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INNOVATIONS IN TEACHING

A Pharmaceutical Biotechnology Virtual Laboratory

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Objectives. To develop a software application for the pharmaceutical biotechnology drug research and development process. The *Pharmaceutical Biotechnology Virtual Laboratory* was offered as a hybrid course in spring 2003. We evaluated (1) the software's pedagogical effectiveness, and (2) how students utilized the software in the teaching/learning process.
Methods. Software development involved software-authoring tool selection, mock-up layouts of content screens, educational content creation, and storyboard development with artwork, animation, and programming. All modules were developed and refined based on student usability testing. Course implementation permitted student choice of face-to-face, hybrid, or online course formats. Student learning was assessed through quizzes, pretests, and posttests; assessment of student mode of learning (eg, how the students used the software and course participation format); and transference of learning from the course to other situations.
Results. Results of student posttests and quiz scores were not influenced by students' choice of course participation format. Hardcopy materials were rated more important than software or electronic materials.
Conclusion. Based on anonymous surveys, students felt that the software was a valuable learning tool. However, students preferred to use their "tried and true" method – studying hardcopy notes.

Keywords: educational software, pharmaceutical biotechnology, biotechnology, asynchronous learning, online learning

INTRODUCTION

Educational materials for the drug development process involving chemically synthesized molecules are readily available via textbooks, articles from the literature, and Web resources; considerably fewer resources exist for the pharmaceutical biotechnology drug discovery and development process involving recombinant peptides and proteins. Currently available pharmaceutical biotechnology textbooks[1-4] discuss knowledge and techniques important to protein and peptide biochemistry, gene cloning, and pharmaceutical aspects of recombinant proteins, but none offers a comprehensive view of the pharmaceutical biotechnology drug research and development (R&D) process.

Project Objectives

We embarked on a 3½-year project to create a virtual, interactive laboratory on the pharmaceutical biotechnology drug R&D process. While there are virtual laboratories available for chemistry and biology, nothing comparable is available for pharmaceutical biotechnology. We wished to (1) address an unmet pedagogical need to educate students in the pharmaceutical biotechnology drug development process; (2) stimulate student interest in the pharmaceutical biotechnology sciences through a virtual laboratory experience; (3) engage the student in an active-learning, decision-making process through a learner-centered focus of the interactive software; (4) introduce and emphasize the application of the scientific method as a guiding decision-based paradigm in solving scientific, clinical, and everyday problems; (5) explore the effectiveness of several course formats for using the software; (6) explore how students utilized the software in their learning process; and (7) evaluate student performance while using the software as a learning tool.

Software Description

The *Pharmaceutical Biotechnology Virtual Laboratory* is an interactive software program in which the student assumes the role of a new employee for a virtual company. As a new employee, the student undergoes a "company orientation" followed by training in the scientific method. Thereafter, the student is responsible for the company's research and development (R&D) of a fictitious protein,

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Table 1. Outline of Modules for *The Pharmaceutical Biotechnology Virtual Laboratory* Software

Module 1: Pharmaceutical Biotechnology Virtual Laboratory Company Orientation, Scientific Method and Native Protein Purification
Module 2: Cloning of the Gene Encoding the Protein
Module 3: Development of a Protein Expression System
Module 4: Protein Isolation and Purification
Module 5: Recombinant Protein Dosage Form Design
Module 6: Preclinical and Clinical Testing and the FDA Approval Process
Module 7: Resource Library (PDF text files)

Prorenata, from discovery through Food and Drug Administration (FDA) approval.

The software program consists of 6 modules illustrating principles of pharmaceutical biotechnology (Table 1). Each of the 6 modules presents scientific, experimental biotechnology problems that must be solved by the decision-making process embodied by the scientific method. The seventh module is a resource module that contains textual information for student reference. Student learning objectives for each module are available at http://ubrxlab.buffalo.edu.

The software was designed for use in pharmacy, pharmaceutical sciences, biomedical, biology, and chemistry curricular programs at interested institutions of higher education. The course could be used alone or as a contributing component to a science-based course on drug development. The software complements current pharmaceutical biotechnology textbooks.[1-4] The *Pharmaceutical Biotechnology Virtual Laboratory* is available as a free download at http://ubrxlab.buffalo.edu in several software formats, ie, Web-based or CD-ROM for Windows and Macintosh platforms.

METHODS

Software Creation

There were 2 main phases to this project: software creation and software use in a course. Software design is a vital prelude to pedagogical effectiveness: well-designed software promotes rapid user acceptance and a positive learning experience; the converse applies to poorly designed software. We embarked on prototype module development for exploration of project feasibility and development of the software's "shape and form." The prototype development process involved (1) software authoring tool selection, (2) design (mock-up layouts of the software interface, eg, content screens, interface controls, and navigation), (3) educational content creation, (4) storyboard development, (5) production (artwork, animation, and programming), (6) student feedback, (7) module usability testing by students, (8) fine tuning of each module based on student feedback and testing, and (9) final module testing (operational, installation, platform) and evaluation. Successive modules were developed using processes 3-9.

Macromedia *Authorware 6* and *Flash 4* (Macromedia http://www.macromedia.com, San Francisco, Calif) were selected as software authoring tools based on (1) Macromedia's strong leadership in educational technologies and substantial commercial viability; (2) the ability to create the *The Pharmaceutical Biotechnology Virtual Laboratory* in 3 formats, ie, Web-based, Windows, and Macintosh platforms; and (3) the relative user-friendly design of *Authorware*, which permits in-house updates.

Drawing from other successful commercial projects developed by one of the authors (Travis Piper of Creative Approaches), mock-up layouts of the interface design (eg, content screen) contained elements of text, graphics with animations, and interactive student choices. Figure 1 is an example of a typical content screen for this project.

