EXPERT REVIEWS

Teaching medical device design using design control

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The design of medical devices requires an understanding of a large number of factors, many of which are difficult to teach in the traditional educational format. This subject benefits from using a challenge-based learning approach, which provides focused design challenges requiring students to understand important factors in the context of a specific device. A course was designed at San Diego State University (CA, USA) that applied challenge-based learning through in-depth design challenges in cardiovascular and orthopedic medicine, and provided an immersive field, needs-finding experience to increase student engagement in the process of knowledge acquisition. The principles of US FDA 'design control' were used to structure the students' problem-solving approach, and provide a format for the design documentation, which was the basis of grading. Students utilized a combination of lecture materials, industry guest expertise, texts and readings, and internet-based searches to develop their understanding of the problem and design their solutions. The course was successful in providing a greatly increased knowledge base and competence of medical device design than students possessed upon entering the course.

Keywords: biomedical engineering • challenge-based learning • design • design control • medical devices

Medical devices have been helping to save and improve patients' lives for decades and are critical components of healthcare around the world. In 2010, the value of the global medical device market was estimated to be US$245.6 billion and in the USA alone – the largest medical device market – it is estimated at US$95 billion dollars [1]. Engineering plays a vital role in the design and often the delivery of innovative medical device solutions. This industry is highly regulated in all major industrialized nations with the goal of ensuring safety, effectiveness and quality [2]. In the USA the regulations are administered by the US FDA, and in Europe the Medical Devices Directive provides the regulatory guidance.

The medical device industry provides an exciting career path for engineers as there are roles in design, manufacturing, quality, testing and many other disciplines. This field is projected to grow by over 70% in the next 10 years, according to the US Bureau of Labor Statistics [3]. There is a mandate from industry to teach design, including team-based experiences and exposure to business, regulatory issues and innovation [4]. In practice, this requires strong academic–industrial collaboration. Design is a topic within engineering in which the basic process can be learned, but proficiency is advanced mainly by experience rather than education. Understanding the design process for a particular company or industry can take years to master and be difficult to distill into an educational experience. 'Design control' (DC) is the process of carefully documenting product design in the medical device industry. Medical device design has additional requirements from design in other industries because of the interaction with the human body, and the criticality of safety and effectiveness. The DC process, as suggested by the FDA guidance document [101], provides an important regulatory foundation for any senior level design course in bioengineering.

Proficiency in design is required for all ABET-accredited engineering degrees. One of the required program outcomes for students is the "ability to design a system, component or process to meet desired needs within realistic constraints, such as economic, environmental, societal, political, ethical, health and safety, manufacturability and sustainability" [5]. For bioengineering accreditation there is an additional requirement that graduates have: "an understanding of biology and physiology, and the capability to apply advanced mathematics (including differential equations and statistics), science and engineering to solve problems at the biology–engineering interface, and the ability to make measurements on and interpret data from living systems,

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addressing the problems associated with the interaction between living and nonliving materials and systems" [5]. However, the knowledge required to successfully bring a medical device to market spans a wide variety of topics, more than can be covered in one semester. The evolution of pedagogy in bioengineering design has been facilitated by organizations such as the Whitaker Foundation and the Biomedical Engineering Society, which have held educational summits, and the Biomedical Engineering Innovation, Design & Entrepreneurship Alliance, which has held annual student design competitions. Several different course models can be found in the literature, each with a different combination of relevant topics and experiences. The majority of these courses have advocated some form of active learning as a means of motivating students to define the scope of their knowledge acquisition and seek the information they need to solve an open-ended, real-world design problem. Problem-based learning or challenge-based learning (CBL) has been shown to be more effective in student learning of problem-solving skills than standard lecture-based courses and have thus been adopted by much of the engineering education community [4,6,7]. These methods have been particularly helpful in teaching hands-on courses such as design or laboratoy practicals [8,9], but often these courses are already too demanding to add another significant topic. Cardinal described a one-semester course to teach FDA design regulation to engineering students using a case-based approach [10]. The Premarket Approval regulatory pathway provided a foundation for examples of device designs but the assignments did not focus on design or innovation. A series of two courses offered by Lai-Yuen and colleagues incorporated medical device applications within existing courses in 'New Product Development and Manufacturing Processes' [11,12]. A problem-based learning approach showed an improvement in student interest and performance, and focused student attention on a specific medical need given to them by a physician. The two-course sequence also enabled prototyping and some testing of student designs, providing a valuable experience for undergraduate students [13].

