Standardization in Action:

A Translational Curriculum

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DREXEL UNIVERSITY School of Biomedical Engineering, Science and Health Systems

DREXEL UNIVERSITY College of Engineering *Materials Science and Engineering*

DREXEL UNIVERSITY Pennoni Honors College

DREXEL UNIVERSITY Westphal College of Media Arts & Design

DREXEL UNIVERSITY CONQUER CollabOrative Cognitive Neuroengineering & Quantitative Experimental Research

INFRASCAN HANDHELD BRAIN DIAGNOSTICS

fNIR DEVICES

Wallace H. Coulter Foundation

National Translational Research Partnership

NIST National Institute of Standards and Technology U.S. Department of Commerce

Standardization in Life Science: An translational Curriculum

	Fall 2016	Winter 2017	Spring 2017
HIST 280: Standardization in Action		X	
BMES 488: Medical Device Development			X
BMES534/535: Design Thinking for Biomedical Engineers		X	
BMES 338: Biomedical Ethics and Laws	X		X
Students senior design thesis	X	X	X

ASTM INTERNATIONAL Standards Worldwide

IEEE STANDARDS ASSOCIATION IEEE

ISO

Topics covered:

Topic are selected based shared core themes among four courses:

- Language & Metadata Standards
- Standardizing Body
- Standardizing Risk
- Standards & Regulation
- Standardization and Innovation
- Standardization & Globalization
- Socio-technical Infrastructures of Standards
- Ethics & Justice of Standardization
- Design and Standards

In and out class activities:

Multi-disciplinary and interactive classroom to teach standards in-the-making and in action (no one knows the “correct answer”)

- Lectures/students’ presentation
- Meet-the-experts from CONQUER CollabOrative, ISO, FDA and IEEE
- Field trip ASTM for mock standard review meetings
- Team projects that combining class with students’ design projects, interests and clinical co-op learning
- Faculty's mutual class visits/teaching support (History, Biomed, Design school)

11 weeks course duration

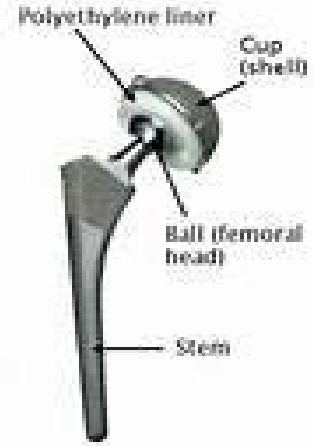
- 22 enrollments
- 22 papers discussed
- 12 experts from FDA, medical device company, ASTM International, ISO, IEEE, English literature, History, transgender professor, etc. were invited as guest speakers
- 1 field trip to ASTM International
- 6 final standard white papers produced, ranging from AI, Uber, battery safety, to alternative medicine
- 3 students joined Standard development organizations (2 ASTM. 1 ISO TC229)
- 1 student took the co-op position in Dongguan, China
- 1 student won ASTM International Student Paper Competition

Meeting the experts:

Teresa J. Cendrowska, Vice President, Global Cooperation ASTM International	Jay Bhatt, Liaison Librarian, Engineering	Antonio Kontsos, Assistant Director, Center of Functional Fabrics, Drexel	David Solt, VP of R&D, Infrascan Inc
Jim Olshefsky, Director, External Relations. ASTM International	Paula Cohen, Distinguished Professor of English, Drexel	Dr. Carole Carey, Chair of the IEEE-EMBS Standards Committee	
Fei, Liu, ASTM's Chief Representative in China	Frederick Klaessig, PhD, Pennsylvania Bio Nano Systems, LLC	Amy Slaton, Professor, Department of History, Drexel University	Jennifer Booker, Associate Teaching Professor of CCI, Drexel University
Ryan Siskey, Principal & Office Director of Exponent	Dr. Sandy Weininger, Senior Biomedical Engineer , CDRH/FDA	Raja Schaar, Assistant Professor, Product Design, Drexel University	

Student Group Presentations

- Body
- Risk
- Objectivity
- Innovation
- Infrastructure



Term Projects

- VR for Proprioceptive Therapy
- VR in Medicine
- CCARE
- Uber (Clients-standards-drivers)
- False Gains – Vitamins & Supplements
- Samsung Galaxy Note 7 Battery

(Perceptions of safety/standards between experts and consumers)

International Visitors

ASTM International 在 Drexel University ◦
1月11日 ·

Liu Fei, ASTM's Chief Representative in China, offered perspectives on standardization in China at the first class of "Standardization in Action: A Global Perspective" today at Drexel University. This course is one aspect of a grant Drexel received from the National Institute of Standards and Technology to teach about standardization at the university level.

