

What's So Distant About Distance Education? Online Learning in Regulatory Affairs Graduate Programs

By Eric D. Kupferberg, PhD, and Charles Kilfoye, MA



Introduction

I am writing as a convert. Not as a zealot, *per se*, but certainly as someone who was not immediately predisposed to be a strong supporter of online graduate education. My own career trajectory pointed in quite the opposite direction. Prior to coming to Northeastern University as an assistant dean in 2006, I had spent nearly 20 years at two of the most prestigious educational institutions in the US. For my doctoral training in the history and sociology of science I followed a traditional path that did not differ from what was common in the late 19th century. I studied at the feet of a world-renowned expert who spoke with an Eastern European accent so thick that no casual listener would believe she had been in the country for three decades. Our seminars were held at her townhouse in Boston's historic South End, with fine wine and cheeses with uncertain smells and unpronounceable names. By the end of each term, only two or three students would remain enrolled in the course. Writing my dissertation was a painful process. When she died in 2000, it felt as if the mantle of traditional graduate studies had fallen upon my shoulders.

My co-author, Charles Kilfoye, is quite the opposite. Trained in the pedagogy of educational technology, he oversees the strategy and implementation of technology-mediated teaching and learning. He founded, directs and teaches in the online graduate program in distance education at Northeastern University. When I became director of the master of science program in regulatory affairs of drugs, biologics and medical devices in January 2007, he helped guide me down the rabbit hole and into the realm of online learning at our college. For my co-author, online learning is not simply the future of education, but the past and present as well. True, the technologies are constantly improving, but the principles of good teaching remained as salient as ever. The task, he insisted, was to bring those principles to new formats and teaching environments.

Home and Away: The Growth of a Regulatory Affairs Program

Online learning is a natural outgrowth of the mission of the College of Professional Studies at Northeastern University. With more than 15,000 students, our college caters to working professionals and career changers. For the most part, our 4,750 graduate students are not typical students in their early twenties, but rather older individuals looking to acquire applied skills. Many of them work full-time and have families. Online degree programs remove the need to come to campus two nights a week. Thanks to their convenience, online courses have been a large contributing factor in the robust growth of our program. Such growth is also seen across the country: the numbers of online students in the US grew approximately 18% in 2010.¹

Our online instruction, as a compliment to on-campus courses, has been an integral part of the growth of the master's in regulatory affairs. As the third largest graduate program in our college, regulatory affairs comprises 37 courses, 24 regulatory faculty and hundreds of students from 38 countries, including Denmark, India, Ecuador, Russia and Brazil. Online instruction enriches classes by including students with different national perspectives as well as different levels of experience and diverse expertise. At present, there is a stable split of students' choice of course format: approximately 30% take courses exclusively on campus, 50% take courses entirely online and 20% combine both formats during their graduate tenure.

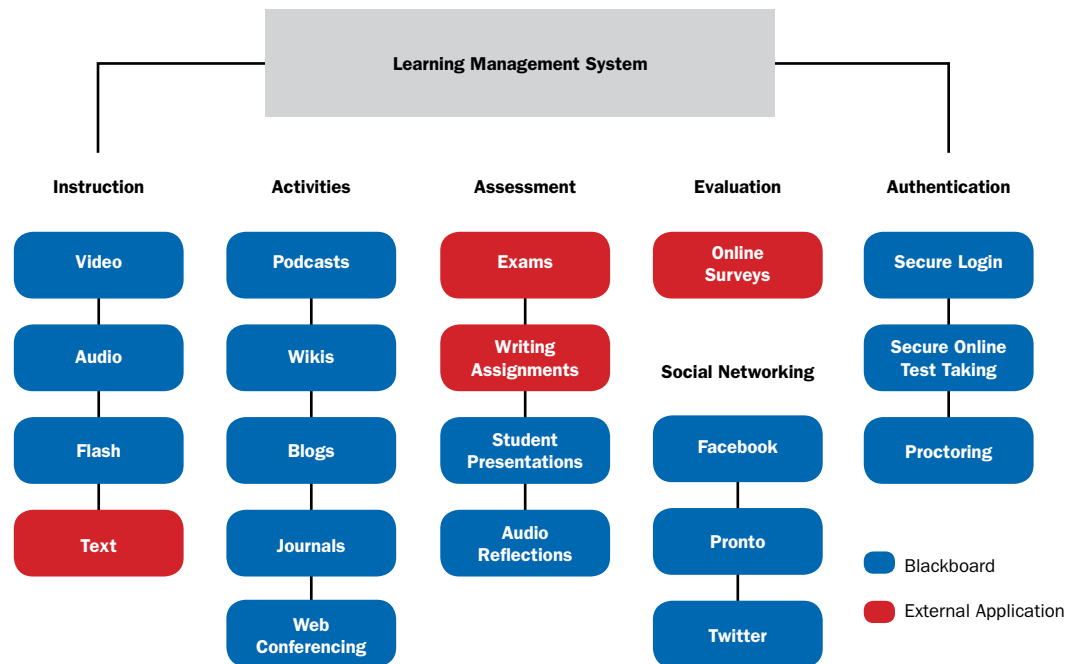
By offering online courses, we can recruit faculty from various sectors and diverse locations. The most experienced adjunct professors are actively working in the field of regulatory affairs. Online instruction removes the barriers that restrict busy and experienced professionals from participating in the educational field. This is an important advantage, given our commitment to offer courses on such topics as international medical device regulations and global regulatory strategy.

