2012

Development, Implementation, and Evaluation of a Pharmaceutical Biotechnology Elective Course in Hybrid Format

Parag Budukh

Christine R. Birnie
St. John Fisher College, cbirnie@sjfc.edu

Development, Implementation, and Evaluation of a Pharmaceutical Biotechnology Elective Course in Hybrid Format

Development, Implementation and Evaluation of a Pharmaceutical Biotechnology Elective Course in Hybrid Format

Parag Budukh, Ph.D. and Christine Birnie, Ph.D.

Wegmans School of Pharmacy, St. John Fisher College, Rochester, NY 14618

BACKGROUND

Biopharmaceuticals is a rapidly growing category of drugs in recent years and the trend is likely to continue in the future. Current research efforts are highly concentrated on these compounds. As a result, future pharmacists are likely to handle and dispense more biopharmaceuticals in their practice.

Biopharmaceuticals differ substantially from small molecule pharmaceuticals in various aspects such as production, physicochemical properties and stability considerations. Pharmacists need to be aware of these aspects in order to be able to handle and dispense these drugs and counsel the patients in the proper use of these drugs.

Currently the pharmacy curriculum includes the pharmacology and therapeutics of biopharmaceuticals, however it does not sufficiently address the impact of physicochemical properties on production, formulation, storage and handling of the drug products. An elective course is a suitable forum to provide pharmacy students a broad perspective on this topic.

Since required course work in second and third professional years is overwhelming for may students, a hybrid format was chosen to relieve the in-class time demand. This would allow the students to learn at their own pace and take partial ownership of their learning.

OBJECTIVES

An elective course addressing the broad scope of pharmaceutical biotechnology was offered in hybrid format. The course was evaluated in an effort to improve content and format for future offerings.

COURSE DEVELOPMENT AND IMPLEMENTATION

- A two-credit elective course – titled 'Pharmaceutical Biotechnology' - was developed to introduce professional pharmacy students to various aspects of biopharmaceuticals.
- The hybrid format involved approximately 60% in-class activities and 40% online activities.
- In-class activities mainly involved lectures, general discussions and guest lectures.
- Online activities involved – reading assignments from textbook, reading assignments from other books and articles provided through Blackboard Learning System and an online webcast of archived webinar.
- Quizzes and final exams were administered online using Blackboard Learning System.
- Recommended textbook: Pharmaceutical Biotechnology: fundamentals and applications / edited by Daan J. A. Crommelin, Robert D. Sindelar, Bernd Meibohm,- 3rd ed (2007).

METHODS – Course Evaluation

- Student performance was evaluated based on class attendance and participation in the in-class and online activities (10%) , completion of online quizzes (50%), an online final examination (20%) and group projects (20%).
- End of the semester course evaluation was administered through E-Value online system.
- A supplemental in-class survey was conducted seeking feedback regarding the course content and format. The survey questionnaire is presented in Table 2.

Table 1. Course syllabus, format and learning activities

Topic	Format	Activity	Evaluation
Introduction	In-Class	Lecture Homework reading assignment [1]	-
Protein Structure	In-Class	Lecture and videos	Participation Final exam
Molecular Biotechnology Methods	Out of Class	Reading assignment – Chapter 1	Online quiz
Production of Biopharmaceuticals	In-Class	Lecture Chapter 3	Participation Final Exam
Protein Delivery and Formulation	Out of Class	Watching webcast of archived webinar [2]	Online quiz
Protein Delivery and Formulation	In-Class	Lecture and discussion Chapter 4	Participation Final Exam
Immunogenicity of Therapeutic Proteins	Out of Class	Reading assignment – Chapter 6	Online quiz
Pharmacokinetics	In-Class	Lecture Chapter 5	Participation Final Exam
Handling and Dispensing	Out of Class	Reading assignment – Chapter 22	Online quiz
Monoclonal Antibodies	In-Class	Guest Lecture – Dr. Ernest Smith, Vaccinex Inc. Rochester, NY	-
Generic Biopharmaceuticals	Out of Class	Reading assignments [3, 4]	Online Quiz
Compounding of biopharmaceuticals and hormones	In-Class	Guest Lecture – Kim Tenriero, RPh Canandaigua, NY	-
Review of Commonly Used Biotech Products	In-Class	Students group presentation	Oral Presentation Written report Peer evaluation
Regulatory aspects	In-Class	Lecture – Chapter 24	Final exam

