Perspectives on Printing Considerations

LT James Coburn MSc
Division of Biomedical Physics
Office of Science and Engineering Laboratories
Center For Devices Radiological Health

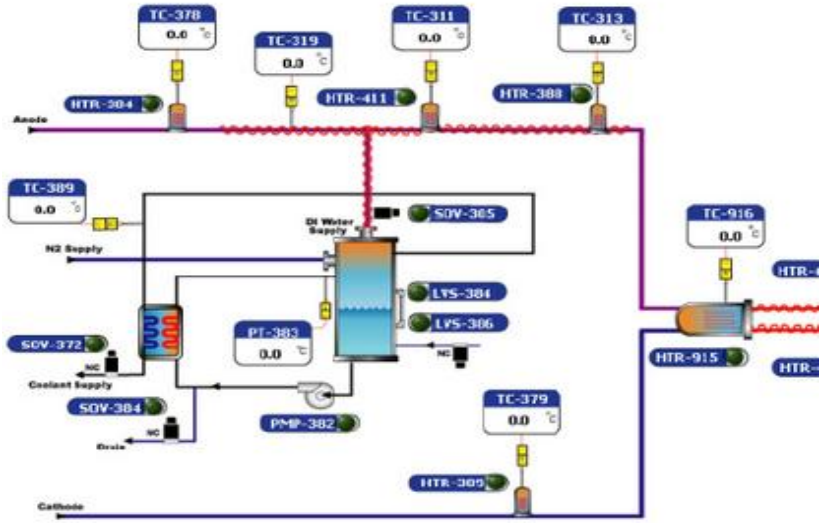
FDA Public Workshop – Additive Manufacturing for Medical Devices
October 8, 2014

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

Wikipedia

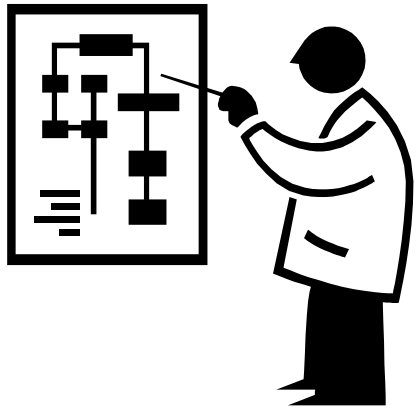
Impact-solutions.co.uk

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