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Research Article

Conversion of a Face-to-Face Short Course to a Blended Distance Education Program Available for Industrial Scientists Worldwide

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Abstract

This study outlines the preliminary results of a converted face-to-face (F2F) drug development program to a blended distance education model due to a reduction of economic resources within the targeted population of pharmaceutical scientists. The economic downturn of the 'Great Recession' resulted in a constriction of professional development participants within historical solid programs offered by the University of Wisconsin-Madison School of Pharmacy, Division of Pharmacy Professional Development. This slump in registrations required faculty to review the process and delivery of programs, as well as identify opportunities for innovation. Converting existing programs to an online model in an effort to address shrinking training and development funds. When comparing the programming evaluation of the F2F program to those of the online learners, preliminary evaluations suggests that programming quality was as high and that the delivery modality did not harm overall content application. Although this program involved the professional development for pharmaceutical scientists, similar approached to repurposing face-to-face educational materials could be used for continuing education programs for other professional audiences.

Keywords: Distance Education, Online Learning, Professional Development, Computer-Based Training (CBT), eLearning, Web-Based Training (WBT), Webinar, Self-Paced Learning

1. Introduction

The Division of Pharmacy Profession Development in the School of Pharmacy at the University of Wisconsin-Madison has a long history of providing continuing education programs for both pharmacists nationwide and pharmaceutical industry scientists worldwide. With industrial downsizing and company reduction in travel allowances, scientists have increasingly requested more accessible programs requiring less travel. To meet these learner's needs the Division decided to modify and repurpose one of its earlier drug development course as a distance education

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program. "An Introduction to the Drug Development Process: Chemistry, Manufacturing and Controls" was based on a previous five-day on-campus short course designed to survey the entire drug development process, focusing mostly on work up to the first-in-man clinical trials. This paper discusses the process used to repurpose this previously well accepted F2F short course into a more easily available distance education offering.

2. Barriers for Participation in Live On-campus Programs

The economic aftermath of the 'Great Recession' in 2008 has been said to be the most significant economic downturn since the 'Great Depression' of 1930 (Hodgson, 2009). The impact on the pharmaceutical industry cannot be understated. According to the Tufts Center for the Study of Drug Development, the most current estimates around brining a new drug to market was roughly $2.6 billion, an increase from $802 million in 2003 (Avorn, 2015; Tufts, 2014). While some may debate how these costs are actually calculated, it is clear that the expenditures are great. According to Raghavendra et al. (2012), biotechnology and pharmaceutical companies are finding ways to regain profitability in a market where a majority of the indicators are pointing towards overall economic health. The Deloitte Centre report (2015) suggests that the drop in research and development (R&D) within pharmaceutical companies, including contract research organization (CROs), has resulted in an immediate cost-saving but not without risk. The report contends that this reduction in R&D will likely produce a recognizable lessening of new product development, putting greater pressure on profitability over the longer term.

The legitimate and real concerns around economic downturn and profitability has recently resulted in numerous closings or mergers and acquisitions within the biopharmaceutical industry. For example, in 2015 Pfizer closed a number or R&D facilities (Carroll, 2015), as well as acquired Allergan Pharmaceuticals (LaMattina, 2015). Other companies such as Roche, Sanofi, GSK, and Merck all made major changes to their R&D operations. In addition, according to a 2014 employment study, Bristol-Myers Squibb and Pfizer experienced their largest layoffs, each terminating 36% of their workforce (Brown, 2014).

As profitability decreases for the larger pharmaceutical companies, travel and educational training budgets are often the first to suffer. Similarly, smaller and start-up companies also have limited budgets to provide training or educational support for their scientists. All result in decreased pool of learners for live professional development programs and scientific conventions. The numbers are fairly clear, there was a decline of $12 billion in the inflation-adjusted U.S. expenditures within pharmaceutical industry from 2007 to 2012 and this was driven by a $12.9 billion reduction in industry's investment in general R&D, including training and professional development activities. The overall impact on the U.S.' share of global industry R&D expenditures decreased from 50.4% in 2007 to 42.3% in 2012" (LaMattina, 2014, page 2).

3. Limitations of Live, Face-to-Face Programs

Continuing education and professional development (CEPD) is a changing field of instruction due to the use of tools that allows for on-demand, anytime access to content. For example, the use of learning technologies enable a more customize and personal approach to professional development

that differentiates learner's experiences when compared with some face-to-face programs (Patterson, Stephens, Chiang, Price, Work, and Snelgrove-Clarke, 2017). However, when considering why the field is changing, it is important to review the overall limitations of live, F2F training. When considering the major limitations to F2F learning it is clear that access (Tiene, 2000), convenience (Johnson et al., 2000) and timing (Meyer, 2003) were all limitations within this model of CEPD. In addition, the target population is changing and may be expecting more online learning opportunities within CEPD programs. According to Burns (2011), learning populations are radically changing in how they interact with information, as well as how they learn and balance life-pressures such as work, family, and other responsibilities. This confirms the past research that identified job constraints, scheduling, and family obligations as barriers to professional development (Hanson and DeMuth, 1991; Hanson et al., 2007). The emerging learners today, or 'digital natives' (Prensky, 2012) are being conditioned to learn through new media (Montrieux, Vangestel, Raes, and Matthys, 2015). This changing population has resulted in the rapid increase of online learning within for-credit programs and are now considered the most common method of delivery (Babson, 2016, Allen and Seaman, 2013; McClinton and Estes, 2013). While the field is changing, research is exploring the ubiquitous teaching methodologies found between each delivery modality (Diaz and Entonado, 2009).