Singapore standard delegates visiting Drexel

Meeting Middle East Standard Experts @ ASTM

ASTM Field Trip

Drexel University HIST 280-130
Visit to ASTM International

-Sponsored by NIST SSD-

March 10, 2017 @1:30 – 4:30pm

ASTM International Headquarters

100 Barr Harbor Drive, West
Conshohocken, PA 19428-2959

Theme: STANDARD MAKING IN A CHANGING WORLD

MSU Trip

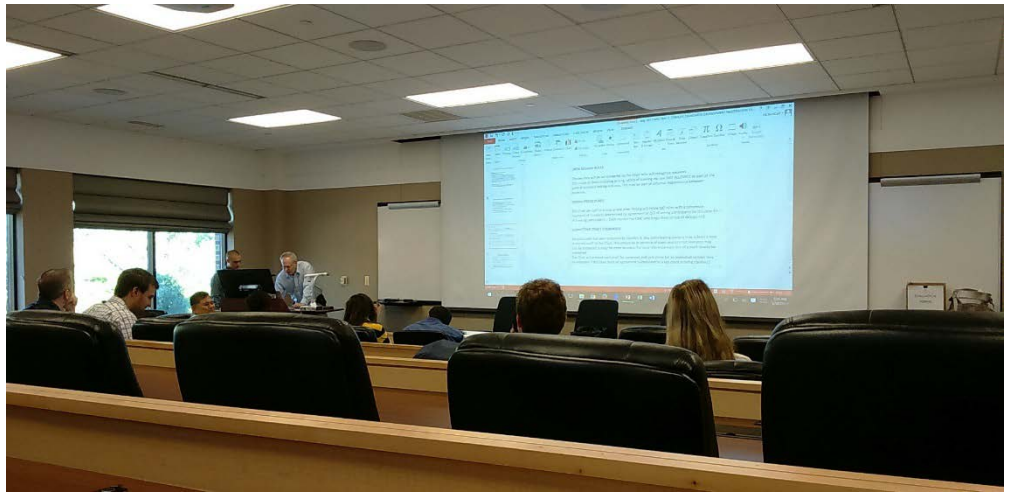
AGENDA

Standards: Enabler of Sustainability

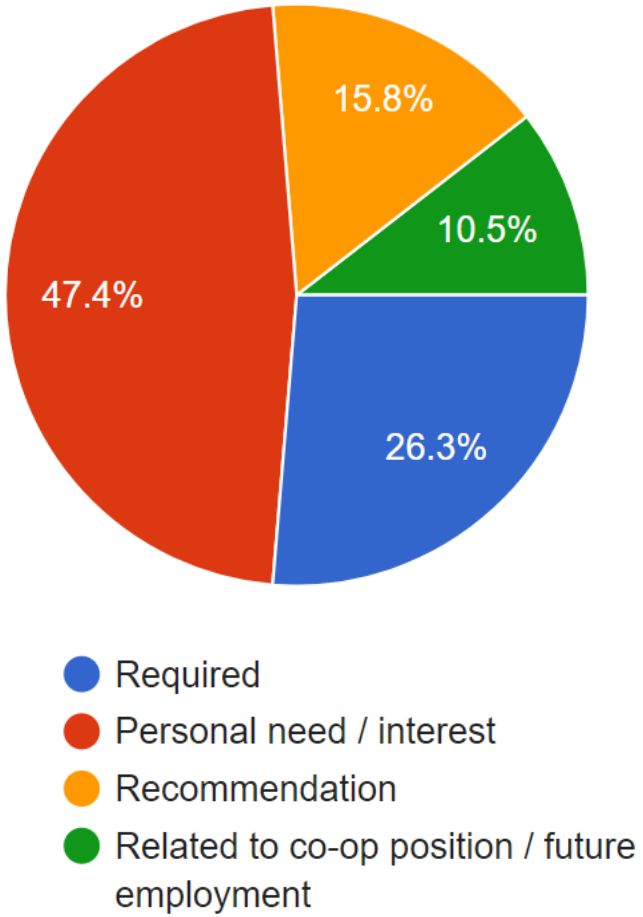
AN ACADEMIC-INDUSTRY WORKSHOP

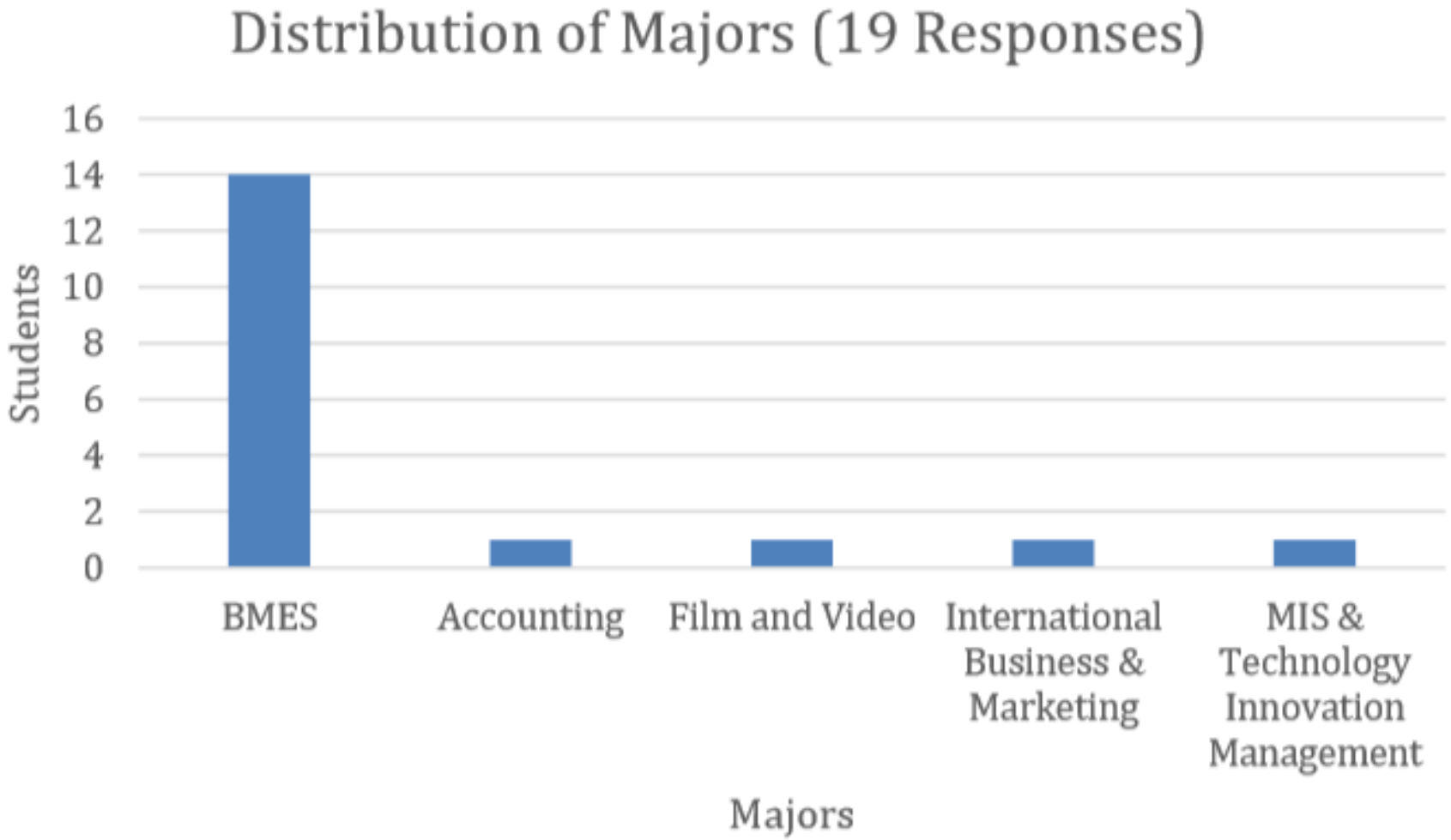
Sponsored and organized by the National Institute of Standards and Technology, Michigan State University, NSF International, and Northwestern University

