Facilitating Active Engagement of Students in an Online Asynchronous Program in Biomedical Regulatory Sciences

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Abstract

Regulatory Sciences courses taught in an online asynchronous environment pose challenges for sustaining student engagement and encouraging active learning. Impediments include limited contact with the instructor and classmates, inadequate interaction with learning materials, content that can be ever-changing, and limited tools for assessing student learning. Therefore, an online program's instructional design team must create learning content that supports active learning to overcome communication barriers, employs creative interaction with the course materials, and provides for inventive student assessments to maximize student learning utilizing tools both inside and outside of the LMS. It is the purpose of this paper to describe the current learning environment for graduate-level students in an online Regulatory Sciences Program at the University of Georgia. This exploration involves identifying existing learning impediments, examining the selected learning and design theory that enhances student engagement, constructivism, and providing active learning design strategies to solve these instructional challenges.

Introduction

The University of Georgia's Regulatory Sciences (RS) online graduate program addresses the regulatory procedures for prescription and over-the-counter healthcare products for human and veterinary applications. The primary regulatory agency on which this program focuses is the US Food and Drug Administration (FDA). The RS Program consists of didactic courses and research or experiential courses. The didactic courses are taught online and are primarily asynchronous. Most learning modules include a recorded video lecture (a MS PowerPoint Presentation with synchronized audio files) and supporting reading materials or video by subject matter experts that provide the necessary foundational knowledge required for students to understand the module's concepts. The recorded lecture is followed by course activities like a quiz, discussion, or writing exercise within the program's learning management system (LMS). This content is facilitated by the RS instructional team, which includes the instructor, who is the subject matter expert, and an instructional designer.

Active learning principles encourage students to engage with the learning content by thinking, reviewing the content, discussing, constructing meaning, and investigating the subject matter (*Active Learning | Center for Teaching Innovation*, n.d.). Research suggests that active learning is more effective than lecture-only instruction (*Active Learning | Center for Teaching Innovation*, n.d.). Active learning implies that "Meaningful learning occurs when the learner engages in appropriate cognitive processing during learning, including attending to relevant aspects of the incoming information, mentally organizing the material into coherent cognitive representation, and mentally integrating it with existing knowledge activated from longer-term memory" (Dempsey & Van Eck, 2017, pp. 261–262).

The online asynchronous learning environment presents some unique challenges in terms of providing active learning activities. The challenge in an asynchronous online setting is to create a learning environment that encourages course engagement and active learning, such as interaction with the learning content and collaboration with other course participants. For the RS program, some potential impediments to active learning are a lack of social engagement among course members as the majority are working professionals and part-time students; limited interactive experiences with modular content; learning content that can be tedious as it can involve the review and analysis of regulatory documents, and limited assessment tools within the LMS facilitating student learning. While the evaluation and performance assessments on course material indicate learning is occurring within the current context, the implementation of selected interventions might improve student learning outcomes and experience.

This paper aims to evaluate limited student engagement within the course content in the Regulatory Sciences Program and identify design strategies to improve student engagement. This evaluation occurs within the constructivism learning model framework. Constructivismis a theory that encourages active learning (Reiser & Dempsey, 2017). This analysis relies on observation, student performance, and course evaluation data. No additional scientific study was performed. The overall goal of this analysis is to identify innovative ways to enhance student learning and performance.

Active Learning

Active learning encourages students to engage with the learning content by thinking, reviewing the content or literature, discussing, constructing meaning, and investigating the subject matter. Research suggests that active learning is more effective than lecture-only instruction (*Active Learning | Center for Teaching Innovation*, n.d.). Active learning implies that "Meaningful learning occurs when the learner engages in appropriate cognitive processing during learning, including attending to relevant aspects of the incoming information, mentally organizing the material into coherent cognitive representation, and mentally integrating it with existing knowledge activated from longer-term memory" (Dempsey & Van Eck, 2017, pp. 261–262). Active learning also emphasizes that students can control their learning (National Research Council, 2000). It requires "that students do something —read, discuss, write—that requires higher-order thinking," (Brame, 2016, para. 1), to promote meaningful learning.

Critical Thinking

Critical thinking is defined as "the intellectually disciplined process of actively and skillfully conceptualizing, applying, analyzing, synthesizing, and evaluating information gathered from, or generated by, observation, experience, reflection, reasoning, or communication, as a guide to belief and action" (*Defining Critical Thinking*, n.d., para. 3). Important skills tied to critical thinking are analysis, synthesis, problem-solving, decision making, and communication (Mintzes, 2020; Nelson & Crow, 2014). It is vital for students in the health sciences "to be able to critique data, to identify whether or not conclusions are supported by evidence, and to distinguish a significant effect from random noise and variability" (Holmes et al., 2015, p. 11199).

