Teamwork in the Development of Orthobiologic Materials

MMA Physician Leadership Effectiveness Program
Bozeman, MT 11/21/14
Disclaimers

Michael Mansfield MS, CTBS

Michael Mansfield is a salaried employee of Bacterin International and holds stock options in the company.
Bacterin is a Montana Tissue Bank founded in 2005

Processor and distributor of allograft tissue and medical devices for transplant. Bacterin is the 4th largest distributor of Demineralized Bone Matrix (DBM) in the United States
The Gift of Donation

Teamwork from Recovery to Implantation

- Recovery
- Testing
- Processing
- Distribution
- Implantation
Development Pathways

The Twin Juggernauts of the FDA

**Allograft Materials**
- Minimally manipulated tissue
- Intended for homologous use only
- Regulated by CBER
  - 21 CFR Part 1271
  - Section 361 PHSA

**Medical Devices**
- Multiple classes based on perceived potential harm
- Specific indications based submitted clinical/preclinical work
- Regulated by CDRH
  - 21 CFR Part 800 and others
Allograft Implant Development

Streamlined development path

- Allograft Idea
- Clinical
- Marketing
- Operations
- RA/QA
Device Implant Development

More stringent regulatory controls
Clinically Demonstrated Efficacy

Collaboration with Clinicians


Clinically Demonstrated Efficacy

Collaborations with Clinicians


- Brigido et al. Retrospective clinical series of OsteoSponge SC for talar dome reconstruction with 2+ year follow up. *Foot & Ankle Specialist.* In press.

- Brigido et al. Retrospective clinical series of OsteoSponge SC and DeNovo for talar dome reconstruction with 1 year follow up. *Foot & Ankle Specialist.* Accepted pending revisions.
Researching Innovation in Montana

Montana Board of Research and Commercialization Technology

- Acellular Nerve Allografts for Transplantation (2014)
  - Mark Schallenberger, MS Principle Investigator
  - Collaboration with the Mayo Clinic

- Allograft Based Bone Void Filler (2007)
  - Greg Juda, PhD Principle Investigator
  - Successfully commercialized 2010