May 17 and 18, 2017 ** The Henry Center, 3535 Forest Road ** Lansing, MI 48910



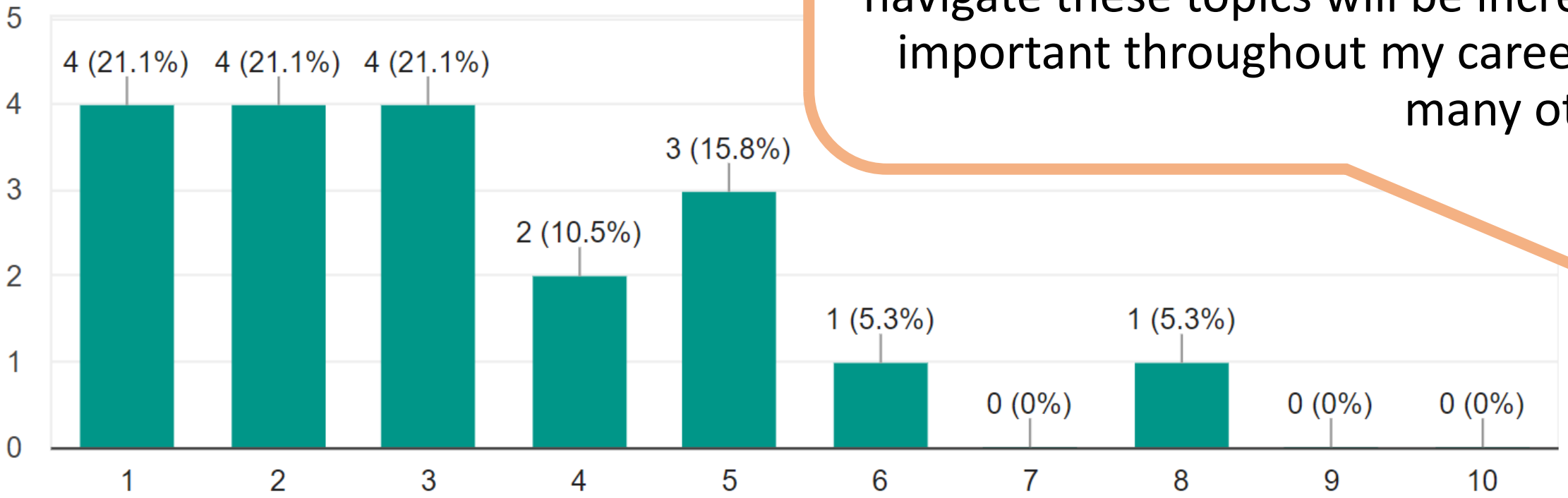
LEARNING RESULTS


15.8%
10.5%
47.4%
26.3%
Required
Personal need / interest
Recommendation
Related to co-op position / future employment


Distribution of Majors (19 Responses)
Students
16
14
12
10
8
6
4
2
0
BMES
Accounting
Film and Video
International Business & Marketing
MIS & Technology Innovation Management
Majors