Active learning strategies support critical thinking skills (BlueSofaMedia, 2012; Reiser & Dempsey, 2017; Walker, 2003) and are essential for all healthcare professionals, including regulatory scientists since they are often asked to problem-solve in unique and stressful situations (Sharples et al., 2017). One who engages in critical thinking will often "recognize problems and find ways to address them" (Clark, 2016, p. 1). In the exploration of a problem, critical thinking skills support the student's investigation of that problem. This exploration process includes recognizing unstated assumptions about the issue. It requires the student to collect relevant information. It involves data interpretation, the assessment of the evidence, and an analysis of the claims or arguments. Moreover, critical thinking skills help students "recognize relationships between propositions" (Clark, 2016), test conclusions, provide solutions, and assess and evaluate the issue from different perspectives. Students then engage in reflective analysis and make decisions based on this information (This list is compiled from four resources: Clark, 2016; Lai, 2011; Nelson & Crow, 2014; Walker, 2003).

Analysis of the RS Program

The Instructional Question

The primary rationale for analyzing the RS Program is a desire for performance improvement among the students. A snippet of data on average student outcomes was extracted from two courses for this analysis. Over the last year, the RS Introduction class has shown an average student grade of 89%. The Ethics in Biomedical Research course, over the same period, shows an average grade of 92%. Our performance goal is to move the average grade from an A-/ B+ grade to a strong A grade.

Like physicians, regulatory professionals need to "be skilled in critically evaluating the current status and provide options to improve" or address a problem (Morrissey & Heilbrun, 2017, p. 1). Concerning the regulatory profession, one learning technologist, when referring to compliance training programs, summarizes the standard teaching approach that many compliance-type programs take. She says, "…[they] follow a rather predictive approach of laying down the facts, policies, and impact of nonconformance and wrap up the training with a quiz. Often, the information is not provided in a format that can truly help learners relate to it, internalize it and push them to do the right thing when faced with situations that need the desired action" (Pandey, 2017, p. 6).

Upon reflection, it appears that many of the RS courses have adopted this approach. At present, a standard learning module for many of the RS courses consists of a recorded lecture and reading materials followed by a module activity such as a quiz, threaded discussion, or writing assignment. The recorded lectures consist of slide-narrated video lectures that can vary in length depending on the need. Some lectures can be 45 minutes to an hour-long. The reading materials can take another 1 to 2 hours. Following the lecture and review of materials, students move to the activity, usually a writing assignment or quiz. Many RS Program courses fit Pandey's prescriptive model, which perhaps does not optimize interaction with the content or help the students internalize the information. As a result, the student learning experience may not be fully developed resulting in a mediocre performance.

The Learners

The learners in the RS program are nontraditional graduate students enrolled in either a graduate Certificate or Masters of Science program in Regulatory Sciences or Clinical Trials Design and Monitoring. These students are often working professionals who hold either a regulatory position or related positions within their places of employment. They are enrolled in this graduate program on a part-time basis. These students are often older, having been out of college five years or more on average. Because they often work in a highly regulated industry, many students come with advanced degrees or certifications and often are intrinsically motivated to gain additional regulatory knowledge. This quality among the students is an essential factor for their continued learning ambitions. Generally, highly motivated students are eager to engage and participate in course activities such as discussions or chat forums. As Schunk notes, "motivation and instruction are linked: Good instruction can raise motivation for learning, and motivated learners seek effective instructional environments" (Schunk, 2012, p. 233).

Theoretical Framework

Constructivism is the most suitable of the learning theory frameworks for encouraging active student learning and critical thinking (Reiser & Dempsey, 2017). Of the many frameworks surrounding adult learning, constructivism is closely linked to developing higher-order thinking skills like problem-solving and critical thinking (Lai, 2011; Reiser & Dempsey, 2017), two skills essential to healthcare professions, including regulatory sciences. It is for these reasons that this approach was selected to frame this analysis.

Simply put, constructivism posits that "learners create their own learning" based on their own beliefs and experiences (Schunk, 2012, p. 230). Constructivism considers that people are active learners. It encourages the inclusion of multiple perspectives when studying a subject, such as reading about a given topic, writing about that same subject, watching a video on the topic, and perhaps engaging in an authentic experience related to that matter. It also assumes the teacher's role becomes more of a facilitator or organizer of the learning content. The instructor's role is to organize the content to encourage social interaction (Schunk, 2012).

