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Design and Implementation of an Interdisciplinary Elective Course in Drug Discovery, Development, and Commercialization

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Abstract

Objective: *To describe the design and implementation of an elective course in drug discovery, development, and commercialization for pharmacy, medical, biomedical graduate, business, and law students.* ***Case Study****: This course included didactic lectures, student group discussions, a longitudinal assignment, and a question and answer panel session. A 9-item instrument using a 5-point response scale was used for course evaluation. The longitudinal assignment was the creation and presentation of a product lifecycle strategic plan (PLSP). Respondents rated 'agree' and 'strongly agree' in the course providing useful information on drug discovery (39% and 53%), drug development (39% and 60%), and drug commercialization (33% and 60%). The majority of student-reported overall understanding of the drug discovery and drug development process was rated 'very good' (49% and 46%), while the drug commercialization process was rated 'good' (46%).* ***Conclusions:*** *An elective course on drug discovery, development, and commercialization included enrollment of students with diverse educational training. The course provided useful information and improved overall student understanding.*

Introduction

In 2011, 3.7 billion prescriptions were dispensed, averaging approximately 12 prescriptions per person in the United States.[1] The United States Food and Drug Administration (FDA) approved 35 new medicines during the 2011 fiscal year, which was the highest number of approvals in the past decade.[2] Although recently approved drugs have addressed unmet medical needs and have improved morbidity and mortality, drug development remains an expensive and time-consuming process. Pharmaceutical companies spend approximately $1.5 billion over 10 years to develop a drug, with approximately 11% of all drugs in development successfully receiving post-marketing approval.[3, 4]

Drug discovery, development, and commercialization is a complex, multiple-step, sequential process. Numerous activities include, but are not limited to, the discovery of novel agents, conducting preclinical animal and toxicology studies, designing and completing clinical studies (e.g. Phase 1, 2, and 3), submitting regulatory documents (e.g. Investigational New Drug [IND], New Drug Application [NDA]), and initiating post-approval commitments (e.g. Phase 4 studies, adverse drug reaction monitoring, post-approval manufacturing inspections). Successful completion of these activities requires a team-orientated, interdisciplinary approach involving the expertise of individuals with advanced training and formal education in pharmacy, medicine, biomedical sciences, law and/or business.[5]

For example, pharmacists rely on pharmacokinetics knowledge such as elimination half-life and clearance to determine appropriate starting doses and dosing intervals for clinical studies. Understanding a drug's absorption, distribution, metabolism, and excretion properties are critical for protocol development in identifying exclusionary medications based on similar mechanisms of action and/or potential for drug-drug interactions. Physicians are responsible for establishing specific 'cut off' laboratory values and in identifying co-morbid diseases when determining inclusion and exclusion criteria. Biomedical researchers evaluate novel biomarkers and rely on laboratory methods and techniques previously acquired or learned during graduate school. Lawyers are essential in providing expertise in patent strategy and patent law. Professionals with advanced training in health economics and outcomes research are needed to assess needs of reimbursement authorities and build evidence to support product value. Individuals possessing formal business training are responsible for developing product portfolio strategies and in facilitating completion of product lifecycle strategic plans (PLSPs). These activities, although quite distinct, are shared

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among all team members and point to the common goal of obtaining drug approval.

There are few reports of the teaching of drug discovery, development, and commercialization to students.[6-10] In the Accreditation Council on Pharmaceutical Education (ACPE) accreditation standards, drug discovery and development are suggested, but not required, science foundations in the pharmaceutical sciences.[11] Additionally, there is no mention of the teaching of drug commercialization. Consequently, the lack of including these topics in a school curriculum may adversely impact students who are interested in career opportunities at a pharmaceutical and/or biotech company. Evidence of student interest in this area exists based on the availability and sustainability of joint pharmacy-pharmaceutical post-doctoral fellowship programs.[12]

In 2009, the University of California, San Diego (UCSD), Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) developed an elective course titled Drug Discovery, Development, and Commercialization. The purpose of this paper is to describe the design and implementation of this elective course offered to UCSD pharmacy, medical, biomedical graduate, and business students, as well as University of California, Irvine (UCI) law students.