Overall, online learning offers a flexibility that is not easily achieved than F2F programs by virtue of enabling access from anywhere with an internet connection (Bhagat, Wu, and Chang, 2015). Several studies have shown that students that took online courses all cites convenience and flexibility as the main reasons for this model of learning (Bhagat, Wu, and Chang, 2015; Van Doom and Van Doom, 2014; Cuthrell and Lyon, 2007; Fortune et al., 2011). Furthermore, it appears that within some populations the traditional F2F learning and delivery model is not conducive to all learning styles (Gilardi and Guglielmetti, 2011; Kuo, Chu, and Huang, 2015; Weiermann, 2012). While both F2F and online learning models have been shown to increase overall knowledge transfer (Mebane et al., 2008), online learning allows for more 'real time' understanding of how students are learning through a variety of analytical tools that come with online learning management systems. This method of empirical data is difficult to collect and analyze while a F2F program is taking place.

While online and F2F learning are considered valuable models of teaching, the data is clear that audience plays a key role in the overall value and effectiveness in learning. Although this may not applied to older learners, the younger 'digital natives' are having their preferences molded through other forms of media and this formulation is leading to changing expectations within their learning. This is resulting in a greater desire for 'on demand' learning when it is convenient for them and the schedules that impact their daily life. Today, millennials are a part of the 'Net Generation' and will continue to drive the behaviors of future learning models due to their deep and vast experience with web-enabled devices such as computers, tablets, and smart phone (Chee, Yahaya, Ibrahim, and Hassan, 2017; Barnes et al., 2007). The interaction with these types of devices has led to a desire for more immediate gratification and feedback by the learners (Khaddage, Muller, and Fintoff, 2017; Sweeney 2006). In addition, faculty and instructors have an equally important advantage to better understand how participants are learning through metrics and analytics.

4. Original On-campus Program

In 2004, a new short course "Applied Drug Development: Preclinical and Drug Product Design

Strategies" was developed by the School of Pharmacy at the University of Wisconsin-Madison to explore the various disciplines responsible for developing and advancing an investigational new drug. Too often scientists become isolated within their own science and lose track of or are never exposed to all the various disciplines involved with drug development. The purpose of the new course was to provide learners a survey of the various aspects of non-clinical drug development from lead molecule characterization and preclinical evaluation, to the FDA approval of a new drug product. Within this context, the learners were to become familiar with the key science and technologies that support the drug development process. The course used examples for both small and large molecules and addressed issues from discovery to NDA/BLA filings. This unique course features two tracks: 1) the CMC (chemistry, manufacturing and controls) aspects of development, as carried out by pharmaceutical chemists and technologists, industrial pharmacists and engineers; and 2) the biology side of the development process as performed by toxicologists, pharmacologists, pharmacokineticists, and clinical project managers (Table 1). After meeting as the total class the first day, scientists attended one of the two tracks for the second and third days. Each track explored the scientific requirements, as well as the interactions essential to all stakeholders in the technical development of a new drug entity and their activities as driven by regulatory mandates. The focus of these two days was on the science of drug development, intended to help the learner better understand how, where and with whom to appropriately follow up with his/her work responsibilities. During the fourth and fifth days the learners met as a single group to discuss a series of case studies and apply the course materials from the first three days. At the end of the fourth day they were divided into teams with learners from both the CMC and biology tracks. These team were presented with a potential drug entity and asked to prepare a work plan on how they would study this drug in preparation for submitting an investigational new drug application (IND). During the final morning each team presented its proposal to senior management (the course faculty). Upon completion of the program the learner were expected be able to: 1) contribute to the overall development plan with activities that are relevant to his/her respective discipline; 2) better understand and explain the relationships and interdependencies between the chemical, biological and clinical disciplines that must collaborate effectively; 3) better anticipate the challenges, choices and key decision-making steps that face the development team in bringing a new drug product to market; and 5) apply a broader understanding of the development process to bring about more effective problem solving to the development program. The course was developed and presented by individuals experienced in working for the pharmaceutical and knowledgeable of the products used in the course case studies.

