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Designing Biomedical Engineering Design Courses*

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This paper discusses an attempt at obtaining a definition for design course content for capstone Biomedical Engineering design courses as currently taught in the United States. The data discussed in this paper have been obtained from a questionnaire developed by the authors and responded to by both academics teaching senior design and by personnel in industry. As is to be expected in an environment where industrial internships are not common, there are some disjoints between industrial needs and academic perceptions. These discrepancies as well as likenesses in perception will be discussed in this paper.

INTRODUCTION

FOR A biomedical engineering program to be accredited in the United States by the Accreditation Board for Engineering and Technology (ABET) a capstone design course must exist that satisfies ABET minimal criteria. Specifically, the course must be of one semester in length (or more), taught at the junior or senior level, require prerequisite work, and comprise at least half engineering design. Engineering design requirements are defined as 'preparation for engineering practice' via 'a major design experience' which includes standards and constraints that include 'most of the following considerations: economic; environmental; sustainability; manufacturability; ethical; health and safety; social; and political.'

Author King has maintained a web-based survey of institutions offering web-locatable biomedical engineering design courses [1]. This listing currently has links to approximately 48 US and 8 non-US biomedical engineering programs and their design courses (primarily senior level, primarily ABET accredited). King also maintains a design education website [2]; from this site a spreadsheet developed by a summer intern in 2000 listing some of the above schools and the textbooks used may be found [3]. An inspection of this list will demonstrate rather quickly that there is no unanimity in textbook selection for senior design courses; rather there is a mixture of textbooks in use, likely dependent on the instructor's past experience. The only text that has a 'biomedical engineering' flavor is that by co-author Fries [4]. The Whitaker Foundation has noticed this gap in the literature and has suggested funding for such a text. The first such text, written by the authors, will be published by Marcel Dekker in August 2002.

The National Science Foundation has funded an Engineering Research Center for Bioengineering Education to a consortium composed of Vanderbilt University, Northwestern University, University of Texas at Austin, and the Health Sciences Coalition at MIT/Harvard [5]. Amongst multiple other tasks, this consortium is charged with developing curricular content recommendations (taxonomies) for a number of subject areas in bioengineering, including capstone design. The work reported here is also a portion of that effort.

METHODS

In order to determine the current state of the art in teaching design in biomedical engineering programs in the US, the authors generated a survey composed of a listing of 42 topics relating to the authors' perception of potential design topics. A copy of the cover letter and survey may be found in the Appendix. The intent of the survey was to enable each person surveyed to report his/her feeling regarding a trial design taxonomy via a ranking of topic importance (high, medium, low, ignore), and to provide a method (free form or otherwise) for suggestions concerning additions to the proposed listing of topics (rough taxonomy). Most of the design instructors listed on the above-mentioned design education web site were initially contacted by telephone (King) to ascertain their interest in the survey, and, if they were willing, an electronic copy was mailed to them. To obtain

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Table 1. Highest ratings, academia v industry

Academia—High scores	Score
1. Product Definition Issues—Initial Specification Issues	2.88
2. Progress Reports—Expectations for Written Reports	2.76
3. Product Specification—Requirements, Design, Reliability, Tracking	2.65
4. Design Examples	2.53
Industry—High scores	**Score**
1. Product Specification—Requirements, Design, Reliability, Tracking AND Risk Analysis/Hazard Analysis (tie)	2.89
3. Design Examples	2.78
4. Product Definition Issues—Initial Specification AND Design Documentation Requirements (tie)	2.67

Table 2. Lowest ratings, academia v industry

Lowest—Academia	Score
1. Professional Societies and Licensure AND Business Plan Development AND The Future of the Design Process (tie)	1.24
4. Reverse Engineering—Software and Hardware	1.17
5. Poster Presentation Basics AND History of Biomedical Engineering Devices	1.06
7. Accident Reconstruction	1.0
Lowest—Industry	**Score**
1. Industrial Design Group Construction and Management AND Accident Reconstruction (tie)	1.0
3. Gannt and Pert Charts and Related Software	0.89
4. Professional Societies and Licensure AND Business Plan Development	0.78

