MEDICAL DEVICE ASSESSMENT AND DEVELOPMENT: UNEARTHING DECISIONS

Joe Tranquillo, Donna Ebenstein, Eric Kennedy, Kathleen Bieryla, Dan Cavanagh

BUCKNELL UNIVERSITY

ABSTRACT

Product archaeology is a pedagogical technique for reconstructing the decision-making processes of the designer. For the past eight years, we have offered a course in which students must unearth the business decisions in bringing a medical device to market. In the first half of the class, teams put themselves in the shoes of the company five years before the product launch. The challenge is to excavate information on topics such as the FDA, consumer trends, supply chains, intellectual property, market dynamics, packaging, and distribution. Just as in real archaeology, students must piece together the decisions based upon what is publicly available. In the second half of the class, teams produce a business strategy document that projects the product forward five years. Their proposal is based upon consideration of all the topics above, but also on the value added, given the costs of changes in business practices, manufacturing, and distribution.

Purpose

Engineering departments have many options for integrating entrepreneurial skills and mindsets into their curricula. Most programs choose to wait until the senior capstone experience. Mindsets, however, are rich mental objects that are most often learned through *repeated* encounters with concrete experiences. A second option is to sprinkle activities throughout the curriculum. But a mindset is a combination of abstractions, and such an approach typically leaves individual topics disconnected. A third option is repeated sprinkling throughout the curriculum, with the senior capstone serving to bind together the mindset.

This paper outlines a course that allows the integration of entrepreneurial topics *before* the senior capstone. The sprinkle approach may set students up, but to form a mindset, a binding experience is needed. Our required junior-level course serves as that binding experience and allows the senior capstone to deal with the application and strengthening of the mindset.

A few other programs (e.g., an Olin course taught by Lawrence Neeley) have adopted a similar required pre-capstone experience. Our innovation lies in the way the course creates the binding experience through product archaeology and forward archaeology on a real device. An overview of the course is provided, followed by a generalization of our approach. The intent is to make the approach more easily transferrable to disciplines outside of biomedical engineering and be tailored to the unique needs of individual programs.

Medical Device Assessment and Development (BMEG 408)

The BMEG 408 required course meets three hours per week and is offered to second-semester juniors. It has been offered every year since spring 2006 and has been taught by all of the authors listed. Over the past eight years, the course has undergone several modifications. The course outline presented below reflects its current state.

Course Overview

The course consists of a series of topics that are first introduced through readings, guest lectures from industry, or discussion, such as:

- Teamwork (group dynamics, reflection)
- Intellectual Property
- Human Subjects Research (IRB approval, Clinical Trials)
- Product Dissection
- Professional Written Communication (Memos, Agendas, Gantt Charts, Handouts)
- Formal and Informal Oral Communication (Pitches, Leading Discussions)
- Standard and Regulatory Bodies (ISO, ASME, FDA, Recalls)
- Environmental Regulations and Concerns
- International Markets

Semester-long Project

Many of the topics listed above are introduced earlier in the curriculum through technical classes and a seminar series, but they are not bound together. In BMEG 408, these topics become the focus of the class and are integrated through a two-part semester-long project. For the first half of the semester, instructor-assigned teams of two or three students receive an over-the-counter medical device (e.g., digital thermometer, breast pump). The teams must imagine that they are the design company who created this device five years before the device has appeared on the shelves. Their goal is to find out as much about the pathway the device followed from concept to the drug store shelf. The assignments that correspond to the course topics are a guide to discovering the information they need. Along the way, students find holes in the story and must attempt to fill them with further research or their best guesses. The final assignment in this first half of the class is a formal presentation to the department.

For the second half of the semester, the teams must project the development of their device forward five years. They are asked to consider the value of these changes very broadly (e.g., technical, marketing, financial) and from multiple perspectives (e.g., the company, users, distributors). SWOT analysis, perception maps, white space analysis (See *GameStorming* by Gray, Brown, and Macanufo) and other techniques are used to determine where maximum value will be gained. Through these exercises, many students realize that value can be created in a product through many pathways. They may also recognize that sometimes a technical change will alter some other dimension (e.g., marketability, user interface, packaging) that may, in sum, decrease the value of the device.

Pedagogical Foundations

The Medical Device Assessment and Development course is an instance of a number of pedagogical innovations. We present the pedagogy so that others may adapt and improve upon our implementation.

Product Dissection

The pedagogical technique of product dissection has a long-standing role in engineering education. Before it was formally introduced into engineering classrooms in the early 1990s, many future engineers experimented with product dissection as children. This is the stereotypical pre-engineer who would take apart appliances, radios and engines to understand how they work.

The formal pedagogical technique is meant not simply to understand *how* an artifact works, but rather to get inside the mind of the designer. The goal is to understand the process by which technical decisions are made. In the context of a class, the student may take apart a device, for example an electric can opener, and ask why the gear ratio was set as it was, why the blade was angled away from the user, and why a handle was used instead of a push button.

BMEG 408 does provide students the opportunity to dissect a medical device and understand the technical features (e.g., specifications, user interface), but that is not the course's primary focus. In fact, students do not dissect their device until the second part of the project.