A fundamental concept that is at the core of constructivism is situated cognition. Situated cognition proposes that the cognitive processes of learning and thinking occur within physical and social contexts (Schunk, 2012). In other words, "people's knowledge is embedded in the activity, context, and culture in which it was learned" (*Situated Cognition (Brown, Collins & Duguid)*, n.d., para. 2). Therefore, engaging the learner with well-designed content within a well-designed context promotes social learning and encourages meaningful learning (Reiser & Dempsey, 2017).

A constructivist perspective assumes "that all knowledge is constructed from previous knowledge, irrespective of how one is taught … even listening to a lecture involves active attempts to construct new knowledge.… However, teachers still need to pay attention to students' interpretations and provide guidance when necessary" (National Research Council, 2000, p. 11). This guidance can be enhanced by the interventions proposed in the upcoming intervention section.

Program Goals

While each course has its own identified course objectives, the overall program goals are to enhance the skills of the regulatory students in solving complex regulatory problems and effectively communicating information to and from regulatory agencies. The instructors' primary focus is, *Are the students able to work through biomedical[1] regulatory hurdles and problems efficiently and effectively?* To achieve these goals, faculty need to help students optimize their problem-solving and critical thinking skills by employing interventions that engage the students with the content and address student social learning needs.

The Interventions

The first step in the Regulatory Sciences intervention process is to reevaluate the four main elements of the instructional situation. The four elements are 1) the instructional question /problem, 2) the learning environment, 3) the role of the learner, and 4) the role of the instructor (Reiser & Dempsey, 2017). Regarding the instructional question, B. Wilson suggests that the instruction be designed around an authentic problem. The learning problem should be complex regarding multiple interconnected factors, and it might have multiple possible solutions (Reiser & Dempsey, 2017). He also suggests that the instructor tie the learning solution with other skills needed to transfer to other applications (Reiser & Dempsey, 2017), like critical thinking. Scenario-based learning opportunities are an excellent way to incorporate levels of complexity and multiple solutions.

Regarding the learning environment, Wilson suggests that the environment should reflect a real-world setting such as those that might actually occur in a regulatory setting. This real-world quality should also be applied to the tools, resources, and information used in the problem resolution. Assessments and feedback should also contain and reflect elements of real-world consequences (Reiser & Dempsey, 2017).

In this constructivist approach, the learner's role is one where the student takes ownership of the problem while the instructor serves as a guide or facilitator rather than the all-knowing subject matter expert (Reiser & Dempsey, 2017). The instructor's role is to encourage active engagement with the material. Intervention strategies that align with this active learning paradigm are numerous and include the following:

Table 1

Common Active Learning Strategies that align with Constructivism

This table is a list of popular active learning strategies that align with constructivism. This list is n*ot all-inclusive.*

Role-play, debate	Problem-based learning	Micro-learning, flashcards
Concept maps	Scenario or case-based learning	Student presentations
Cooperative learning groups	Student Blogs	Simulations
Collaborative learning activities	Gamification of content	Interactive Lectures
Poll-taking	Threaded discussions	Pause for reflection
Brainstorming	Inquiry Learning Techniques	Self-Assessment

(Sources. BlueSofaMedia, 2012; *Implementing active learning in your classroom, CRTL, UMich, para. 3;* Lai, 2011; Pandey, 2017; Reiser & Dempsey, 2017; Yoders, 2014)

Using the data from final student grades and student feedback over the last year for two required RS courses, many stakeholders and decision-makers conjecture that there is a critical need to help students achieve higher RS content competencies. The students enrolled in the Introduction and Ethics in Research courses, both foundational courses, are the focus of these improvement strategies. The expected outcomes, if achieved, are higher information retention, increased critical thinking, and improved problem-solving skills among the students. Improved student outcomes are directly linked to higher grades and increased student satisfaction.

To increase student engagement in the Regulatory Sciences program, the instructional design team is implementing improvement strategies to 1) address the lack of social engagement among course participants; 2) improve interactive experiences with modular content; 3) enhance learning content that might be considered tedious; 4) "chunk" content that moves rapidly and is substantial, and 5) develop innovative assessment strategies. The following are part of the improvement implementation approach. The instructional design team selected these interventions based on student feedback and the availability of the technology.