Table 3. Industry v academic: topic v weight v t-test value

Topic	Ind.- Acad.	p
1. Software and Process Design Considerations	+.76	0.12
2. Risk Analysis/Hazard Analysis	+.71	0.01
3. Brainstorming/Idea Generation	−.75	0.05
4. Gannt and Pert Charts & Related Software AND Progress Reports—Expectations (tie)	−.87	0.03

industrial input regarding their desired preparation a number of design professionals in industry were also polled (Fries). Most of the data collection was done in Spring 2001; the results were collected, tabulated, and analyzed for this paper.

RESULTS

The results of this survey, and academic v industrial viewpoints, will be discussed in this section. The use of these results to develop a taxonomy of design specific for biomedical engineering instruction will also be discussed.

BME-specific topics

The design survey consisted of 42 questions; the development of this list generated a subset unique to the practice of biomedical engineering design. These subtopics include:

1. Definition of a medical device.
2. History of biomedical engineering devices.
3. FDA and human factors considerations.
4. Design and process documentation regulations.
5. Animal and clinical trials.
6. Materials and environmental considerations.
7. Safety and reliability considerations.

As will be discussed, the survey results did not dismiss these terms. This implies that BME design considerations cannot be completely met by lectures normally given in one of the classical disciplines, such as mechanical engineering. Such lectures would comprise at least an additional 20% above a generic discipline design topic listing.

Table 4. Topics maximally agreed upon

Topic	Rank	p
1. Accident Reconstruction	1.0	1.0
2. QFD Approaches	1.9	.99
3. Decision Matrix Approaches	2.1	.99
4. Future of the Design Process	1.2	.97
5. Estimating Life Cycle Costs	1.6	.94
6. Formal design approaches AND	1.8	.90
Reverse Engineering AND	2.2	.90
DFMA AND	1.9	.90
FDA/ISO input	2.2	.90
10. Product Safety & Liability	2.2	.88

Response rate and data analysis

Completed surveys were returned by 17 instructors of senior design courses in biomedical engineering design (from 17 of the 47 listed on the design education website) and from 9 industrial responders from 8 different industries. The data responses H, M, L, and X were recoded as scores of 3, 2, 1, and 0 in order to enable relative rankings of responses and average responses by academia v industry. The academic responses were further compared with industrial responses using a two-tailed different variance t-test as is imbedded in the Microsoft Excel software in order to determine the probability that the mean response from each set was the same.

Highest rated design topics

Table 1 lists the resulting highest ratings for coverage of design topics from the academics that responded v the industrial respondents.

Lowest rated design topics

Table 2 lists the bottom rated design topics in each category.

Maximum difference: industry-academic

Table 3 lists the topics valued maximally differently by academics v industrial respondents. This table lists the topic, the difference in weight given to the subject (Ind.-Acad.), and the probability based on the above t-test that the means are the same (p).

Maximum agreement: industry-academic

Table 4 lists the topics found to be most similar in ranking between industry and academia based on the p value that the means are the same. Listed are the topic(s), the average importance rank, and the p value representing the t-test value for the probability that the two means are from the same distribution.

Table 6. Suggested additions to the design content list

Topic	Number
Ethics	7
Economics/ Cost/Benefit analysis	2
Package design and test	1
Medical and large system errors	1
Experimental design	1
Freedom of information	1
Systems engineering	1
Object Oriented Programming	1

Maximum disagreement: industry-academic

Table 5 lists the topics that achieved very low p values that industry and academia agree (Ind:Acad) on the relative importance of the topics (p).

Suggested additions

Table 6 lists some of the non-repeating additions suggested by academia and industry.

DISCUSSION

This survey was developed as an initial attempt to define the taxonomy of the relatively young field of biomedical engineering design as taught to senior year biomedical engineering students. It is apparent that there are several points of agreement between current academic instructors and industry representatives, as well as a few major disagreements. One of the desired long-term outcomes of this survey would be to decrease the number of disagreements or at least decrease the differences in rankings. Each of the results listed above will be discussed below.

