

Meshing Goals: Bringing a Computer-Aided Engineering Course with Biomedical Applications, Engineering Communications, and FDA Reporting Guidelines into Alignment Towards Stronger Student Outcomes

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Abstract – *A 10-year working partnership between engineering instructors and communication instructors for a course called “Computer-Aided Engineering: Applications to Biomedical Process” aims to enrich the professional skills of the engineering students overall. This paper provides a window to the ways the course aids students in improving their engineering/technical writing and presenting skills. This year, an added influence came with the incorporation of new FDA guidelines for biomedical computational modeling, released in September 2016. We report on this integration, why such an infusion of professional-level guidelines is desirable for an academic course, and provide an overview of the partnered courses (biomedical and communication), briefly covering how one might consider ABET alignments. We hope to set out a useful roadmap for other university instructors in how they might align their course deliverables with “real world” expectations and guidelines while addressing the complexity of classroom expectations versus professional expectations of communicative ability.*

Index Terms - *Engineering communication, technical communication, biomedical engineering, FDA guidelines, engineering communicative practice.*

INTRODUCTION

From alumni surveys, to anecdotal stories from engineering students returning from the internships and co-ops, to researchers in engineering education, it has been repeatedly noted that engineering education too often falls short of preparing undergraduate students for the realities of professional practice [1]. In truth, academe has its familiar responses to that observation that fall into three categories: A) the university experience

should not be a workplace training program [2]; B) those who craft and implement engineering curricula cannot keep pace with rapid workplace developments [1]; and C) university students learn about engineering generally, though they may fail to understand in a more nuanced, complex way what professional engineering work is, which must be an acceptable situation [3].

The magnet-like forces between the engineering concepts taught in university settings versus practicing “real world” engineering (sometime attracting, sometimes repelling) plays out energetically for those of us who teach technical, scientific, and engineering communication inside colleges of engineering. It is no revelation to state that within engineering contexts, communication is usually contextualized on a vastly different plane than when it is framed in a university setting versus “real world” (RW) engineering settings.

Herein, we outline our attempt, as communication instructors, to wrestle these issues within a capstone engineering course called “Computer-Aided Engineering: Applications to Biomedical Process” which has partnered for over a decade with our Engineering Communications program. The partnership aims to enrich the professional skills of the engineering students overall, with special attention to their engineering/technical writing and presenting skills. This year, an added influence came with the incorporation of new FDA guidelines for biomedical computational modeling, released in September 2016. We discuss why such an infusion of professional-level guidelines is desirable for an academic course, we provide a brief overview of the partnered courses (biomedical and communication), and address briefly how one might consider ABET alignments. We hope to set out a useful roadmap for other university instructors in how they might align their course deliverables with “real world”

(RW) expectations, guidelines, or laws while addressing the complexity of classroom expectations versus professional expectations of communicative ability. (The debate/discussion about whether or not student perceive university work as “real” work is not a debate we intend to begin or continue here. It’s well established that students (and many instructors) see the division between what happens at the university as being somewhat removed from workplace practice. The authors accept and even welcome that communicative complexity into their classroom discussions and pedagogical stances.)

CONTEXTUALIZED COMMUNICATIVE PRACTICE, CLASSROOMS, AND INSTRUCTIONAL TRANSPARENCY

The discussion about and disconnect between RW engineering communication and academically situated (AS) communication is all too familiar. For AS communicative action, the valued exchange is usually between the student (or student team) and the instructor; that is, in the most simple terms, students work for knowledge acquisition and are rewarded with a grade. In more creative classrooms, perhaps an external client is brought in to enrich the RW milieu in an attempt to make the project more substantially contextualized. Despite outside clients, RW projects and other efforts to bring the realities of professional practice to the classroom, students are very savvy about where to place their energy. They understand that the primary value for them is the grade [4], which is the immediate valued outcome for them. This is not to say that students don’t appreciate the efforts to bring in RW expectations; they do. But the value for them is often a higher GPA over almost anything else, and that is precisely because their economic exchange (tuition) provides access to institutional valuation (GPA) for external consumption (future employers value GPA as an indicator of quality for new entry-level hiring of graduates).