A survey of universities and courses did not find the prevalent use of DC in medical device design. The survey was conducted using the 2008 Whitaker Foundation curriculum database [102], which included 120 universities with biomedical engineering programs. Several searches were performed on the course database using keywords and course titles to determine course content. Approximately 72 universities offered courses with the words 'medical' and 'design' in the course title, with 48 of the universities offering courses that were clearly engineering with significant design content. The course titles included terms such as senior project [14], artificial organs [15] or medical device design [10]. The ten programs that offered courses entitled medical device design were surveyed to determine their deployment of DC theory and practices in their medical device design courses. Four programs responded, the feedback from these responses indicated that two of these universities taught DC in their courses. Thus, our survey indicated that few courses in medical device design emphasize FDA DC, one of the most useful design frameworks for the medical device industry. While ABET accreditation requires design, the applications taught to students vary, thus accounting for the diversity of approaches used at different universities.

As articulated by Lerner *et al.* there are several goals of bioengineering design education for students: experience the process of designing a new biomedical technology; develop a knowledge of the unique elements of the design process in the biomedical field; develop an improved understanding of relevant engineering and biomedical principles; learn about sources of information; expand basic communication skills; and experience a team-based work environment [4]. These goals must then be meshed with those of industry in the design of medical devices, which are: first, the design of safe and effective implants and instruments to facilitate the medical treatment of patients; second, the development of products that can be commercialized under the auspices of regulations administered by the FDA; third, to commercialize in other international markets through CE mark administered by registered notified bodies or local governmental regulations; and fourth to sell the product at a fair market value that will generate profit for the company. The purpose of framing a design course around the concept of DC is that the design process is logically sequenced, is amenable to multidisciplinary teams, and reinforces the importance of sufficient documentation to demonstrate safety and effectiveness prior to commercialization in the highly regulated medical device industry. Putting this process (which may appear similar to other senior level capstone design projects) into the context and language that the medical device industry must follow in order to commercialize under the auspices of a regulatory body evaluation provides the students with a more unique learning opportunity.

Design control

The importance of engineering documentation in the design process is underscored by the FDA's issuance of the guidance document UC070642 on DC [101]. This guidance document provides the requirements for an FDA submission of a medical device and stipulates the required framework for product design in the medical device industry. The engineering documentation submitted for regulatory clearance or approval is summarized in the device 'design history file'. The guidance document is sufficiently general because DCs must apply to a wide variety of devices from implantable orthopedic and cardiovascular devices to diagnostic instruments. The regulation describes a framework that manufacturers must use in the design process and the documentation of design as opposed to prescribing the specific practices for the various entries into the medical device industry [15,16]. This provides sufficient flexibility so that manufacturers can comply with the regulations and design their products in a structured manner [14,17]. Patient safety is one of the overarching considerations in product design, and must be critically documented and assessed [18].

The FDA describes DC in the following manner:

"DCs are an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances. DCs make systematic assessment of the design an integral part of development. As a result, deficiencies

in design input requirements, and discrepancies between the proposed designs and requirements, are made evident and corrected earlier in the development process. Design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use."

– FDA [101].

The introduction of the DC guidance document describes the well-known fact that design errors are less costly to correct when they are detected earlier in the design cycle [19]. This fact provides one of the inherent values for companies to apply DC procedures. DCs are a component of an entire quality system for a company that is a requirement of the Code of Federal Regulations administered by the FDA [101].