BME-specific topics

Of the seven BME-specific topics listed, only number 2, history of biomedical devices, received a relatively low rating by both industry and academia (1.4:1.1) which would indicate that this material, if at all, should be covered in earlier coursework (such as in an instrumentation

Table 5. Topics minimally agreed upon based upon t-test

Topic	Ind:Acad	p
1. Risk/Hazard Analysis	2.9:2.1	0.01
2. Computer aided design considerations AND	2.1:1.4	0.03
Gannt/Pert and related software	0.9:1.8	0.03
4. Written Progress Reports	1.9:2.8	0.04
5. Brainstorming	1.6:2.4	0.05
6. Animal/Clinical Trials AND	2.2:1.6	0.1
Good Laboratory Practice AND	2.2:1.6	0.1
Medical Device Definition AND	2.6:1.9	0.1
IP Considerations	1.4:2.0	0.1

course), rather than being a part of a design course. Anecdotally, very positive feedback has occurred from students who were heavily exposed to FDA and related standards lectures, and who went into industry.

Response rate

This questionnaire has had a significant response rate from the current academic community. To better refine the industrial needs, an expanded survey with a breakdown by product may be necessary (devices, drugs, implants, etc.) This has been suggested to the editor of one of the current design magazines, but no response has occurred to date. Further work should be done in this area in order to generate data of higher significance.

Highest rated design topics

It is good to see agreement that the essence of design is ranked highest by both academia and industry, as expected. Industry rates two other major design considerations very highly—the aspects of risk analysis and design documentation—while academia stresses written communication. This result is not unexpected; the results emphasize practice v preparation for practice. Both camps recommend the use of design examples.

Lowest rated design topics

This section yielded a few surprises. Rated very low was the topic 'accident reconstruction'. Perhaps the topic should have been labeled 'medical accident reconstruction' to imply that the topic would include case studies from 'Medical Device Accidents' [6] and 'Set Phasers on Stun' [7], or consulting practice. Perhaps the respondents felt that this type of inquiry belonged at an earlier level. Very surprising also was the low rating of 'professional societies and licensure' by both camps as these topics were felt to be a natural entry to the need for professional engineering licensure and a discussion of the ethical standards associated with both licensure and BME related professional societies (see this topic again later). Business plan development also took a low position in this poll, perhaps because the respondents felt that this work was more in the realm of the manager rather than the designer. Industry rated design group construction low for perhaps the same reason. Academia rated poster presentations and device history in the low importance range, these topics can easily be done in prerequisite courses, but it was surprising to find that reverse engineering also fared poorly. Input is needed as to the low rating of Gannt and Pert charts by industry.

Maximum difference: industry-academic

Industry significantly rates risk analysis/hazard analysis and process design considerations higher than academia; this implies that these topics likely need to be stressed more in academia in order to better prepare graduates for employment in industry. Academia apparently significantly overestimates the need for brainstorming, Gannt charts, and written progress reports.

Maximum agreement: industry-academic

In assessing the possibility that academia and industry agree on any items ($p > 0.88$ that the means are equal selected here) it was good to see that there are several topics that qualify. Interestingly, 'accident reconstruction' is the winner in the 'agreement' category, *and* is very lowly ranked. Most of the remainder of this list is generic design topics, which should be agreed upon. The one biomedical exception is the reasonably high ranking of FDA and other standards.

Maximum disagreement: industry-academic

There are a number of areas that demonstrate a high likelihood that industry respondents disagree significantly (here taken to be $p < 0.1$ that the means are the same.) The most significant of these is the apparent disagreement about the value of risk and hazard analysis, with industry emphasizing this technology. Computer-aided design considerations is a skill emphasized by industry but not by academia. Academia seems to overvalue intellectual property compared to industry; the other topics on this list were also listed earlier in listings of maximal disagreements.

