Board 23: Work In Progress: Quality Management Systems Applied to Assessment in a Biomedical Engineering Course

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Introduction

In the field of biomedical engineering and medical devices, quality management systems (QMS) [1] and document control [2] are used in concert to assess all activities pertinent to a design. Controlled documents are drafted and subsequently reviewed by designated, qualified individuals who with their signature attest to the credibility, acceptability, and completeness of the work. Once approved, the design is published and distributed for use [2]. Documents which are not approved have the ability to be revised and reviewed again. This industry practice is a stark contrast to how biomedical engineering students' coursework is typically assessed. In many engineering courses, a 0-100 point scale translates to an A-F scale. This is then interpreted as an objective measure of student learning and achievement. Instructors miss the opportunity to use assessment as a learning tool to prepare students for careers in regulated environments.

Moreover, a 0-100 point, A-F scale could be counterproductive to the biomedical engineering design process. In project based learning, students have an incentive to choose a risk averse project problem or design solution in order to optimize an A-F grade. A QMS approach could allow students opportunities for risk taking and error-making without the fear of punishment. Next, the QMS assessment is more representative of the design process. A bio-design process could be characterized as iterative and made up of gradual successes [3]. An assessment approach that allows for resubmission could permit and encourage learning through design failure. Similarly, QMS emphasizes feedback for continuous improvement. In contrast, assigning a number or letter grade is associated with finality and has been shown to undermine the value of instructor feedback [4]. Finally, the assessment technique deals with the inherent difficulties in assigning grades to multiple, unique, interdisciplinary projects and problems seen in many biomedical engineering courses. It gives the instructor flexibility to conduct assessment through the combination of descriptive feedback and student engagement.

The minimum criteria for constructing a QMS based grading system is that there is a controlled document, expert review, boolean outcome, and the opportunity to make revisions. There are several learning assessment methods that could be used. For example, standards, criterion, or rubric based grading could be implemented. By demonstrating mastery of the learning objective the student work becomes reviewed and approved. The benefit of this approach is that the written objectives give students clear learning targets, which translates to more engaged learning [5] and consequently greater academic achievement [6]. A potential drawback is that the review process is constricted to heuristic evaluation based on the predetermined criteria. Another approach could use ungraded assessment methods. This approach is reflective of an expert review process. In the place of alpha-numeric grades, students receive constructive criticism and feedback. The summative assessment is the only course aspect that receives a score. University-wide ungraded policies allows students to work effectively with their peers, increases motivation to learn, and reduces competition for letter grades [7 - 8]. Within engineering, ungraded problems improve learning, experience, and engagement [9]. In a thermodynamics course, student centered assessment normalizes mistakes, creates community, and empowers self-directed learning [10].

In the proposed study, a sophomore level biomedical engineering design course will use an assessment method intended to mimic the quality management systems (QMS), specifically document controls, and the 510(k) submission process used in the medical device industry. Instead of 0-100 point, A-F grades, documents (assessments) are drafted, reviewed, and approved. If a

document is not approved, it may be redrafted and reviewed again. The value added of this approach is thought to be twofold. First is to teach and reinforce medical device quality. Students will get practical experience with industry practices of documentation. Next is to allow students to interact with the design process in a way that reduces the emphasis on grades and encourages exploration, iteration, and mastery. To test these ends, this study will assess student knowledge of document controls and explore whether the absence of alpha-numeric grades on assignments affects student motivation, performance, grade satisfaction, or project completion.

Project Approach

The course (Biomedical Design and Manufacturing I) is an introductory class consisting of both large group and lab based topics. The large group topics consist of the bio-design process [3] with a focus on clinical needs identification. Labs teach students technical engineering skills such as computer aided drafting, embedded systems, mammalian cell culture, and 3D printing. The main deliverable of the course is a project where student teams identify an unmet medical need and develop a proof of concept. The course is a required class for graduation. All students will receive course credit as part of their participation in the study. The planned timeline of this study is one semester, beginning in August 2023.

The grading system for this course will parallel the QMS and document control process used for medical devices. First, the assignment, called a document, is given to the students. Students draft the document, oversee revision control, conduct a student initiated review and approval (students sign their own document), and submit to the instructor. See Figure 1. For final document approval, student work must be found to be reviewed and approved for adequacy by the instructor or teaching assistant(s). If all the learning objectives are met the document is approved. If not, the document is returned to students with individualized comments and corrections. Students can resubmit following revision controls until the document is approved or until a final cutoff date. The cutoff date is the end of classes for project documents and two weeks after review for lab assignments. Student may submit unlimited times, without penalty.