The Revolution Will Not Be Televised

Distance learning at Northeastern University predates commercial use of the Internet. Twenty-five years ago, we delivered off-campus instruction via closed-circuit television. Today's online education could not be farther from that technologically. These days, online instruction is typically delivered via a learning management system (LMS), typically developed and licensed by a private software vendor. We use one of the dominant systems, Blackboard, featuring consistent but enabling structures that make it easy to create and deliver course material (see **Figure 1**). Employing an LMS with a template-driven framework allows the instructor to concentrate on subject matter within his or her own area of expertise rather than focusing on becoming an educational technologist. To help in the administration and oversight of classes, Blackboard also provides tools, such as online grade books, electronic assignment submission and an online "assessment engine," which make it relatively easy to access online students and report on their progress electronically.

We want to add a qualification to the descriptions that follow. Blackboard is only one of many complete LMS solutions. While Blackboard supports robust e-learning right out of the box, we have also upgraded it with additional tools and technologies from third-party vendors (shown in the blue boxes). While we believe that our LMS platform provides our students with leading-edge learning technologies,

Figure 1. Learning Management System Basic Functionalities



we hope that our description does not seem like a sales pitch for any particular product.

Our regulatory affairs courses are organized in a week-by-week structure, with each week’s material made available on a Sunday evening and closed the next Sunday afternoon. Materials include: lesson objectives or outcomes; readings or handouts; lecture materials or instructor perspectives, usually in multimedia; written assignments and presentations; discussion boards; and timed online exams. Regulatory affairs students tend to be logged onto the course website for 45–60 minutes per day, five days a week. In addition, they spend time on required readings, writing papers, preparing presentations, taking exams and digesting lecture material.

Typically, an instructor will post three to five broad and provocative questions per week, with the request that the students post a response to some or all of the questions. The students are also expected to address a handful of responses posted by their classmates. The primary goal of the discussion board is to advance a collective and ongoing exploration of the central interpretive themes or particular facts for that week’s topic. This resembles the traditional discussion sections of courses conducted in classrooms, but in this format it is sustained over several days, rather than limited to a single room and a single hour or hour and a half.

New Web 2.0 tools facilitate both real-time and asynchronous communication and collaboration (see **Figure 2**). Blackboard embeds such tools

as wikis, blogs and shared journals. We have also enlisted a host of third-party vendors for podcasting, asynchronous voice discussion groups and audio-narrated presentations. Students can collaborate with other students using forum style web conferences and one-to-many video conferencing tools.

Designing the User Part 1: Effective Online Students

Savvy technological designers recognize that the design task does not end with the machine or the program. One must design the system with the new user in mind. For online learning management systems to be highly effective, students must become active participants and partners (with faculty) in the exploration, discovery, examination and discussion of communal knowledge.^{2,3} Effective online learning requires self-reliance, diligence and the ability to communicate effectively. Online courses necessitate that students manage their time spent on the course very carefully, as time commitment can easily balloon to the detriment of work and family life.