And while this may be frustrating for instructors who want to set up exercises and experiences that mimic or incorporate aspects of RW engineering in order to provide “authentic engineering experiences,” acknowledging the value exchange that students hold is important. The situational limitations of the classroom loom large in how we frame work for students; it isn’t feasible to fully contextualize RW professional engineering or technical communication because the students aren’t inside a RW engineering organization. They are in a classroom or lab.

But we can try. We can help students to understand that on the job, each piece of communication has consequence not only for the sender and receiver but for the entire organization. Marie Paretti states, “Proposals, progress reports, design documents, and similar texts represent engineers’ work to those empowered to act on it, and thus they serve critical functions in the ongoing work of an organization” [5]. Knowing the kinds of

documents that engineers use allows instructors to introduce those genres and formats to students.

Despite knowing the kinds of RW communication pieces, a classroom setting cannot provide an authentic RW experience because teachers and students simply are not themselves (usually) practicing engineers, managers of engineers, clients, or even stakeholders in any substantive way that exists outside of the university construct. Dannels has noted that even with project-based projects, with RW clients, the students often still work for the grade and the learning experience, not the design, not a promotion, not for a raise, not to secure a contract. If we are to be truthful, any engineering endeavor for students has an overlay that colors the genuine engineering and communicative purpose or purpose; no matter what faculty do, the reality of school versus RW will always be a factor [4]. Usually, faculty don’t need a technical report to make a technical decision; they need a technical report or presentation to assess the students’ ability to deploy engineering solutions which demonstrate specific university-sanctioned learning outcomes [5]. (This is necessarily complicated when project-based or problem-based engineering projects are in the mix, because outcomes might not be fully known until implementation [6].)

We believe that the university should prepare students, to some degree, for professional work while also conveying larger-order concepts (professional skills, mathematical process, engineering theory, technical theory, engineering ethics, etc.) that will allow these future professionals to be agile when facing new challenges [7]. It’s an element of life-long learning. And, we agree with Walther *et al.*, that much more can and should be done to incorporate the *how* of engineering competence along with the *what* in order to facilitate that effective integration [1]. However, we also believe that we must acknowledge up-front the complexity of such an undertaking, as university work and professional work are so often very different creatures [2].

In the end, we hold that instructors must be transparent with our students about this divide of school versus work construct. No class-based assignment will fully frame a project in a professional engineering construct (the grade will always influence the endeavor). But, as instructors, we can frame projects in a better or worse way, providing a situational learning experience that may help them transition more easily [8].

HOW WE MESH: A WELL-ESTABLISHED PARTNERSHIP

At Cornell University, we have enjoyed a decade-old partnership between a senior-level engineering course called “Computer-Aided Engineering: Applications to Biomedical Process” and the Engineering Communications Program. The teaching partnership itself has become richer and more engaging each year,

morphing a bit with each iteration to better serve the students, reach desired course outcomes, and address changing software applications and their increased capabilities and power.

In the fall of 2016, our teaching team became aware that we should hone this class once again in light of the newly-released US Federal Drug Administration guide titled “Reporting of Computational Modeling Studies in Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff” [9]. Drafted in 2014 and officially released in September of 2016, this non-binding guide promotes for computational modeling studies (CM&S) a common structure and organization for communication process, methodology, findings/results, and the discussion thereof. The guide contains language that clearly states its purpose: “...to improve the consistency and predictability of the review of CM&S studies and to better facilitate full interpretation and complete review of those studies” [9, p. 1].