Social engagement (#1)

A fundamental component of the constructivist approach to learning is the sense of the learner's social engagement with the course (Reiser & Dempsey, 2017; Schunk, 2012; Vianna & Stetsenko, 2006). Social engagement can take many forms. An essential component to supporting socialization is to increase instructor presence in online courses (Dixon, 2010; Rapp & Anyikwa, 2016). Recent research suggests that students preferred multiple ways of interacting with the instructor. These interactions could include "announcements on the homepage of the course delivery system, emails to students, discussion forums in which the instructor interacts, and online lectures or connect sessions and chats, to enhance engagement" (Dixon, 2010, p. 8). In summary,

> Instructor presence… involves instructors facilitating course flow and content, encouraging student participation, directly interacting with students, providing timely responses to questions, and promoting involvement with discussion questions. Studies suggest that the instructor is essential to the learning community and have found learning outcomes directly tied to active instructor presence in the course (Rapp & Anyikwa, 2016, p. 3).

Most of the current RS asynchronous courses include welcome videos, a detailed course syllabus, and a course orientation video. Students are welcomed to the class with an introductory email and a live online activity (Zoom meeting or chat session) during the first week of the class. Moreover, in the content delivery, the instructor often provides recorded lectures and reading materials. Initially and at the start of the course module, the RS Program has strong instructor involvement.

RS courses that employ asynchronous threaded discussion tools help to encourage student dialogue. Course discussions, however, are often short-lived because of time constraints and the need to move on to the next modular topic. If students wish to continue the discussion or engage with the course participants, they are responsible for initiating the request. Moreover, the instructor often serves as an

observer of the discussions and does not interject comments until assigning the grade. This approach is not an effective use of the discussion tool for enhancing student social engagement. Faculty in the Regulatory Sciences Program should consider participation in the discussion, not to stifle but to encourage the discussion. This simple approach can provide students with additional interaction with the instructor.

Other considerations to encourage student social engagement include "think-pair-share activities." These include group projects, discussions, and problem-solving assignments. In this strategy, for example, following a lecture, the instructor might group the students into teams to work on collaborative projects, like group presentations or a group website, that demonstrates their learning. These kinds of approaches can easily translate to the online asynchronous environments using collaborative online and web conferencing tools where students can share documents and engage with one another, tools like Zoom, Google Suite, Microsoft Teams, Slack, Blackboard Collaborate, and other applications.

Content experiences (#s 2, 3, & 4)

There are multiple strategies to more fully engage students with course content. One easily accessible tool is again using the threaded discussion tool to engage the students through peer feedback and assessment. Not only can it be used to engage the students socially, but it can also be used to engage the students with the content if appropriately designed. Assigning an activity that requires the students to reflect on the lecture or topic as a writing exercise and posting that write-up in the threaded discussion allows for this engagement. An advantage to this approach is that the students are afforded an extended "reflection time" and have the "opportunity to compose thoughtful, probing contributions" (Riggs & Linder, 2016, p. 2).

Regarding limited interactive experiences with modular content, going into this analysis, the author assumed that current RS recorded lectures were limited in their support of student learning. Some research, however, has suggested otherwise. Recorded lectures can support student engagement (Dixon, 2010; Riggs & Linder, 2016). About the existing recorded lectures, students can "re-watch recorded lectures as many times as they need to in order to understand the content and can make use of closed captions or transcripts to improve comprehension" (Riggs & Linder, 2016, p. 2).

The lecture materials in the RS Program, however, could be improved to increase comprehension and engagement. For example, multiple lectures are an hour or more in length. These could be improved by editing or recreating the video into smaller pieces, perhaps no more than 18-20 minutes in length (*The Science Behind TED's 18-Minute Rule*, 2014). While our lectures do not claim to be as polished as TED Talks, there is science behind their 18-20-minute rule that should be considered when including recorded video lectures. Recent research suggests that the act of listening is equally as strenuous as other cognitive exercises, and students tend to recall new information if it is presented in smaller increments (*The Science Behind TED's 18-Minute Rule*, 2014). For the RS Program, breaking down hour-long lectures into 2 or 3 segments will be considered.

In addition, recorded lectures and major assessments could be revised to include small exercises, games, or problem-based tools at each section's close. These activities can be included in the lecture or accessed outside the lecture. In problem-based learning, the threaded discussion tool would be an excellent area to pose problem situations and ask for feedback on how students might solve this difficulty. The "problems" discussed in these threads should also have real-world application.

With video-based lectures, another strategy that could be considered is that of concept mapping.[2] A simple concept mapping assignment could have significant benefits for student comprehension and could easily be applied in many circumstances. This tactic helps students organize complex concepts (Schunk, 2012) and recognize links between the topic. While these are not the only solutions to improve engagement with the content, this strategy can be quickly adapted to the RS situation where recorded lectures are an essential part of the learning.

