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DELIVERING SCIENTIFIC RESOLUTION

# Materials, Medicine & Manufacturing:

## *Materials Awareness and Selection*


Dr. Crystal G. Morrison

Principal Investigator and Senior Materials Scientist


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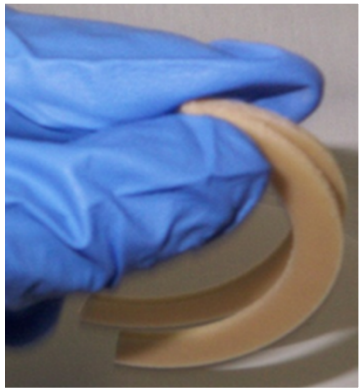
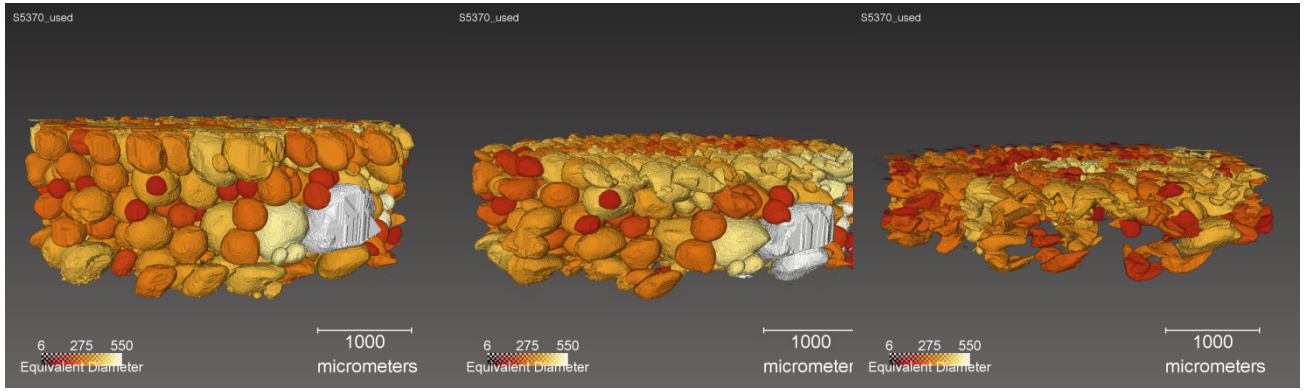
# Dr. Crystal G. Morrison

- Ph.D. – University of Michigan
- Postdoc – Agnew National Security Fellow at Los Alamos National Laboratory (LANL)
- Lead Polymer SME for LANL Nuclear Weapons Program



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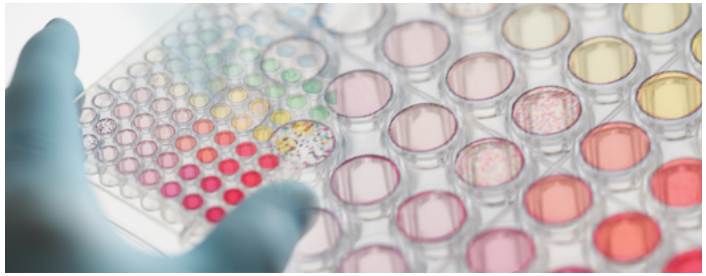
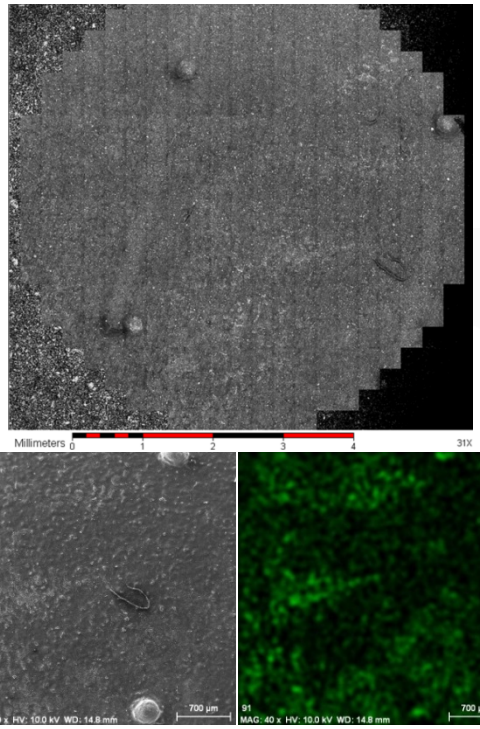
# Dr. Crystal G. Morrison

– Technical Lead for Polymeric Materials



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# Additive, Military and Medicine?

- Additive Manufacturing Direction
  - Rapid prototyping …
  - Novel designs…

  BUT,
  - Increasing interest and focus on using AM for high value, high performance, critical parts and assemblies


# Materials Emphasis

- AM Trend:
  - High Value and Performance
- AM Focus:
  - Materials → Processes → Product V&V
- Materials understanding across the lifecycle of the product

*Awareness of Considerations Unique to the AM Community*

# Possibilities and Questions

I've made a zillion rapid prototypes with this material.
I can move forward with production, right?

ABS, ABS "like", medical grade, food grade… it's all the same. Or is it?

I have years of data on this device design made with X plastic using injection molding. I'm going to use X plastic with an AM method. Do I really need testing?

I buy my powered raw materials from X, who gets them from Y, who is a distributor for Z. I think it's good stuff. Right?