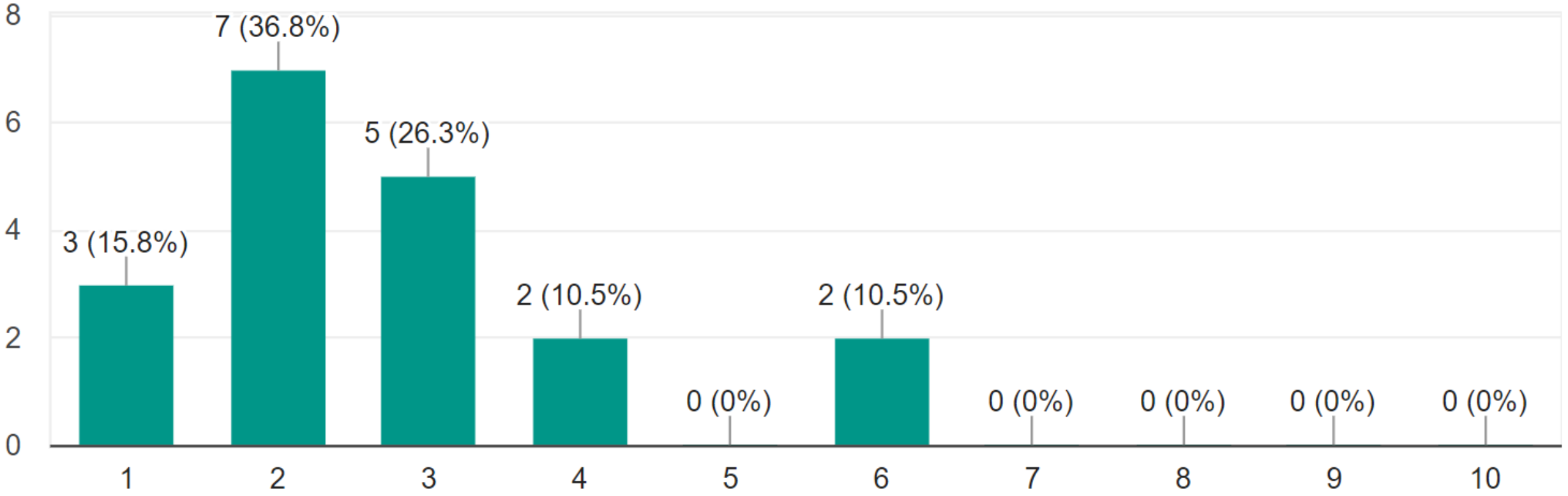
Have you covered standards in other courses? If so, to what extent?

I knew the importance of standards and the necessity to understand how they are integrated to design and production. Understanding how to navigate these topics will be incredibly important throughout my career and many others.



What was your level of knowledge about standards before taking this course?

How do you feel about your knowledge now that the course has been completed?



What are the most memorable topics? What aspects would you have been interested in that weren't covered?

RISK/REGULATION; PATENT/INNOVATION

I think I enjoyed talking about risk, because I never really understood what it means in different social and cultural contexts.

The regulatory factor of standards coming from people **volunteering** to follow it because everyone else does is interesting. The fact that most, almost all, are put in place by different associations of volunteering opinions is amazing.

Patents vs. Standards. This topic is vital in the sense that I never knew that someone could patent something and that patent be partially taken away to be used by all [standard essential patent]. Standards taking over a patent was mind-blowing.