We developed a tentative outline of the major biotechnology R&D processes for a therapeutic protein (discovery, characterization, cloning, production, formulation, preclinical/clinical testing, and FDA approval). This outline served to determine the general title of each module. Thereafter, specific content outlines were developed for each module.

Because scientific research is not necessarily a linear path, the "employee's" progression through the *Pharmaceutical Biotechnology Virtual Laboratory* is not linear. Students must interactively choose from various experimental designs and then select a variety of options for each experimental factor. Students receive immediate feedback. Based on their choices, students are taken to the next screen, which poses another scientific problem. Depending on the quality of their choices and decisions, students may discover different ways of solving a scientific problem, or follow fruitless leads that return them back to the beginning where they must start over.

This approach required the development of a complex storyboard on which each possible screen resulting from a user's choice branched out. An example of a storyboard, consisting of a flowchart with text, is shown in Figure 2. The flowchart was accompanied by another file that contained content text, along with suggestions for interactions, graphics, and animations.

Flowcharts, content text, graphics, and animations were used to develop and program a draft module for student feedback and faculty members' review.

Student feedback proved invaluable in the creation of the software. Students were recruited from the under-

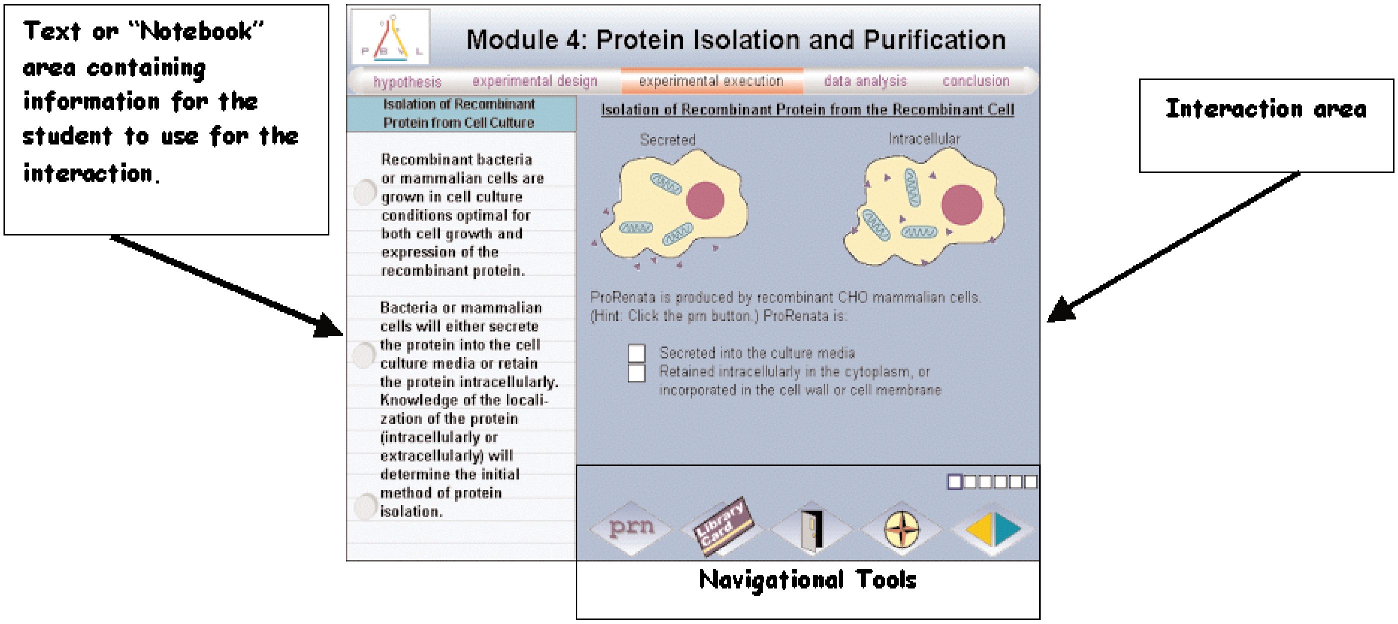

Figure 1. Typical content screen of *The Pharmaceutical Biotechnology Virtual Laboratory*.

graduate and graduate levels and compensated financially for their efforts. Informal student focus groups provided feedback on content development and improvements of each draft module. A formal software usability survey was conducted when the project was half completed (Modules 1-4).

Software Use in a Course

The next phase was to implement the *Pharmaceutical Biotechnology Virtual Laboratory* software in a credit-bearing course. We wished to understand how students would learn from the software.

Careful thought was given to the dilemma of how to utilize the software in a course format in a way that would maximize active learning. While the software could be used as an independent tutorial, we were uneasy and unsure about allowing undergraduate students the complete flexibility to learn at their own pace. While this approach may be satisfactory for a graduate student or mature learner, many undergraduate students need guidance and structure.

We decided to offer the course in several formats. Accordingly, students could chose from the following course participation options: (1) traditional, weekly face-to-face classroom discussions facilitated by the instructor (face-to-face); (2) weekly asynchronous discussions via a course management system discussion board (online), or (3) a combination of face-to-face and asynchronous discussions (hybrid).

The first class of the semester was a required face-to-face meeting in which the course syllabus was discussed. The syllabus detailed which modules were covered during each week of the semester, and specified dates for mandatory, face-to-face quizzes. Providing a module completion date was important as this kept the students "on time" and "on task." Also discussed were the course format options (face-to-face, online, or hybrid), student participation requirements, and assessment criteria.

Student Activities

Distance-learning survey. Students had the choice of either attending the weekly online session or the face-to-face discussion sessions. However, before deciding, each student was required to take a distance-learning survey to assess his or her learning style preference. The survey was obtained from a web site of the Public Broadcasting Service on adult education, http://www.pbs.org/campus/003_Advice/003-06.html. The results of the survey would empower students to make informed decisions on their choice of course format.

