Share and Learn Discussion Notes: April 20th, 2022 1-2pm EST

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Teaching Design Controls Biomedical Engineers

Presentation Notes:

- Started teaching with a lecture and no project, now a 4 unit class with a project
- 10-12 elements of design control book:
    - Design Controls, Risk Management and Process Validation for Medical Device Professionals by Vern Geckler
    - https://www.amazon.com/Controls-Management-Process-Validation-Professionals/dp/0692835415
    - Has templates for Design History File, Design Document and Plan in word doc format
    - Goes in order through the design controls process in industry to create design control documents
    - Works best with senior design capstone project and master's level project as it helps with "intended use" and "indication for use" understanding
    - Highlights importance of going to physicians to ask about user needs and how to draft design requirements based on user needs
    - Other Book:
    - Design Controls for the Medical Device Industry, 3rd Edition, by Marie Teixeira
    - https://www.amazon.com/Design-Controls-Medical-Device-Industry/dp/0815365527
- Products/Project Ideas:
    - Master's and PhD Level students: may not come in with a project, so Verna chooses a percutaneous balloon angioplasty catheter (PTCA) as project for them to work on, can buy for $20-30 on Medcart and can add accessories to see how it interacts with guide wire/sheath/etc. to see how to write specifications for when device interacts with other devices
    - To Purchase: https://medicalmaterials.com/ or https://www.medicalecart.com/ or https://www.esutures.com/
- Course Structure:
    - Elective course for Juniors through Master's interested in Medical Device Track (compared to other tracks: PreMed and Biomolecular tracks)
    - Start with device classification to learn regulatory pathway in US and in ISO 1345 (European) pathway based on project
    - Turn in as individual: design and development plan, user needs document, risk management document
    - Turn in as team: best elements of above and turn in mini Design History File
    - Last module on Process Validation, connects to design control as last element before transition towards manufacturing and commercialization (how something is made and manufacturing processes that need validation vs those that are easily verified)

Open Discussion:

- Lori Herz – Lehigh University has tracks (BioPharm and Biomechanics/Biomaterials tailored to medical devices), all students take it junior year prior to capstone course
    - Links to project to sophomore class of artificial heart valve
    - In capstone, they apply the FDA regulations class to their design project which may or may not be a medical device
- Regulation of Pharmaceuticals course?
    - Santa Clara has most basic science courses and can go drug or device path, but nothing required
- When do you start design?
    - Need some basics to be able to understand design controls
    - Lori – capstone starts junior spring semester, design doesn't start until then
    - Freshman course – introduction to engineering practice to decide major, added a project with a device (fabricated prosthetic hand to reverse engineer)
    - Sophomore course – introduction to bioengineering, project where they design heart valve with CAD and 3D printing and can play/test junior year
- Does anyone teach course specifically on design controls over 10 weeks?
    - Dan Puperi – teaches junior year since they don't get it in senior design
    - Dan Puperi – students want authentic documentation example, but hard to find
    - Verna Rodriguez – works with EQMS provider, used Greenlight Guru, but is too user intensive for students to use, so she created templates for class and will share for basic documents
    - Verna Rodriguez – takes good examples from past students, and limit to 10 line items to risk analysis documents
    - Instead of design/process/use FMEA, doing a risk hazards analysis document instead
        - Emphasizes harm vs. hazard (hazardous situation, harm, severity, risk level, mitigation techniques in design)
- Plan:
    - Design and Development Plan (on Greenlight Guru) – intended use, indication use, team members, responsibilities, classification of device
    - Roles – team leader, regulatory person, clinical and preclinical person, R&D engineer, manufacturing engineer, quality engineer
        - 1 team meeting per week, with agenda/topic etc. that would go in Design History File
        - 1 cross products meeting with counterpart function with another team
            - Dan Puperi – does this with a "design review" meeting
    - User Requirements and User Needs – draft design inputs on excel spreadsheet, 10 line items, include environmental conditioning of packaging, sterilization, interaction with accessories
    - Final Project: combined 30 line items of all documents
- Ethan Geheb and Clarissa – how important is statistics preparation prior to taking design controls?

    - Verna - Geckler book has good chapter on statistics for test method validation and sample size determination
    - Verna – good Book for Statistics:
        - Statistical Procedures for the Medical Device Industry by Dr. Wayne Taylor
        - https://variation.com/product/statistical-procedures-for-the-medical-device-industry/
        - Good because it discusses when they need to use MiniTab or Jump and in what documents
    - Test Method Validation – would be a very good course to teach
- Lori Herz – do you have any references on Clinical Trials in Medical Devices?
    - Verna – doesn't teach clinical trial design, usability studies and clinical trials all fall under design validation
- Jan Stegemann – BME at University of Michigan, how do you incorporate a Design History File into a 10 week or year long course? It can take away from other things students are doing
    - May be done differently at different companies and venues, how do you generalize it?
    - Verna – mini-DHF is created, they make a design and development plan, risk/hazard analysis, risk management plan, risk management report, trace matrix, user steps analysis for harms for usability, and then give a DHF index (table of contents) and fill out where those documents go and create titles for each (e.g. component specification, test method example, sub-assembly or component external to company document)
    - When doing trace matrix from user needs to design verification/validation, they make title and description of which tests to do to verify/validate each design element (e.g. for strength of element, state tensile test done for that element with title and description and put this in the DHF index)
    - Component – assembly drawing – test, do this for 9 elements and list which specs are verification tests required and proposed test they need to create, so every line item ends in a verification or a validation test description
- Dan Puperi – students don't like doing the documentation, and it's hard to fit it into the building aspect of the device (too much documentation and not enough time building stuff)
    - In device industry, you design it, you don't solder it yourself!
    - Verna – starts class with the Bleeding Edge (https://en.wikipedia.org/wiki/The_Bleeding_Edge) to show that you will be working with a boss that is not following the law and is unethical and why it is important to find the balance between design controls/regulations and design
    - Verna – uses software and methodology for writing product specifications – INCOSE guidelines (https://www.incose.org/incose-member-resources/working-groups/process/requirements) and Easy Approach to Requirements Syntax (https://ieeexplore.ieee.org/document/5328509) and QRA Consulting Software (https://qracorp.com/)
        - QRA software used, works with their engineers when students use this software, follow EARS document, then plug into GVscribe to grade selves and turn in product specifications

- QVScribe searches between specifications for inconsistencies or conflicting specifications, university allows them to use it for academic discounted rate (reach out to Verna for introduction to get demo)