5. Development of a Certificate Program in Drug Development

Shortly after the introduction of "Applied Drug Development: Preclinical and Drug Product Design Strategies" two additional CMC courses (24 hours each) were developed "Physicochemical Characterization, Solubilization and Solid Form Screening for Drug Candidate Selection" (2007) and "Practical Strategies for Phase 1 Oral Drug Formulations" (2008) to complete a curriculum on early drug development. Based on these previous student requests, it was decided to develop a certificate program in drug development with these initial three course constituting the "core" curriculum. The certificate program was initiated for scientists completing these three CMC core courses and selected elective which could be selected based on the needs or interests of the individual learners. The certificate program is not for academic credit and does not lead to the conferral of a degree as defined by the University of Wisconsin (UW) Graduate School. Rather, a

certificate program is a focused series of courses, that when completed, afford the student a record of coherent academic accomplishment in a given discipline or set of related disciplines.

A minimum of 100 hours (four or five courses) are required to receive a drug development certificate. In addition to the core and elective courses, learners are required to submit a reflection exercise on the course work completed and application to current or future work in the pharmaceutical industry. This required report was intended to allow the learner to discuss the learning experience, what materials were learned, how the materials had been or will be applied in future work endeavors, aspects of the courses that were most useful, and things lacking in the course contents that would improve their utility. Not only does the exercise serve as an evaluation of the certificate program as a whole, but also allows the learner to reflect back on the course materials learned and look forward on how this newfound knowledge can be applied to his or her profession.

However, with the downturn in economy, reductions in staff and travel allocations, outsourcing of discover and analytical activities, and reductions in travel and training budgets; attendance at in the original annual course began to decrease. Even though over 95% of the participants "agreed" or "strongly agree" that they would recommend this course to their colleagues, enrollments dropped. Registrations fell from high of 38 learners in 2007 to only 13 in 2010. Finally in 2011 it was decided to discontinue the original F2F program because large enough audiences for the two track course could not be recruited to maintain the two separate tracks, sufficient discussion for the case studies and composition of the role playing teams. Evaluations for the 31 hour live course were excellent. Presented in Table 2 are the cumulative evaluations for the seven years this course as offered. Because of the response to the program, it was decided to attempt to repurpose the contents of the CMC track as a distance education program.

With the discontinuation of the initial five-day short course, a previous elective course "CMC Project Team Leadership - The Science, Principles, and Practices for Successful Technical Teams" was modified and expanded to include some of the course materials from the discontinued course. The CMC team management course became the replacement core course for the certificate program.

6. Development of a New Distance Education Program

Early in 2014 the faculty from the original drug development short course met to discuss the possibility of modifying the program and offer it as a distance learning experience. The six faculty members represented over 85 years of experience in drug development in the pharmaceutical industry. During three teleconferences the contents for the new course were developed based on the faculty's industrial experience and from what they observed teaching the original live program.

Since two other course existed with a focus on the CMC track in drug development, it was determined to initiate development of a new "introductory" course and that it would emphasize only the CMC aspects. It was further decided that the course would be a "blend" distance education course with asynchronous lectures that the learners could listen to at their leisure and live webinars where case studies could be discussed and questions could be addressed to the faculty.

All the faculty agreed to participate by: 1) updating and recording their previous lectures and 2) making themselves available for discussions with the students on drug development issues. The course development involved recording and editing the individual lectures for the asynchronous portions of the program and revising the case studies for the live webinars. All the case studies involved products where at least one of the faculty members was involved with its actual development. These were accomplished during 2014 and the course was initially presented during Spring 2015.

7. Advantages of a Blended Distance Education Program

The changing learner demographics has driving many of the changes within higher education resulting in new and innovative way of teaching a wide variety of audiences. With the advent of online learning many continuing education and professional development programs are being forced to discuss a variety of assumptions around the expectations and demands of the potential audiences (Garrison and Kanuka, 2004). Today the term distance education has been absorbed by the term online education (Larreamendy-Joerns and Leinhardt, 2006), with blended learning being considered a component. When discussing online learning, it is clear that many suggest quality is a concern. However, research suggests that there is no significant difference between traditional F2F learning models and the more recent online learning environments (Lorenzo and Moore, 2002; Swan, 2004). According to the U.S. Department of Education (2010, page xviii) "…when used by itself, online learning appears to be as effective as conventional classroom instruction, but not more so." While there appears to be little difference between the two delivery models, some are considering the potential benefits of blended learning programs.

Even though there is no clear metric for the needed mix between online and F2F learning, this model of instruction does have benefits (Garrison and Kanuka, 2004). The advantage to blended learning is that is allows for a variety of individual learning styles and allow all enrollees to participate equally through a variety of methods such as live, technology mediated conversation, discussion forums, as well as the ability to build and maintain a community of inquiry through practice (Wenger et al., 2002; Garrison and Kanuka, 2004; Gray, 2004; Hudson, 2002). Blended learning enables the social and instructional interactions that may not lend themselves to online delivery leading to the potential for deeper understanding than left to learn the information in a very connected manner. For example, Hudson suggests, "that the very basis of thinking is rooted in dialogue, drawing on a socially constructed context to endow ideas with meaning" (Hudson, 2002, page 53).