I. First: the current BEE course standards

As a three-credit capstone course housed in the Biological and Environmental Engineering department, students must have taken a heat and mass transfer course as a pre-requisite for this class on computer-aided modeling for biomedical processes. This course aims to introduce professional standards for work in biomedical processes, which can be an advantage for students overall [10]–[13]. For years, the BEE course’s stated desired performances have been in place; the syllabus states that, as part of their work in a team, students should

- think of computer simulation as an important practical tool in design and research projects in the industry as well as academia
- know the machinations of a typical computer prototyping software
- have realistic ideas about the advantages and pitfalls of such a software
- know about thermal therapy
- be comfortable in solving less complex problems and working with a group of experts in solving problems with increasing complexity
- communicate findings and processes in an appropriately professional manner while working in teams. [14]

With the understanding that physical prototypes for design ideas are expensive and that they have many drawbacks, computer prototyping or simulation-based design has become an important supplement to the design process, sometimes drastically reducing the amount of physical prototyping.

Teams of senior-level students have a different self-selected projects, and they build a computer model in COMSOL, validated by specialized use of mathematical

equations; the aim is to come as close to the physical model as possible. The project framework introduces the computer prototyping process, using a physics-based simulation software that is used extensively in industry. Students come to learn that the software cannot be used as a black box, appreciating that the complexity of the computer simulation process and the many ways the software can provide the wrong answer. RW projects are the centerpiece and reflect mastery of the course outcomes, investigating heat and mass transfer problems in biomedical processes such as cryosurgery, hyperthermia, laser surgery, and drug release from polymeric implants.

II. Second: the communication component

For the 21 years that the BEE course has been taught, at the end of the term, student teams have been tasked with formal reporting of methodologies/processes, results, and discussion. As well, students are required to give a formal presentation to the entire class about the work, with all team members speaking equally, using slides (and sometimes now 3D printed models). The teaching partnership between the BEE course and the Engineering Communications Program started, over a decade ago, with the intent to move final student deliverables away from pieces that looked like school work towards more professional-style work. The final deliverables are demanding, long, thorough, and highly technical, as they are windows to the teams’ complex modeling, schematics, equations, outcomes, and assessments of those findings.

As with any good communication instruction, all of the instructors use a continuous drafting and revision cycle for the final written report. Teams meet with the communication instructors three times during the semester to refine drafts as they progress through the modeling/reporting cycle. And the end of the term, the instructional staff begins to meet every course hour with the teams for further refinement. The final reports and talks by these undergraduate teams are likely to be some of the most complex pieces students will ever create unless they go on to get a Ph.D. Undergraduate teams produce works like these: “Procoagulant Microparticle Interactions Due to P-sel-Ig in Hemophilia A Patients”[15], “Modeling Carmustine Diffusion from Gliadel® Wafers in the Brain to Optimize Cancer Treatment and Minimize Damage to Healthy Tissue” [16], and “Modeling an Injection Profile of Nanoparticles to Optimize Tumor Treatment Time with Magnetic Hyperthermia” [17]. As well, we have a good amount of certainty that these student works are useful beyond coursework assessments of technical ability, as some of them have been downloaded thousands of times. (See <http://4530.bee.cornell.edu/> for a complete archive and download count).

As part of the end of term grading, teams have always given a formal presentation of their findings to the entire

class. Four years ago, we began to focus more on making those talks function at a higher caliber, as if students were presenting at a conference. We incorporated the tenets of the assertion-evidence slide design [18], [19] with the intent to get students to professionalize their talks. These efforts have proven to be very fruitful because student teams now execute practice talks with the communication instructors, they have a methodology for organizing their talks, and they have a set of specific, malleable techniques that allow them to showcase their technical work in a very professional manner.

Note: It may be of interest for programs and administrators to know that in the last two years, the College of Engineering has formalized the work relationship between the BEE course and the Engineering Communication Program (ECP) by requiring that students who register for the BEE course also register for a one-credit ECP course. This formalizes the intensive communication component for both the instructional team and for the students. Previous to this decision to add on one credit for communication, communication instructors been providing intensive off-record instruction, feedback, and workshops, and their workload was not formally recognized within the university's workload system for instructors or students. With the one-credit communication partnership, students get the benefit of having an explicit Engineering Communication course on their transcript, which potential employers appreciate. We want to be clear; the workload for the students has not been increased; they have always and still have writing and presentations deadlines all semester long, they submit a final report, and they give a final presentation. In the last two years, the formalization (with the one-credit ECP credit) allows for that work to be recognized at all levels.