For the regulatory student, the online format carries many advantages. Many regulatory professionals work in periods of extreme activity, punctuated by times of relative calm. Many also travel a great deal, thus making it difficult to attend a weekly class. Online learning removes the constraints of time and space by enabling our students to participate from anywhere at anytime over the Internet.

RAPS Webcasts



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6 October	The Challenge of Developing a Regulatory Intelligence Network to Support Global Clinical Trials: Communication & Collaboration

Figure 2

TECHNOLOGY	DESCRIPTION	USE
Adobe Presenter	PC-based PowerPoint-to-Flash rapid multimedia development tool	Create Flash-based lectures from PowerPoint with audio, video, and text; outputs to flash
Camtasia/Relay	PC-based desktop screen camera capture tool	Use for video screen captures; audio; delivery formats include Windows Media, QuickTime, AVI and RealMedia streaming video, as well as animated GIF's and iPod output
Wimba Voice Tools	Asynchronous audio suite for delivering engaging voice recordings in multiple delivery formats	Use to create podcasts, standalone voice recordings, voice discussion forums, voice emails, voice-supported Web presentations; for students and instructors
Wikis	Online text collaboration space for group work and presentations and development	Use to enable student group work on projects embedded in Blackboard courses; supports export
Blogs	Online text presentation tool delivers text comments or links one to many	Use for student comments, presentation, review work or other group work
Streaming video	Fixed camera lecture capture technology	Capture classroom lectures with slides and audio; outputs proprietary format in web links; requires professional editing
Flip video	Handheld video capture	Capture short audio and video for use on web; uploads to YouTube; Outputs HMP4; converts to MP4 to AVI, MPG, MPEG, WMV, FLV
Smartpens	USB pen technology	Record handwritten lecture notes, presentation notes, and more in digital format with audio; for students and instructors
Voice Threads	Asynchronous voice discussion thread	Creat voice discussions or commentaries around audio, video, or visual displayed in the thread; share, record audio, or post text responses
Adobe Connect	Web conference system	Deliver web presentations one to many with audio, video and desktop sharing; Flash-based; no client plug-in
Wimba Live Classroom	Web conference system	Deliver web presentations one to many with audio, video and desktop sharing; browser-based; client plug-in required

Distance education facilitates the creation of a truly global learning community. As the field of regulatory affairs becomes more global in nature, with any one particular nation's system impacting many others, a global classroom becomes a great imperative. Removing geographic barriers allows students in different regions to learn from one another. Further, expanding discussion over several days encourages normally quiet students to participate and gives students prone to quick declarations the chance to ponder the full dimensions of an issue before posting their definitive answer. All work is archived and can be revisited throughout the course, thereby allowing an understanding of difficult material to accrete over several weeks.

Online courses are well suited to regulatory topics of study. Multimedia tools facilitate the compilation and transfer of information from a wide variety of sources (e.g., legislative hearings, webcasts, podcasts, newly issued guidance documents, Warning Letters). The overlay of

diverse source material enhances the students' ability to learn concepts and fundamental practices through applied examples. True, traditional courses can enlist the same range of materials, but the classroom format makes it more difficult to include them all.

Online learning, however, is not for every regulatory affairs graduate student. It requires continuous involvement over the course of a week. This precludes the time-honored practice of coasting through many weeks of the term and then studying intensively for exams or quickly preparing papers and presentations. There are students who greatly rely on positive reinforcement from instructors and classmates and others respond best when reading visual clues or listening to subtle shifts in intonation. Web 2.0 tools can approximate many of these interpersonal touches, but cannot fully duplicate a classroom environment.

Online education requires students to have a willingness to learn and master an expanding

set of technological tools. For some Internet users, web-based communications and electronic resources are synonymous with instant messaging and Wikipedia. Yes, online learning can be fun, but it also demands a seriousness equal to traditional classroom decorum. For students accustomed to working with others in the friendly confines of a graduate student lounge, the transition to Blackboard's environment might take some adjustment. A more pressing challenge faces students whose English skills lag behind their classmates'. It may take them longer to compose written contributions to threaded discussions.

