A Proposed Regulatory Framework for 3D Printing Implants at Point-of-Care (PoC) Facilities

America’s Got Regulatory Science Talent Competition
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3D Printing is Revolutionizing Healthcare

Patient-Specific implants improve patient outcomes

3D Printing is Revolutionizing Healthcare

Manufacturing & Supply-Chain Flexibility reduces costs

https://miro.medium.com/max/1300/1_1DSyW1pXeiO-TMyQ2t6gA.png
Status of PoC 3D Printing

The technical infrastructure already exists!

The Problem:
A regulatory framework does not exist to ensure safe and effective implants can be manufactured at the point-of-care.
FDA Priority Area

3. Assure safe and effective medical innovation

   c. Help stimulate the development, standardization, and validation of new techniques to assess safety and effectiveness.
3-Pronged Solution

- PoC-Cleared
- Implant
- Presentation
3-Pronged Solution

Data

PoC-Cleared Implant

PoC-Cleared Implant
3-Pronged Solution

Validation Techniques

PoC-Cleared Implant
3-Pronged Solution

- Training
- PoC-Cleared Implant