Perspectives on Printing Considerations

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Goals

• Summarize current FDA approach towards:
  – Printer control software
  – Initial material properties
  – Printing parameters
  – Quality control

• Introduce Speakers
Printer Control Software

• Define configurable parameters for
  – Vendors
  – Device Manufacturers
  – Users

• Fill and support calculation algorithms
Initial Material Properties

• Material type
  – Crystallinity
  – Melting and glass transition

• Printer
  – Powder size distribution
  – Deposition velocity
  – Reusing powder
Printing Parameters

- Beam energy density
- Scanning speed
- Environment
- Local changes to chemistry
- Bulk heating uniformity
Quality Control

• Process Flow Diagram

• Determining reproducibility
  – Validation, verification
  – Documentation

• Revalidation

• Identifying problems during a run
Thank You

Acknowledgements
Additive Manufacturing Working Group

Contact
AdditiveManufacturing@fda.hhs.gov
Include “Workshop” in the subject line
Subject Matter Experts

- Jon Cobb
  Stratasys

- Ernesto Rios
  Renovis Surgical Technologies

- Scott J. Hollister, PhD
  University of Michigan
Continuing the Discussion

• Breakout Sessions

• Docket open for comments and responses
  – Docket Address