The formal concept of DC is illustrated in Figure 1, which represents the 'waterfall model'. In the waterfall model, the design process proceeds in a sequential manner with multiple review points. Requirements are developed, the device is designed to meet those requirements, the design is evaluated, transferred to production and manufactured. Design reviews are an integral part of the design process and are shown between each phase in this schematic model. In practice, the mandatory design reviews may be specified at strategically important intervals. Feedback and iteration are assumed between each phase but are omitted from the diagram for simplicity. When the design input is reviewed and the requirements determined to be acceptable, the requirements are then translated into high-level specifications and each output is verified as conforming to its input. Design verification is used to establish conformance of the design to its own specification and is used to answer the question: did we make the product right? Validation is conducted prior to the transfer of the design to production and is used to ensure the final design conforms to the user needs or answers the question: did we make the right product? The waterfall model is useful in concept but in practice is enhanced with concurrent engineering principles for improved efficiency. It is essential that all elements outlined in the waterfall model be represented but how these activities are completed is defined by the quality system of the individual companies. Instead of a sequential process of design followed by production, they are often performed in parallel with continuous interaction and iteration among the departments involved in many companies. In the concurrent engineering model, there is involvement of production and service personnel throughout the engineering design process, resulting in increased efficiency and optimization. The concurrent engineering model emphasizes that the development of production processes is a design rather than a manufacturing activity, and may require more frequent reviews to ensure unverified or unvalidated designs or changes do not enter production prematurely. Commercialization occurs after the transfer to production which is generally much more efficient utilizing a concurrent engineering approach. Most successful companies employ a multidisciplinary approach to DC and include coordination of development engineers, marketing, quality, regulation, manufacturing, purchasing and others in their DC procedures. Involving these groups at various stages of the review process improves communication and efficiency. Risk management is another key element of DC that is not explicitly explained in the waterfall model but is a necessary part of activities and documentation, and is a requirement to incorporate into DC procedures.

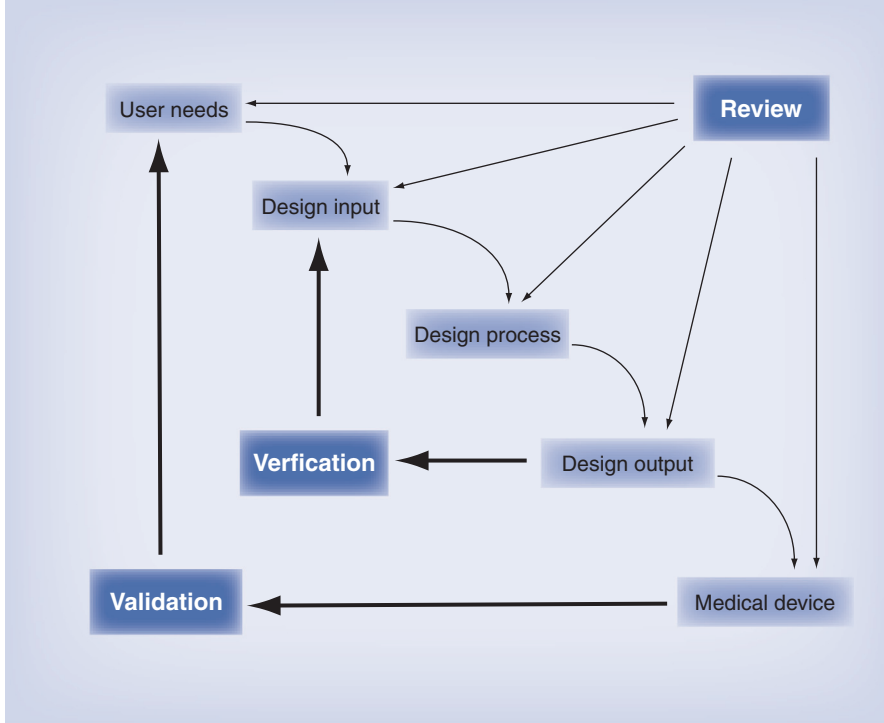

Figure 1. The waterfall model illustrates the application of US FDA design controls to the medical device design process.
Reproduced with permission from [5].