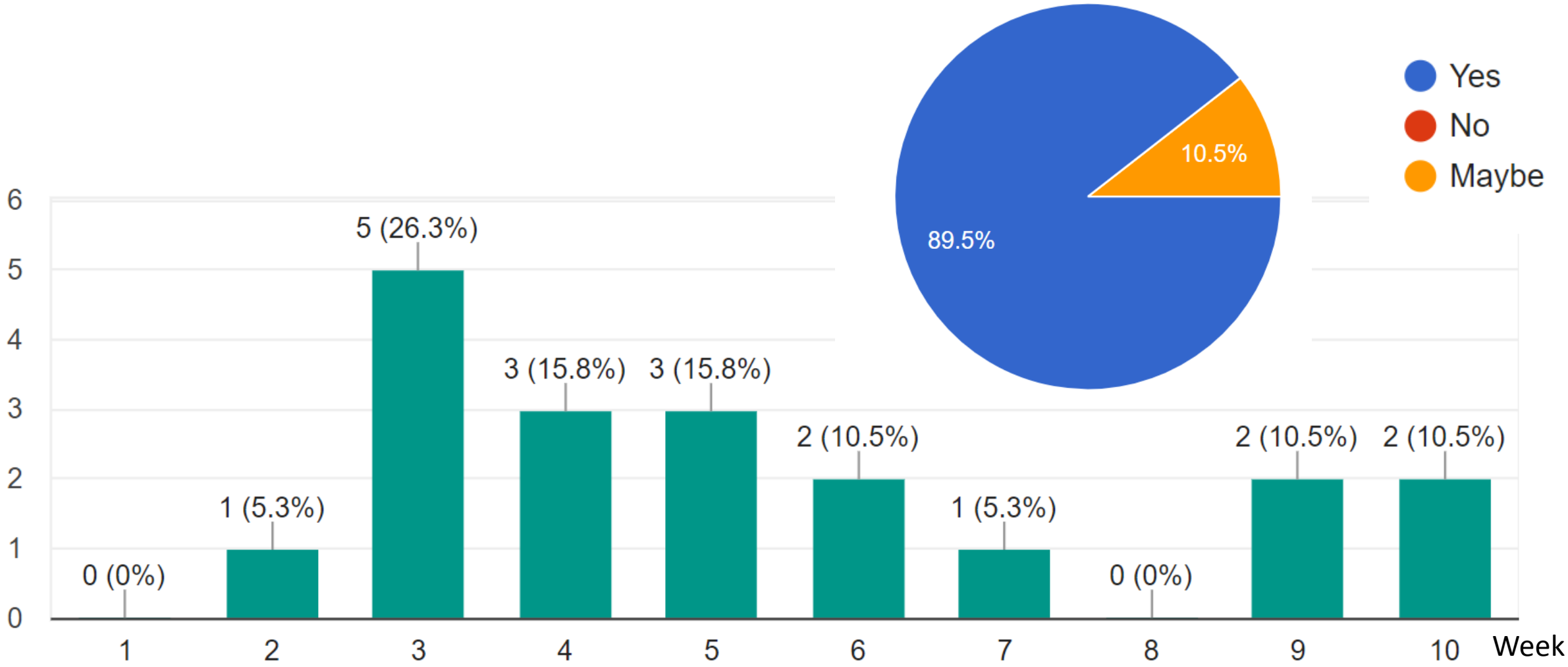
BODY/SEXUALITY/DISABILITY

The human body and gender… really interesting how a 'standard' body really depends on who's perspective you're looking from, be it a surgeon trying to use hardware to replace a joint that is irregular (to their standard), or a patient who does not follow the western view of how to treat a body and has acupuncture or the suction cup treatment to increase blood flow.

I never stopped to think about the difference between gender, sexuality, etc. before that lecture even though it's constantly being debated in the news. **That lecture felt the most... "connectable"...** since it's a topic we always hear about with regards to bathrooms and LGBT rights (although now that the professor mentioned it, T does not belong there!).

The lecture on gender I think was really eye opening to me because the idea that not everything has to fit in a discrete box like male or female was very foreign to me, and **I did not realize how many things in life we do that process** (putting into boxes to simplify things) to which was just very interesting.

Would you recommend that the ASTM trip be incorporated into the standardization curriculum?



Did you find the ASTM Trip to be valuable, if so, why? Which part of the meeting was most enjoyable for you?

Absolutely! The ASTM trip is very essential to the understandings of Standards that we had been learning about. The whole point of a class is to teach someone what it is like in the real-world without the actual real-world feeling. **The trip was that aspect that is always missing in a class. We didn't go somewhere to be lectured, but to immerse ourselves in an environment we really to never would have experienced otherwise.**

Before the trip, we only understood standards through a series of lectures and group presentations; after the trip, we understood standards through the standards-making process; including as a series of compromises between heavily involved actors. The toy standards-making discussion was **the most enjoyable for me because it gave us a hands-on view of how standards are made and really enhanced my overall understanding of standardization.**

I think that missing out on the connections and the out of classroom experience some of the learnings we had would go to waste and not really get people interested in going to the meeting because promotion of something is best done when actually there rather than hearing about it over and over again.