The distance-learning survey score was converted to a percentage scale ranging from 33% to 100%. A score of 33% (the minimum score for answering all 10 questions) indicated that the student should not take an online course. A score of 34%-66% suggested a learner preference for face-to-face classroom environment. A score of 67%-100% indicated a preference for an online course.

Students could switch between online and face-to-face formats as many times as they wished, as long as they fulfilled their weekly participation requirement. The online sessions required weekly postings in the discussion board section of *Blackboard*, a course management system (Blackboard Learning System, version 5.1

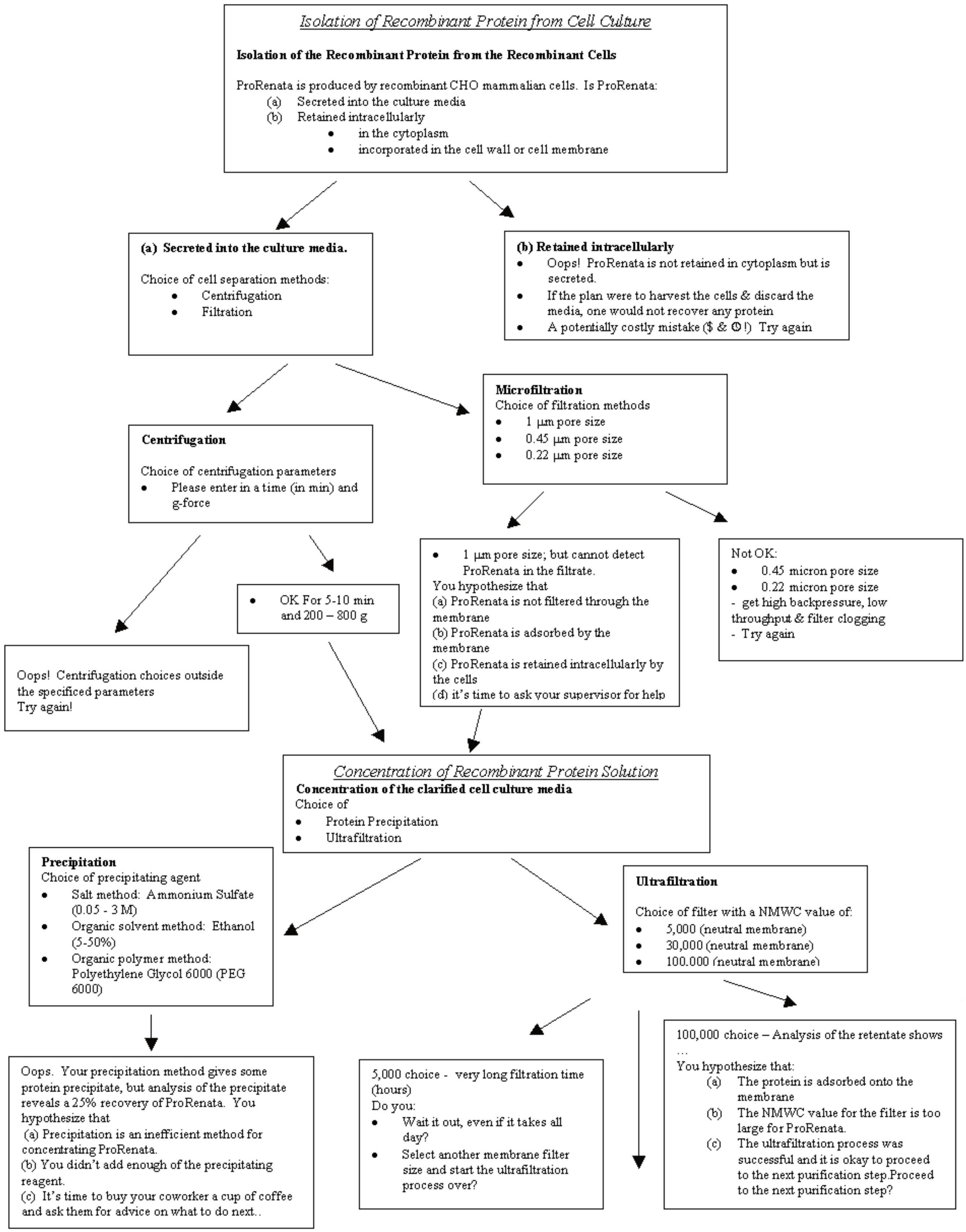

Figure 2. Example of one page from a storyboard flowchart to illustrate the variety of decision pathways for the student to make. Each box represents a content screen.

Washington, DC, http://blackboard.com). Students were required to post 3 questions and answer 2 classmate questions for that week. The face-to-face sessions consisted of class discussion of student questions; students were required to bring 3 questions to class for discussion and hand in their questions at the end of the session as "proof of attendance."

Students were required to complete pretests and posttests during the first and last weeks of the semester, respectively. Regardless of their preference of learning format, students were required to attend the 4 face-to-face class sessions during which quizzes were administered. The dates, content coverage, and format of each quiz were published in the syllabus. Quizzes consisted of short-answer essay questions.

Students participated in a final group project in which they gave a presentation on a pharmaceutical biotechnology problem or issue to another class. The instructor was obliged to facilitate the face-to-face class meetings each week; monitor the *Blackboard* discussion postings; construct, administer, and grade quizzes; construct, administer, and evaluate the distance survey, pretests and posttests, and end-of-semester student course evaluation; and monitor student access of the software to understand how the students used the software.