Suggested additions

The suggested additions list is fairly sparse, considering that there were 26 respondents in all. Six of the seven who suggested the addition of ethics were academic; this suggests that academia may consider that the senior design course may be the correct place to discuss this topic. As the ABET definition for a capstone design course does specifically mention this item, it is our oversight in not making it a line item on the survey (instead of being an implied subset of licensure and professional societies.) Two mentions were made of economics and cost/benefit as an additional topic (in addition to the listed life-cycle costs.) One industry respondent suggested systems engineering as a topic, one suggested object-oriented programming as a separate subject, the remaining topics on the list were from academia.

DISCUSSION OF RESULTS

In brief, this study suggests that there is generally a reasonable mapping between academic perceptions of needed content in a senior biomedical engineering design course and the expectations/needs of industry. For graduates of such courses to be sought after as being well prepared, individual courses may need to be modified to add more instruction of relevance to industry, this

study should allow for a first cut at this modification.

It may be of value to survey more industries to determine if there exists both a generic biomedical engineering design sequence as well as a 'track' sequence that might be required, such that a design sequence might prepare one for work in the pharmaceutical versus the medical device industry, if appropriate. The authors invite collaboration in this effort.

FURTHER ACTIVITY

The results of this study are a starting point for further activity intended to create a deeper understanding of biomedical engineering design and what concepts are at the core of the design curriculum. A first step in this continued activity is being undertaken at Vanderbilt, combining the expertise of both the Biomedical Engineering and Psychology and Human Development departments. Participants, both from academia and industry are being asked to construct a concept map of their conceptual understanding of biomedical engineering design. The group at Vanderbilt will then generate a list of concepts included in the concept maps. Once the list is developed, the participants will be asked to rate each of the entries on the list. Once this information has been reviewed and a new list, based on the rating, generated, the participants will be asked to construct a second map, using the concepts identified as the most salient to the biomedical engineering design process.

Once these concept maps from the experts are developed, students in the Biomedical Engineering curriculum will be asked to produce concept maps at various points in their development, to determine how much information is being retained and where each of the students is in their development, related to the 'expert' knowledge. Results of this activity will be reported in a separate paper.

CONCLUSIONS

Capstone design courses in accredited biomedical engineering programs must be 'preparation for engineering practice' and as such must reflect the needs of the industries where the graduates will be employed. This cannot involve a narrow preparation; it must include exposure to other than generic design, and must include exposure to the interaction with economic, ethical, health and safety, and political considerations. The topical listing of items for inclusion in senior design was meant include these considerations; the only major suggested addition by the respondents was the suggestion for an explicit inclusion of ethics.

The number of topics to be included if the complete original listing is to be covered (42) does suggest that approximately one semester of a design sequence could be lecture based. Including a major design project to the mix would then imply another term of project work. The experience by author King has been that a two-term design sequence has resulted in far more complete and comprehensive projects compared to the output from a single term.

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APPENDIX

Taxonomy survey instrument

Dear Dr.

I am writing to request your assistance in defining the current state of the art for instruction in Senior Level Biomedical Engineering Design courses. My colleague, Richard Fries, and I are conducting a survey to identify the critical issues related to the Design of Biomedical Engineering Devices and Systems as a way to prioritize what needs to be taught to undergraduate engineering students. There are three significant reasons for pursing this effort including –

Contribution to the development of a taxonomy of Biomedical Engineering Design.

Currently, I am involved in an NSF funded Engineering Research Center called VaNTH (see www.vanth.org), which seeks to improve Bioengineering Education. VaNTH is a consortium of universities comprising Vanderbilt, Northwestern, University of Texas at Austin, and Harvard/MIT. Part of my responsibilities as the thrust leader of the biomedical engineering design domain is to create a taxonomy of this domain to be published on a design engineering education website: (http://vubme.vuse.vanderbilt.edu/King/design_education.htm.)