In addition, the creation of online and blended learning programs allow for a strategic advantage for organizations. Higher education institution are routinely focused on budget constraints within every corner of the institution and blended learning may offer some ability to reduce costs on a variety of fronts. Offering traditional F2F programs requires physical space, which is usually at a premium within institutions of higher learning. By offering blended programs, institutions are able to robustly diversify offering in a way that does not put greater dependence on physical infrastructure, such as classrooms (Osguthorpe and Graham, 2003). Similarly, blended learning may offer an ability to utilize subject matter experts (SME), not just full-time instructors. For this course, financial considerations were not as important as the creation of structure (beginning and ending webinars) and the opportunity to interact with the program faculty.

8. New Blended Distance Education Program on Drug Development

The new course is titled "An Introduction to the Drug Development Process: Chemistry, Manufacturing and Controls" to clearly identify the focus of the course and the scientist most appropriate for participating in the course. The purpose of this blended distance education course is to provide the learners with a comprehensive overview of the process of nonclinical drug development from lead molecule characterization and preclinical evaluation, to the approval by various agencies of a new drug product. The primary objectives are to understand: 1) the relationships and interdependencies between the chemical, biological and clinical disciplines in a collaborate effort to develop a pharmaceutical produce; 2) how the overall product development plan relates to his/her respective discipline; 3) what challenges, choices and key decision-making steps are faced by the development team in bringing a new drug product to market. To accomplish these objectives the attendee are to become familiar with the key science and technologies that support the drug product development process. The course uses therapeutic examples presented as case studies and addressed key regulatory issues arising from discovery to NDA filings. Overall the learner should be more effective in problem solving during the development program.

As noted in the initial planning for the course, rather than offering a completely asynchronous web-based program, it was decided to present the course with definite starting and closing dates by using webinars to introduce and end the program. The presentations for this course consist of an initial webinar with two introductory lectures and is followed by 12 asynchronous lectures that the scientist can complete at their leisure over a six to eight week period. In order to advance to the next lecture, the learner is required to complete a self-check test to help reinforce the important points in each lecture. Six to eight weeks later there is an intermediate webinar to review an exercise form the last asynchronous lecture and discuss a drug product case study. Then over an additional three to four week period the enrollees are required to complete six additional asynchronous lectures using the same format as the previous lectures. The course concludes with a webinar which reviewed any new regulatory issues (e.g., FDA guidances or EMA requirements), presented two case studies and provided the opportunity to ask questions of any of the program faculty. During any of the three webinars, learners have the opportunity to share any concerns they have regarding the course materials and request additional information or clarification from faculty members. The contents of the blended course are presented in Table 3. The initial offerings of the course was presented during in the Spring and Fall of 2015 and the Spring of 2016.

9. Program Evaluations from the Initial Presentations

The initial three offerings of this new distance education course during 2015 and 2016 consisted on only 27 students, but represented a course completion rate of 84.4%. This was a very good completion rate compared to other distance education programs, as suggested by Nash (2005). Historically, learners within distance education programs drop-out for a variety of reason, some of which include timing, familial responsibilities, and overall workload (Thompson, 1997). The 'true' average of completion rates for online learners has yet to be identified. However, some suggest that the completion rate for F2F students is double that of online learners (Willging and Johnson, 2004). Completion rates get evermore cloudy when we consider non-credit students. However, it is known

that completion rated for Massive Open Online Courses, or MOOCs, are consistently between two and 10 percent (Reich, 2014).

To complete the course participants were required to complete a course evaluation which included their certification that they completed the entire program. Evaluations of this course were extremely positive (Table 4). In addition to the results reported in Table 4: 1) most learners (92.6%) felt the amount of time work required to complete the course was just right; only two people thought it was too much; 2) all the learners felt the program was fair, balanced, and free of commercial bias; and 3) regarding the technology involves in presenting/receiving this program 96.3% agreed that it was about right, only one person thought it was too technical. There were no significant differences is responses among the three groups taking the distance education program. With respect to scheduling, a total of 81.5% indicated that the length of time between the webinars required to complete the asynchronous units was about right. For the Spring of 2016 the times allowed for the asynchronous portions were shortened and the result was an increase in the proportion of people who thought the time was too short (25%). It appears that longer time periods for asynchronous lesson completions are preferred by the learners. This might have also been reflected in the scoring for the effectiveness of the asynchronous portions with a decrease from a mean of 4.00 for the first two presentations to a mean of 3.58 for the Spring of 2016.

10. Summary

When producing an online course or program some may assume this is a process that allows for a 'build and forget it' model that allows for little to no updating. With the conversion of this online program, it is clear that requirements for providing a useful learning experience requires a far deeper understanding of the learners. The preliminary reviews of the online course were positive and were in line with the previous F2F course. With the original course lasting a mere five days when compared to the current model of approximately three months, instructors and students are required to be far more engaging, responsive, and connected. With the new course having a longer timeline, the opportunity for external events impacting learner's ability for completion is greater. It is remarkable that this the completion rate has stay at the level being reported. Additionally, it should be noted that the assessments related to overall quality and application are still very high, even with a far more rigorous expectations. Overall, the new program allows for more interaction between learners enabling deeper application and more value to the organizations paying for these professional development programs.