# Response

## Don’t assume or underestimate!

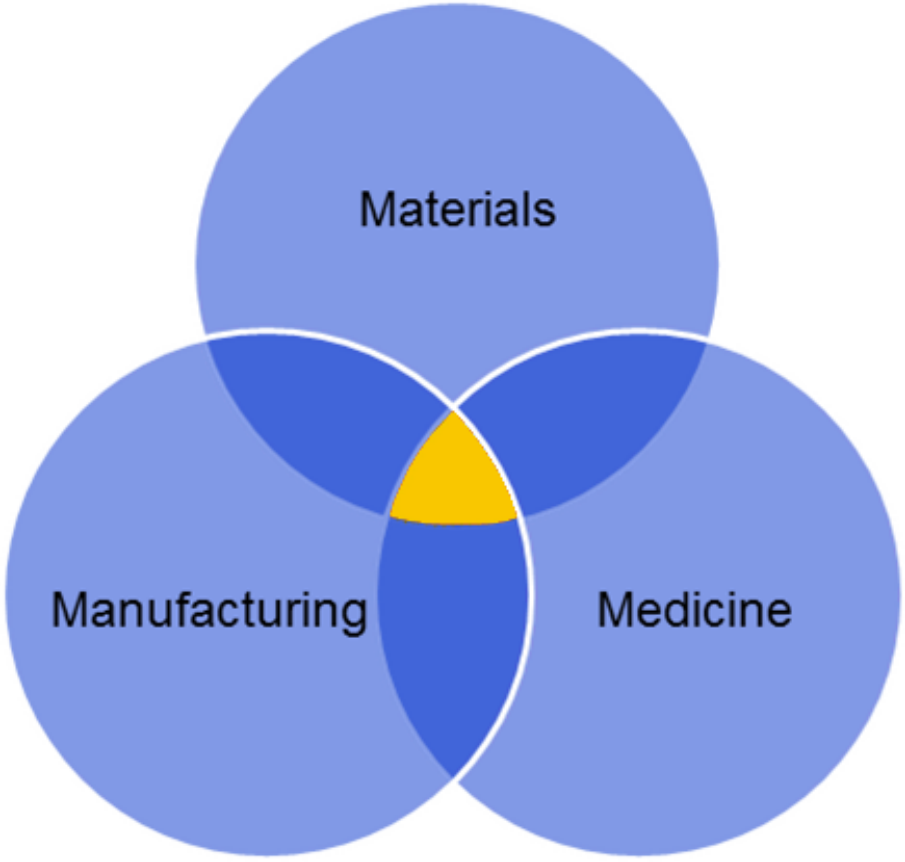
Q: Where do I start when selecting polymeric materials for an AM-produced device?

A: Use systematic materials assessment with focus on Requirements, Materials Screening, and Manufacturability

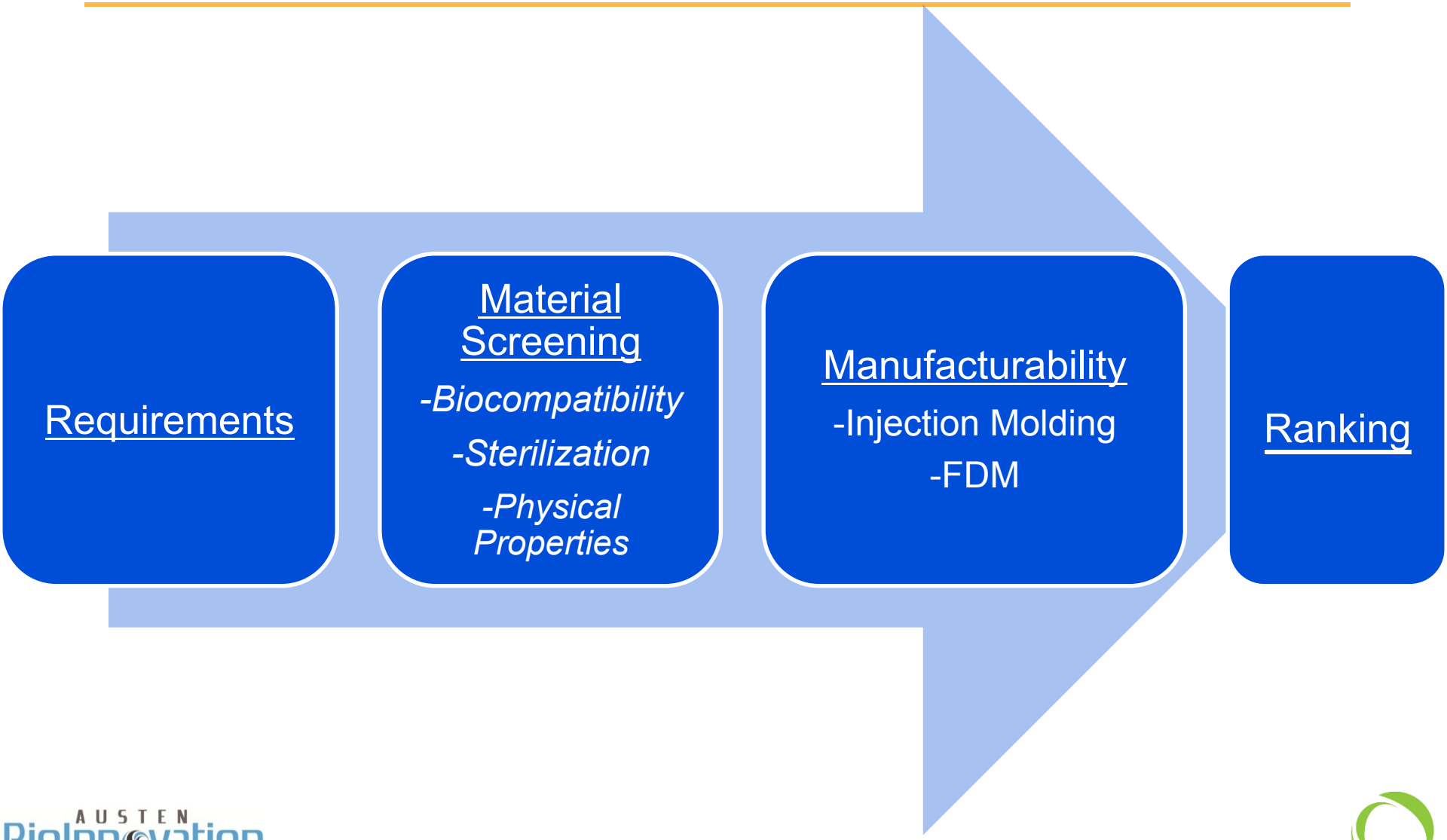
# Moving forward…

- Polymers and Plastics in Medical Devices
  - Emerging Considerations
- Selection Process Overview
- Considerations for Additive Manufacturing
  - Requirements
  - Material Screening
  - Manufacturability
  - Ranking
- Summary