1. Biotechnology and Biopharmaceuticals, by Rodney J. Y,. Ho and Milo Gibaldi; John Wiley & Sons, Inc. (2003) – Chapter 2: Comparative Drug Development of Proteins and Genes Versus Small Molecules.
2. "Strategies of Protein Formulation - Role of Pharmaceutical Sciences and the Development of Rapid Efficient Development Practices – Parts 1 and 2 " Conducted by - Nick Warne, Ph.D., Pfizer, Inc. – Webinar archives on Used with permission from American Association of Pharmaceutical Scientists (AAPS) eLearning).
3. "What Is a Generic Biopharmaceutical? Biogeneric? Follow-on Protein? Biosimilar? Follow-on Biologic? – Part 1: Introduction and Basic Paradigms" by Ronald A. Rader; *BioProcess International*; March 2007; p. 28-36.
4. "What Is a Generic Biopharmaceutical? Biogeneric? Follow-on Protein? Biosimilar? Follow-on Biologic? – Part 2: Information, Nomenclature, Preparations and the Market" by Ronald A. Rader; *BioProcess International*; May 2007; p. 20-28.

Table 3: Course evaluation by students through E-Value

Question	Applicable Answers	Mean	Scale	Std
The assignments/projects/papers helped my understanding of course content.	19	6.21	1 to 7	0.63
The course objectives were clearly stated.	19	6.26	1 to 7	0.65
The course objectives were met.	19	6.21	1 to 7	0.63
My grades accurately reflect my performance in this class.	19	6.32	1 to 7	0.67
I learned a lot of valuable information in this course.	19	6.21	1 to 7	0.71

Table 2: Supplemental In-Class Survey

1. The course objectives were clear.
2. The difficulty level of the reading material was appropriate for the intended student population.
3. The quizzes were adequate to evaluate my understanding of the reading materials.
4. The lecture delivered by guest speakers were informative and interesting
5. The lectures delivered by guest speakers were appropriate for the intended audience.
6. I would have liked more guest speakers in the course.
7. Hybrid format (part in class and part home-work/online) was suitable for the course contents.
8. This course can be taught in 'completely online' format.
9. In my opinion, this course should be offered as a summer course in completely online format.
10. In your opinion, which of the topics in the course were the most interesting?
11. In your opinion, Which of the topics in the course were the least interesting?
12. In you opinion, did you gain any new knowledge in this course? Please list a few concepts that you think were valuable to you.
13. If you could change the war this course is designed and taught, what would you change?
14. Please suggest any specific topics or concepts that you think should be included in the course in order to make it more valuable for the future pharmacists. (Think about your experiences during IPPE rotations, internships and regular work in various pharmacy settings.)

RESULTS

- All nineteen students successfully completed the course.
- Eighteen (94.7%) students demonstrated very high understanding of the material as evident by their course grades (A).
- Sixteen students completed the supplemental survey.
- 93.75% (n=16) respondents strongly agreed that the hybrid format was appropriate for the course.
- Student comments in the course evaluation and supplemental survey offered valuable suggestions to modify the contents and the format of the course.
- Students preferred hybrid format over completely online.
- Selected suggestions by students for future offering include – patient counseling for biopharmaceutical products, discussions about specific products.

Figure 1: Hybrid format was appropriate for the course contents

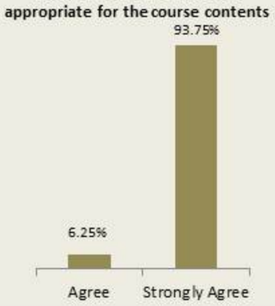
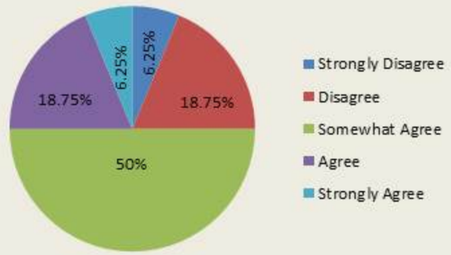


Figure 2: This course can be taught in completely online format



IMPLICATIONS

It is important that future pharmacists understand the unique properties of biopharmaceutical drugs and their impact on manufacturing, use and handling of drug products. An elective course introducing these various aspects would be a good addition to the pharmacy curriculum. Teaching the course in hybrid and possibly in completely online format would help students learn at their own pace reducing the in-class time burden.