The final course grade was based on quiz scores, weekly participation, completion of the distance-learning survey and pretests and posttests. The latter 3 items (survey and pretests and posttests) were assessed on a completed/not completed basis. An anonymous, final course survey was optional. Students who completed the survey received bonus points towards their final course grade.

Assessment of Student Learning

Students were required to complete a pretest and posttest to assess knowledge gained from the course. The pretest was a 20-question, multiple-choice test administered during the first week of class; the posttest was the same test administered during the last week of class. The test questions and answers were not available to the students following the pretest. A total of 14 weeks intervened between administration of the pretest and posttest.

The software consists of 6 interactive modules and a seventh module containing text-only files (in nonprintable PDF) of the information in the other 6 modules, as well as additional information and references (glossary, tables, references). We were interested in whether the students would prefer to use and learn from the interactive modules, the library text-only module, or some combination of both. An understanding of how students used and learned from the software involved analysis of (1) student use of the software through software-access tracking, (2) responses to quiz questions, and (3) survey responses of student preferences.

The software was made available through *Blackboard* such that the course-tracking feature would compile student general access statistics during and at the conclusion of the semester. All modules were available in a non-printable, electronic format only, so as to obtain accurate student software access data. Student access (consisting of software "hits") over time was monitored for: (1) the interactive modules versus the library module; and (2) access hits (stratified by interactive modules versus library module) compared to each quiz score and the average quiz score. The student access information yielded data on the number of times the files were accessed, but not on the length of time that the student was connected to the site where the files were located.

For quiz question analysis, all quiz questions were short-answer essay. Each quiz was constructed such that appropriate answers could be deduced from a knowledge of the interactive modules or library PDF text. The point values for each student's response to each question for each quiz were recorded and analyzed according to the question source (interactive module versus library PDF text). To facilitate comparisons of the overall quiz score with the question source scores, the point scores were converted to a percentage, ie, a score of 100% meant all possible points were earned for that question source.

Finally, student preferences for the interactive modules and library PDF files were solicited by an anonymous survey at the end of the semester.

Student transference of learning was gauged by (1) assigning an applied scientific-method problem following completion of module 1 and (2) requiring students to give a presentation to a different class at the end of the semester.

One of the learning goals of module 1 is to introduce and emphasize the application of the scientific method as a guiding decision-based paradigm in solving scientific, clinical, and everyday problems. The applied scientific-method assignment measured how well the student could apply the scientific method to an ordinary problem that the student encountered during a 2-week period. Students needed to identify a problem (scientific, clinical, or everyday) and explain how to apply the principles of the scientific method to solve the problem. Problems were graded based on originality, insight, and appropriate application of the scientific method.

The presentation activity gauged how well the student applied and incorporated the knowledge gained from the software and the course into the presentation. Students were assigned into teams; each team had to give a *Powerpoint*

Table 2. Student Responses on the Software Usability Survey, N=13

Student impression of the	Very Positive	Positive	Neutral	Negative	Very Negative
Overall software	54%	46%	0%	0%	0%
Opening animation (when the software was launched)	38%	38%	24%	0%	0%
Notebook text	30%	62%	8%	0%	0%
Interaction area	30%	54%	8%	8%	0%
Screen graphics	46%	46%	8%	0%	0%

Data expressed as a percent of the student focus group.

presentation on some aspect of pharmaceutical biotechnology to a different pharmaceutical science class (with an enrollment of approximately 60 pharmacy and pharmaceutical sciences students). Teams could select a topic from a list of themes provided by the instructor: bioengineered foods, gene therapy, antisense therapy, insulin drug delivery, patient safety in pharmaceutical biotechnology clinical trials, stem cell therapy, chimeric antibodies, and biotechnology vaccines. After the presentation, each student was required to submit a list of 5 concepts, techniques, or facts that were learned from the software and incorporated into the group presentation. This assignment was a retrospective, reflective activity, as students were given this assignment after all presentations were delivered. This ensured that students would not deliberately incorporate software information into the presentation. The instructor reviewed each submission to determine whether each listed item represented (1) knowledge learned from a specific module that was covered in the presentation; (2) a concept, fact, or technique; (3) material used as background, direct, or applied information in the presentation.

At the end of the semester, all students anonymously completed a survey covering areas of: (1) perspectives towards online (distance) learning; (2) computer and software access and usability; (3) overall satisfaction of the software; (4) perceptions on the learning/knowledge value of each module; (5) self-reported utilization of the software in their learning process; (6) perceptions of the use of the discussion board in the course; (7) perceptions of the pharmaceutical biotechnology virtual laboratory course structure and software implementation; and (8) general perspectives on the pharmaceutical biotechnology virtual laboratory course.

The data were scored using a 5-point Likert scale (1 = strongly disagree; 2 = disagree; 3 = neutral; 4 = agree; 5 = strongly agree). Data were analyzed using descriptive statistics to arrive at a mean score plus or minus the standard deviation, median, and mode scores. Where appropriate, data were analyzed by ANOVA with Newman-Keuls post-hoc testing or Student's unpaired *t* test, with the level of significance set at $p<0.05$ (two-tailed).

RESULTS

Software Creation

Once the prototype module was completed, the rate-limiting step for the remaining modules was content development. The storyboard development, production, usability testing, feedback, and final testing proceeded at a good pace.

Feedback from student focus groups influenced many aspects of software design. For example, clicking on the navigational "prn" button (Figure 1) provides additional physical and chemical information on the fictitious protein, Prorenata (prn), which is the focus of the drug development process. For the "prn" button, students selected a table format over a scrolling-text format, thereby improving page-by-page navigation for information retrieval. Students also suggested adding outlines of the major procedural steps, which are displayed at the beginning and end of each module. In another case, students decided on the format of the software's response when a student selected an interactive choice on a content screen: a scrolling text box was selected over a pop-up window because students wanted to see both the question and the response. Lastly, students strongly expressed a limit as to how much text they were willing to read on a monitor; they suggested making the "Notebook Text" area (see Figure 1) printable. This led to the development of module 7, the Library, where students can obtain text-only PDF files of each module.