Course Design

The course was developed by two pharmacy faculty serving as course co-chairs who were previously employed at various pharmaceutical/biotech companies. The co-chairs desired local pharmaceutical/biotech employees to provide a portion of didactic lecture content. Due to the lack of didactic teaching experience of some of the selected lecturers, educational resources (e.g. how to write goals and objectives) were provided. The remaining lecturers were SSPPS faculty who had previous experience in the pharmaceutical/biotech industry serving as an employee or as a consultant.

This was a 3-unit (30 in-class hours) elective that utilized a Satisfactory/Unsatisfactory grade. Course grades were determined by attendance (50% of grade) and a formal oral presentation of a PLSP (50% of grade). The elective was conducted once weekly in the afternoon for 10 weeks. The first two hours of each week were dedicated to didactic lecture, while the third hour was dedicated to student groups working on the PLSP. In 2012, an audio and video feed was set up to enable remote participation for law students. Video and audio equipment included a LifeSize™ 4x HD camera, Lifesize™ codec, wireless remote control, and microphone setup. Dual HDTVs were set up; with one to view the MS Powerpoint ™ presentation and the second HDTV to view the lecturer and law students. Law students were also invited to attend the lecture in-person, but few were able to attend due to the commute time between UCI and UCSD (approximately 60 minutes each way). During the last week of the course, PLSP presentations were conducted with course co-chairs and students in attendance. Each PLSP presentation was limited to 45 minutes and each student group was required to present a component of the PLSP. For the law students, they were provided the option of presenting in-person or via audio and video teleconferencing.

Learning Objectives

The course was offered once each academic year starting in 2010. The course focused in areas related to discovery, development, and commercialization of a drug. The course objectives were to:

1. Differentiate between small molecule and biological agent discovery processes;
2. Identify the tools and methodologies utilized in the drug discovery process;
3. Identify the required pre-clinical studies needed for drug approval;
4. Compare and contrast phase I, II, III, and IV clinical trials;
5. Describe the regulatory process for an investigational new drug (IND) application and new drug application (NDA);
6. Identify components of a commercialization strategy and marketing plan;
7. Develop a product lifecycle strategic plan (PLSP).

Learning objectives 1 and 2 were created based on previous literature describing the evaluation of drug discovery and the impact of new technologies being used for drug discovery.[13, 14] Learning objectives 3, 4, and 5 were created based on FDA Drug Guidance documents which represent current thinking of the FDA on a particular subject.[15] Learning objectives 6 and 7 were developed based on the commonality and frequency of use within pharmaceutical/biotech companies.

Student Participants

To enroll in the course, pharmacy, business, and biomedical graduate students needed to be in at least their second year, while medical and law students in their first year of their respective curriculum. One individual was identified from each school to facilitate enrollment and maintain a list of students who enrolled. When the course was first offered in 2010, there was a maximum enrollment of 24 students (e.g. 6 students from each school). During the subsequent quarters, the maximum enrollment increased to 30 students. Law students first enrolled in the course in 2012. The prerequisite for enrolling students in a specific year of their program and class size limitation was done to ensure an interactive, small group learning environment. One exception was made in 2012 as a first year pharmacy student who had previous work experience at a large pharmaceutical company was allowed

to enroll. In the event that student enrollment limits were not met from a professional or graduate school, students from other schools were enrolled at the discretion of the course co-chairs.