In place of an alphanumeric grade, students receive two review indicators depending on the status of the document within the approval process. These appear as checkmarks in the online course management system. First is the Acceptance Review. Within the FDA the purpose of the Acceptance Review is to ensure that the submission meets a threshold for substantive review. For the course, this review assesses students' timely submission, formatting, document control, revision control, and that a reasonable attempt (~50% correct) was made at all parts of the document which ensures quality feedback can be given. The second review is the Substantive Review. In the FDA, this is a comprehensive review of the submission to determine whether substantial equivalency (SE) was demonstrated. Here the instructor or teaching assistant(s) review the quality of the submission and issue a decision whether to accept or not accept the document. This decision is based on both a list of criteria which is made up of the learning objectives and expert opinion as to what solution or design is best for the problem. There are no partial approvals. The only exception is for non-participation in group related work. Students can track their document status and address comments in real time through the course management system (Moodle).

In accordance with university requirements, an A - F letter grade is given for the class. The final A-F letter grade is a weighted average consisting of a document review ratio (75%), proof of concept (15%), and a presentation (10%). The document review ratio is calculated as: $\frac{Documents_{scored\ submitted} + Documents_{scored\ approved}}{TotalDocuments_{submitted+approved}} * 100$. The proof of concept and presentation

(replaces the final exam required by university policy) are reviewed and approved as individual assessments using the same methods described above.

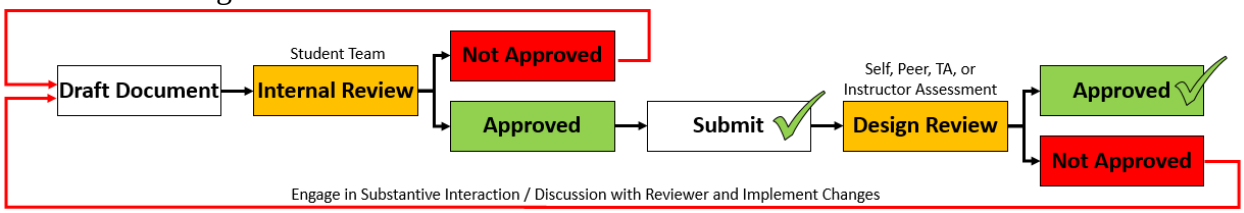

Figure 1. The flowchart shows the process by which assignments are reviewed and approved. Students review and approve their own assignments before submitting them for final review and approval.

The implementation of the grading strategy will be assessed in multiple ways. First a questionnaire will determine the students' understanding of the FDA design process pre and post course. Students' attitudes and perceptions will be determined using a survey utilizing a Likert scale. The questions will gauge the following: students' attitude towards the grading method, perception of difficulty, motivation to continue design projects, preferred grading method, assessment of their own learning, quality of the feedback, type of feedback, and teamwork. All student responses are anonymous and contain no identifiable information.

Results and Discussion Outlook

QMS and Document controls are critical practices and regulatory requirements within the medical device, biotechnology, and pharmaceutical industry. For biomedical engineering students, it is imperative that they execute and enforce the procedures to prepare them for careers in regulated environments. In this study, students will not only actively participate in the process but will be affected by the assessment outcomes. This serves to reinforce a key learning objective. Students' knowledge and proficiency of the medical device documentation practice is expected to improve with engagement, implementation, and repetition.

The document review and approval process may also help with learning. For example, feedback in the form of personalized constructive criticism without grades could improve future performance. The rationale for this is that gradeless content could normalize mistakes, allow for self-regulated learning [11], and mastery through repetition. This study will examine whether the same principles extend to this assessment method. A final area of study is the effect grades have on the student design process and experience. Whereas traditional grading policies deliver concrete and unwavering decisions of student work, the approach here emphasizes the fluidity and uncertainty of a design process. A key element is iteration and gradual improvement. When students submit work with errors they are both permitted and expected to self-correct. Whether students will interpret this as extra work or a key element of the design process is unknown. In addition, the absence of grades will be investigated with respect to team dynamics and student motivation.

Implementing a course void of alpha-numeric grades on individual assignments has caveats inherent in the design. As most students will not have experience with this type of assessment, there is a potential for creating confusion or anxiety. Allowing students to resubmit assignments multiple times increases the time spent grading. Individualized feedback on documents is time consuming. Care must be taken in planning the course to limit the number of assignments. In this course the time spent grading will be somewhat mitigated by having students work in groups and dividing the feedback responsibilities between the instructor and teaching assistants. Overall, the benefits of a QMS grading approach are thought to outweigh the drawbacks for this course.

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