The software usability survey response rate was 25% (13 of 52 students); 9 students were new users and 4 had previously reviewed the software in informal focus groups. Few problems were identified with the usability mechanics (software launching, navigation, module selection). Students were also positive about the software interface design (which included the design feedback suggestions from informal student focus groups).

Survey results are reported in Table 2. Sixty-two percent of the students found the software very interesting and 38% found it somewhat interesting. Eighty-five percent of the students indicated they would recommend the software to a friend, and 15% indicated they would highly recommend the software to a friend. Sixty-nine per-

Table 3. Student Demographics

Average age (± SD)	23 ± 2 years (range 21-32)
Gender	
Male	41%
Female	59%
Ethnicity	
Black	4%
Hispanic	4%
Asian or Pacific Islander	37%
White	56%
Students whose first language is not English	22%
Average overall grade point average* (± SD)	2.87 ± 0.43 (range 2.18 – 4.00)
Average course credit load for spring 2003 (± SD)	16.6 ± 2 (range 12-23)

*0-4 scale

Table 4. Distance Learning Survey and Quiz Scores as a Function of Course Participation

Participation Mode	Online (n=14)	Hybrid (n=13)	Statistical Significance
Distance Learning Survey Scores	73.8 (4.5)	74.0 (8.8)	Not significant
Average Score of All Quizzes	79.2 (15.2)	81.6 (19.3)	Not significant
Quiz 1 (module 1)	84.1 (15.6)	82.6 (14.6)	Not significant
Quiz 2 (modules 2 and 3)	82.0 (10.9)	80.1 (26.1)	Not significant
Quiz 3 (modules 4 and 5)	72.7 (17.9)	69.6 (20.2)	Not significant
Quiz 4 (module 6)	77.5 (14.9)	81.4 (13.1)	Not significant

cent of the students felt that they would use the software on their own; 23% would use the software if a course or instructor required it, and 8% were uncertain of how they would use the software.

Software Use in a Course

Following creation of the software, we were faced with a fundamental question pertaining to all educational technologies: how can the *Pharmaceutical Biotechnology Virtual Laboratory* be effectively integrated into a collegiate course to enhance student learning? After careful thought, we elected to pilot test the software in one of our courses.

We decided to offer the course to only pharmaceutical science majors,* with future course offerings open to all pharmaceutical sciences and pharmacy students. *The Pharmaceutical Biotechnology Virtual Laboratory* was the focal point of a pilot 1-credit course (PHC 407) offered in spring 2003 (over one 14-week semester). Twenty-seven students enrolled in the course: 23 were pharmaceutical science baccalaureate majors (10 juniors and 13 seniors); 1 was a pharmacy/pharmaceutical sciences double major; and 3 were combined bachelor's/master's degree pharmaceutical science majors. Table 3 presents student demographics.

Approximately half of the class (52%, n=14) participated in the online course format. The remainder (48%, n=13) participated in a hybrid (face-to-face and online) mode. No student chose an entirely face-to-face participation format. Of those who participated in the hybrid format, the average number of face-to-face classes attended was 2.5 ± 1.9 (range 1-7), or 28% of the available 9 class sessions. Of note is that 2 academically successful students (grade point averages > 3.75) attended 4 and 7 of the 9 class sessions; when queried about why he/she chose to attend class, each student responded that it was much easier and more intellectually satisfying to verbalize his/her questions and participate in an in-depth discussion in a face-to-face format. The distance-learning survey score was an informal advisement tool that empowered students to select their personalized mode of course participation. The average score (± SD) for all students (n=27) was 73.8% ± 6.7% (range 63%-93%), indicating that the majority of students had a preference for an online course format. A comparison of the distance-learning survey scores for the online versus hybrid groups revealed no significant differences (Table 4).

Analysis of the distance-learning scores and final quiz grades (average of 4 quizzes) for the online group versus the hybrid group revealed no significant differences (Table 4). Moreover, there were no statistical differences for each of the quiz scores between the 2 groups. The quiz scores tended to average around 80% for both groups; however, the results for the third quiz tended to be lower for both groups (approximately 70%). One possible explanation for the lower scores on the third quiz is that this quiz was administered 2 days after spring break ended; students may not have studied during spring break and instead crammed the night before.

A significant difference ($p<0.001$; by ANOVA with Newman-Keuls post-hoc testing) was observed between the pretest and posttest scores, indicating that the students acquired knowledge during the semester (Table 5). The posttest scores were not significantly different from the final quiz grade. In addition, there were no significant differences in either the pretest or posttest scores when these scores were analyzed by student choice of course participation (online versus hybrid; data not shown).

Table 5. Pretest, Posttest, and Average Quiz Scores, N=27

	Mean (SD)	Median	Range
Pretest scores (%)	43.4 (15.5)	44.4	16.7 – 72.2
Posttest scores (%)	76.1 (18.0)*	77.8	22.2 - 100
Average score of 4 course quizzes (%)	78.8 (17.3)	79.8	54.6 – 97.9

*Significantly different from the pretest score; $p<0.001$ by ANOVA with Newman-Keuls post-hoc testing.

