Standards Modules for Engineering Curriculum: A Case Study Approach

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Overview

- Goals & Objectives
- Approach / Methodology
- Communication Plan
- Resources
- Current Work



Goals & Objectives

- Primary Goal
 - Develop standards education modules centered on case studies, suitable for remote or on-site learning.
 - Modules are intended for integration into first year (Introduction to BME), senior year (capstone BME/Macro/Electrical), and graduatelevel engineering courses at CWRU. Also to be tested at University of Mount Union.
- Short Term
 - Needs analysis (underway)
 - Content identification & acquisition
 - Content integration & testing
- Long Term
 - Module Assessment
 - Refinement
 - Release



Approach / Methodology – Part 1

- Content Identification and Acquisition
 - Interviews with device designers working in the field
 - Cross-cutting analysis to identify common themes
 - Development of two case studies
 - Materials selection for a joint replacement device
 - Investigation of the complexity of a closed-loop diabetic pump with software control
 - Module content would include all pertinent write-ups, forms, references, and videos for seamless integration into current courses
 - Key standards incorporated into curriculum
 - ISO 10993-1: 2018 (Biocompatibility)
 - ISO 13485:2016 (QSR)
 - IEEE 829 (Software and System Testing Documentation)
- Content Integration
 - First-year "Introduction to Engineering" traditional case study activities
 - Senior year "moot court" exercise
 - Graduate-level "deep dive" on medical device design



Approach / Methodology – Part 2

- Initial Testing (year 1)
 - Senior Design courses at CWRU (BME, EE, and MacroE) & UMU
 - Assessment of curriculum both pre- and post-introduction (students, staff, & NIST)
- Impact Assessment
 - Identification of "hits" and "misses" regarding retention, understanding, and implementation
 - Review by third-party educational consultant
- Refinement (year 2)
 - Revision of content to ensure enduring understanding of the material
 - Apply "lessons learned" in implementation to expanding curriculum materials



Example Case Study Development Structure



- Gain insight on those standards and related guidance document in device design.
- · Identify the steps in the design process where standards play a critical role.

Learning Objectives



Communication & Information Sharing

- Licensed under Creative Commons 4.0
- Publicly available on the Open Science Framework (OSF) and hosted by CWRU
 - Complete "kits" for implementation in pertinent engineering courses
 - Final summary report
- Modules shared to the Canvas LMS Commons
- Publications & Conference Presentations
 - Journal of Engineering Education
 - Annual Meetings of the Biomedical Engineering Society (BMES) & American Society for Engineering Education (ASEE)
 - Other local and regional conferences



Resources & Collaborators

• Staff

- Colin Drummond, PhD
 - 20 years in industry
 - Former director Coulter-Case Translational Research Partnership
 - Current instructor of applicable senior capstone and graduate courses
- Matthew Williams
 - Focus on experiential learning
 - Current instructor of applicable first-year and senior capstone courses
- Daniela Solomon
 - Research Services Librarian liaison to the Case School of Engineering
 - Actively involved in increasing standards awareness of engineering students through oncampus workshops
- Key Resources
 - Extensive network of industry contacts
 - CWRU institutional support
 - Access to standards via Library
 - OSF account
 - MediaVision production group
- Collaborators
 - University of Mount Union



Current Work

- Current Activities
 - Have reached out to six key opinion leaders from industry
 - 1. Steris Corp (2 people)
 - 2. US Endoscopy
 - 3. Lubrizol Life Sciences
 - 4. Invacare Corporation
 - 5. COTS Works (small firm)
 - 6. Orbital Research (small firm)
 - Interviews on "needs" underway
 - Completed one interview (Lubrizol Life Sciences)
 - Five pending
 - Have created Canvas site to develop curriculum
 - Have create OSF account for sharing with all NIST partners.
- Next Steps