# Emerging Considerations



# Selection Process Overview

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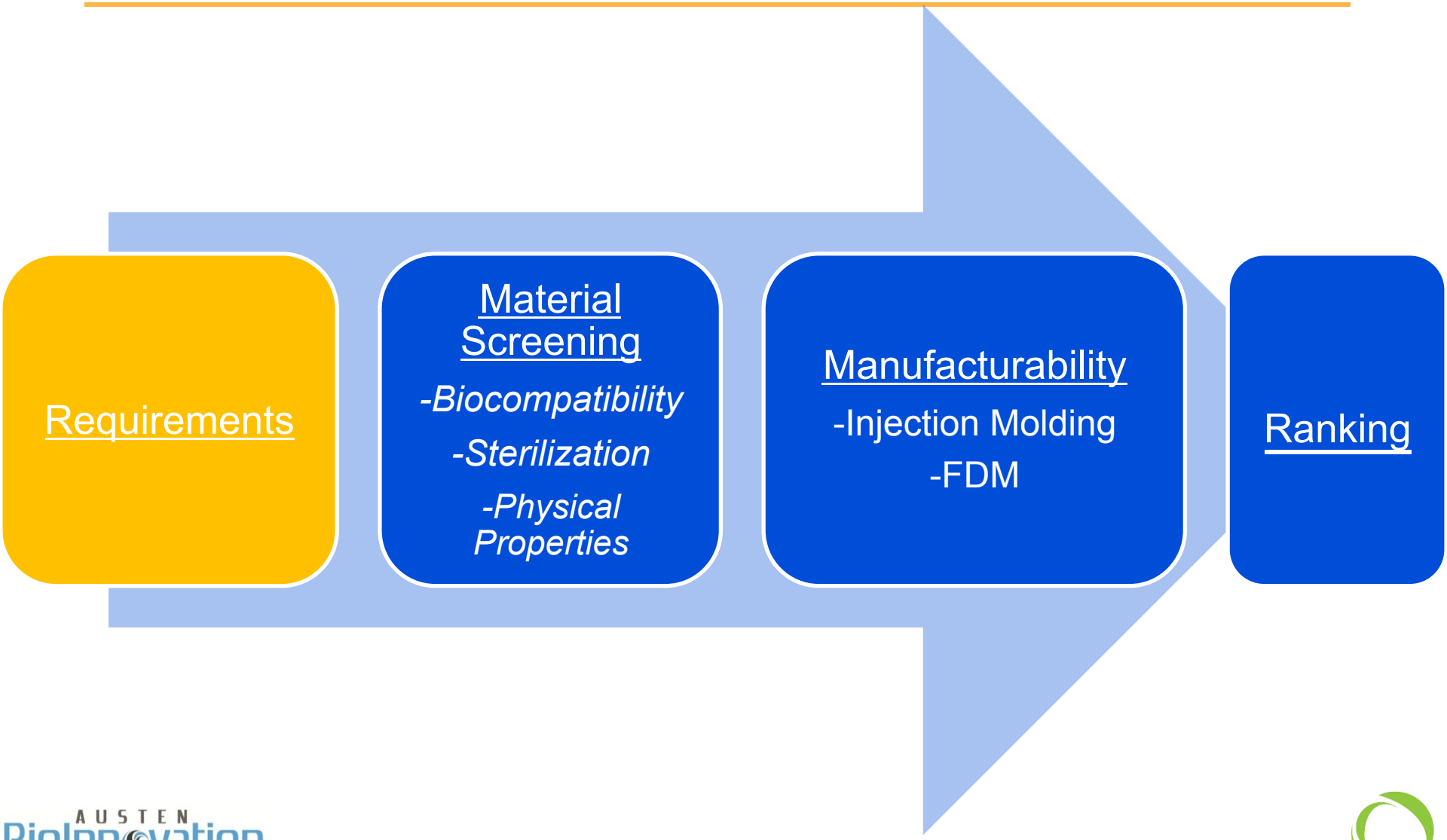


