



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

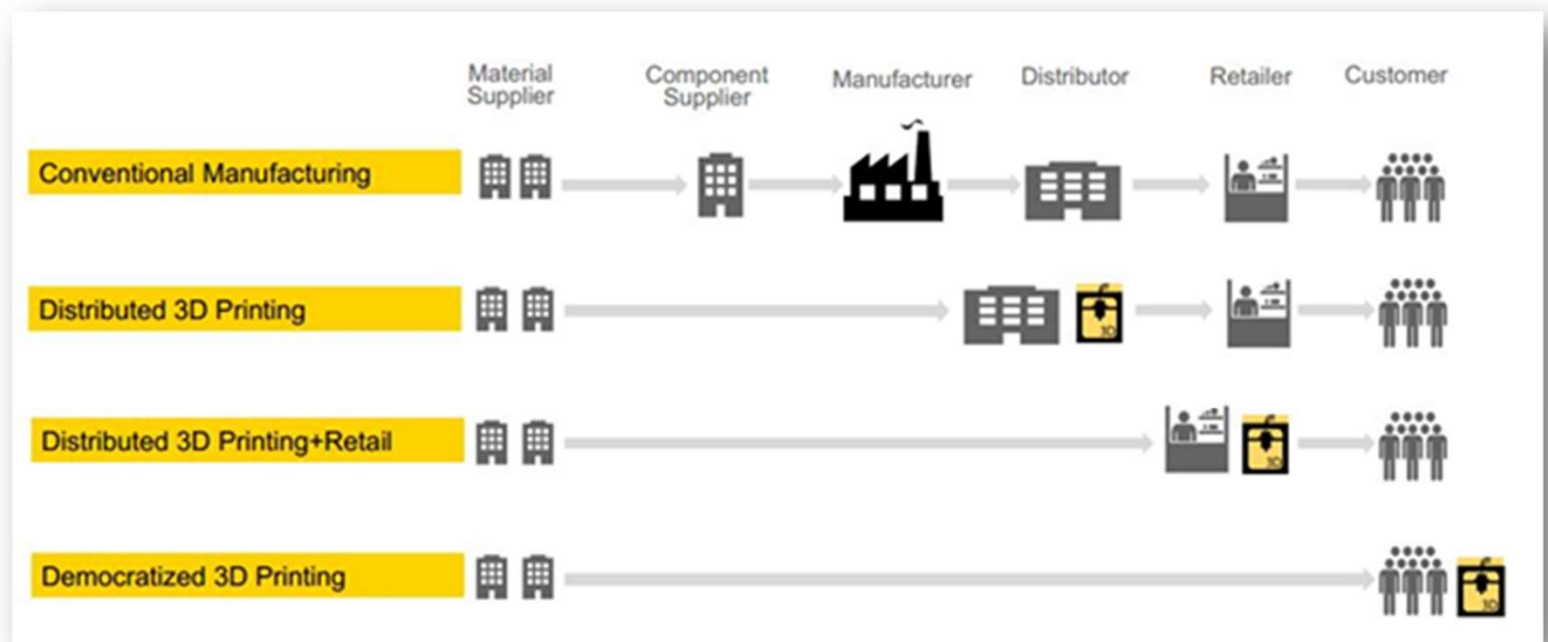
Patient-Specific implants improve patient outcomes