III. Third: the FDA's guidelines

When the USFDA released its revised and released its "Reporting of Computational Modeling Studies in Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff" guidelines in September 2016 [9], the instructors welcomed the opportunity to look anew at the course and try to align some of the specifics of the course outcomes with the FDA protocols. Incorporating professional standards, like FDA guidelines, can be an effective way to traverse the gap between school work efforts and professional efforts [20]. It is worth the time to mention here that the FDA guidelines are simply that—guidelines. They do not carry the weight of FDA regulatory compliance standards, but they do inform those standards. The guidelines we use impact the writing of compliance, not the compliance itself (although sometimes they are hard to tease apart). Felse notes that "regulatory requirements are redefining the landscape of chemical, pharmaceutical and biotech industries to an extent not seen before" [21].

A look at the FDA's Table of Contents reveals that the overall organization is familiar, following the IMRD pattern (Introduction, Methods, Results, Discussion) with some more applicable fine-grained pieces in the mix. Further integration into course expectations became more of an exercise, by the instructors, of alignment in the assignment. Because of our classroom constraints, some elements of the FDA guide could not be met, but most could.

In some instances, we ask students to think beyond the guideline to incorporate strong communication practices where the FDA guide remains silent. One example of this is with the use of figures; the FDA guide does not specify expectations for figures beyond a mention in "System Geometry/Mesh" in one of the appendices.

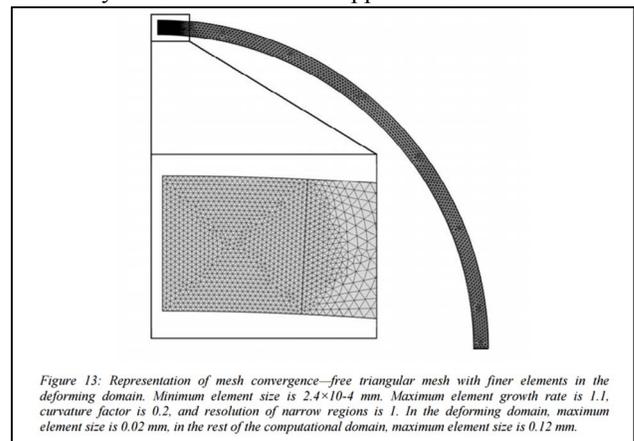


FIGURE 1. EXAMPLE CAPTION WORK FOR MESH CONVERGENCE FROM A TEAM PROJECT. STUDENTS ARE REQUIRED TO CRAFT FULL CAPTIONING FOR THEIR FIGURES AT ALL TIMES. THIS EXAMPLE DEMONSTRATES STRONG DEPLOYMENT OF THE LABEL, TITLE, EXPLANATORY CAPTIONING. THE USE OF STRONGER CAPTIONING MAKES THE REPORT TECHNICALLY MORE FULL WHILE ALSO ENHANCING ITS ACCESSIBILITY AND SEARCHABILITY [29].

We encourage, for a variety of reasons related to ADA accessibility issues--along with addressing color issues for colorblind users [22]--searchability, and retrievability that any figure have full caption work, which includes a label (Figure X), a title (name the figure) and an explanatory caption that decode the meaning/impact of that figure for the context. As well, of course, if the figure is borrowed from another source, it needs a citation [23]–[28]. An example of a student team's figure depicting mesh convergence is shown in Figure 1, displaying strong incorporation of the course expectations.

As noted above, the deliverables for the BEE/Comm partnered course we already hefty. Early in the term, with the FDA guide on hand, the instructors ask teams to determine which of the five subject matter categories in the FDA guidelines applied to their project and to read and apply those more fine-grained expectations. The five

categories are these: Computational Fluid Dynamics and Mass Transport; Computational Solid Mechanics; Computational Electromagnetics and Optics; Computational Ultrasound; and Computational Heat Transfer.