It is envisioned that this course will be offered twice a year. Based on the evaluation results and economic/logistical considerations, other UW- Madison on-campus short courses may be converted to distance education programs using this same or a similar format.

11. Tables

Table 1. Course Design for Original Live Drug Development Program

	Contents
Day One	1. Welcome and course overview

	2. Introduction to the Drug Development Process 3. The Regulatory Environment 4. Drug Development on a Global Stage 5. Stages of Research and Development 6. An Introduction to the Investigational New Drug Application 7. Introduction to the Biology Track 8. Introduction to the CMC Track 9. Physical and Chemical Factors in Candidate Selection and Optimization 10. Biopharmaceutical Factors in Candidate Selection and Optimization: Preclinical Studies 11. Biopharmaceutical Factors in Candidate Selection and Optimization: Basic Pharmacokinetics and Pharmacodynamics
CMC – Track Days Two and Three	1. The "first 'C'" in "CMC" - How Does the Chemical Structure of an API Influence Its Formulation and Use? 2. Chemical Properties and Chemical Stability 3. Options for Optimizing the API Properties 4. Anatomy of the Dosage Form 5. Oral Drug Delivery and Dosage Forms 6. Parenteral Delivery 7. Other Dosage Forms 8. Open Discussion with Instructors 1. The "M" in "CMC" -- Process Development for API and Drug Product 2. The "second 'C'" in "CMC" -- Analytical Methods Development and Quality Control 3. Drug Product – Analytical Controls for Different Dosage Forms - Setting Specifications for the Certificate of Analysis 4. Clinical Supplies Manufacturing and Packaging, and Quality Assurance 5. Technology Transfer and Scale-up to Production/QC and the "Commercial" Product 6. Final CMC Remarks and Discussion
Biology – Track Days Two and Three	1. Introduction to Preclinical Drug Development ('Early Development' to IND Filing) 2. Small Molecule Therapeutics: Pharmacology & Pharmacokinetics ('Early Development' to IND filing) 3. Small Molecule Therapeutics: Toxicology Aspects ('Early Development' to IND filing) 4. Introduction to Preclinical Drug Development (IND Filing to NDA Filing) 5. Small Molecule Therapeutics: Pharmacology & Pharmacokinetics (IND Filing to NDA Filing) 6. Small Molecule Therapeutics: Toxicology Aspects (IND Filing to NDA Filing) 1. Biotechnology Therapeutics: Pharmacology & Pharmacokinetics ('Early

	Development' to IND Filing) 2. Biotechnology Therapeutics: Toxicology Aspects ('Early Development' to IND Filing) 3. Biotechnology Therapeutics: Pharmacology & Pharmacokinetics (IND to BLA) 4. Biotechnology Therapeutics: Toxicology Aspects (IND to BLA) 5. Current Scientific and Regulatory Issues Associated with Drug Development 6. Informal Round Table Discussion with Biology Track Faculty
Day Four	1. Introduction to Case Studies - - Patient, Technology, Regulatory & Competitor Considerations 2. Case Study 1 3. Case Study 2 4. Case Study 3 5. Case Study 4 6. Introduction to Project Team Role Playing and Plan Development 7. Group Activities: Preparation for Friday's Project Team Role Playing
Day Five (half-day)	1. Patenting Pharmaceuticals and Biopharmaceuticals 2. Regulatory Submissions 3. Submitting the NDA and Post Marketing Surveillance 4. Planning for pre-IND Success (presentation of role playing exercise)

Table 2. Evaluation Results for the Original Live Drug Development Course

	Mean	SD
Evaluation based on a Likert Scale (5 = excellent and 1 = poor)		
The total course	4.53	0.46
The instructors	4.40	0.63
The printed materials	4.22	0.57
The physical facilities	4.22	0.58
Evaluation based on a Likert Scale (5 = strongly agree and 1 = strongly disagree)		
The content seemed current.	4.52	0.45
The program content was relevant to my work responsibilities.	4.36	0.53
Overall, the program provided a valuable learning experience.	4.66	0.45
My personal objectives in attending the symposium were fulfilled.	4.47	0.50
I would recommend this program to a colleague.	4.67	0.41

Cumulative results from 153 learners, representing an 85.5% response rate.