Curriculum Content

Lecture topics are summarized in Table 1. The course utilized a variety of teaching and learning methods, including didactic teaching, interactive student groups, a longitudinal assignment, and a question and answer panel session. There was no required textbook but recommended readings were provided for each lecture topic. Six hours of didactic lecture were dedicated to drug discovery. These lectures were presented first. Subsequent lectures included 8 hours for drug development and regulatory affairs, and 5 hours for pharmacoeconomics and drug commercialization. With regards to the design, a significant amount of information could be included as course content. The challenge was to determine specific topics for 20 didactic hours to be divided in discovery, development, and commercialization. Previous reports of drug development courses were valuable in determining lecture topics/content. For example, 4 hours were dedicated to early and late stage clinical development (e.g. Phase 1, 2, 3, and 4 clinical trials) as previous reports consistently selected these topics.[7, 8]

Upon completion of all didactic lectures, a question and answer panel session was conducted. Panel members were biomedical graduate-, medically-, and pharmacy-trained individuals currently employed at a pharmaceutical/biotech company. Panel members provided examples of how knowledge acquired from past didactic and clinical training were relevant to drug discovery, development, and commercialization. The panel also provided a perspective of their own career paths within the pharmaceutical company and current job responsibilities.

PLSP Assignment

Students were assigned into groups of 4 to 5 and were provided a drug to develop a PLSP presentation. Although an ideal group would be composed of a student from each discipline, this was not possible. However, each group had at least two different disciplines represented in each group. During the in-class time to work on the PLSP presentation, groups would review and discuss relevant literature related to the assigned drug. Groups were encouraged to discuss PLSP content with course co-chairs and lecturers, of which several lecturers were available to students during the dedicated PLSP in-class time. Students were also encouraged to engage in debate and practice their oral communication skills in preparation for the PLSP presentation.

Based on personal experience as previous employees for pharmaceutical and/or biotech companies, the co-chairs selected the drugs in specific categories for the PLSP. Drug selection for PLSP presentation was based on the desire for student exposure related to development of a small molecule (e.g. atorvastatin, rosiglitazone) and biologic (e.g. infliximab), the withdrawal of a drug due to safety concerns (e.g. rofecoxib, cerivastatin), novel commercialization/marketing strategies (e.g. epoetin alfa), and transition of a drug to over-the-counter status (e.g. omeprazole). These drugs continued to be used for PLSP presentation in the subsequent academic years. PLSP presentation required discussion of the following sections: drug background, product portfolio planning, preclinical and clinical development strategy, formulation development, regulatory strategy, and a commercialization/marketing plan. Specific content for students to address in each section of the PLSP presentation is summarized in Table 2.

Student Perceptions

There were 24, 25, and 23 students enrolled in the course during the 2010, 2011, and 2012 academic years, respectively. The profile of students was 36% (n=26) pharmacy, 28% (n=20) business, 22% (n=16) biomedical graduate, 10% (n=7) medical and 4% (n=3) law. A 9-item survey instrument using a 5-point response scale was developed based on a previous survey instrument for a finance elective course.[16] The instrument was administered to students at the end of the course to assess objectives, content organization, usefulness, and overall recommendations (Table 3). UCSD IRB (#10125) approval was obtained and students provided written informed consent prior to evaluating the course. Fifty-seven students completed the survey instrument (79% response rate). Survey respondents were 37% (n=21) pharmacy, 26% (n=15) biomedical graduate, 25% (n=14) business, and 12.3% (n=7) medical students. Course evaluation measures are summarized in Table 3. The majority of students rated 'agree' or 'strongly agree' that the course was well organized (61% and 26%), included interpretation and application of information (68% and 26%), and provided an unbiased perspective (63% and 23%). Ninety-three percent of students rated at least 'agree' in recommending this course to other students and in rating this course highly. However, it should be noted that there were no law students who completed the survey instrument. Consequently, one is not able to determine if similar course outcomes were achieved by law students. Thirty-three percent, 49%, and 14% of students reported overall understanding of the drug discovery process as 'good', 'very good', and 'excellent', respectively. Overall understanding of the drug development and commercialization processes was predominantly rated as

'very good' (46% and 33%) or 'good' (32% and 46%) (Table 4). Regarding the usefulness of program components, the majority of students rated the PLSP presentation (49%) and question and answer panel session (46%) as 'useful'.