DESIRED COURSE OUTCOMES FOR COMMUNICATION PROWESS

It is important to note that the instructor for the Biomedical course has a specific mandate: meeting expected university-approved course outcomes. One of those stated outcomes is “communicate findings and processes in an appropriately professional manner while working in teams.” This focus is taken very seriously, and the partnership with the Engineering Communication Program (ECP) is indicative of that dedication. In turn, the ECP staff aim to provide not only heightened awareness of good writing and presenting practice, but they aim to contextualize it as best possible for a situated learning experience. All three instructors (one biomedical, two engineering communication) work together to accomplish this goal.

More specifically, the ECP instructors, during their extended team meetings with students, bring to the table four concepts for this engineering work: communicative context, communicative design, communicative practice, and engineering identity. In this way, we hope to provide via situated learning the transitional knowledge that will make seniors, soon to enter their adult work lives, into agile life-long learners and communicators.

- **Communicative Context:** *situational structures that influence the communication.* For our purposes, the context is both the BEE course, its partnered ENGR course, and the imposed guide from FDA to situate the course deliverables in a context wider than coursework output. Students begin to understand the complex web of expectations and responsibility engrained with this type of research and modeling for medical devices and procedures.
- **Communicative Design:** *all communication has structure, including that for profession-based needs; designing with purpose for specific professional needs.* This may be one of the easier transfers, because the FDA guide is specific as to order, labeling, content, etc. We have discussions with students as to why those expectations are in place, the functionality of the order, and the reasoning for such [8].
- **Communicative Practice:** *professional communication as a situated form of social action, purpose.* The communication instructors emphasize that the deliverables are part of larger social/professional body that has engrained needs, expectations, and desires about others that

are deemed part of that professional body of knowledge. Students work to create deliverables that would be not only “doing something” within those technical demands but also meeting the expectations of the members already in those circles.

- **Engineering Identity:** *how an engineer labels or projects expertise to the world.* We ask teams to consider what professionalism looks and sounds like in this field, and we push them to meet or exceed those unstated qualities (the oft-unstated set of expectations called “professional” or “expert”) and how they plan to demonstrate (or resist) those expectations.

ABET ALIGNMENT FOR COMMUNICATION COMPONENTS

In the past, the communication instructors have had colleagues ask us how to increase their value when partnering with technical courses to provide technical or engineering communication instruction. One of the value-added ways to document and assert that value is to align the engineering communication efforts to the ABET a-k criteria [30]. Of course, it’s important to do this work in concert with your engineering departments and the ABET coordinator for your campus.

MOVING FORWARD

As a capstone computer skills course for BEE majors, the course is a demanding one. The computational modeling is complex, and it takes a team of four gifted students an entire semester to bring their models to work well. However, it’s not enough just to make a computer model run; the other technical work that makes the models matter is the communication of the problem statement, modeling goals, transparency in stating assumptions, the elucidation of process and method, and the framing of results in a useful way for other researchers (not just the instructors).

We find the overlay of the 2016 FDA guidelines to have two main advantages: 1) we can provide a framework, beyond just getting a grade, for why strong communication is essential for engineering work and 2) the experience allows students to understand how their work situates within a larger body of knowledge that exists beyond the textbook and course notes. This intertwining of complex, nuanced applications of communicative practice and communicative context allows for students to design their communications more purposefully and to a standard that exists outside of the university context; the experience also allows students (maybe for the first time) to understand themselves as contributors to the engineering, scientific, or technical fields in a realistic and concrete manner.

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Ashim K. Datta, Ph.D., has research and teaching programs that are built around the application of transport phenomena (e.g., energy and water transport, fluid flow) in biological processes in an effort to better understand their complexities with the intent of improving them through optimization. He has been active in primarily the application areas of industrial food processing but we have also worked in biomedical applications. In food process engineering, he develops mechanistic understanding of process, quality and safety for complex food processes and under various heating modes (such as microwave and infrared), with a goal to improve their safety and quality. His teaching program provides the knowledge base in transport processes through two well-coordinated courses. The first course deals with the basics of energy and mass transport and the second one builds on the first one through class projects involving real-life biomedical processes.