<https://amhub.net.au/wp-content/uploads/Renishaw-implants-AMTIL.jpg>

3D Printing is Revolutionizing Healthcare

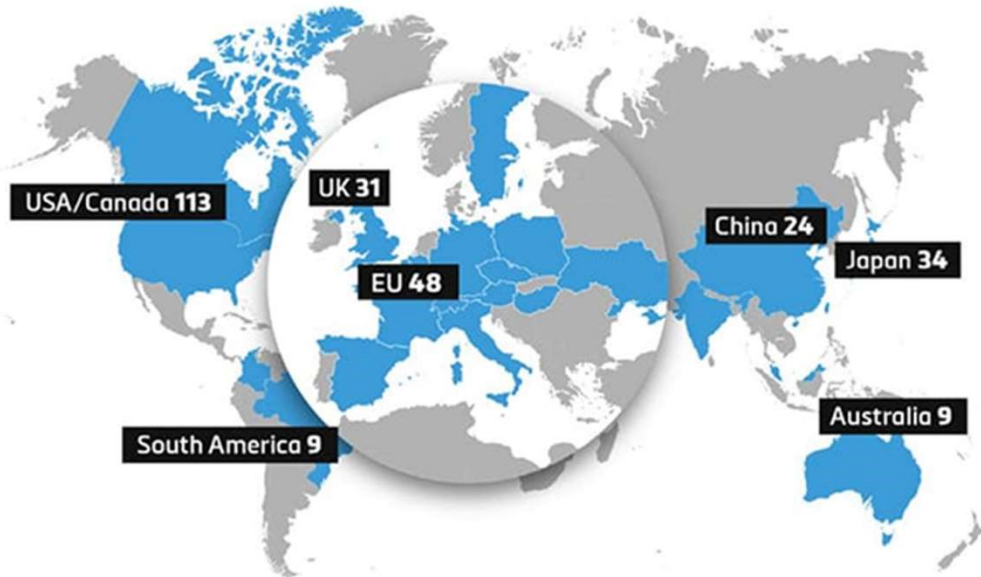
Manufacturing & Supply-Chain Flexibility reduces costs



https://miro.medium.com/max/1300/1*DSyW1pkteIO-TMYO2f6fA.