Lessons Learned

Two key implementation aspects were to have this course cross-listed and to have a staff individual from each school assist with enrollment. Cross-listing the course is the creation of a different course number for each school. This was the preferred method by non-pharmacy schools. For each school, course elective descriptions are available online. If a student was unable to attend the course information session, then the only way for a student to be aware of the course is by online searching of all offered electives. If the course was only listed with a SSPPS number, students from non-pharmacy schools would not be able to access the course online. Individuals who assisted with enrollment had detailed knowledge of their school curriculum and student schedule to help facilitate the best date/time to conduct the course. They also served as the first contact with the student, were able to triage student questions (e.g. grading requirements, classroom location), and defer student questions about course content to the course co-chairs.

One perceived strength by the course co-chairs was the selection of lecturers employed at local pharmaceutical/biotech companies. These individuals provided expertise for several topics, with many of these lecturers having at least 10 years of experience. Many of these lecturers not only provided adequate teaching of basic concepts, but also were able to provide case examples for emphasis of key concepts. Concern was expressed from school faculty of the potential for bias in selecting lecturers employed at a pharmaceutical/biotech industry. Previous drug development courses offered to students have utilized individuals from the pharmaceutical/biotech industry to provide lecture content.[7, 8] However, these reports provide no data on whether there was student perceived bias. Regarding the course, there were 20 hours of didactic lecture, with individuals from the pharmaceutical/biotech industry providing 8 to 11 didactic hours. The course co-chairs communicated to all lecturers the desire to minimize bias in their presentation and reviewed presentation content prior to providing to the students. Furthermore, the majority of students reported the course provided an unbiased perspective (Table 3). Consequently, the concern for bias in selecting lecturers from the pharmaceutical/biotech industry is minimal and should be encouraged for future course development.

The number of medical students enrolled in the course was 6, 0, and 1 for 2010, 2011, and 2012, respectively. We speculate that the primary reason for the low medical student enrollment in 2011 and 2012 was due to implementation of a revised medical school curriculum in the fall of 2011, which resulted in decreased medical student availability. We also observed a low number of enrolled law students in 2012. This may be due to the lack of relevant content, thus negating law student interest. In 2013, the course co-chairs revised the didactic lectures to include discussion of intellectual property and patent strategy to provide relevant content for law students.

The majority of students rated the question and answer panel session as 'useful' (Table 3). It may be possible that speakers who were not specific to the student's profession (e.g. physician speaking to a business student), may not be perceived as 'useful' by the student. One modification being considered is to decrease the time for a panel session and to allocate the extra time to have the speakers meet with students who are in the same profession.

Implications of the PLSP Assignment

The PLSP assignment was created for students to actively work together to prepare them for the multidisciplinary environment similar to what one would expect for a project team in a pharmaceutical/biotech company. PLSPs are commonly performed in a pharmaceutical/biotech company. Members of the project team are responsible for providing written and verbal input on specific content, which is then used by upper management in making key decisions for the drug under development. As described in Table 2, specific content includes, but is not limited to, preclinical, clinical, and regulatory strategy. Often such content are provided by a project team member with training in a specific discipline. Consequently, it was critical for the course to enroll students from different disciplines to fully maximize the PLSP assignment. Student input and perspective was expected to vary based on formal training. For example, business, but few pharmacy and medical students, readily identified a SWOT analysis, drug value proposition, and drug positioning statement. In contrast, pharmacy and medical students readily identified phase 3 primary and secondary endpoints and key clinical study design aspects.

The majority of students rated the PLSP assignment as 'useful' (Table 3). One challenge of the PLSP project was the difficulty of obtaining relevant literature on a specific drug for a PLSP. Students were familiar with searching for research articles on PUBMED, but were unaware and/or unfamiliar with regulatory and financial websites. Future revisions to the PLSP assignment are to include an example PLSP

presentation as course material, highlight suggested websites to obtain PLSP information, and provide recommended readings regarding PLSPs.