Table 6. Student Access Hits of Online Material for a Pharmaceutical Biotechnology Course, N=27

	Percent of Total Hits*				Number of Hits Per Student, Range
Material Accessed Online	Mean (SD)	Median	Range	Statistical Significance	
Interactive Modules					
First half of course material (covered in quizzes 1 and 2)	24.0 (3.90)	23.8	16.1 – 32.3	*vs* interactive modules accessed during the last half of the course, $p<0.001$	12 - 75
Last half of course material (covered in quizzes 3 and 4)	12.9 (5.2)	12.3	4.4 – 24.6	*vs* library PDFs accessed during the last half of the course, $p<0.001$	4 - 48
Library PDFs					
First half of course material (covered in quizzes 1 and 2)	43.7 (11.6)	45.9	18.3 – 62.1	*vs* interactive modules accessed during the first half of the course, $p<0.001$	11 - 125
Last half of course material (covered in quizzes 3 and 4)	19.4 (10.43)	21.0	0 – 37.4	*vs* library PDFs accessed during the first half of the course, $p<0.001$	0 - 77

$P<0.001$ by ANOVA with Newman-Keuls post hoc testing.
*Hits indicate the number of times number of times the material was accessed.

Student Access Hits for Interactive Modules and Library Text

An examination of the distribution of student access hits (interactive modules versus library PDF text) was performed for the first and last half of the semester (Table 6). These data illustrate that students accessed the library PDF text module twice as frequently as the interactive modules for the first half of the semester ($p<0.001$ by ANOVA with Newman-Keuls). Since paper copies of the library PDF text were made available for purchase via a photocopy service at mid-semester (due to unrelenting student requests), student access hits for the library text significantly declined during the last half of the semester ($p<0.001$ by ANOVA with Newman-Keuls). Moreover, students accessed the interactive modules substantially less during the last half of the semester following the availability of paper copies of the library text ($p<0.001$ by ANOVA with Newman-Keuls).

No significant correlations (data not shown) were observed for student access hits for: (1) the interactive modules versus individual quiz scores or final quiz scores; (2) the library PDF text versus individual quiz scores or final quiz scores; and (3) the total of interactive modules plus library PDF text versus individual quiz scores or final quiz scores. Hence, the extent of student software access had no relationship to student quiz performance.

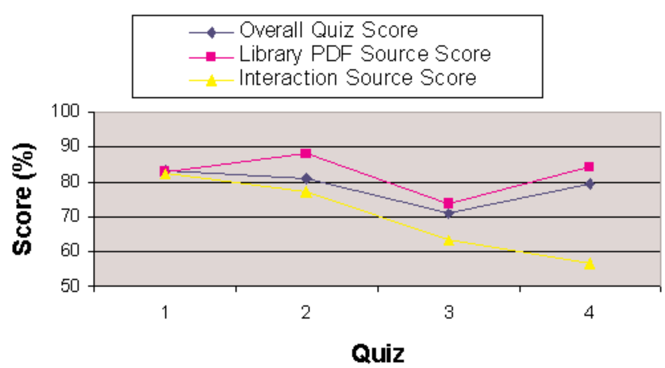

Figure 3. Mean student scores on quizzes according to the source of material used.

Figure 3 presents the quiz analysis by question source. While the library PDF question source score mirrored the overall quiz score throughout the semester, the interaction question source score dramatically declined for the third and fourth quizzes. Given that student access hits declined for the interactive modules in the last half of the semester (due to the release of the library

PDF text files in paper format), a decline in the interaction question source score was not surprising.

Transference of Learning and the Scientific Method Applied Problem

Twenty-five of 27 students completed the assignment. Of the 25, only 2 student assignments lacked originality and 1 student applied the scientific method to a problem involving his research project. Additionally, 3 of 25 students missed several critical steps in applying the method to their problem. The class average was 90% (± 27%, n=27) for this assignment.

Transference of Learning and the Pharmaceutical Biotechnology Presentation

The presentation gauged how well the student applied and incorporated the knowledge gained from the software. Of the items submitted by the students, 66% (86 of 130 submitted items) represented knowledge learned from the software. The remaining 34% (44 items of 130) did not represent information learned through the software and/or were not covered in the presentation.

Of the 86 qualified items, 39.5% represented conceptual material, 40.7% conveyed factual information, and the remaining 19.8% consisted of scientific techniques. Students were more apt to utilize facts and concepts as background material in their presentations. Modules 5 and 6 (Dosage Form Design; and Preclinical/Clinical Testing and FDA Approval, respectively) were the source of 64.6% items covered in the presentations. Modules 2 and 3 (Gene Cloning and Development of an Expression System, respectively) served as information sources for 23.3% of the items. The heavy influence of modules 5 and 6 may represent the comfort level of student understanding of those modules and/or the fact that the completion dates of these modules coincided with the presentation date (at the end of the semester). Overall, the data suggest that students did utilize their knowledge of the information gained from the course in giving a presentation to a different class.

Student Course Survey

Student opinions on the innovation and effectiveness of this project were solicited through an anonymous, end-of-semester course survey (Table 7). The survey completion rate was 100%, aided by a reward of extra credit for completing the survey.

For 80% of the class, this course was the first distance/face-to-face learning hybrid course ever taken. Most students enjoyed using the Internet as a tool to learn new information and would likely take more hybrid courses (Table 7). However, students were neutral about enrolling in other hybrid courses to reduce the time spent in face-to-face classroom instruction. This may suggest that while students are enthusiastic about online courses, they still prefer some aspect of face-to-face instruction.

Students were typically positive regarding computer and software access and usability (Table 7). Because the University at Buffalo strongly recommends that students have their own computers, and provides strong support for student access at public computing sites, students encountered minimal access problems. Students were satisfied with the access and navigational aspects of the course management system, *Blackboard*, and the *Pharmaceutical Biotechnology Virtual Laboratory* software.

Students enjoyed using the *Pharmaceutical Biotechnology Virtual Laboratory* software to learn about the drug development process in biotechnology (Table 7). The software was favorably viewed as a tool for understanding basic concepts in the biotechnology drug development process. Each module was favorably viewed as a tool for learning about each module's topic (Table 7).