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

4. Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

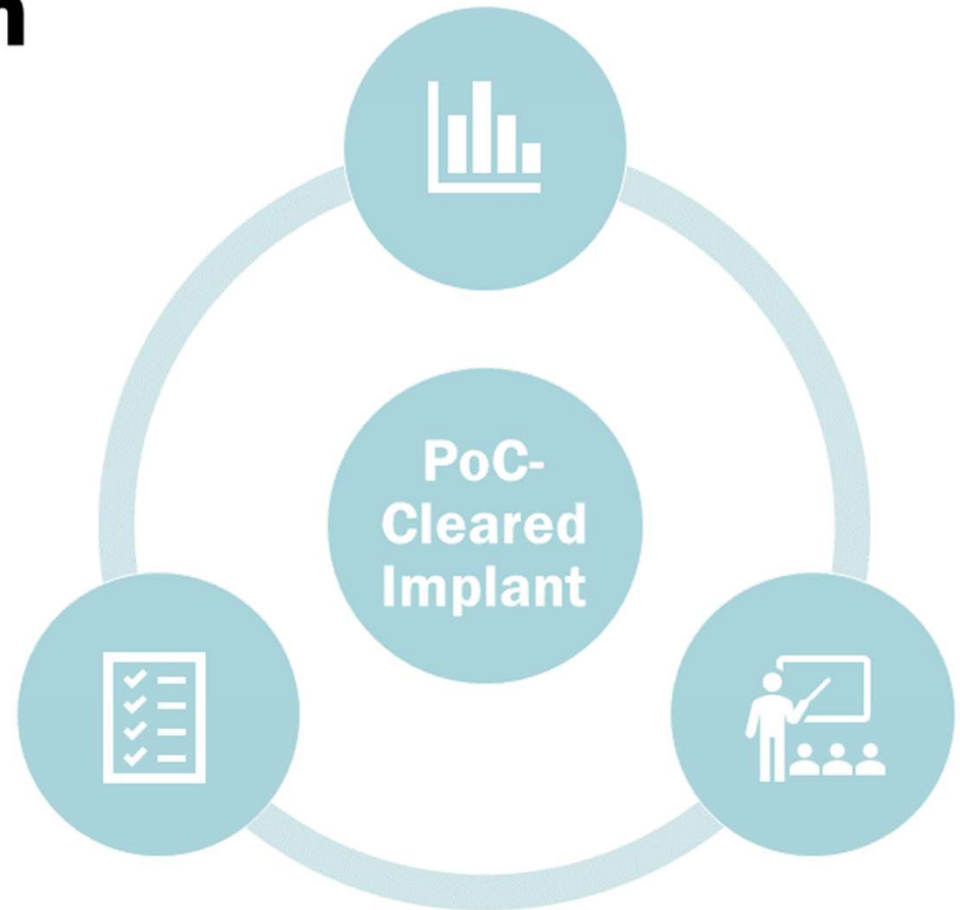
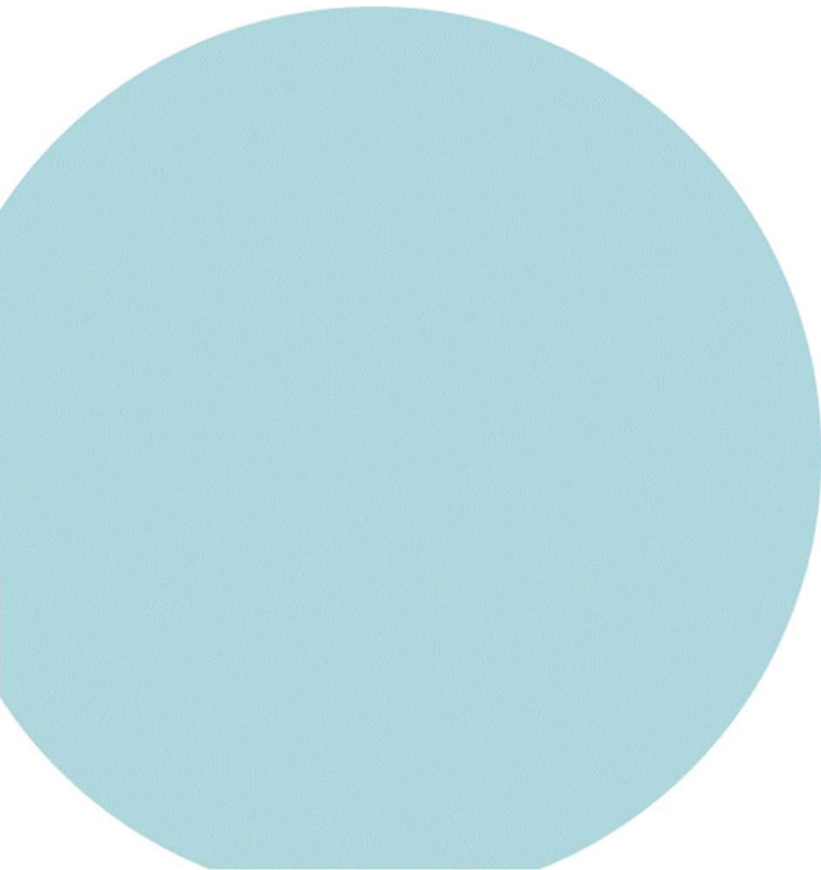
3. Assure safe and effective medical innovation