A survey of 26 practicing engineers in the medical device industry also provided information about gaining experience with DC. Most of these engineers (88%) had more than 3 years of experience as an engineer in the medical device industry and the same percentage felt they had a good or very good understanding of FDA DC principles and practice. Over 90% of these engineers understood DC somewhat or not at all before working in the medical device industry, and felt that this knowledge would be beneficial to a career in engineering outside the medical device industry. Opinions differed on how DC is best learned, with approximately 30% for 'doing' and the same percentage for 'study/practice', the rest distributed among 'review', 'on the job', 'case studies' and 'mentorship'. When asked to give a rating from one to ten on how DC could best be translated into a structured learning environment for engineering students, the engineers surveyed ranked

'training courses' first, followed by 'FDA guidance documents' and 'guest speakers – technical'. The San Diego State University (SDSU; CA, USA) course incorporates the latter two extensively, but as an academic course at a university is naturally distinctive from a typical industry training course. However, this type of training course would provide a complementary experience for learning DC.

The local San Diego medical device industry articulated a need for engineers with experience not only in design, but with a keen understanding of the importance of design documentation conformance with FDA regulations. In response, a course was created collaboratively by the authors (two bioengineers, one in academia and one in industry) for engineering students at SDSU. The broad goal of developing a course in medical device design was to enable better preparation of engineers for the medical device industry. The course was intended for graduate students from undergraduate engineering backgrounds and as an elective for select senior mechanical engineering students at SDSU. The goal was envisioned to be accomplished by facilitating students to properly apply DC principles to the design and documentation for two common medical devices, using the 510(k) pathway as an example. The student learning objectives of the course were: to gain an in-depth understanding of the medical device industry, to apply the principles of DC appropriately in two design projects, and to acquire expert knowledge and context through lecture, class activities, industry guest lectures and field trips.

Description of the SDSU course

The course was conducted using the principles of CBL to drive the lectures and discussion using the two design challenges as focal points. The essentials of CBL include the use of realistic, open-ended projects to stimulate student interest in learning, integration of knowledge from several areas to solve the project challenge, and a guided learning process in which the student progresses from introductory to more advanced levels with both self-learning and facilitated group discussions [6]. Often these experiences are organized around a small groups of students, for which the instructor serves as a facilitator of 'just-in-time' knowledge [7]. To prepare for this mode of learning, instructors should prepare self-contained lectures on all topics relevant to the problem solution and deliver them 'spontaneously' as students ask questions.

The course was taught three times over a period of 3 years. Graduate or senior undergraduate students with a background in mechanical design and biomechanics are eligible for the course. The class meets twice weekly for 75 min in a lecture-style environment and enrolls 15–25 students, which can be broken into small groups of four to six or design teams of two to three. The course grade is based 30% on the first design project, 45% on the final design project and 25% on class discussions. The lecture topics were chosen to provide the students with the background needed to complete their two design projects, and were divided into the cardiovascular module (7 weeks) and the orthopedic module (8 weeks). The modules each began with a design challenge. Two texts were selected to provide background and reference information for both projects: *The Medical Device R & D Handbook* by Kucklick [20] and *Spine Technology Handbook* by Kurtz and Edidin [21]. The lecture slides, reading assignments, discussion and design assignments were all posted on a website administered via Blackboard® but presented in an order based on the students' identification of knowledge needed for the design project during group discussions. Several general topics were presented to the class, including regulatory legislation, cost of goods and intellectual property protection. Both knowledge acquisition and innovation were considered important proficiencies to be demonstrated for assessment.

Design challenge 1

The first challenge consisted of a two-part assignment to design an angioplasty catheter for the treatment of coronary stenosis. The first part was to design a catheter that was substantially equivalent to one of the current catheters on the market (a specific make/model provided to the students). The major deliverables were the design input and output documents, which included the requirements shown in **Box 1**. The second part of the assignment was to propose a new innovation for percutaneous atherosclerosis treatment, which would be developed and presented to the class in a 3-min 'elevator pitch'. At the beginning of the semester, students were first required to visit the cardiac catheterization laboratory at a local hospital, where they spent 4 h observing patients undergoing percutaneous procedures and talking to the cardiologists, technicians and sometimes product representatives from catheter companies (**Figure 2A**). This brief immersion in the operating environment of the medical device is very effective at engaging the students' interest in the needs of physicians and patients, and raising questions that drive further knowledge acquisition. This knowledge is provided in the form of lectures, which cover topics including cardiovascular physiology, vascular biomechanics, polymer biomaterials, pressure vessel analysis and fluid drag. Industry speakers provided their perspectives on the general topic of DC and catheter design. The guest on catheter design had <15 years of experience at one of the world's leading angioplasty catheter companies, and brought a demonstration of a simulated arterial model, which allowed students to manipulate catheters through tortuous polymer 'arteries' (see **Figure 2B**). All students participated in peer grading of the presentations.