It was incredibly valuable…**an introduction to understanding the reality of creating and debating standards.** …I felt the mock meeting was the most valuable and should have been given more time in the field trip to delve deeper into how people conduct themselves in this environment… **Before the field trip it was hard to really wrap my head around all of the drama they were discussing. Getting the chance to visit ASTM and visualize the first-hand perspective solidified many of these previously abstract issues.**

My most enjoyable part would be the skit that was put on. **The skit gave a great insight into an actual meeting with explanations within the little breaks that were taken.** The reason being, this gave me a feeling of what actually ensued in a meeting. Reading meeting minutes afterwards can be a bore and not give the personal feeling of a real meeting and I think that this gave that feeling. For me personally, I could see myself showing up a meeting and partaking in the meeting, either of this topic or another, because it would give me a voice into a matter that means something to me and would actually be heard for its value.

I think the best part was the mock trial and to be able to hear the perspectives of standards in South Korea and Saudi Arabia. We had mostly learned about American standards in class and some Chinese so **it was very interesting to see how other countries make standards and how they are similar/different to the American standards.**

Would you recommend this course again?

Yes. The class **opened my eyes** to how standards are created and used, especially in biomed.

Yes. This is a unique class within the Drexel system in that it does not base its curriculum on a textbook. Instead **it focuses on concepts and how they affect the world around us. Standards are everywhere** so reading about how they are implemented, hearing from professionals describing their experiences with them really provided a huge perspective on a rather uncommon topic. Hearing from regulation makers, regulation followers, and everyone in between was very interesting. **This class will also help with other Drexel courses** such as the senior design sequence **and for a career where most things are based on predicates.**

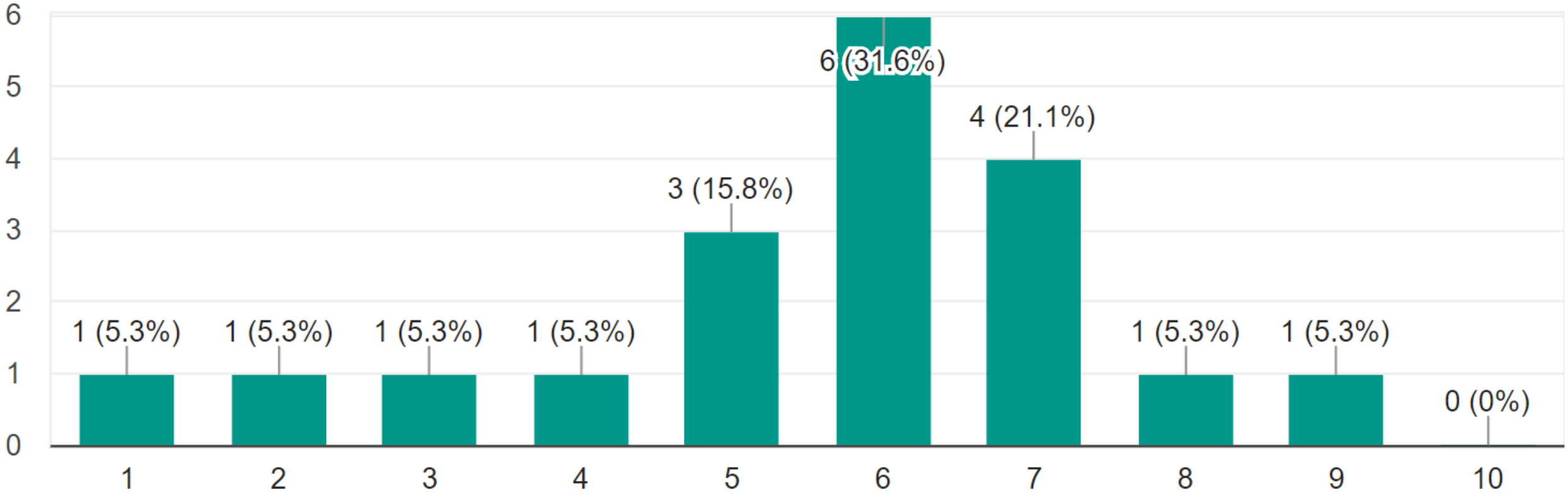
I definitely would recommend this course again. **It covers a unique perspective that is not usually covered in STEM courses, despite the fact that standards are very influential in the STEM field.**

