Presentation to the IEEE EMBS Standards Committee for the Proposed PAR

Guide for a Software Change Control System for Three-Dimensional (3D) Bioprinting of Tissue-Engineered Medical Products (TEMPs)

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BACKGROUND

- April 16, 2019
  - BioFabUSA held an in-person meeting of their Standards Working Group
- Discussed three areas for standards development in bioprinting
  - Biomaterials and Bioinks – ASTM
  - Hardware – ASME
  - Software and Data Management/Governance – IEEE-SA
- Group identified potential topics for standards development in each of these areas
- Smaller working groups established for each of the three areas

Guide for a Software Change Control System for Three-Dimensional (3D) Bioprinting of Tissue-Engineered Medical Products (TEMPs)

- Need to log and track what was changed during printing down to the software level
- Creation of a manufacturing "chain of custody" for the print
- Could improve costs and safety (i.e., assist in CAPA investigations)
- **Purpose of Standard**: To establish a guidance for accurate and optimized software change code procedures for TEMPs and anatomic modeling development via 3D bioprinting.

Scope

This standard provides guidelines for how to develop and implement a software change control system to manage all changes made during three-dimensional (3D) printing of medical products to create tissues or tissue-like structures (bioprinting) for transplantation into an animal or human, and/or anatomic modeling purposes. The change control system will provide a process to ensure that the changes made to the product are introduced in a controlled manner.

Need

Bioprinting has high technological barriers that do not exist in other industries, such as, the use of living cells during printing which necessitates manufacturing materials and resources that are biocompatible and non-toxic. This standard would help improve the safety and quality of the printed medical product because it would help ensure that no unnecessary changes are made, all changes are documented, product manufacturing is not unnecessarily disrupted, and materials are used efficiently.

Stakeholders

- Medical Practitioner, Healthcare Manager, Medical Researcher
- TEMP Developer, Technical Expert
- 3D Bioprinting Company, 3D Biomaterials/Bioink Manufacturer
- Medical Imaging Equipment Manufacturer
- Manufacturer of 3D Devices, including 3D monitors and 3D display panels

QUESTIONS?

For additional questions or comments please contact:

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