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

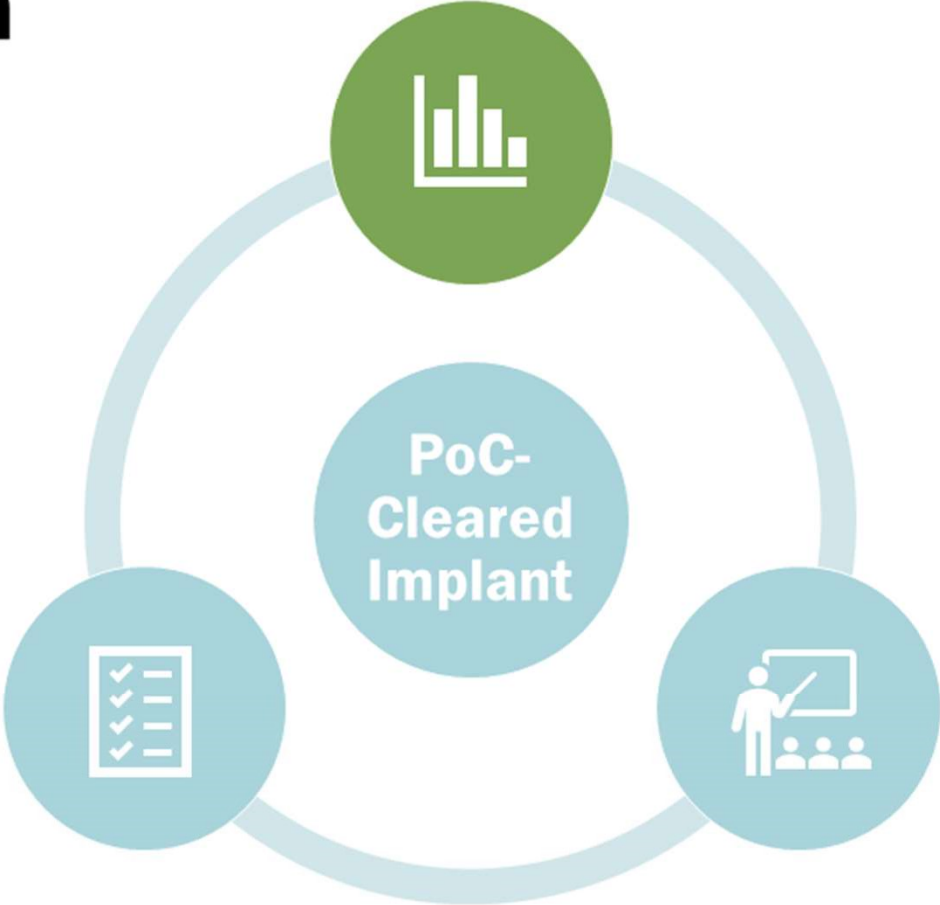


<https://www.fda.gov/science-research/advancing-regulatory-science/strategic-plan-regulatory-science>

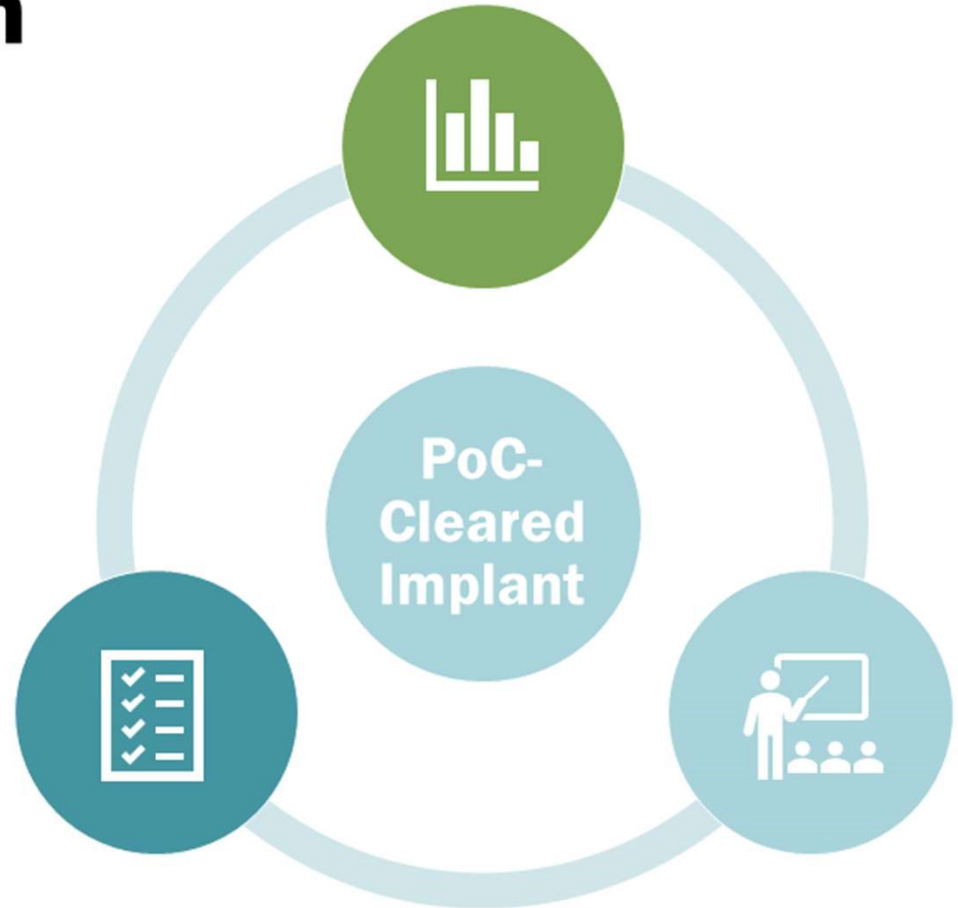
3-Pronged Solution



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