When students were assigned a new module to learn, 55% reported that they would examine the interactive module first; while the other 45% reported that they would review the library PDF text files first. Although students rated both the interactive modules and library PDF text files as being important (Table 7), the rating for the library PDF files was significantly greater (interactive modules, 4.05 ± 0.15 vs. library PDF files, 4.40 ± 0.20; $p<0.001$ by Student t test). Fifty-six percent rated the library PDF files as more important to their preferred method of learning, 26% rated both the modules and library PDF files as being equally important, and 18% felt that the interactive software modules were more important.

For purposes of preparing for in-class quizzes, students favored studying the library PDF files, as students estimated that 58% of their study time was devoted to the library PDF files, with the balance of their time spent on the interactive software modules.

Students tended to be neutral in their perception of the use of the online discussion board as a valuable learning tool (Table 7); this was in contrast to 48% of the students who attended at least one face-to-face discussion session, where these students were significantly more positive about the learning value of face-to-face discussion sessions (discussion board, 3.33 ± 0.17, n=27; face-to face, 3.71 ± 0.16; n=13; $p<0.001$ by Student's unpaired t test). Students were positive in that the discussion board required them to think more carefully about their posted questions and answers. Approximately 70% of the class checked the discussion board postings 1 to 2 times per week to answer and

Table 7. Student Evaluation Survey of the Pharmaceutical Biotechnology Virtual Laboratory Course and Software

Student Perspectives Towards Online (Distance) Learning	**Mean**	**SD**	**Median**	**Mode**
In general, I enjoy using the internet to learn of new information.	4.00	0.16	4	4
If given the opportunity, I would take more distance learning (or on-line) courses.	3.90	0.18	4	4
Overall, I think that it would be a good idea if other courses were developed that use a distance, on-line learning approach to reduce the amount of time spent in face-to-face classroom instruction.	3.40	0.21	4	4
Computer and Software Access and Usability				
I spent too much time trying to get access to a computer to do the coursework effectively.	2.19	0.22	2	2
The time I spent using the technology required for this course would have been better spent in the classroom.	2.56	0.18	2	2
Accessing and starting the Pharm Biotech Virtual Lab through Blackboard was easy, convenient and fast.	3.78	0.18	4	4
The Pharm Biotech Virtual Lab was easy to navigate & move around.	3.89	0.16	4	4
Once the Pharm Biotech Virtual Lab was started, the time to move from screen to screen was reasonable & did not keep me waiting.	3.99	0.21	4	4
Overall Student Satisfaction of the Software				
I enjoyed using the Pharm Biotech Virtual Lab through Blackboard to learn about the biotechnology drug development process.	3.88	0.12	4	4
Overall, using the Pharmaceutical Biotech Virtual Lab contributed to my understanding of basic concepts in pharmaceutical biotechnology drug development.	4.19	0.10	4	4
Student Perceptions on the Learning/Knowledge Value of Each Module ***Concerning the Pharm Biotech Virtual Lab (software program & library files):***				
Module 1 helped me to learn about the pharmaceutical industry organization and the scientific method.	3.92	0.14	4	4
Module 2 helped me to learn about Gene Cloning (Part 1) involving PCR techniques.	3.85	0.21	4	4
Module 3 (Gene Cloning - Part 2) helped me to learn about the selection and testing of a cloned gene from transformed expression system, and to develop a stable expression system harboring the cloned gene.	3.82	0.18	4	4
Module 4 (Protein Purification and Isolation) helped me to learn about techniques to purify and characterize proteins.	3.99	0.15	4	4
Module 5 (Protein Dosage Formulation) helped me to learn about how to design a protein formulation for dosing to patients.	4.00	0.13	4	4
Module 6 (Preclinical and Clinical Studies / FDA Approval Process) helped me to learn about the types of preclinical & clinical studies and the steps involved in the FDA approval process.	4.04	0.11	4	4
Student Utilization of the Software in His/Her Learning Process				
Please rate the importance of the software modules to your preferred method of learning.	4.05	0.15	4	4
Please rate the importance of the library files (electronic or paper) to your preferred method of learning.	4.40	0.20	4	4
Student Perceptions of the Pharmaceutical Biotechnology Virtual Lab Course Structure and Software Implementation				
Overall, I found that I was able to control the pace of my learning more effectively because of the way this course used Blackboard & the Pharm Biotech Virtual Lab	3.65	0.15	4	4
Because of the format of this course (student choice of face-to-face classroom discussion or distance, on-line learning), I was better able to juggle my course work with my work, other and/or home responsibilities.	3.96	0.15	4	4
I felt that the format of this course (choice of face-to-face class discussions or distance on-line learning) made me feel less connected with the instructor and with the other students in this course.	2.89	0.18	3	3
General Student Perspectives on the Pharmaceutical Biotechnology Virtual Laboratory Course				
The Pharm Biotech Virtual Lab course is relevant to my view of pharmacy / pharmaceutical sciences.	4.30	0.13	4	4
The Pharm Biotech Virtual Lab course contains a good mix of theory and applications.	4.22	0.13	4	4
The Pharm Biotech Virtual Lab course enhanced by analytical thinking, creativity, technical skill or competence.	4.11	0.14	4	4
The Pharm Biotech Virtual Lab course met my expectations of what I wished to learn.	3.96	0.13	4	4
I would recommend the Pharm Biotech Virtual Lab course to other students.	3.81	0.17	4	4

review classmate postings. Only 15% reported that they did not review classmate responses at all.

For the purposes of formulating questions for the discussion board posting, 52% reported that they referred to the software modules when synthesizing questions or answers, 30% referred to the software modules and the library PDF files, 15% referred only to the library PDF files, and 4% used other materials.