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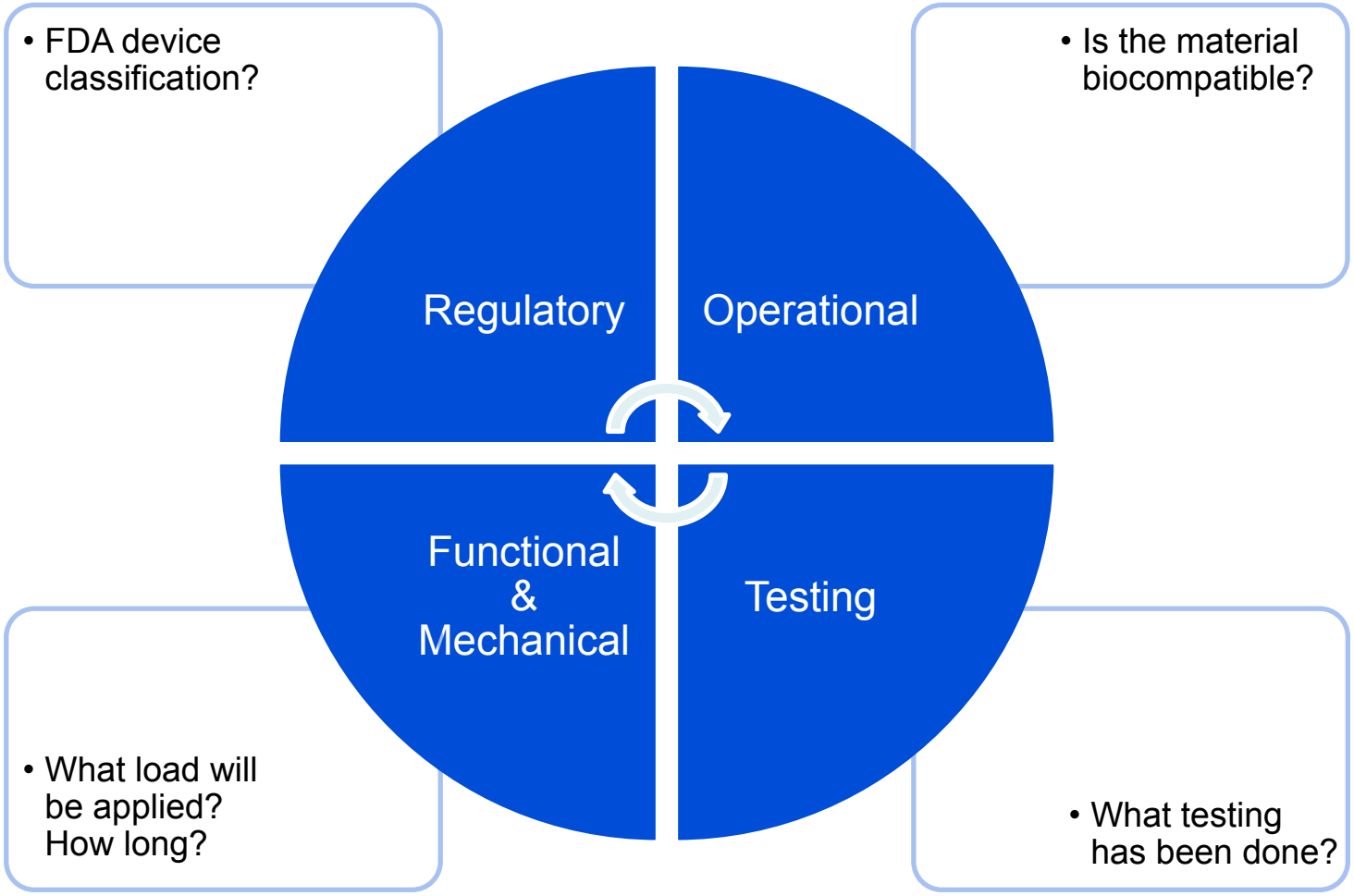
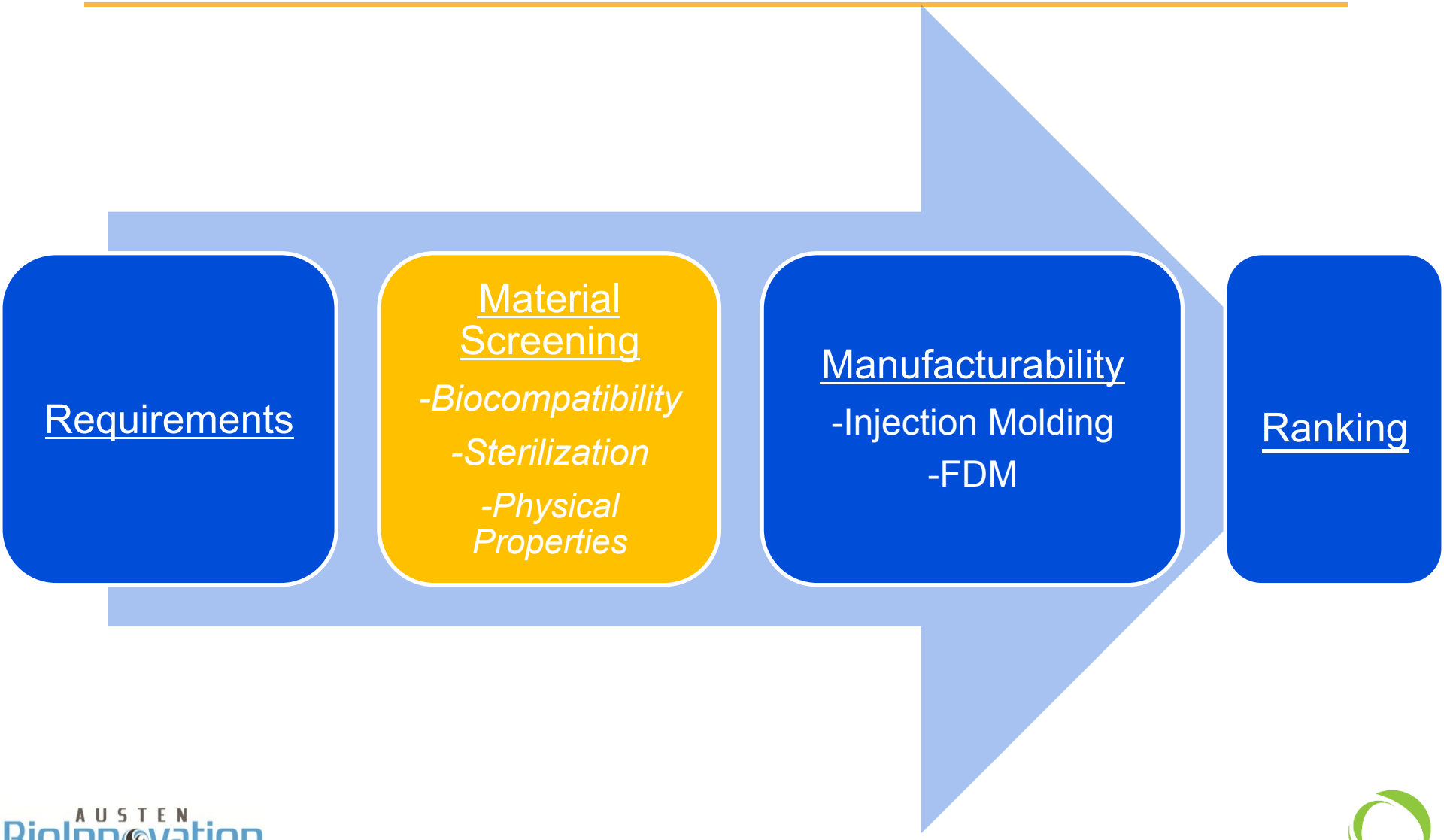
# Requirements



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# Materials Screening

- Biocompatibility
  - USP Class VI
  - ISO 10993
    - Nature of physical contact vs biological risks
    - Cytotoxicity, Sensitization, Irritation

Limited selection of materials for AM now… but not for long.