Design challenge 2

The second challenge required that groups of two to three students work together to select and design an orthopedic or spinal implant. Students were instructed to develop design documentation to support the 510(k) regulatory pathway, demonstrating the new device can obtain substantial equivalence to a predicate (currently cleared) device. The main deliverable is a comprehensive final report, including design input, output, verification and validation plans (see **Box 2**), supplemented with a 20-min final presentation. The field experience was to visit the design and manufacturing center for NuVasive, a local spinal implant company, which allowed the students to discuss details of several implants and surgical tools with practicing engineers and participate in a mock minimally invasive surgery using foam cadavers (**Figure 2C**). Lecture topics included bone and fracture healing, metal biomaterials, an overview of total joint replacements, biocompatibility,

and preclinical research. Several different engineers in the field gave interactive seminars on their specialty, providing students with an industry perspective on finite element analysis modeling and testing medical devices, combined with biologics and how Centers for Medicare & Medicaid Services reimbursement impacts upon medical device design. Students worked collaboratively on the final report and presentation, which provided the team's detailed design and regulatory plan.

Several lecture periods were abbreviated during the course of this project in order to provide team members time to meet and discuss questions with the instructors or guest speakers. Three guided class discussions were held on prepared topics, one per month. The students were provided with background material to inform their participation in the discussion. The first topic was a review of polymer biomaterials, in which each student selected a different material and completed a material data sheet listing the chemical structure, formula, material properties, medical applications and sources for medical-grade material. Data sheets from all students were scanned and made available on the course website, which provided background information on material selection for the first design challenge. The second discussion was focused on regulatory terms and processes, and was held midway through the semester. The third discussion was held shortly after the second design assignment was given. Three lengthy review articles on metal biomaterials were used to inform a discussion of porous biomaterials that provided a targeted background for the second design assignment. Students were highly encouraged to participate in class and to share information with their peers on the projects.

Box 1. Percutaneous transluminal coronary angioplasty catheter design project: requirements for the first design challenge.

Design input document requirements

- Brief background and medical need (including estimate of potential market)
- Engineering specifications:
  - List of components and their critical dimensions
  - Desired material and mechanical characteristics
  - Proposed manufacturing, assembly and bonding methods
  - Proposed sterilization method
- List of design constraints and assumptions

Design output document requirements

- Instructions for use
- List of design constraints and assumptions (refined)
- Component and assembly drawings for each part, including all relevant dimensions
- Bill of materials
- Analysis of stress in the wall of the catheter and balloon; make sure that the rated burst pressure can be achieved
- Analysis of time of deflation of balloon
- Manufacturing, assembly and bonding methods
- Sterilization procedure

Course outcomes & assessment

The deliverables for the design projects included both presentations and design reports, following the DC format shown in Box 1 & 2. The deliverables were scored for both innovation as well as robustness of the design. Students were involved in the grading process through peer evaluation. Report and presentation grades were based on the instructors' evaluation of the deliverables, using the requirements outlined in Box 1 & 2 (70%), the average evaluation score from the peer grading (20%) and participation in the peer grading process (10%). Assessment of student learning and engagement was performed with both direct and indirect methods. For direct assessment, the threshold for desired competency was set at 80% of the total points for each grade category: the two design assignments and participation in class discussions, as well as for the overall course grade. The competency levels are reported in Table 1 for each of the three semesters it was offered.