Future Direction and Research

Interest has been expressed to provide this elective as an online course. There has been significant adoption of internet-based instruction with the proliferation of massive online open courses (MOOCs). MOOCs are a distance learning model providing large-scale interactive participation. Instructional design approaches include peer-review, group collaboration, and automated quizzes and exams.[17] Significant developments have occurred, such as increased acceptance by higher education institutions and the ability to obtain course credit.[18]

In April 2013, this elective was made available as a MOOC.[19] One key difference between the MOOC and 'live' course was the lack of student prerequisites for the MOOC. This was done to maximum student interest and enrollment. Live lectures were videotaped, edited by on campus media consultants, and then uploaded onto a website. Multiple choice quizzes for each lecture were implemented for the MOOC. Regarding the PLSP presentation, an informational video presentation was developed for the students. Students self-organized into groups by communicating through a posted, discussion forum. PLSP presentations in PowerPoint™ format with audio were uploaded into a website for review. A grading rubric for the PLSP presentation was developed and implemented (Appendix 1) for the MOOC, which will also be adapted for the 'live' elective course.

Although our primary intention of the MOOC was to provide a course to students from other Schools/Colleges of Pharmacy where a course on drug discovery, development, and commercialization was not offered, students from various disciplines and educational backgrounds enrolled in the MOOC. The co-chairs speculate that offering such as course would spur not only pharmacy student interest, but interest from students with different educational backgrounds to potentially look beyond his/her traditional work practices. In our experience with meeting SSPPS students, several have expressed interest in the pharmaceutical/biotech industry, but lack sufficient background and depth of pharmacist roles, responsibilities, and expectations when employed for such industries. Whether or not such as course leads to an increase in pursuing postdoctoral pharmaceutical fellowships remains an intriguing area of future research. We hope that a course on drug discovery, development, and commercialization allows students to foster an appreciation for the process and to be better informed about the safety, efficacy, and economic aspects of novel drugs and treatments.

Conclusion

Drug discovery, development, and commercialization is a complex process requiring an interdisciplinary approach involving individuals with advanced training and formal education in pharmacy, medicine, biomedical sciences, law, and business. Offering an interdisciplinary elective course to students is an opportunity to increase understanding of the drug discovery, development, and commercialization process. Didactic teaching, interactive student groups, a longitudinal assignment, and a question and answer panel session were instrumental in the implementation of the elective course. The course provided useful information in the drug discovery, development, and commercialization process, with student-reported understanding in these areas.

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Table 1. Didactic lectures for elective course in drug discovery, development, and commercialization

	Lecture Topic
1.	Current state of affairs of the pharmaceutical/biotech industry
2.	Development of a life cycle strategic plan and intellectual property strategy
3.	Drug targets and tools during preclinical development
4.	Role of genomics and proteomics in drug discovery
5.	Compound selection and preclinical studies
6.	Impact of translational research in drug discovery
7.	Clinical development: Strategy and design
8.	Role of the Food and Drug Administration (FDA) and overview of the Investigational New Drug (IND) process
9.	Formulation development and manufacturing
10.	Clinical study start-up activities
11.	Clinical trials: Phase 1,2,3,4
12.	Pharmacoeconomics in drug development
13.	New Drug Application (NDA) filing and product labeling
14.	Drug commercialization strategies
15.	The value of marketing research
16.	Business development in the pharmaceutical/biotech industry
17.	Managed care and sales strategies

Table 2. Content specifics for the student group product lifecycle strategic plan