# Materials Screening

3DSYSTEMS

- Select VisiJet® clear materials
- Accura ® ClearVue and Y-C 9300R
- Dreve Fototec hearing aid material
- DuraForm® PA and PRO

- Somos® materials
  - Watershed XC11122
  - ProtoGen 18420
  - BioClear

- Select e-Shell materials

- PA 2200

Fortus®
- PC-ISO
- ABS-M30i

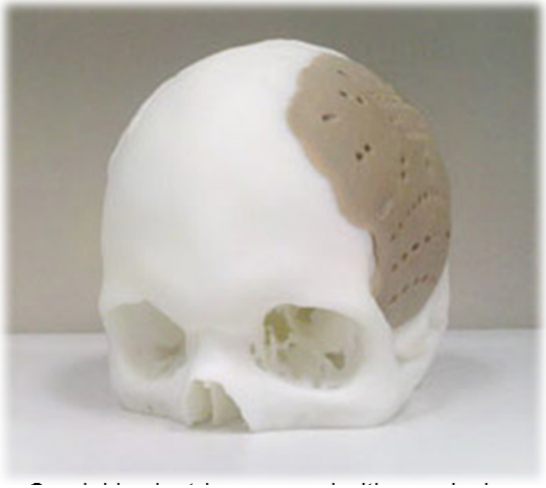
Objet
- MED610

- OXPEKK®

List compiled by Sam Anson for Medical Plastics News.

# Materials Screening

- The first FDA approval for an additively manufactured polymer implant was Oxford Performance Material's OsteoFab® cranial device made from PEKK
- FDA 510(k) clearance for its 3D printed OsteoFab® Patient-Specific Facial Device (OPSFD).



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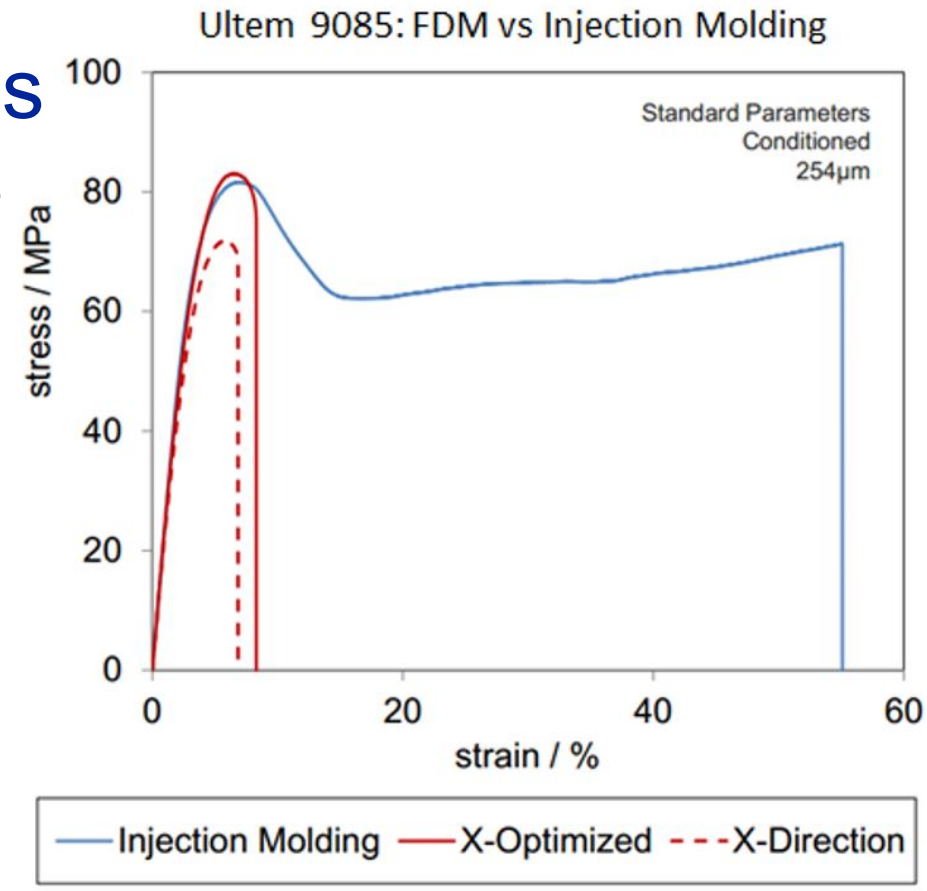
# Materials Screening

- Sterilization
  - Radiation (gamma/e-beam)
  - Chemical (EtO)
  - Autoclave (steam)

