

**PHA 5172 “Biotechnology & Industry (Research & Practice)  
Fall, 2005, Course Outline of Topics and Class Dates**

**Part 1: Educate about the Exploding Science & Industry Environment**

**Week # 1, August 25, 2005; Topics 1-19 (#19):**

Course Introduction

***1A. Biological Basis of Biotechnology:***

1. Prevalence and Costs of Disease
2. Definition Of Biotechnology
3. Origins of Biotechnology
4. Evolution of Biotechnology
5. Patient Groups Benefiting from Biotech Products
6. Impact on Providers
7. Impact on Payers
8. Societal Impact of Biotechnology
9. Agronomic Benefits from Biotechnology
10. Development of GM Foods, Safety
11. Definition of Biotherapy
12. Central Dogma of Biology
13. Proteins, Description
14. Proteins, 3-Dimensional Structure
15. Chromosomes, Genes and DNA
16. Genetic Code
17. Genes, Introns and Exons
18. Y-Chromosome
19. Drug Development – Phases and Content

**Week # 2, September 1, 2005; Topics 20-42 (#20):**

***1B. The Industry and Product Discovery:***

20. FIPCO
21. Pharmaceutical Company – Development
22. Pharmaceutical Company – Marketing
23. Pharmaceutical Company – Sales
24. Pharmaceutical Company – Medical Affairs
25. Pharmaceutical Company – Manufacturing
26. Pharmaceutical Company – Global Operations
27. Culture of Biotech
28. Problem with Drug Development

**Part 1: Educate about the Exploding Science & Industry: (Continued)**

**Week # 2, September 1, 2005; Topics 19-38 (#23):**

***1B. The Industry and Product Discovery (Continued):***

29. R&D Challenges in Drug Development
30. Discovery Processes (Steps) in Drug Development
31. Discovery Overall Goals in Drug Development
32. Current Discovery Focus
33. Product Choices – Drugs versus Biologicals
34. Serendipity versus Rational Design
35. Assay Development
36. Targets in Oncology
37. Discovery in Drug Development – Process Needs for Best Product Development
38. Pharmaceutical Industry Issues for Collaborations in Drug Discovery
39. Alliances with Universities in Discovery
40. Preclinical Safety
41. IND-Toxicology Studies and Costs
42. The IND

**Week # 3, September 8, 2005; Topics 43-59 (#17):**

***1B. Core Technologies in Product Development:***

43. Major Techniques in Biotechnology
44. Tools of Recombinant DNA (R-DNA) Technology
45. R-DNA Technology, Restriction Endonucleases
46. R-DNA Technology, Plasmid
47. Host Cells and Protein Production
48. R-DNA, Protein Isolation/Identification, Hematopoiesis
49. R-DNA Technology, Gene Isolation
50. R-DNA Technology, Cloning & Expression
51. R-DNA Technology, Protein Production – Mammalian
52. R-DNA Technology, Fermentation - Roller Bottles
53. R-DNA Technology, Protein Production – Bacterial
54. Protein Production Variables
55. R-DNA Technology, Quality control
56. R-DNA Technology, Protein Separation by HPLC
57. Monoclonal Antibodies Introduction
58. Monoclonal Antibodies Technology
59. Monoclonal Antibodies, Chimera and Conjugates

**Part 1: Educate about the Exploding Science & Industry: (Continued)**

**Week # 4, September 15, 2005; Topics 60-77 (#18)**

***1C. Genetic Technologies and Applications:***

60. Polymerase Chain Reaction
61. Human Genome Project
62. Gene Therapy – Goals, Targets, & Challenges
63. Gene Transfer / Delivery
64. Gene Therapy Methods
65. Nucleotide Blockade (Antisense)
66. Ribozymes
67. Antisense MOAs
68. Protective Effects of Antisense (Example)
69. Genomics
70. X-Chromosome
71. Pharmacogenomics I
72. Pharmacogenomics II, SNPs
73. Pharmacogenomics III, Polymorphisms in Drug Action
74. Pharmacogenomics IV, Outcomes
75. Pharmacogenomics V, Complexity of Genetic Variation
76. Pharmacogenomics VI, Drug Development – Pros & Cons
77. Proteomics

