Ensuring FDA's Readiness to Evaluate Additive Manufacturing

Rochester Regulators

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[image] Dilbert (2012).

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Additive Manufacturing

- Sequentially build 2D layers to construct part
- Allows manufacturers to design custom shapes for personalized medical applications
- FDA guidance document
- ASTM F42 committee standards

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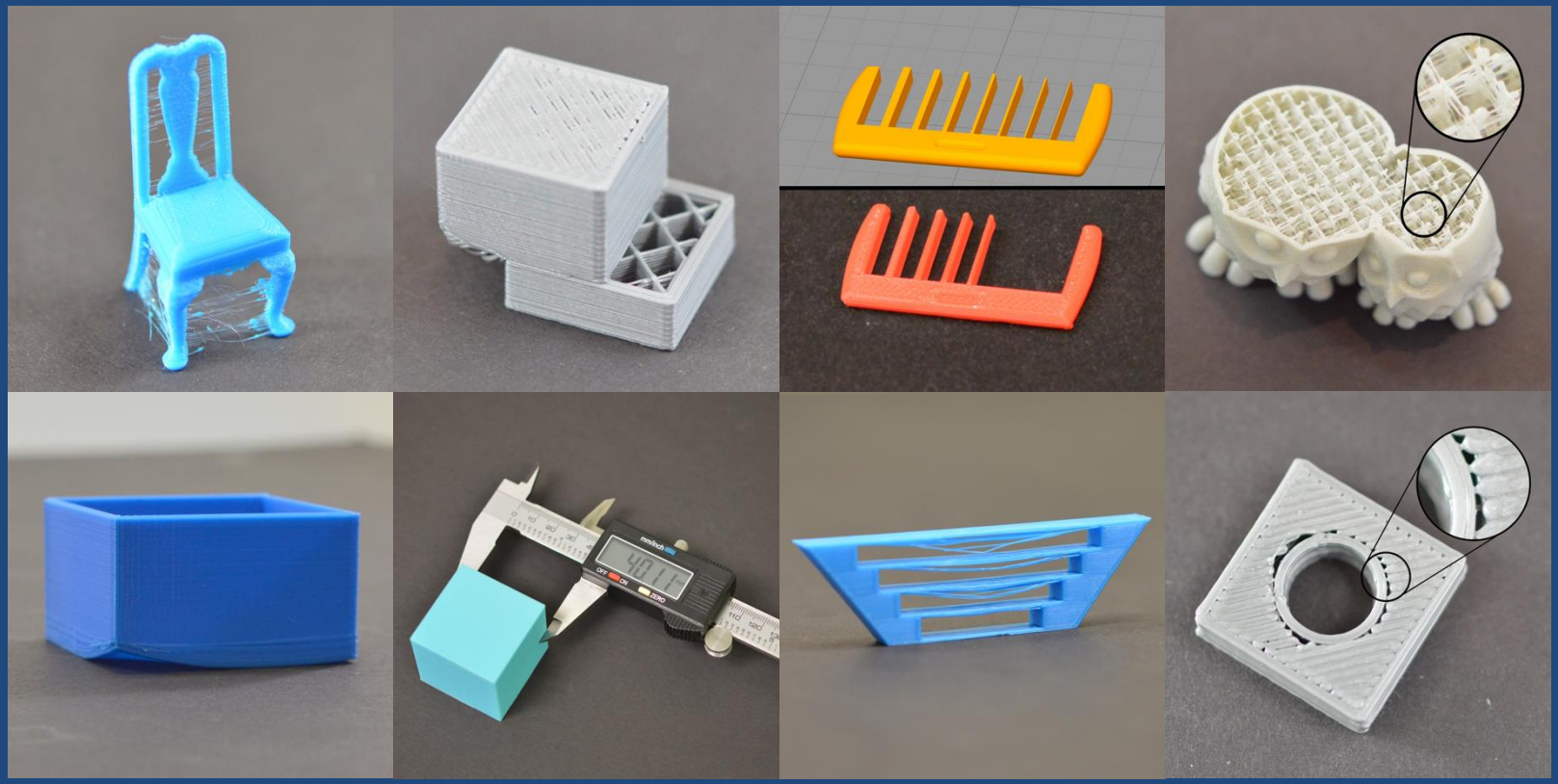
[video] ZME Science (2015). *3D printing to the next level: Terminator style.*
[Image left] NIH. (2018). *3D-Printable Prosthetic Devices.*
[Image right] Hobson, B. (2018). *3D-printed medical implants.*

3D Printing Problems



[Images] Simplify3D. (2018). *Print Quality Troubleshooting Guide.*

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Quantitative Evaluation Toolkit

- Quantitative imaging biomarkers to identify print defects
- Real-time monitoring of AM processes for defects
- Realistic printer performance and resolution metrics
- Monitor properties of print material as they heat, cool, or cure.

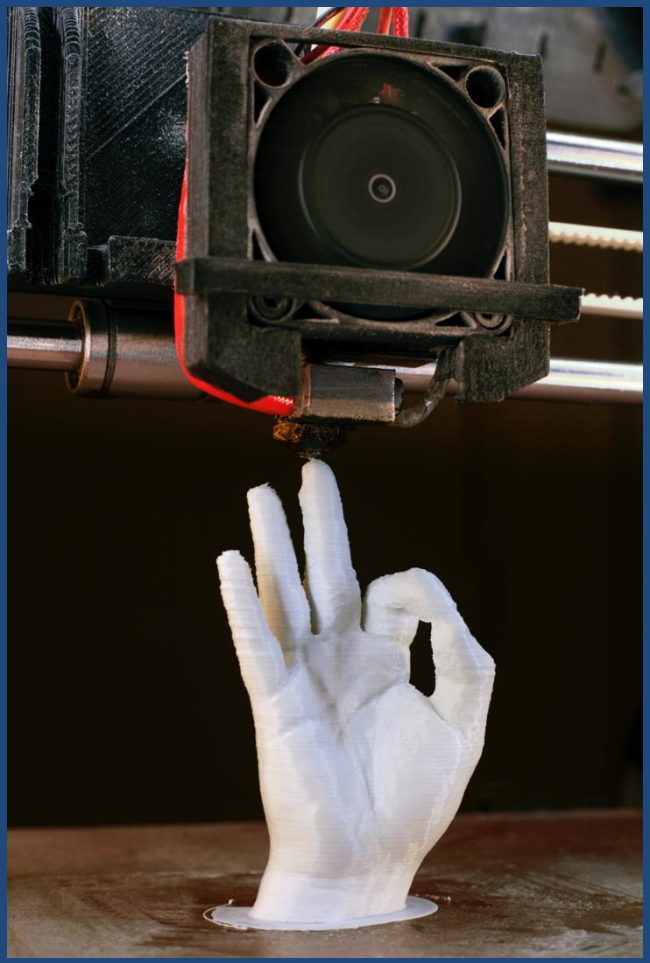
Benefits of an Evaluation Toolkit

- Quantitative performance metrics
- Identification of defects and potential effects on device
- Ensures tolerances and consistency with predicted vs expected devices
- Ability to quantify differences between printing methodologies

Summary

- Additive manufacturing is a growing technology in the medical field
- New quantitative metrics are needed to evaluate emerging technologies going through FDA review
- This toolkit would allow for build and post-processing validation

Questions



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[Images] Thermo Fisher Scientific. (2016). *Plastic Is Still the Leading Material in the 3D Printing Industry*