- Chemical Resistance
  - Isopropyl Alcohol
  - Bleach
  - Peroxides

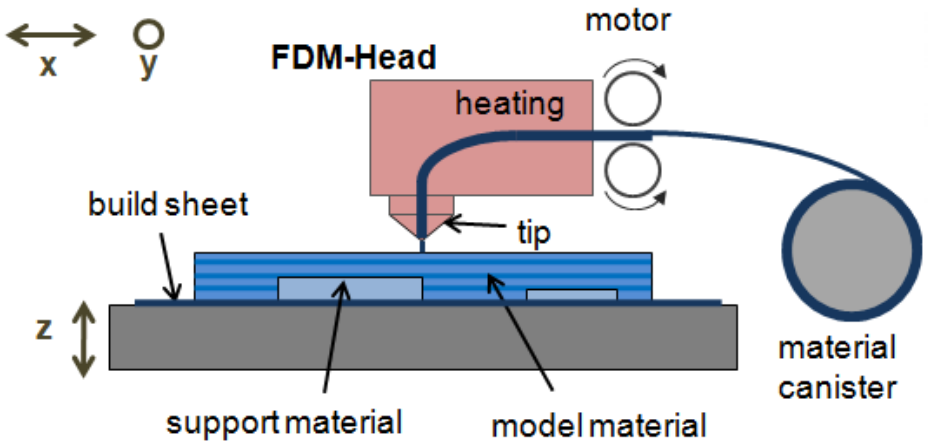
# Materials Screening

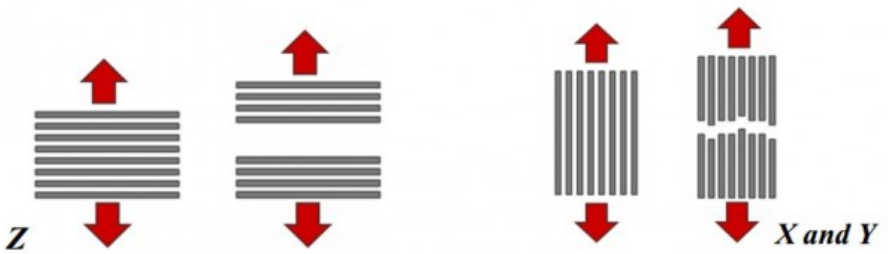
- Mechanical Properties
  - Conventional vs. Additive
  - Ultem® amorphous thermoplastic polyetherimide (PEI) resin family from SABIC



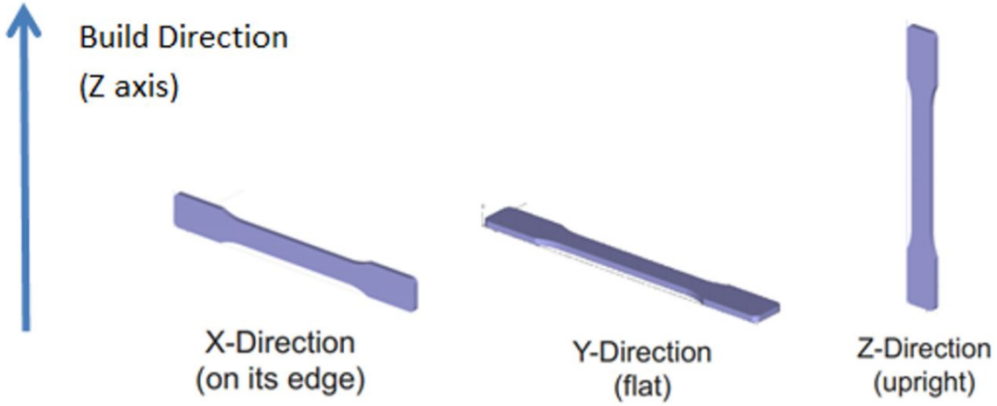

*Research from Fischer and Josupeit at Direct Manufacturing Research Center (DMRC) in Paderborn Germany*

# Materials Screening




Tensile strength is much greater in X direction rather than Z build direction.

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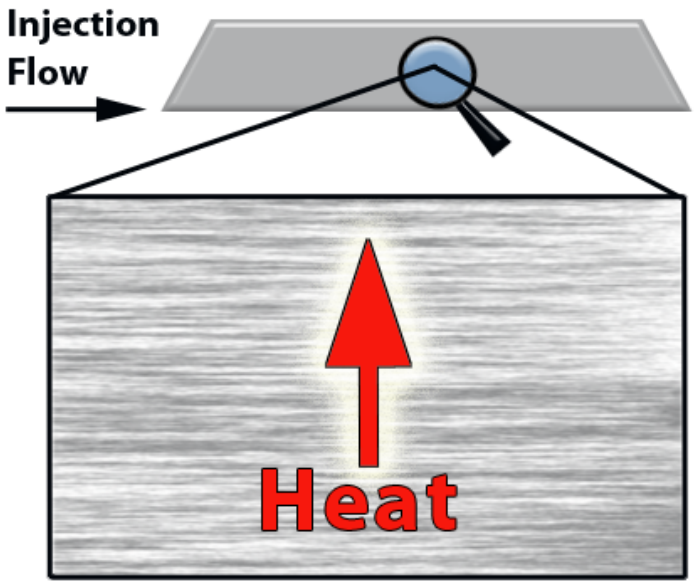
# Materials Screening