Students tended to be positive about being empowered to control the pace of their learning more effectively because of the course design (Table 7). Similarly, students were positive about the flexibility of the course format (face-to-face discussion and/or online learning) in helping them to manage other responsibilities.

Interestingly, 54% felt that future *Pharmaceutical Biotechnology Virtual Laboratory* courses be offered with the same format (student choice of online and class discussions), while 41% felt that there should be a different format involving some mandatory discussion sessions and some mandatory distance (online) sessions; only 4% (1 person) felt that the course format should be all mandatory face-to-face class sessions. Seventy-four percent of the students felt that the course format (choice of face-to-face discussions or online sessions) should be extended to other courses; 15% felt that there should be only face-to-face discussions, and 11% had no opinion. To learn about other topics in the pharmaceutical sciences, 2 out of 3 students would chose a hybrid course over a face-to-face class.

Pharmaceutical Biotechnology Virtual Laboratory Course was, overall, rated quite highly by the students in the areas of (1) relevancy to the student's view of pharmacy/pharmaceutical sciences, (2) good mix of theory and applications, (3) enhancement of analytical thinking, creativity, technical skill, or competence, and (4) meeting the student's expectations of what they wished to learn (Table 7). Students tended to be positive towards recommending the course to other students.

DISCUSSION

The *Pharmaceutical Biotechnology Virtual Laboratory* software addresses an unmet pedagogical need to educate students in the pharmaceutical biotechnology drug-development process. The innovation and uniqueness of this project derives from its (1) educational content and software design, as no other biotechnology drug R&D instructional software is currently available; (2) extensive use of the principles of the scientific method as a strategy for solving various types of problems; (3) interactive, learner-centered, asynchronous approach in several software formats, ie, internet-based or CD-ROM for Windows and Macintosh platforms; (4) inventive course format (student choice of face-to-face class, online or hybrid); and (5) incorporation of research methods, which enabled an understanding of how students utilized and learned from the software. Importantly, the course structure employed in this project could serve as a model for the use of other software applications in other pharmacy, biomedical, or science disciplines.

The *Pharmaceutical Biotechnology Virtual Laboratory* software would be useful to other schools of pharmacy for several reasons. It is a tool for maintaining and enhancing the science-based knowledge of the pharmacy and pharmaceutical sciences curriculum. It promotes student-centered active learning in an important new therapeutic area of biotechnology drugs and it provides schools that have limited resources with an economical means for introducing pharmaceutical biotechnology into the curriculum.

Valuable insights were gained from utilizing the software in a pilot course. For the class composition of juniors and seniors, the validity of offering students a choice of course formats was supported by the fact that no student failed or dropped out of the course and by positive student perceptions of the software and course format. Student choice of course participation did not correlate with the final average quiz grade, suggesting that students made choices appropriate for their learning preferences and lifestyle without detrimental effects on their learning. However, since no student scored in the range of 34%-66% on the distance-learning survey (learner preference for face-to-face), these results may not be readily extrapolated to other types of students. Evidence of student acquisition of knowledge was demonstrated by the significant increase in the posttest scores, compared to the pretest scores. Student knowledge was also assessed throughout the semester by quizzes; in general the quiz scores remained constant (about 80%).

Students favorably viewed the choice of course formats as a positive aspect of the course. However, from the instructor's viewpoint, the workload for concurrent offerings of face-to-face sessions and monitoring of an online environment was greater than that for one format.

While students typically valued face-to-face discussion slightly more than asynchronous discussion-board postings, participating in the discussion-board postings stimulated students to think more carefully. Students reported that their preference was to refer to the interactive software for the discussion-board posting process. Of note, the weekly requirement to post to the discussion board eventually became tedious for those students who elected to participate in the online course format. In addition, a few students were confused occasionally about whether the class discussion they attended (on an irregular basis) fulfilled their weekly participation requirement.

An analysis of student access hits for the interactive software and library PDF files relative to quiz questions provided meaningful insights. Student access hits declined for the interactive modules in the last half of the semester when the library PDF files were available in paper format, suggesting student preference for hardcopy materials. While the library PDF question source score mirrored the overall quiz score throughout the semester, the interaction question source score dramatically declined over the semester. Also, student survey results favoring the library PDF files as a study resource for quizzes are consistent with findings that student access hits on the interactive module files decreased after the library text files were made available in hardcopy.

In summary, students appreciated the choice of course formats and rated the software as a valuable learning tool. However, hardcopy materials were deemed more important than the software or electronic materials. Although students reported that they enjoyed learning from interactive software, they still preferred textual materials to aid in the learning and studying processes. However, this is based on a student population that was highly experienced in learning from text-based materials and had limited experience with software-based materials (as indicated on the student survey). Students tended to utilize the "tried and true" learning strategies they had developed during their freshman and sophomore years, ie, using the hardcopy, text-based materials to learn and study from for quizzes. Students' preference for text materials may change over time, as more students gain exposure to software-based materials and as they develop effective learning strategies for incorporating software into their learning process. These preferences may also change if the methods for student evaluation differed from those used here (that is, formalized testing via quizzes).

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*The Pharmaceutical Sciences baccalaureate degree at the University at Buffalo was created in 1962 with the objective of educating students in methods of pharmaceutical science research. The program has remained true to its original objective and has sustained its own identity throughout the years as a four-year, scientific research educational program distinct from the six-year Doctor of Pharmacy program.

The Pharmaceutical Sciences BS program is neither a required "gateway" to the PharmD degree nor a fall-back option for students who have encountered academic difficulties in the Doctor of Pharmacy curriculum. It is an independent degree program, just as is the case with any Biology or Chemistry degree programs.

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