The Medical Device Innovation Consortium

Michelle McMurry-Heath, MD, PhD
Associate Director for Science
Center for Devices and Radiological Health,
U.S. Food and Drug Administration
The Medical Device Industry is Critical to Our Nation’s Health...

- Total Knee Replacement: 676,000
- Total Hip Replacement: 327,000
- Cardiac Catheterizations: 1.1 million
- Arteriography & Angiocardiology: 1.9 million
- Insertion of Coronary Artery Stents: 528,000
- Diagnostic Ultrasound: 902,000
- CAT Scans: 497,000

CDRH is responsible for regulating firms who manufacture, repackage, re-label, and/or import medical devices sold in the United States.
“Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world. The U.S. is the world’s leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality. Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.”

Faster, Cheaper, Safer
Office of the Center Director (OCD)

- Office of Compliance (OC)
- Office of Device Evaluation (ODE)
- Office of In Vitro Diagnostics and Radiological Health (OIR)
- Office of Surveillance & Biometrics (OSB)
- Office of Communication and Education (OCE)
- Office of Management Operations (OMO)
- Office of Science & Engineering Laboratories (OSEL)
What is Regulatory Science?

- Provides the tools, standards, and approaches needed to evaluate the safety, effectiveness, performance, and quality of medical products
- Benefits patients by speeding the rate of important technologies reaching market
- Reduces time and resources needed for device development, assessment, and review. For example:
  - Can lead to quicker, more efficient device approvals
  - Can decrease the size and duration of pre-market clinical trials

**Faster, Cheaper, Safer**
Advancing medical device innovation, and evaluating new and emerging technologies
Improving device quality and manufacturing
Analyzing medical device performance
Improving medical device safety
Developing novel ways to use clinical data in evaluating medical devices
Protecting against emerging infectious diseases and terrorism
Improving the health of pediatric and other special populations
Medical Device Development

The Total Product Life Cycle

- Invention + Prototyping
- Pre-Clinical
- Clinical
- Regulatory Decision
- Product Launch
- Post-Market Monitoring

Faster, Cheaper, Safer
MDIC: Why is it Important?
**MDIC Strategy:**
Create a Public-Private Partnership between Industry, FDA and Non-profits

**PPP Goals**
- Align Resources
- Accelerate Progress
- Achieve Results

- Working cooperatively with FDA to re-engineer pre-competitive technology innovation
- Reducing the time and resources needed for new technology development, assessment, and review
- Helping patients benefit by gaining access to new medical technologies sooner
Memorandum of Understanding (MOU) submitted December 2011

Business plan created October 2012

MDIC website launched Nov 12 2012

MDIC at LSA Conference December 5 2012

Articles of Incorporation filed August 2012

MDIC Nationwide rollout Washington, D.C. December 2012

Convene First meeting of the full Board Approve Bylaws; approve Budget & administrative structure, confirm initial work priorities Feb 26, 2013

Convene Second meeting of the full Board. Gain approval of scoped projects May 28, 2013

Convene Third meeting of the full Board. Review project structure & plans. Sept 12, 2013

Respond to Membership Requests December 2012

Sept 12, 2013

Align | Achieve | Accelerate