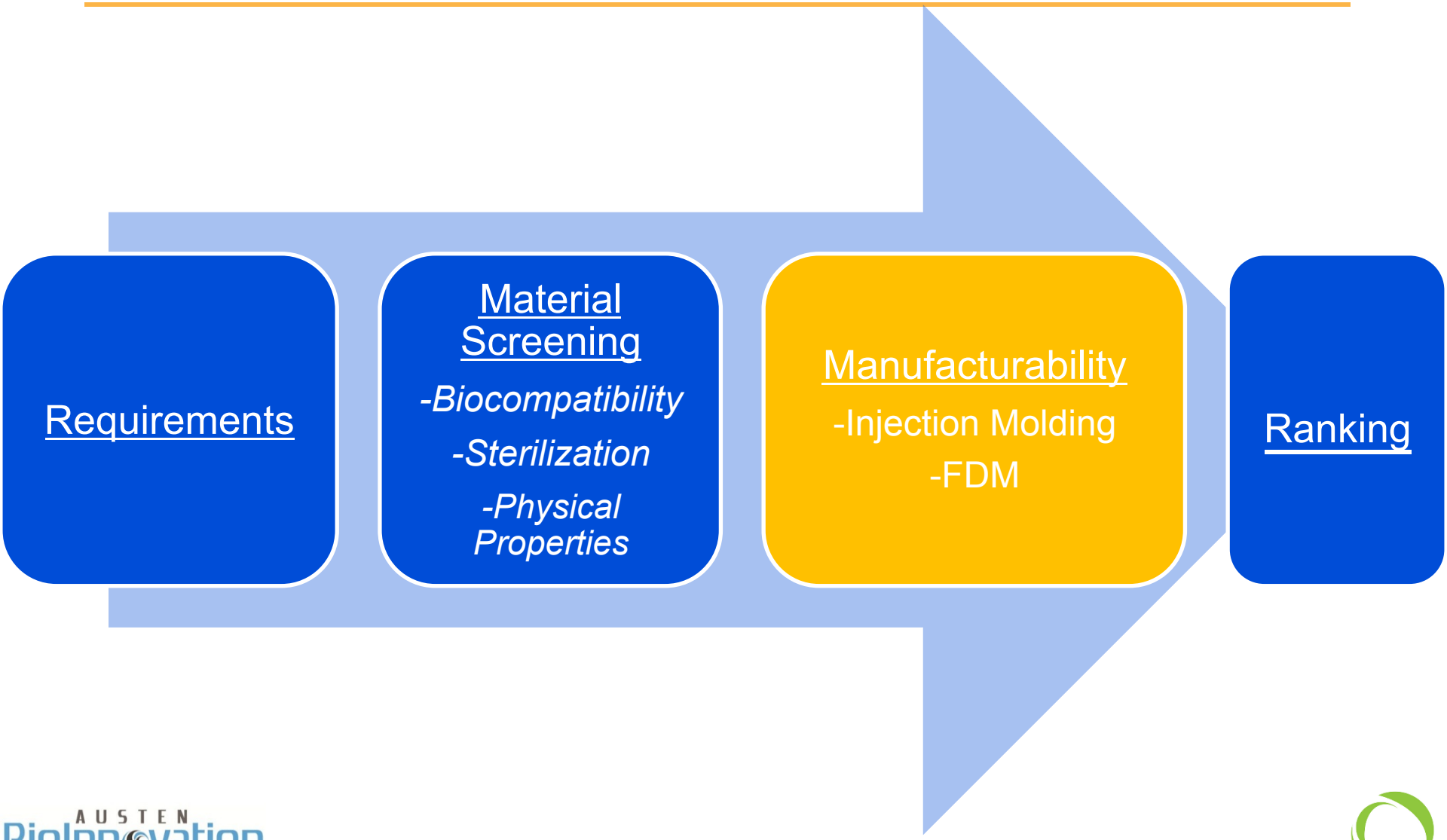
- Wear Resistance
  - Mechanical properties can be different
  - Surface properties and wear debris
  - Other factors
    - Pairs (combination of materials in contact)
    - Conditions (wet or dry)
    - Configurations (rotating, sliding, oscillating)

# Materials Screening

- Thermal Properties
  - Filler
  - Orientation
  - Crystallinity

  - Conventional vs. Additive



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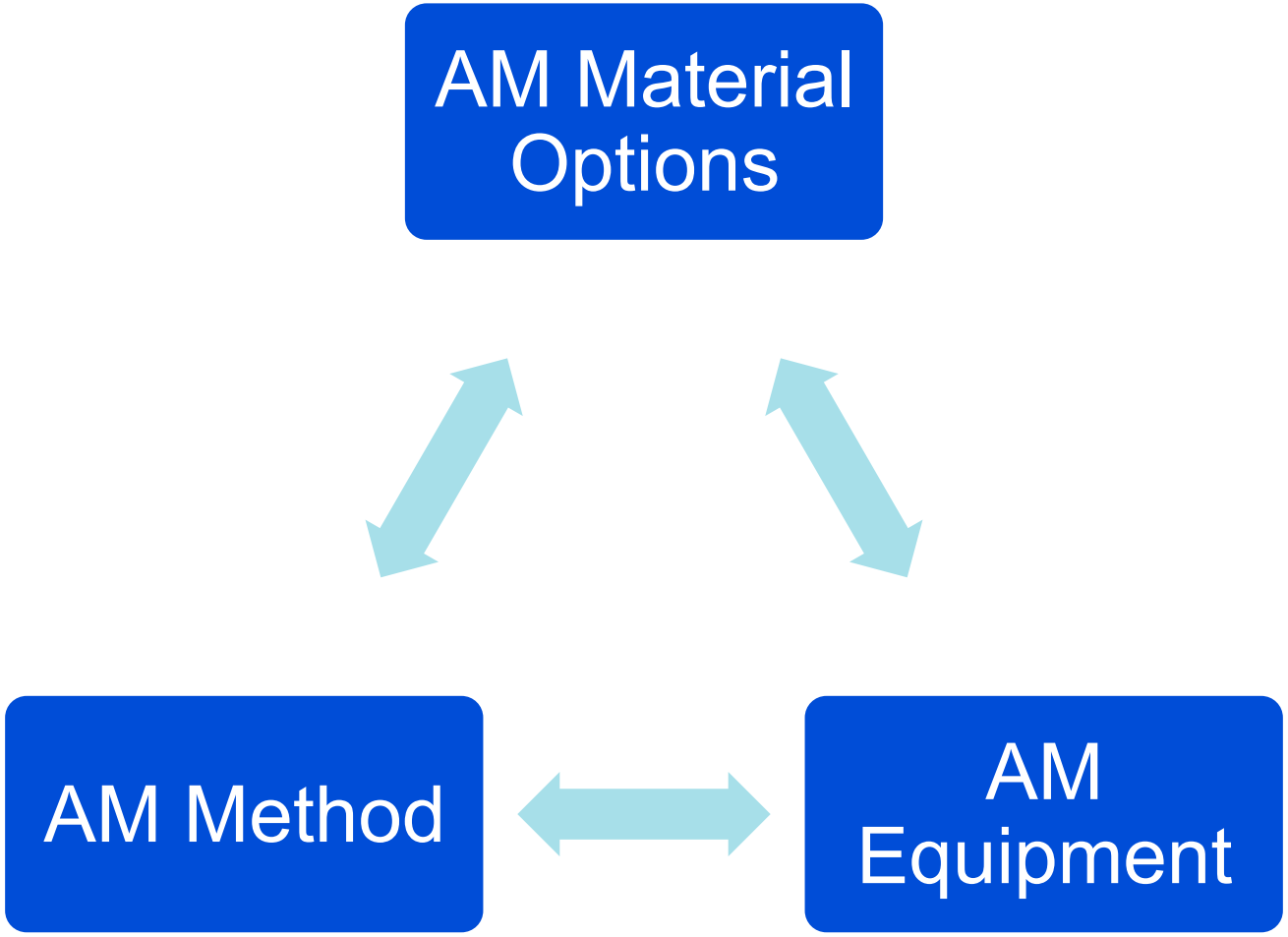
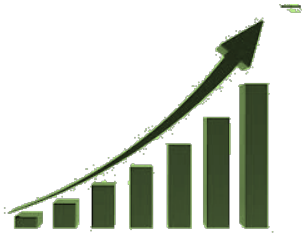
# Manufacturability