Table 3. New Blended Course Design

Format	Contents
Live	Opening Live Webinar – One hour 1. Welcome and course design, deadlines 2. Introduction to the Drug Development Process *The drug product development process: it takes a team.* 3. An Introduction to the Investigational New Drug Application *The evolution between two key regulatory documents: the "IND" and how it evolves into the "NDA"or "BLA"*
Asynchronous	1. The Regulatory Environment on a Global Stage *The FDA considered as a "key customer", but is satisfying the FDA good enough for European and Japanese regulatory agencies?* 2. Stages of Research and Development and Associated Biology Issues that Need to be Considered *How does "R" develop into "D," and why does it get so expensive? The pre-clinical scientist must work with CMC to establish clinical product safety.* 3. Relevant Physical and Chemical Factors in Lead Optimization and Candidate Selection *The key physicochemical factors that are evaluated and often assist in distinguishing "lead compounds" from "development candidates."* 4. Preclinical Studies Supporting Candidate Selection and Optimization *The basics of testing API in animals and how these relate to CMC.* 5. The "first 'C'" in "CMC" – How Do the Chemical Structure and Associated Physical Chemical Properties of an API Influence Its Formulation into a Drug Product *How the chemical nature of a drug candidate influences its formulation and delivery.* 6. Chemical Stability in Drug Development *The importance of chemical stability in the development of new drug candidates.* 7. Options for Optimizing API Properties *What options are available to the chemist and pharmaceutical scientist to improve API properties?* 8. Anatomy of the Dosage Form *From "Target Product Profile" to Bottle: general aspects of formulation and dosage form.* 9. Oral Drug Delivery and Dosage Forms *The science behind designing the effective oral dosage form, liquid and solid.* 10. Parenteral Delivery *Designing the injectable when required, for small molecules and large-molecule biologicals.* 11. Other Dosage Forms

	When more specific routes of delivery are in order, such as oral inhalation, nasal, topicals and transdermals. 12. The "second 'C'" in "CMC" -- Analytical Methods Development and Quality Control *Typical approaches to small and large molecule API and Drug Product analysis, from* 13. Drug Product – Analytical Controls for Different Dosage Forms - Setting Specifications for the Certificate of Analysis *Appropriate product control, from manufacture to expiration.*
Live	Midcourse Live Webinar – Two hours 1. Review of Control Exercise 2. Case Study #1 3. Discussion and Questions on Any Materials Presented *Opportunity for participants to ask questions/clarification of faculty on any of the information presented up to this point in the course.*
Asynchronous	8. The "M" in "CMC" -- Process Development for API and Drug Product *Developing a reliable, scalable manufacturing process.* 9. Clinical Supplies: Manufacturing, Packaging, and Quality Assurance *From Preclinical product to Clinical product—the GMP jump.* 10. Technology Transfer and Scale-up to Production/QC and the "Commercial" Product *Effective technology transfer is a team sport.* 11. Regulatory Submissions *Anticipating the development cycle on the way to NDA and common technical document preparation, and how "compliance requirements" change during the course of development.* 12. Post Marketing Surveillance *If the NDA is "in," is the development scientist finished with the program?*
Live	Concluding Live Webinar – Three hours 1. Final CMC Remarks *Highlights on the previous discussions and a preview of upcoming case studies.* 2. Case Study 2 3. Case Study 3 4. Discussion and Questions on Any Materials Presented *Opportunity for participants to ask questions/clarification of faculty on any of the information presented up to this point in the course.*

Table 4. Evaluation Results for the New Blended Drug Development Course

	Mean	SD

Evaluation based on a Likert Scale (5 = excellent and 1 = poor)		
Practical nature of the information presented	4.04	0.34
The information presented in this program is of consistent quality.	4.30	0.52
The tasks in the course were easy to locate.	4.26	0.20
The asynchronous portions of this course were well designed.	3.96	0.58
The instructors' ability to convey the subject matter clearly.	4.30	0.83
Effectiveness of the learning activities in the asynchronous portions.	3.81	0.62
Effectiveness of the learning activities in the webinars.	3.67	0.92
Evaluation based on a Likert Scale (5 = strongly agree and 1 = strongly disagree)		
The program content was relevant to my work responsibilities.	4.33	0.23
I will be able to apply the information I have learned in this program.	4.37	0.32
Overall, the program provided a valuable learning experience.	4.19	1.16
My personal objectives in attending the symposium were fulfilled.	4.35	0.32
I would recommend this program to a colleague.	4.15	0.52

Results from 27 learners completing the initial three offerings of the course.

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Conflict of Interest

None

References

Allen, I. E., & Seaman, J. (2013). Changing course: Ten years of tracking online education in the United States. Babson Park, MA: Babson Survey Research Group.

Avorn, J. (2015, May 14). The $2.6 Billion Pill — Methodologic and Policy Considerations. The New England Journal of Medicine, 1877-1879. doi:10.1056/NEJMp1500848

Barnes, K., R.C. Marateo, & Ferris, S. P. (2007). Teaching and Learning with the Net Generation,. Innovate: Journal of Online Education 3 (4): Article 1. doi: http://nsuworks.nova.edu/cgi/viewcontent.cgi?article=1091&context=innovate

Chee, K., Yahaya, N., Ibrahim, N., & Hasan, M. (2017, April). Review of Mobile Learning Trends 2010-2015: A Meta-Analysis. Journal of Educational Technology & Society, 20(2), 113-126. Retrieved from http://www.jstor.org/stable/90002168

Bhagat, K., Wu, L., & Chang, C. (2016, January). Development and Validation of the Perception of Students Towards Online Learning (POSTOL). Journal of Educational Technology & Society, 19(1), 350-359. Retrieved from http://www.jstor.org/stable/jeductechsoci.19.1.350