Materials in the RS program are often content-heavy and move at a rapid pace. These characteristics can negatively impact student learning. This characteristic can feel like "trying to drink water from a fire hose" (Monahan, 2015, para. 2), i.e., too much, too fast, and too little time to digest and reflect on the content. A possible solution is for instructors to 1) eliminate any excessive content from lectures to reading materials and 2) enhance student abilities to recognize what information is useful and accurate (Monahan, 2015), i.e., put the students in charge of identifying topics and content with instructor guidance.

Assessment strategies (#5)

Some courses in the RS program depend on the traditional assessment tools built into the LMS, primarily the quiz tool with various question types. These types of quizzes do not include many real-world characteristics. In constructivism, the emphasis shifts to more authentic assessments (Dikli, 2003; *How Do I Apply Constructivism in My Classroom?*, n.d.). Authentic assessment occurs most naturally and lastingly when it is meaningful and relates to students' authentic concerns and problems. Tests … ask, "Do you know this material?" Authentic assessment activities ask, "What do you know?" (*How Do I Apply Constructivism in My Classroom?,* n.d., principle 5). In the case of Regulatory Science students, the question can be rephrased to "can you apply learned content to solve problems or address federal or state requirements?"

Alternative authentic assessment strategies that easily transfer to an online asynchronous environment. For quizzing, the facilitator can present case-based problems and have students propose solutions as short answers. Other open-ended questions for students to address involve using the LMS discussion board or online student presentations, either live or recorded; research projects or papers; online journaling; wikis, timeline creations; and e-portfolios (Barber et al., 2015; Berkeley Center for Teaching & Learning, 2017; Dikli, 2003; Eddy & Lawrence, 2012) Currently, the instructional team depends on research papers and presentations. The implementation of these other strategies could afford the students additional opportunities to reflect on their learning.

Case Study

Recently, the RS program completely overhauled its Ethics in Research course with the principles outlined in this document. The instructional design team created more visually engaging video lectures that were shorter in length. The team supplemented the modules with additional activities and reading materials with opportunities for the students to explore the learning content from different angles. For example, with real-world significance, the ID team added CITI Training (Collaborative Institutional Training Initiative) activities, a necessary training that many of the students will need for their future research projects. The course revision also included the addition of the National Institutes of Health training module called *The Research Clinic*. This program allows students to become four different clinical research professional characters dealing with ethical issues related to biomedical research. This exercise provides students with some real-world examples of critical problem-solving.

Each module has threaded discussion opportunities that help the students engage with one another and reflect on their learning. The instructor participates with the students using this forum. The team also added periodic webinars using Zoom for student "check-ins." The redesigned course also includes two small ethical papers on a topic of the student's interest. The final capstone project involves the use of a concept map activity. The use of the concept map has helped students tie together the course concepts and visualize the relationships between course concepts of ethical research and how it relates to Regulatory Sciences. The course is still about 95% asynchronous, an important desirable characteristic identified by the students. The redesign, however, has altered the activities to allow the students more opportunity to engage with the material.

To date, the feedback on this redesign has been positive. Students overwhelmingly agree that this redesign facilitated their understanding of the materials. Most felt the course was logical and easy to follow, and up-to-date. Most importantly, many commented that the redesign enhanced their understanding of regulatory concerns related to biomedical research.

Conclusion

Currently, RS Program courses that appear more teacher-centered in their approach to instruction need to shift their focus on student-centered activities to encourage more active engagement with the modular content. Through the lens of constructivism and active learning principles, the ID team has identified specific strategies that will help change this focus. Implementing the methods and strategies outlined in this reflective paper has a high probability of facilitating more active student engagement and learning, resulting in improved performance.

As educational practitioners, understanding how students learn and identifying ways to maximize their learning experience is important to support this program's active learning and critical thinking objectives. In summary, this analysis has provided the instructional design team and administrators an objective assessment to understand the current state of the courses in this online asynchronous program. This reflective process has identified areas where adjustments and improvements can be made to make the RS program more successful and beneficial to our students.

[1]"Biomedical" is an adjective that describes scientific research that is used to study both human and animal health.

[2] Concept mapping is an instructional activity that helps students to visualize newly learned concepts. It involves the student creating a structural diagram of newly learned information. It often helps students to understand how different concepts can be related. A resource on concept mapping is https://ar.cetl.hku.hk/am_cm.htm.

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