideas: What is main idea of the work? What makes it good, different, or groundbreaking?
* Quotes: What quotes stand out? How can you demonstrate the author’s talent or the feel of the book through a quote?

**When You Are Ready to Write**

Begin with a short summary or background of the work, but do not give too much away. Many reviews limit themselves only to the first couple of chapters or lead the reader up to the rising action of the work. Reviewers of nonfiction texts will provide the basic idea of the book’s argument and organization without too much detailed discussion.

The final portion of your review will detail your opinion of the work. When you are ready to begin your review, consider the following:

* Establish a Background, Remember your Audience: Remember that your audience has not read the work; with this in mind, be sure to introduce individuals and business areas carefully and deliberately. What kind of summary can you provide of the main points or main subjects that will help your readers gauge their interest? Does the author’s text adequately reach the intended audience? Will some readers be lost or find the text too easy?
* Minor individuals: Deal only with the most pressing issues in the book. You will not be able to cover every individual or idea. What principles/characters did you agree or disagree with? What other things might the author have researched or considered?
* Organize: The purpose of the review is to critically evaluate the text, not just inform the readers about it. Leave plenty room for your evaluation by ensuring that your summary is brief. Determine what kind of balance to strike between your summary information and your evaluation. If you are writing your review for a class, ask your instructor. Often the ratio is half and half.
* Your Evaluation: Choose one or a few points to discuss about the book. What worked well for you? How does this work compare with others by the same author or other books about entrepreneurship? What major themes, motifs, or terms does the book introduce, and how effective are they? Did the book appeal to you on an emotional or logical way?

**Revising**

When making the final touches to your review, carefully verify the following:

* Double-check the spelling of the author name(s), subject names, special terms, and publisher.
* Try to read from the vantage point of your audience. Is there too much/enough summary?
* Does your argument about the text make sense?
* Should you include direct quotes from the reading? Do they help support your arguments?
* Double-check your quotes for accuracy.

Remember we also want a verbal summary of your book review no more than 10 minutes- you should try and avoid PowerPoints- just tell us the background of the book and the high points of the review. Don’t read it to us. You can use notecards.

I have a wide range of popular science books on the business of new drug development, start-up of companies like AmGen and introduction of drugs like Herceptin. Students will select a book from this list of recommended books and write a book review.

* Her-2: The Making of Herceptin, a Revolutionary Treatment for Breast Cancer Robert Baze Random House (2011)
* Genentech: The Beginnings of Biotech by Sally Smith Hughes University of Chicago Press (2011)
* Science Lessons: What the Business of Biotech Taught Me About Management by Gordon Binder Harvard Business Press (2008)
* The Philadelphia Chromosome: A Genetic Mystery, a Lethal Cancer, and the Improbable Invention of a Lifesaving Treatment by Jessica Wapner The Experiment (2013)