The first time the course was taught in Fall 2007, only half of the students achieved the desired competency on the first design challenge. Several students did not clearly understand the expected rigor of their designs, which was corrected in future assignments by being more explicit in the instructions. This cohort of students greatly improved on the second design challenge, with 82% achieving the desired competency level. Most students satisfied the required participation, but due to the first assignment, only 45% of the students achieved competency in all three grade categories that semester. The second time the course was taught, students achieved higher competency on the design challenges, resulting in an overall 77% for the class. That time, students were shown examples of excellent reports from the previous course, which provided a model to follow. The lower competency on the second design challenge reflects a single team that did not perform well on that assignment. The third time the course was taught, the desired competency improved to 88% for the first design challenge, 82% for the second, 100% for participation and an overall competency of 82%. Most of the grade was based on meeting design specifications provided by the instructor, but part of the grade was assigned for innovation. Some examples of the innovations for catheter design include a multiple balloon catheter, with different balloon sizes mounted to the same catheter and a flash freeze device that uses a balloon to deliver a cryopulse to the tissue, a spiral shaped balloon that could treat a long spiral vessel segment, and a balloon that can perforate the arterial wall and allow penetration of drug delivered with the balloon. Some of the interesting innovations for the orthopedic and spinal design challenge were a polymer-based spinal fusion cage, femoral stem implant with embedded damage monitoring and a composite pedicle screw/rod system.

Indirect assessments of student opinion were captured by a survey administered anonymously through the course website. Assessment results were pooled for the three times the course

Figure 2. Hands-on experiences complement challenge-based learning for enhanced student learning. (A) Students speak with a catheter company representative while visiting the cardiac catheterization laboratory. **(B)** Testing a catheter in the simulated arterial model demonstrates that catheterization is not as easy as it looks. **(C)** Students perform minimally invasive spinal surgery on a foam cadaver while visiting NuVasive.

was offered. The students identified and ranked how the following elements of the course were helpful in completing the design projects:

- Textbooks – 30% important, 35% somewhat important, 35% not important or irrelevant;
- Field trips – 70% very important, 30% important;
- Guest speakers – 60% very important, 40% important.

Of the students, 95% agreed that the scope and timeline of the design projects were appropriate. These findings related to the course structure indicate that better textbooks are needed and will be sought in future offerings of this course. At the beginning of the course, only 40% of the students were familiar with the principles of DC; by the end of the course, 95% of the students felt that they understood DC principles well or very well. The survey showed that 94% of the students agreed that the course objectives were clearly defined and the same percentage found the course well organized. In total, 88% stated that the interest in the subject stimulated by the course was above average. The instructor's survey provided more detail, with 100% of the students agreeing or strongly agreeing that the course provided an improved understanding of the medical device industry, and agreeing that they had learned all aspects of the design process for one cardiovascular and one orthopedic medical device. All students felt that they had a better appreciation of the various roles that engineers can play in the medical device industry. Overall, 65% of the students strongly agreed, and 20% agreed, that the course has increased their interest in pursuing a career in the medical device industry. 100% of the students said that they would highly recommend the course to others in engineering. There was generally a high level of enthusiasm about the course, and several of the students elected to pursue their thesis research on topics in the medical device field. Some of the comments included:

"I really liked the industry oriented approach of this class. All of the guest lectures were really helpful to know the real industrial practices. Especially, both the design projects helped me to understand the actual design documentation."

"I really enjoyed this course and feel confident in designing devices. The field trips were very beneficial in understanding important aspects related to design and usage of the device in surgical procedures."

"I like this course. It's very helpful for me to decide whether I would like to pursue my career in this field or not."

The course was developed to include both design and regulatory components taught in a challenge-based learning format but could not incorporate prototype development and manufacturing. The realization of a product in physical form is an important step in learning design and would serve as an excellent focus for a second course in the future.

Conclusion

The broad goal of developing a course in medical device design was to enable better preparation of engineers for the medical device

industry. The instructors focused on achieving this goal by harnessing the stipulated requirements of DC provided by the FDA guidance document UCM070642, to structure the deliverables of two design challenges. The guidance document describes desired principles that can be applied through more specific standard operating procedures by companies depending upon their product. Furthermore, the DC approach provided a broad overview of the essential elements of design and a more structured approach to the documentation that is a required element of design within the highly regulated medical device industry.