Product Archaeology

The pedagogical technique of product archaeology is a widening of product dissection. The goal is to understand more completely why certain decisions were made. For example, in the can opener example, students may discover that a handle was chosen for some non-technical reason. It may be that the first company that made can openers had core competencies in that area (or intellectual property) and later companies followed suit simply because of path dependencies. Product archaeology provides many opportunities for students to discover the complex interweaving of technical and non-technical concepts. More details of the pedagogy can be found at http://productarchaeology.org/.

In BMEG 408, student assignments in the first half of the project have students considering the origin of the packaging, intellectual property, marketing, clinical trials, path through the FDA, distribution, and other non-technical aspects of their medical product. For example, economics may have driven the decision to package the device with some self-assembly required. Students can also be prompted to consider the wider economic, regulatory, and social environment in which decisions were made. For example, design decisions made for a device currently on the shelves were made in the uncertainty of the developing 2008 financial crisis. Similarly, any device created after 2004 might have opted to use Facebook to market their product.

Forward Archaeology

Forward archaeology is based upon the ideas of product archaeology, but projected to some future design archeologist. Students propose technical and business actions that will be clear and justified to someone doing product archaeology on their product five years from now. Is there a rational course of action that will be coherent enough to be excavated in the future? Phrased in this way, students not only are able to draft a course of action but identify problems with their current proposals. The framework of forward archaeology is therefore a mechanism to make complex decisions given the current and projected economic environment, regulatory landscape, bleeding-edge technology, and movement of competitors.

After experiencing the archaeology of their device in the first half of the project, students have many of the tools needed to perform a forward analysis. Along the way, they often discover new tools and concepts. For example, they may realize the power of leaving the path purposely unclear to secure a long-term competitive advantage in the marketplace. Likewise, they may consider how new technologies might become powerful marketing tools (e.g., Snapchat, future iPad and smartphone applications).

Mindsets

The overall goal of product dissection, product archaeology, and forward archaeology is to guide students toward an integrated entrepreneurial mindset. A mindset is a complex psychological object, based not in concrete skills or abstractions, but instead on the attitude toward challenges. Carol Dweck lays out two primary mindsets (http://mindsetonline.com/). An individual with a *fixed* mindset approaches a challenge as just that, an obstacle to be overcome. Results and success are therefore extrinsic, visible, and measured by how well the challenge is met. Dweck makes the observation that much of our education, parenting, economic, and other systems reward the fixed mindset. An individual with a *growth* mindset approaches the same challenge as an opportunity to learn something new that can be applied to some later challenge. Success is therefore less visible and more intrinsic. It is the growth mindset that forms the basis for lifelong learning and self-efficacy.

No one has a pure fixed or growth mindset, and clearly the same individual may adopt a fixed mindset in some areas and growth mindset in others. The claim of the growth mindset, however, is that the long-term focus on intrinsic learning ultimately leads to extrinsic success. The rationale is that those with a growth mindset bootstrap themselves to take on more and more difficult challenges. Perhaps the most important aspect of Dweck's data, however, is that with some guidance, an individual can change from one mindset to another.

Although the growth mindset is used subtly throughout our curriculum, it comes into clear focus in BMEG 408. There are no right answers, no instructor-constrained domain of knowledge to draw from, and students must make their own decisions. Learning during the first part of the project is the pathway to success in the second half. Students must themselves identify the areas in which they need the most improvement (e.g., video analysis of presentations, self-analysis of their writing). Whereas most courses in our curriculum are challenging because of the technical content, BMEG 408 is unexpectedly difficult for students who have succeeded in a fixed mindset environment. In fact, the course can reset the typical class hierarchy of who is "smart" and who is not. Lastly, not all students leave the class with a growth or entrepreneurial mindset. Sometimes we see the connections being made in the senior capstone. But we often hear back from graduates who have connected the dots back to BMEG 408 as the experience that set in motion a more holistic view of their education.

Variations

Many ways exist to modify the BMEG 408 framework while retaining the underlying pedagogical value. We do assess a number of ABET outcomes in BMEG 408, but there are others that could be assessed, further unloading the constraints placed on the senior design capstone experience. There is no need to use a medical device; nearly any artifact could be used. The format could be changed as well, perhaps placed earlier in the curriculum, or the course changed from required to an elective or possibly moved outside of the engineering curriculum (e.g., arts, management). The makeup of the students could be interdisciplinary (either within engineering or across colleges). It could also be used in conjunction with other techniques. For example, the product archaeology phase could be driven by filling out as much of the business model canvas (http://www.businessmodelgeneration.com) as possible and making educated guesses for the rest.

Conclusion

Sprinkling entrepreneurial topics throughout the engineering curriculum is a place to start, but will rarely result in a coherent mindset. On the other hand, introducing and integrating the entrepreneurial mindset in senior design is difficult because of the other demands placed upon the capstone experience. What is presented here is a transition course that ties together the two approaches into a coherent whole. The use of product archaeology in both a backward and forward pass is a mechanism for binding together topics in a way that can be useful to an engineer. Students leave BMEG 408 with more technical and non-technical tools, a new methodology for thinking about how to make complex decisions, and a new mindset. BMEG 408 primes students to approach their senior capstone as more than a course to be checked off to graduate.