Section
1. The Market
a. State if the drug addresses an unmet medical need
b. Determine if there is a market opportunity for the drug
c. Summarize benchmarking analysis information
d. Summarize competitive landscape for the drug
2. Preclinical
a. Summarize current product profile
b. Identify mechanism of action
c. Summarize animal data regarding pharmacokinetic data, efficacy, and toxicity
d. Describe current dosage forms and route of administration
3. Early clinical development
a. Summarize phase 1 safety and tolerability data
b. Summarize human pharmacokinetic properties of drug
c. Summarize phase 2 dose finding or dose ranging study findings
d. Determine recommended starting dose and dose frequency from phase 1 and 2 studies
4. Late clinical development
a. Identify phase 3 primary and secondary endpoints
b. Describe phase 3 clinical study design
c. Provide additional safety data from phase 3 clinical studies
d. Summarize finding of pharmacoeconomic studies
5. Regulatory strategy
a. State which regulatory agencies have approved the drug
b. Determine if a local or global regulatory strategy was implemented
c. State 1 indication the drug is approved for
d. State approved dosage form and dosing schedule
e. Identify anticipated or desired patient population
6. Marketing strategy
a. Determine appropriateness of the drug's marketing strategy
b. Describe the market at the time of drug launch
c. Interpret strength, weaknesses, opportunities, and threats (SWOT)
d. Develop a drug value proposition
e. Develop a drug positioning statement
f. Identify pricing strategy
7. Sales strategy & managed markets
a. Describe sales strategy
b. Identify the sales tactics or methods when the drug was first launched
c. Describe advertising campaigns
d. Summarize sales volume of drug
e. Determine stage of the life of the drug (e.g. Introduction, growth, maturity, decline)

Table 3. Course evaluation scores completed by students enrolled in drug discovery, development, and commercialization elective (n = 57).

Item	Student Response, n (%)				
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Course objectives were clear	0 (0)	1 (2)	3 (5)	32 (56)	21 (37)
Course content was well organized	0 (0)	0 (0)	7 (12)	35 (61)	15 (26)
Course included interpretation and application of information	0 (0)	2 (4)	1 (2)	39 (68)	15 (26)
Course provided an unbiased perspective	1 (2)	1 (2)	6 (11)	36 (63)	13 (23)
Course provided useful information on:					
drug discovery	0 (0)	0 (0)	5 (9)	22 (39)	30 (53)
drug development	0 (0)	0 (0)	1 (2)	22 (39)	34 (60)
drug commercialization	0 (0)	0 (0)	4 (7)	19 (33)	34 (60)
I would recommend this course to other students	0 (0)	0 (0)	4 (7)	26 (46)	27 (47)
Overall, I rate this course highly	0 (0)	0 (0)	4 (7)	20 (35)	33 (58)

Table 4. Student-reported understanding and usefulness of various program components (n = 57).

Item	Student Response, n (%)				
	Poor	Fair	Good	Very Good	Excellent
Overall understanding of the drug discovery process	0 (0)	2 (4)	19 (33)	28 (49)	8 (14)
Overall understanding of the drug development process	0 (0)	3 (5)	18 (32)	26 (46)	10 (18)
Overall understanding of the drug commercialization process	0 (0)	5 (9)	26 (46)	19 (33)	7 (12)
	Not at all Useful	Not Useful	Neutral	Useful	Very Useful
Product lifecycle strategic plan presentation	0 (0)	2 (4)	19 (33)	28 (49)	8 (14)
Question and answer panel session	0 (0)	3 (5)	18 (32)	26 (46)	10 (18)

Appendix 1. Grading rubric for student group product lifecycle strategic plan

Criteria	**Scale** 2 = excellent; 1 = average; 0 = poor		
Presentation Content			
The market	0	1	2
Preclinical	0	1	2
Early clinical development	0	1	2
Late clinical development	0	1	2
Regulatory strategy	0	1	2
Marketing strategy	0	1	2
Sales strategy and managed markets	0	1	2
Presentation Style			
Each student created section of presentation	0	1	2
Organization of presentation	0	1	2
Quality of presentation materials	0	1	2
Poise of verbal delivery of presentation	0	1	2
Grammar and punctuation of presentation	0	1	2
Thoroughness of presentation	0	1	2
Clarity of presentation	0	1	2
Perceived student knowledge of the drug	0	1	2
Total possible points (maximum of 30 points)			