Brown, A. (2014). Pharma & Biotech 2014 In Review. EP Vantage. ed. Urquhart L. London, England: Evaluate Ltd. Retrieved from http://info.evaluategroup.com/rs/evaluatepharmaltd/images/EPVPB2014.pdf

Burns, E. C. (2011). The Adult Learning: A Change Agent in Post-Secondary Education. Online Journal of Distance Learning Administration, 14(2). http://eric.ed.gov/?id=EJ941219

Carroll, J. (2015, February 24). Exclusive: Pfizer is once again cutting back R&D staff in reorganization. FierceBiotech. doi: http://www.fiercebiotech.com/r-d/exclusive-pfizer-once-again-cutting-back-r-d-staff-reorganization

Cuthrell, K., & Lyon, A. (2007). Instructional strategies: What do online students prefer? MERLOT Journal of Online Learning and Teaching 3 (4):357-362. http://jolt.merlot.org/documents/cuthrell.pdf

Diaz, L., & Entonado, F. (2009). Are the Functions of Teachers in e-Learning and Face-to-Face Learning Environments Really Different? Journal of Educational Technology & Society, 12(4), 331-343. Retrieved from http://www.jstor.org/stable/jeductechsoci.12.4.331

Fortune, M., Spielman M., & Pangelian, D. (2011, March). Students' Perceptions of Online or Face-to-Face Learning and Social Media in Hospitality, Recreation and Tourism. MERLOT Journal of Online Teaching and Learning 7 (1):1-16. http://jolt.merlot.org/vol7no1/fortune_0311.htm

Garrison, D. R., & Kanuka, H. (2004). Blended learning: Uncovering its transformative potential in higher education. The Internet and Higher Education 7 (2):95-100.

Gilardi, S., & Guglielmetti, C. (2011). University Life of Non-Traditional Students: Engagement Styles and Impact on Attrition. Journal of Higher Education 82 (1): 33-53.

Gray, B. (2014). Informal Learning in an Online Community of Practice. Journal of Distance Education 19 (1), 20-35

Hanson, A. L., & De Muth, J.E. (1991). Facilitators and barriers to pharmacists' participation in lifelong learning. American Journal of Pharmaceutical Education 55 (1):36–39.

Hanson, A. L., Bruskiewitz, R.H., & De Muth, J.E. (2007). Pharmacists' perceptions of facilitators and barriers to lifelong learning. American Journal of Pharmaceutical Education 71 (4): Article 67.

Hodgson, G. M. (2009). The great crash of 2008 and the reform of economics. Cambridge Journal of Economics 33 (6), 1205-1221. August 17, 2009. doi:10.1093/cje/bep050

Hudson, B. (2002). Critical dialogue online: Personas, covenants, and candlepower. In Handbook of Online Learning: Innovations in Higher Education and Corporate Training, eds. Rudestam, K.E. and J. Schoenholtz-Read, 53–90. London, England: Sage Publishing.

Johnson, D., Sutton, P., & Poon, J. (2000). Face-to-face vs. CMC: Student communication in a technologically rich learning environment. Paper presented at the 17th Annual Conference of the Australian Society for Computers in learning in Tertiary Education: ASCILITE 2000, Coffs Harbour, Australia Retrieved from http://www.ascilite.org/conferences/coffs00/papers/daniel_johnson.pdf

Khaddage, F., Muller, W., & Flintoff, K. (2016, July). Advancing Mobile Learning in Formal And Informal Settings via Mobile App Technology: Where to From Here, and How? Educational Technology & Society, 19(3), 16-26. Retrieved from http://www.jstor.org/stable/jeductechsoci.19.3.16

Kuo, Y., Chu, H., & Huang, C. (2015, April). A Learning Style-based Grouping Collaborative Learning Approach to Improve EFL Students' Performance in English Courses. Educational Technology & Society, 18(2), 284-298. Retrieved from http://www.jstor.org/stable/jeductechsoci.18.2.284

LaMattina, J. (2014). Pharma R&D Cuts Hurting U.S. Competitive Standing. Forbes. January 3, 2014. Retrieved from http://www.forbes.com/sites/johnlamattina/2014/01/03/pharma-rd-cuts-hurting-u-s-competitive-standing/#259d4dd101fc

LaMattina, J. (2015). Will Acquiring Allergan Impact Pfizer's R&D? Forbes. November 2, 2015. Retrieved from http://www.forbes.com/sites/johnlamattina/2015/11/02/will-acquiring-allergan-impact-pfizers-rd/#567324d5708b

Larreamendy-Joerns, J., & G. Leinhardt (2006). Going the distance with online education. Review of Educational Research 76 (4):567-605.

Lorenzo, G., & Moore, J. (2002). The Sloan Consortium Report to the Nation: Five pillars of quality online education. Newburyport, MA: Online Learning Consortium. November 2002. Retrieved from http://wwww.edtechpolicy.org/ArchivedWebsites/Articles/FivePillarsOnlineEducation.pdf

McClinton, J., & Estes, M.D. (2013). Vision and Strategy for Developing a Successful Online Degree Program on a Shoestring Budget. In Cases on Educational Technology Implementation for Facilitating Learning. Eds. Ritzhaupt, A. D, & Kumar, S. 253-271. Hershey, PA: IGI Global.