Designing the User Part 2: The Instructor

We want to acknowledge that teaching your first online class is no walk in the park. Our college requires potential instructors to complete a comprehensive, instructor-led online training program much like the online course that they will teach, followed by an online certification exam. Instructors fully prepare the first two weeks of course material as part of their training. Moreover, our faculty are subject to ongoing oversight by the instructional design team, program directors and the senior assistant dean.

Unlike traditional instruction, where the time devoted to teaching can be confined to a single day, online courses require involvement across the week through discussion board responses and the use of other synchronous and asynchronous tools such as online conferences and online text chats. A good rule of thumb is that an instructor replies to every third to fifth post in a discussion board thread or as needed to validate or redirect student discussions. We expect regulatory instructors in our program to log onto the course website for an average of 45 minutes, at least five days a week. Students anticipate that their queries will be answered within 24 hours, although nearly all will agree to wait longer if the faculty member sends a quick note indicating when they can expect a full reply. The bottom line is that an online course, like a classroom course, is only as good as the engagement of the instructor.

Instructors must be willing to keep absolutely current and adjust the course material in real time. Adherence to regulatory textbooks is a recipe for mediocrity. Discussion board questions must be open-ended and thought provoking. Questions eliciting facts do not tend to foster discussion. The assignments must be crafted to allow students in various locales or working in different contexts to complete them. For example, some students may have access to the *Pink Sheet*, *Gray Sheet* or other trade publications, while others do not. Exams are almost always open book, which eliminates many of the most common conventions for tests and quizzes.



There are many advantages of online instruction for committed faculty, beginning with the most obvious: they do not need to be in any particular location at any given time. Our courses are asynchronous, although still instructor led. With students participating across several time zones, all presentations, lectures and discussions are available throughout the day or throughout the week. Using the LMS, faculty can update their materials in real time or immediately after a course ends. This is an essential element of effective regulatory education as court cases, FDA policy and enforcement trends shift continuously. As instructors become more familiar with our system, we encourage them to develop advanced courses tailored to their specific areas of interest and expertise.

As with the caveat about students in the prior section, online teaching is not for everyone. We have a handful of faculty who attempted online teaching but concluded after one course that it was not for them. Some instructors are drawn to the performance aspects of teaching, while others crave the human contact that comes with a seminar format for graduate classes. Some instructors experience great frustration because they cannot simply import their well-tested, on-ground courses into the online format. Effective online instruction requires instructors to reconfigure their courses and retool, a process that can be as painful as it is enlightening.⁴ Several faculty members have had difficulty establishing limits on their students' demands for near-immediate responses to their queries.

Online classes may require a faculty member to adjust his or her style of interacting with



students. Friendly sarcasm can be greatly misinterpreted online. Attempts at humor can go horribly wrong. One faculty member teaching a week on orphan drugs made an allusion to the musical plays *Annie* and *Oliver*, only to discover later that one student worked for a company specializing in orphan drugs and another student's mother had been saved by a drug from that same company. Also, instructors must be confident enough to accept the fact that a few or more students may have a greater understanding of particular areas of the profession than he or she does. Because online students are drawn from a much wider pool of candidates (global, not regional), the likelihood of encountering a student with a narrow but deep understanding of an arcane area of regulatory affairs is greater.

Forecasting the Future

When looking to the future of online education, no one has a crystal ball. In fact, we cannot speak for any other college or regulatory affairs graduate program. Northeastern University has made a sizable financial and human resource investment in online learning. The leadership of our university has shown an enduring willingness to test and incorporate new technologies if they carry a clear benefit. It is uncertain whether smaller colleges or nascent regulatory affairs programs have this level of resources at their disposal.

For the moment, our greatest challenge is to find and recruit top-quality faculty, particularly as our graduate program continues to grow. Those with regulatory experience of 25 years or more tend to be less willing to jump into online teaching than younger regulatory professionals who, while more proficient in Web 2.0, have less expertise to share with students. It will remain a challenge to find the instructor who is both fluent in e-learning and seasoned in the field. As online tools become more commonplace in the work setting, this gap will shrink. We can also expect that the generation of students now being trained in online education will return to teaching once they have gained the experience and expertise needed to become productive faculty.

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