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| **Course Outline** |

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| **Department & Number** | Biological Sciences 182 | **Number of Weeks** | 18 |
| **Course Title** |  GLP and GMP; Principles and Compliance | **Lecture Hours** | 18 |
| **Prerequisite** | none | **Lab Hours** |  |
| **Challenge Policy**  |  | **\*Hours By Arrangement** |  |
| **Co-requisite** |  | **Units**  | 1 |
| **Challenge Policy**  |  |  |  |
| **Advisory** | none |

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| **\*HOURS BY ARRANGEMENT:** | none | Hours per term. |
|  **ACTIVITIES:** (Please provide a list of the activities students will perform in order to satisfy the HBA requirement): |
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| **COURSE/CATALOG DESCRIPTION** |

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| This course will introduce students to the laws, regulations, and quality practices associated with the biotechnology industry, with emphasis on the development of pharmaceuticals and medical devices. Students will gain hands-on experience navigating and using the Food and Drug Administration (FDA) website.  |

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| **COURSE OBJECTIVES** |
| At the completion of the course the student will be able to: |

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| Describe different levels of regulation and determine which regulation(s) is appropriate. |
| Describe the development of a new biotechnology product, from research and development through various phases of testing to gaining FDA approval, and the regulations that pertain to each phase. |
| Demonstrate facility with the FDA website by completing worksheets requiring use of the website. |
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 **COURSE CONTENT:** (In detail; attach additional information as needed and include percentage breakdown)

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| Guided work with the FDA website. |
| Regulatory environment and quality systems. |
| Product development in biotechnology. |
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| **METHODS OF INSTRUCTION** |

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| Lecture |
| Laboratory experimentation, including small group/team work |
| Guided exploration of the FDA website |
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| **INSTRUCTIONAL MATERIALS** |

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| **Textbook Title:** | Code of Federal Regulations, Title 21, parts 210 and 211.  |
|  **Author:** | U.S. Congress  |
|  **Publisher:** | U.S. Government |
|  **Edition/Date:** | 2009 |

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| **COURSE EXPECTATIONS** (Use applicable expectations) |

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|  **Outside of Class Weekly Assignments** | **Hours per week** |

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| Weekly Reading Assignments | 1 |
| Weekly Writing Assignments |  |
| Weekly Math Problems |  |
| Lab or Software Application Assignments | 1 |
| Other Performance Assignments |  |

 **STUDENT EVALUATION**: **(Show percentage breakdown for evaluation instruments)**

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| --- | --- | --- |
| 35 | **%** | Completion of web assignments |
| 35 | **%** | Completion of take-home assignments |
| 30 | **%** | Accomplishment of experiments |
|  | **%** |  |

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|  **GRADING POLICY (Choose LG, CR/NC, or SC)** |

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| X | **Letter Grade** |  | **Pass / No Pass** |  | **Student Choice** |
| 90% - 100% = A  | 70% and above = Pass | 90% - 100% = A |
| 80% - 89% = B  | Below 70% = No Pass  | 80% - 89% = B |
| 70% - 79% = C  |  | 70% - 79% = C |
| 60% - 69% = D  |  | 60% - 69% = D |
| Below 60% = F  |  | Below 60% = F |
| *or* |
| 70% and above = Pass |
| Below 70% = No Pass |

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| **Prepared by:** | Katherine Krolikowski, PhD |

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| **Content Review Date:**  | October, 2013 |

Revised 04/13