Yes, I think that I would recommend this course to my peers **who have a greater interest in 'why' I think could learn more from a class like this one.**

Yes, I would definitely recommend this course again, especially to students not pursuing Biomedical Engineering. This course gives students exposure to a variety of perspectives and gives them connections with some wonderful professors and people, thus fulfilling the definition of a liberal arts course. Although it is not perfect, **this course expands students' ability to use critical thinking and reflection** when evaluating standards and technology, and **it is one of the few well-designed liberal arts courses I have found at Drexel.** This course is an exciting option, even for those who aren't engineers, because it shows them how to navigate an arcane set of rules; **once completed, the course gives students access to a powerful new language.**

As the teaching assistant for this course, I was lucky enough to have the opportunity to interact with the experts outside of class, as well as connect with students on a personal level … By seeing the course from multiple perspectives as a TA, RA and as a student at the same time, I could argue that I – more than anyone - got the most out of the course.

Have your career goals been influenced by what you've learned in this course?



Improvement

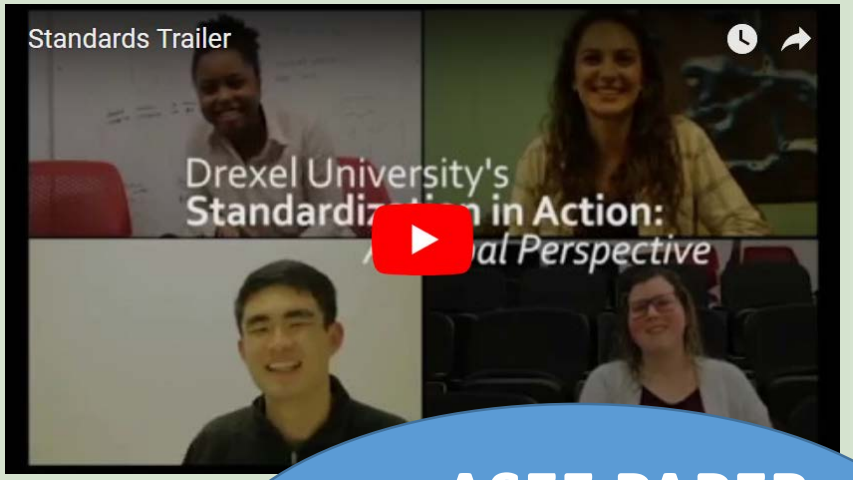
- **Incorporate more hands-on activities**
- **Dedicate more class time to discussion**
- **ASTM International Trip should be earlier in the course**
- **Include a course project focusing on designing a medical device, and cite which standards to use and why**

I would recommend doing the ASTM trip in the middle of the course next time because it gets people excited about standards and gives them a more broad, holistic view of standards; I feel like the end of the course is too late to start molding that hands-on view.

Lesson Learned

- Social science and humanities led Standard Curriculum
- Critical inquires on Rule/Rule-following/Rule-making in broader socio-political context
- Interactive classroom and Out-of-Classroom activities
- Partnership with SDOs
- NIST support is critical to bring this new paradigm in to university education.

Other Deliverables

Surgeon Skills VR	Course Website	Documentary
		
www.mishi-01.github.io	www.hist280.wordpress.com	https://youtu.be/H8MDUNG81TU

- ASEE PAPER
- 2018 Drexel Workshop

Globally Planting the Seeds of Standards Education

Drexel University
University of Virginia

Turkey

China

Korea

Japan

Drexel:

- 'Standards development modules' imbedded in the 'modeling and design' course series.
- An upper level and graduate course on 'biomedical innovation' that will heavily borrow from the 'Standards in Action' course material to help students explore the socio-technical infrastructures of de-novo biomedical technology.

UVA:

- 'Standards course modules' in Engineering Ethics
- Global classroom with Tsing Hua University in 2018 Spring
- Standard and Diversity workshop in preparation.

- TA Mashaal Syed is currently in Japan for her fellowship training

- Leveraging the Drexel-SJTU partnership for preparing a summer school session Standardization and Global Innovation