One of the most important features of this course was the study of two devices in great depth, as opposed to surveying a large number of devices. Through a focused 'just-in-time' concept introduction, a knowledge base for each device can be built in the same way, resulting in a more detailed understanding of the device within a few weeks. Going through this experience twice, first individually and then as part of a team, enables the students to better generalize the learning process for other devices. This understanding of the design process cannot be appreciated with only a superficial exposure to a medical device. Thus the application of DC in the classroom can serve to contextualize knowledge acquisition and facilitate greatly improved learning in the field of medical device design.

Box 2. Orthopedic/spinal implant design project: requirements for the second design challenge.

Design input document requirements

- Brief background and medical need (including estimate of potential market)
- Identification of predicate device
- Engineering specifications:
  - List of components and their critical dimensions
  - Desired material and mechanical characteristics
  - Proposed manufacturing, assembly and bonding methods
  - Proposed sterilization method
- List of design constraints and assumptions

Design output document requirements

- List of design constraints and assumptions
- Component and assembly drawings for each part, including all relevant dimensions
- List of materials and possible sources
- Analysis of device under appropriate loading conditions
- Manufacturing, assembly and bonding methods
- Sterilization procedure

Verification and validation document requirements

- Plan for a 510(k) regulatory submission following the substantial equivalence approach. Provide the documentation to substantiate your selected regulatory pathway
- Plan for verification testing (can include FEA, mechanical testing and so on). Please list relevant standards for the verification testing if appropriate
- Plan for validation testing:
  - Should include description for design validation
  - Should include description for process (manufacturing method) validation
- Acceptance criteria

FEA: Finite element analysis.

Expert commentary

CBL is a proven approach to learning in interdisciplinary subjects, and works well for medical device design. Using the framework of FDA DC, this topic can be covered effectively in a semester by focusing on two in-depth design projects. As the FDA requirements evolve and change over time, the curriculum must adapt to teach what is commonly practiced in industry.

Five-year view

Many universities with bioengineering programs have a course or specialization in medical device design. Often the instructor is hired to teach from industry and thus adequately covers relevant topics but may not have the pedagogical background to translate their industry expertise into an effective learning experience for students. The other approach is for a faculty member to teach the course, but rarely does this individual have the experience from industry to thoroughly prepare the students for employment. In either case, following the guidelines issued by the FDA provides a contextual framework for design and documentation practices at most medical device companies, and can be used as a basis for course assignments and grading. Basic design skills, as well as creativity and innovation, are required for building medical products that work reliably. Our experience indicates that a collaboration between a faculty member and an industry leader leverages the respective contributions from both arenas, resulting in an effective learning experience for the student.

By adapting coursework to the industry and regulatory environment that our graduates must operate in, we can maintain curricular relevancy and successful preparation. Improved surgical techniques and innovative medical devices have been increasing life expectancy and improving patients' lives for decades. Societal issues will continue to motivate innovative and efficient device development practices, and enable better design for technology

Table 1. Direct assessment of student learning: percentage of students reaching desired competency level.

Semester	Students (n)	Design project 1 (%)	Design project 2 (%)	Participation (%)	Overall (%)
Fall 2007	22	50	82	86	45
Spring 2009	13	92	77	92	77
Spring 2010	17	88	82	100	82

by thoroughly considering the impact of the product on the end user during product design. Innovation from multiple perspectives – education, design, manufacturing and implementation – will continue to be an important driver to fulfill society's demands for improved value in the delivery of healthcare.

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Key issues

- The field of medical device design is predicted to grow steadily over the next decade and provides an exciting career path for engineers.
- Teaching a course in medical device design requires both industry relevance and academic structure to be successful.
- Product design in the medical device industry is uniquely regulated – hence the importance of understanding the language and context of 'design control'.
- US FDA 'design control' provides a framework for medical device design in industry and can serve as a platform for medical device design education.
- In-depth design challenges rather than broad surveys are better experiences for building and assessing medical device design proficiency.
- Teaching innovation is important, but must be supported with a strong foundation of design principles.

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