We would like to generate a text that the majority of our departments can use, rather than continue adopting and adapting textbooks generated outside our domain. Both independently and with my colleague Richard Fries, an outline for a design textbook was proposed to the Whitaker Foundation for funding. My original submission was not accepted, but our joint outline was accepted. However, our original chapter drafts were not acceptable to the reviewers because they felt the text was too encyclopedic and would not meet the needs of the undergraduate biomedical engineering student. They did not feel they would adopt our text as they determined it appeared to be addressed to the practicing engineer, rather than the undergraduate student. Therefore, we are seeking your input on what is valued by the instructors of bioengineering design for undergraduate education. My colleague is taking a similar survey to people in industry. (Richard is a practicing Reliability Manager with 20+ years of experience in the medical device industry and has written three related textbooks published by Marcel-Dekker.)

Finally, the results of this survey will be shared in a session I'm chairing at the 2001 BME Society Meeting October 4–7, 2001 (Durham, NC) called 'Curriculum, taxonomies, and needs in BME Education—Biomedical Engineering Design'. Please advise me of your interest in participating in this session.

We thank you for your time and consideration in researching this important topic. Your input will help define the focus for biomedical engineering design education. We will make the results of our survey public at the conference and on the above web site so you may learn about what your colleagues indicated as valued to biomedical engineering design education.

Sincerely,

Paul King and Richard Fries

For a senior level design course, what topics do you think ought to be covered? Below is a topical listing of subjects for such a course—please indicate in the right hand column your opinion regarding the topic covered—H (highly recommended), M (medium), L (low coverage), X (omit entirely.) Please add topics at the end of the list that you feel should added for your offerings.

Topical listing of items for BME design on the Senior Level:

	H/M/L or X?
Definition of a Medical Device or Process	
History of Biomedical Engineering Devices	
Need for Improvement of Devices and Systems	
Generic Design Processes in ME, EE, CE, etc.	
Industrial Design Group Construction and Management	
Professional Societies and Licensure	
Design Documentation Requirements (Property & Quality Issues)	
Progress Reports—Expectations for Written Reports	
Oral Reporting Basics (PowerPoint and the like)	
Poster Presentation Basics	
Product Definition Issues—Initial Specification Issues	
Needs and Demands Documentation	
Quality/Function/Deployment Approaches	
Decision Matrix Approaches to Initial Designs	
Brainstorming/Idea Generation Techniques	

Web and Patent Database Search Techniques	
TRIZ and Formal Design Approaches	
Business Plan Development	
Gannt and Pert Charts and Related Software	
Flowcharting Software in Design Environments	
Product Specification—Requirements, Design, Reliability, Tracking	
Risk Analysis/Hazard Analysis	
Safety Engineering and Related Software	
Human Factors Issues, FDA Recommendations	
Computer-aided Design Considerations	
Reverse Engineering—Software and Hardware	
Materials Selection Considerations/Biocompatibility	
Quality Control Issues (QI, QSR, etc.)	
Software and Process Design Considerations	
FDA and Standards Organizations Input to the Design Process	
ISO and other International Design Standards Inputs, the CE Mark	
Animal and Clinical Trials Requirements, Good Laboratory Practice	
Prototyping and Testing Considerations	
Estimating Life Cycle Costs	
Patents, Copyrights, Trade Secrets	
Manufacturing and Quality Control, Good Manufacturing Practice	
Design for Manufacture and Assembly	
Tracking Reliability Growth in the Field	
Product Safety and Liability Issues	
Accident Reconstruction	
Learning from Failures	
The Future of the Design Process	
Design Examples	
Other Topics which Should Be Included	

Thank you for taking the time to reply to this request; I will share the results shortly. Please feel free to visit the Vanderbilt design course web sites at http://vubme.vuse.vanderbilt.edu/King/bme272.htm and http://vubme.vuse.vanderbilt.edu/King/bme273.htm

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Richard C. Fries is the Manager of Reliability Engineering for Datex-Ohmeda in Madison, Wisconsin. He is a licensed Professional Engineer in the state of Wisconsin, is certified as a Reliability Engineer by ASQ, and is a certified ISO 9001 TickIT Lead Auditor. He is the author of several books and articles on reliability engineering, medical device design, software quality, standards and regulations.