**Week # 5, September 22, 2005; Topics 78-97 (#20):**

***1D. Discoveries with Cells & Product Development Advances:***

78. Mediators – Interferons
79. Inflammation (Tissue Level)
80. Mediators – Inflammation (Cellular Level)
81. Inflammation and Disease
82. Mediators – Cytokines, Interleukins & Immunity
83. Cellular processes –Telomeres
84. Cell Processes – Apoptosis
85. Cell Processes – Protein Kinases
86. Advantages of Protein Kinases
87. Transgenic Animals, Disease Model
88. Combinatorial Chemistry
89. High Throughput Screening
90. Molecular Engineering - Proteins 1
91. Molecular Engineering - Proteins 1
92. Molecular Engineering – Glycosylation

**Part 1: Educate about the Exploding Science: (Continued)**

**Week # 5, September 22, 2005; Topics 78-97 (#20) (Contin.):**

***1D. Discoveries with Cells & Product Development Advances:***

93. Molecular Engineering – Pegylation 2
94. Pegylation – Clinical Impact
95. Cell Therapy – Stem Cell Therapy
96. Cell Therapies – Tissues Engineering
97. Cell Therapies – Tissues Engineering, Scaffolds

**Week # 6, September 29, 2005; Topics 98-112 (#15):**

***1E. Formulations and Manufacturing Issues:***

98. Stability and Degradation of Proteins
99. Delivery Systems for Biologicals
100. Disposition In Vivo of Products
101. Formulation and Stability
102. Formulations, Goals and Components
103. Proteins – Absorption and Formulations Factors
104. Proteins – Formulation Modifications
105. Concerns with Protein Modifications
106. Protein Manufacturing – Biosimilars
107. Drug Delivery – Liposomes
108. Drug Delivery – Polymers
109. Product Distribution
110. Bioinformatics
111. Matrix of Biotechnology
112. Research Teams in Biotechnology

**Part 2: Elucidate Expanding List Challenges for Biological Products:**

**Week # 7, October 6, 2005; Topics 113-137 (#25):**

***2A. Approved Biological Products:***

113. Blockbuster Products, Drivers
114. Blockbuster Products in Pharma
115. Blockbuster Products in Pharma over Time
116. Blockbuster Products in Biotechnology
117. Top 10 Biotech Companies
118. Approved Products, Hormones
119. Enzymes
120. Growth Factors
121. Monoclonal antibodies 1
122. Monoclonal antibodies 2
123. Interferons
124. Blood factors and Interleukins
125. Vaccines and Liposomes
126. Tissue Engineering
127. Other Products 1
128. Other Products 2
129. Biological Products from Animal Sources
130. Biological Products and their Diagnostic Tests
131. Diagnostic Products

***2B. Diseases and Indications:***

132. Cancer
133. Cardiovascular Disease
134. Infectious Disease
135. Inflammation
136. Endocrinology
137. Other Diseases

**Extra Session, Oct. 10, '05 (5-7PM); Mid-Term Exam [Weeks #1-7]**

**Week # 8, October 13, 2005; Topics #138-155 (#18):**

***3A. Pipeline & Product Development (Clinical Research) 1:***

138. Biotechnology Landscape
139. Biotech Business Model, Changing
140. Top 10 Biotech Companies
141. Growing Biotechnology Market

**Part 2: Elucidate the Expanding List of Biological Products:**

**Week # 8, October 13, 2005; Topics #138-155 (#18): (Contin.)**

***3A. Pipeline & Product Development (Clinical Research) 1:***

142. Diseases Targeted
143. Product Pipeline
144. NDAs and NMEs
145. Number of Biologicals in Development
146. Types of Biologicals in R&D by Products
147. Types of Biologicals in R&D by Therapeutic Areas
148. Biotechnology Product Failures
149. Paradigm of Product Development – 7 Ps for Success
150. Product R&D – Decision Criteria
151. Product R&D – Decision Criteria (Examples)
152. Technology Bases for Research Development
153. Product Licensing and Discovery
154. Company Collaborations (Research and Business)
155. Success of Alliances, Factors