# Impact

**Schedule**

**Testing**



**Success**

**Design**

**Process Improvement**

**Troubleshooting**

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# Impact – Manufacturer Liability

- Biomaterials Access Assurance Act (BAAA) of 1998
- Responsibility and liability for the device performance
- High quality materials and testing

# Summary/Conclusion

- Landscape is exciting… and overwhelming
- Awareness of materials considerations
- Systematic assessment
- Requirements, Materials Screening, Manufacturability
  - Simultaneous, Evolving Dialogue
- Impact

# Questions?

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MPN MEDICAL PLASTICS NEWS

"Creating Vision Across the Polymer Lifecycle" published September 11th, 2013

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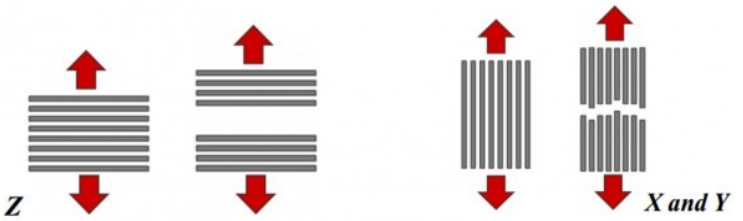
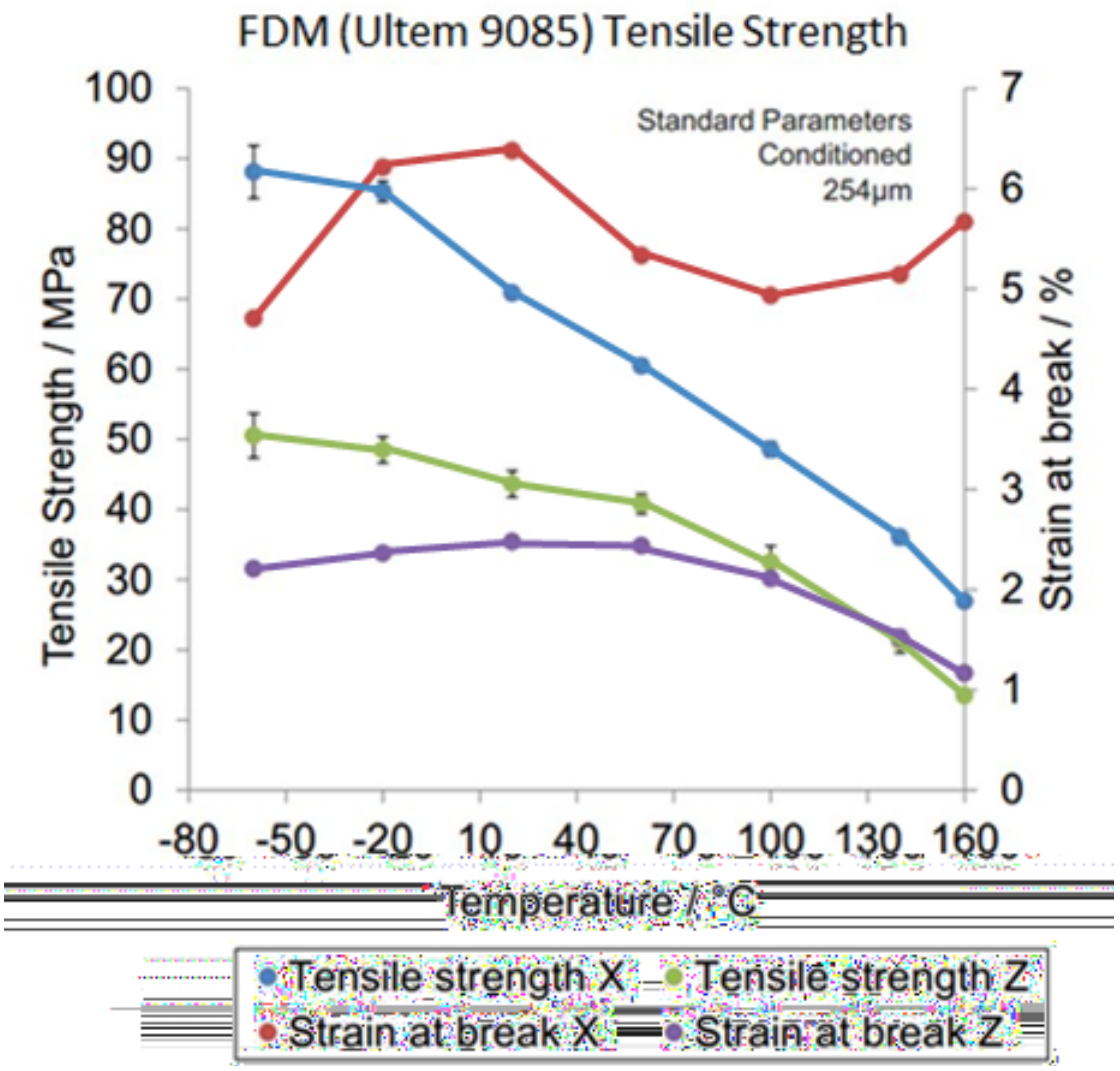
# Materials Screening

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