References

Bandura, A. 1977. "Self-Efficacy: Toward a Unifying Theory of Behavior Change." Psychological Review 84:191-215.

Duval-Couetil, N. 2013. "Assessing Entrepreneurship Education: Challenges and Approaches." Journal of Small Business Management 51(3):394-409.

Duval-Couetil, N., T. Reed-Rhoads, and S. Haghighi. 2012. "Engineering Students and Entrepreneurship Education: Involvement, Attitudes and Outcomes." International Journal of Engineering Education 28(2):425-435.

Dweck, C. 2007. Mindset: The New Psychology of Success. New York: Ballantine Books.

Eisenstein, E. 2010. "Engineering and Entrepreneurship: Creating Lasting Value from Engineering." Presented at the 2010 IEEE Conference, Dublin, Ireland, April 6-9.

Fiet, J. O. 2000. "The Theoretical Side of Teaching Entrepreneurship." Journal of Business Venturing 16:1–24.

Gray, D., S. Brown, and J. Mancanufo. 2010. GameStorming. Sebastopol, CA: O'Reilly Media.

Lamancusa, J., M. Torres, V. Kumar, and J. Jorgensen. 1996. "Learning Engineering by Product Dissection." Presented at the ASEE Annual Conference and Exhibition, Washington DC, June 23-26.

Lewis, K., and D. Moore-Russo. 2011. "Upper Level Engineering Design Instruction Using a Product Archaeology Paradigm." Presented at the ASME International Design Technical Conferences - Design Education Conference, Washington, DC, August 29-31. DETC2011/DEC-47933.

Lewis, K., T. W. Simpson, W. Chen, G. Kremer, and A. McKenna. 2010. "From Product Dissection to Product Archaeology: Understanding the Global, Economic, Environmental, and Societal Foundations of Engineering Design." Presented at the ASME Design Engineering Technical Conference, Montreal, Quebec, Canada, August 15.

Lewis, K., D. Moore-Russo, O. Ashour, G. Kremer, T. W. Simpson, X. Neumeyer, A. McKenna, and W. Chen. 2011. "Teaching the Global, Economic, Environmental, and Societal Foundations of Engineering Design through Product Archaeology." Presented at the ASEE Annual Conference and Exhibition, Vancouver, British Columbia, Canada, June 26-29. ASEE-1149.

McKenna, A., X. Neumeyer, and W. Chen. 2011. "Using Product Archaeology to Embed Context in Engineering Design." Presented at the ASME International Design Technical Conferences - Design Education Conference, Washington, DC, August 29-31. DETC2011/DEC-48242.

Mickelson, S. K., R. Jenison, and N. Swanson, N. 1995. "Teaching Engineering Design through Product Dissection." In Proceedings of the ASEE Annual Conference and Exhibition. Washington, DC: ASEE.

Ochs, J., G. Lennon, T. Watkins, and G. Mitchell. 2006. "A Comprehensive Model for Integrating Entrepreneurship Education and Capstone Projects while Exceeding ABET Requirements." In Proceedings of the ASEE Annual Conference and Exhibition. Washington, DC: ASEE.

Ogot, M. and G. Kremer. 2006. "Developing a Framework for Disassemble/Analyze/Assemble (DAA) Activities in Engineering Education." Presented at the ASEE Annual Conference and Exposition, Chicago, IL, June 18-21.

Reid K., and D. Ferguson. 2011. "Enhancing the Entrepreneurial Mindset of Freshman Engineers" Presented at the Frontiers in Education Conference, Rapid City, SD, October 12-15.

Renfrew, C., and P. Bahn. 2004. Archaeology: Theories, Methods, and Practice. New York: Thames & Hudson.

Shartrand, A., P. Weilerstein, M. Besterfield-Sacre, and K. Golding. 2010. "Technology Entrepreneurship Programs in U.S. Engineering Schools: An Analysis of Programs at the Undergraduate Level." In Proceedings of the ASEE Annual Conference and Exhibition. Washington, DC: ASEE.

Sheppard, S. 1992. "Dissection as a Learning Tool," In Proceedings of the IEEE Frontiers in Education Conference, Nashville, TN, November 11-14.

Sheppard, S. D. 1992. "Mechanical Dissection: An Experience in How Things Work." In Proceedings of the Engineering Education Conference: Curriculum Innovation & Integration, Santa Barbara, CA, January 6-10.

Ulrich, K. T., and S. Pearson, S. 1998. "Assessing the Importance of Design through Product Archaeology." Management Science 44(3):352-369.

West, T., A. Feurstein, and S. Shooter. 2008. "Using Cyber-Infrastructure Enhanced Product Dissection to Introduce Engineering to Middle School Students." Presented at the ASEE International Conference on Engineering Education, Pittsburgh, PA, June 21-24. ASEE Paper No. AC2008-590.