**Weeks # 9 & # 10; 2B. Student Presentations**

*October 20 & 27, 2005: Gainesville Campus*

*October 31<sup>st</sup>, 2005; Jacksonville Campus (1 PM)*

*October 28, 2005; St. Petersburg (1-2PM) &*

*Orlando (5-6PM) Campuses*

**Week # 11, November 3, 2005; Topics 156-173 (#18):**

***3A. Pipeline & Product Development (Clinical Research) 2:***

156. Investment in Research & Develop., Pharma / Biotech
157. Biotech Research Costs
158. R&D Spend over Time
159. Types of Clinical Studies
160. Maps for Planning and Conduct Clinical Studies
161. Clinical Research Organizations, Services
162. R&D Spend by Research Phase
163. Drug Development Times
164. Product Life Cycle Management
165. Product Pipeline Early Biotech Company
166. Product Pipeline Later Biotech Company
167. Product Pipeline – Pharma Company
168. NDA/BLA and FDA, Content and Factors Influencing

**Week # 11, November 3, 2005; Topics 156-173 (#18): (Contin.)**

***3A. Pipeline & Product Development (Clinical Research) 2:***

- 169. Patents in Biotechnology
- 170. Financing in Biotechnology
- 171. Product Life Cycle Planning
- 172. R&D Success Factors 1
- 173. R&D Success Factors 2

**Part 3: Envisage (Appropriate) Biological Product Usage:**

**Week # 12, November 10, 2005; Topics #174-194 (#21):**

***3B. Health Care & New Product Launches***

- 174. Healthcare Spend in US
- 175. Healthcare Spend, Changes over Time
- 176. Healthcare Improvement over Time
- 177. Product Launch Plans, Part 1 – Premises
- 178. Launch Success Models (“The 6 + Months”)
- 179. Basics of Product Marketing (The 4 Ps +)
- 180. New Product Marketing in Development
- 181. Product Delivery – Facilitators & Barriers
- 182. Product Pricing, Traits of Disease, Patient, & Products
- 183. Product Pricing, Purchase Decision
- 184. Patient Demand for Products – Internet
- 185. Patient Demand for Products – DTC
- 186. Product Pricing, Cash Flow in R&D and S&M
- 187. Medicare RX Legislation 2004, Industry & Drug Usage
- 188. Product Launch Plans, Part 2 – Marketing
- 189. Product Launch Plans, Part 3 – Sales
- 190. Building a Salesforce
- 191. Product Launch Plans, Part 4 – Clinical / Medical
- 192. Phase 4 Trials 1
- 193. Phase 4 Trials 2
- 194. Reputation, Pharmaceutical Companies

**Week # 13, November 17, 2005; Topics 195-208 (#14):**

***3C. Pharmacoeconomics: Issues in Drug Develop. & Usage.***

- 195. Cost-Benefit Issues with Biologicals
- 196. Conducting Healthcare Cost Related Analyses
- 197. Pharmacoeconomics – Definition & Concept of Value

**Part 3: Envisage (Appropriate) Usage of Biological Products (Contin.)**

**Week # 13, November 17, 2005; Topics 195-208 (#14) (Contin.)**

***3C. Pharmacoeconomics : Issues in Drug Develop. & Usage***

198. Types of PE Studies I
199. Types of PE Studies II
200. Pharmacoeconomics – Quality of Life
201. Pharmacoeconomics – Drug Development Challenge
202. Pharmacoeconomics – Application Challenges
203. Usage Projections – Biotech vs Traditional Drug
204. Product Reimbursement
205. Biotech Payment Procedures
206. Product Usage – Procedures and Guidelines
207. Product Evaluation Checklist I
208. Product Evaluation Checklist II

**Week #14, November 24, 2005; THANKSGIVING HOLIDAY**

**Week # 15, December 1, 2005; Topics 209-225 (#17):**

***3D. Patients, Companies and Pharmacy Issues:***

209. Handling of Biological Products
210. Administration of Biological Products
211. Distribution Issues with Biological Products
212. Specialty Community Pharmacy, Biotech, What Needed
213. Specialty Community Pharmacy, Biotech, Servc. Options
214. Specialty Community Pharmacy, Biotech, Advantages
215. Manufacturer Support Systems – Information
216. Manufacturer Support Systems – Research
217. Manufacturer Support Systems – Pharmacoeconomics
218. Manufacturer Support Systems – Disease Management
219. Manufacturer Support Systems – Reimbursement
220. Biotech Information Sources
221. Maintaining Knowledge of Current Research
222. Top Things to Know, Administrators
223. Top Things to Know, Patients
224. Top Things to Know, Providers
225. Future of Biotechnology

***Final Exam***      Date & Time in December, 2005:      TBD