Means, B., Toyama, Y., Murphy, R., Bakia, M., & Jones, K. (2010). Evaluation of evidence-based practices in online learning: A meta-analysis and review of online learning studies, Washington, D.C.: U.S. Department of Education, Office of Planning, Evaluation, and Policy Development.

Mebane, M., Porcelli R., Iannone, A., Attanasio, C., & Francescato, D. (2008). Evaluation of the efficacy of affective education online training in promoting academic and professional learning and social capital. International Journal of Human-Computer Interaction 24 (1):68-86.

Meyer, K. A. (2003). Face-to-Face versus threaded Discussions: The role of time and higher-order thinking. Journal of Asynchronous Learning Networks 7 (3):55-65.

Montrieux, H., Vangestel, S., Raes, A., Matthys, P., & Schellens, T. (2015, January). Blending Face-to-Face Higher Education with Web-Based Lectures: Comparing Different Didactical Application Scenarios [Electronic version]. Educational Technology & Society, 18 (1), 170-182.

Nash, R. D. (2005). Course Completion Rates among Distance Learners: Identifying Possible Methods to Improve Retention. Online Journal of Distance Learning Administration, 8 (4) Winter 2005. Retrieved from http://www.westga.edu/~distance/ojdla/winter84/nash84.htm

Osguthorpe, R. T., & Graham, C. R. (2003). Blended learning systems: definitions and directions. Quarterly Review of Distance Education 4 (3):227–233.

Patterson, C., Stephens, M., Chiang, V., Price, A., Work, F., & Snelgrove-Clarke, E. (2017, January). The significance of personal learning environments (PLEs) in nursing education: extending current conceptualizations. Burse Education Today, 99-105. doi:10.1016/j.nedt.2016.09.010

Prensky, M. (2012). From Digital Natives to Digital Wisdom. Thousand Oaks, CA: Corwin, a SAGE Publishing Company. Retrieved from http://marcprensky.com/writing/Prensky-Intro_to_From_DN_to_DW.pdf

Raghavendra, M. S., Raj, J.R., & Seetharaman. A. (2012). A study of decrease in R&D spending in the pharmaceutical industry during post-recession. International Journal of Academic Research 4 (5):29-47.

Reich, J. (2014). MOOC Completion and Retention in the Context of Student Intent. Educause Review. December 8, 2014. Retrieved from http://er.educause.edu/articles/2014/12/mooc-completion-and-retention-in-the-context-of-student-intent

Swan, K. (2004). Learning online: Current research on issues of interface, teaching presence and learner characteristics. In Elements of Quality Online Education: Into the Mainstream, eds. Bourne, J.R., & Moore, J.C., 63-80. Needham, MA: Sloan Center for Online Education.

Sweeney, R. (2006). Millennial behaviors and demographics. Retrieved from https://pdfs.semanticscholar.org/4fda/fa7b40ada4037374fe4c0c5ad60ee22f5124.pdf

Terry, C., & Remnant, J. (2015). Measuring the return from pharmaceutical innovation 2015. London, England: Deloitte Centre for Health Solutions. Retrieved from https://www2.deloitte.com/content/dam/Deloitte/ec/Documents/deloitte-analytics/Estudios/pharma-innovation.pdf

Thompson, E. (1997). Distance education drop-out: What can we do? In Learning Through Teaching, Proceedings of the 6th Annual Teaching Learning Forum, eds. Pospisil R. and L. Willcoxson, 324–332. Perth, Australia: Murdoch University. Retrieved from http://clt.curtin.edu.au/events/conferences/tlf/tlf1997/thompson.html

Tiene, D. (2000). Online discussions: A survey of advantages and disadvantages compared to face-to-face discussions. Journal of Educational Multimedia and Hypermedia 9 (4):371-84.

Tufts Center for the Study of Drug Development. (2014, November 18). How the Tufts Center for the Study of Drug Development pegged the cost of a new drug at $2.6 billion. Retrieved from http://csdd.tufts.edu/files/uploads/cost_study_backgrounder.pdf

Van Doom, J. R., & Van Doom, J.D. (2014). The quest for knowledge transfer efficacy: blended teaching, online and in-class, with consideration of learning typologies for non-traditional and traditional students. Frontiers in Psychology, 5:324, April 17, 2014. doi. 10.3389/fpsyg.2014.00324

Weiermann B., & Meier, B. (2012). Implicit task sequence learning with auditory stimuli. Journal of Cognitive Psychology 24 (4):468–475. doi. 10.1080/20445911.2011.653339

Willging, P.A., & Johnson, S.D. (2009). Factors that Influence Students' Decision to Dropout of Online Courses. Journal of Asynchronous Learning Network 8 (4): 105-118.

Wenger, E., McDermott, R., & Snyder, W.M. (2002). Cultivating Communities of Practice: a guide to managing knowledge. Brighton, MA: Harvard Business Publishing.