

Syllabus guidelines for new course proposals to the Graduate Curriculum Committee (GCC).
 To facilitate GCC review of your course proposal, please provide the following information.

Prefix: ___ ___ ___ **Number:** ___ ___ ___ ___ **Title:** _____

Meets: ___ hours ___ times per week for ___ weeks

Grading weights (what percentage of the grade comes from each exam, report, presentation, and so on; whatever elements constitute the final grade)

- ___% of the final grade comes from _____ (requirement)
- ___% of the final grade comes from _____ (requirement)
- ___% of the final grade comes from _____ (requirement)
- ___% of the final grade comes from _____ (requirement)
- ___% of the final grade comes from _____ (requirement)

Text required (if any) including authors, title, year, publisher: _____

Is the course web based? Yes No

If yes, is the course taught in synchronous or asynchronous format? _____.

If yes, and if "class participation" contributes to the grade, how is class participation graded?

List of topics

Week	Topic
1	
2	
3	
4	
5	
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11	
12	
13	
14	
15	

Course description: _____

University of Florida College of Medicine Master's Program
Proposed Biologic Drug Development Course
Center of Excellence for Regenerative Health Biotechnology

- 1) Catalog description.

Discoveries made in the research laboratory are transitioning into products to deliver improved health protection and disease prevention/treatment at an ever-increasing rate. This course will cover the manufacturing and testing of biomedical products, quality control and quality assurance responsibilities, and regulatory compliance. The course will provide a practical understanding of the successes and hurdles that are faced in biopharmaceutical product development today.

The course will meet for 1.5 hours twice per week. For each class a 30 minute lecture will be given by the instructor, followed by laboratory and on-line exercises.

- 2) List prerequisites for class.

None

- 3) Course summary of topics to be covered

I. Biomanufacturing

- A. Product Development Overview
- B. Regulatory Affairs
 - 1. GLP/cGMP/GCP regulations
 - a) Domestic and worldwide
 - 2. FDA Organizational Structure
- C. Quality Assurance
 - 1. Regulatory Compliance
 - 2. Documentation
 - a) Types of Documents (Forms, Test/Batch Records, Certificates of Analysis, SOPs, etc)
 - b) Standards for writing Documents (Format, Signatures)
 - c) Document Control
 - d) Writing SOP's
 - 3. Audits, Investigations & Reviews
 - 4. Raw Materials, Qualification & Product Release
 - 5. Specifications
 - 6. Validation
 - a) Validation Master Plans
 - 7. Deviations and excursions
 - 8. Change Control
- D. Facilities & Operations
 - 1. Cleanroom Architecture
 - 2. Cleanroom Operations
 - 3. Gowning and Personnel Qualification
 - 4. Environmental and Personnel Monitoring (QC)
- E. Aseptic Processing
 - 1. Media and Solution Preparation
 - 2. Cell Culture
 - 3. Filtration
 - 4. Filling

II. Upstream Processing

- A. Cell line engineering
- B. Mammalian Cell Culture and/or Fermentation
 - 1. Bench to large Scale Tissue Culture techniques

2. Media Formulation
3. Storing cell-lines (freeze/thaw)
4. Master and Working Cell Banks
5. Cell counting and viability/growth monitoring
6. Harvest

III. Downstream Processing

- A. Process Design and Development
- B. Column chromatography
 1. Principles of ion exchange, HIC, Affinity....
 2. Column sizing, packing
 3. Programming/Running FPLC
- C. Filtration
- D. Centrifugation

IV. Quality Control

- A. Assay Development
- B. Assay Validation
- C. Process Sampling Points and Sample processing
- D. Product Testing
 1. Purity Assays
 2. Potency Assays
 3. Safety assays (sterility, adventitious agents, endotoxin, etc)
 4. Identity Tests
 5. Stability testing
- E. Identification and Quantification of microorganisms

V. Pre-clinical and clinical considerations

- A. Product configuration
- B. Dosage
- C. Formulation
- D. Packaging

4) Text:

Drugs-From Discovery to Approval. John Wiley & Sons, Inc. Rick Ng, 2004

Other Handouts and on-line references will be provided.

The class will be 15 credit hours, (2) 1.5 hour classes per week for 5 weeks taught in Alachua, 4:00-5:30pm on Thursdays + Fridays. Module 3 for 2008.