

MDIC Case for Quality Forum



November 15, 2017

<http://mdic.org/CFQ>



Welcome





The Business Case for Quality

Vision

*Elevate the focus of **all medical device stakeholders***

*from baseline regulatory compliance to **sustained, predictive practices***

*that **advance** medical device quality and safety to achieve better **patient outcomes.***



The Business Case for Quality

Goals

*Develop new **tools, methods and metrics**
for **innovators, manufacturers, regulators, and
providers**
that improve **product quality and patient
experience***





A brief history

- FDA launched the Case for Quality in 2011 after a series of reports identified how a culture of compliance in medical device manufacturers was not producing a culture of quality
- In 2015, MDIC was awarded a contract from FDA to advance the Case for Quality by:
 - Researching and piloting a maturity model that could be applied to medical device manufacturers
 - Convening Forums to get industry, hospital, physician regulator support and contributions to the Case for Quality
- In 2017, MDIC has continued to advance the Case for Quality by continuing to advance the Maturity Model and to provide operational support as CDRH prepare to launch their voluntary quality review program

MDIC Case for Quality in 2017

Outreach

- 10/26/16 – MDIC Case for Quality Forum
- 2/14/17 – MDICx webinar – Making the Business Case for Quality
- 4/6/17 – MDICx webinar - Quality Metrics Best Practices
- 5/2/17 - Workshop – Case for Quality Metrics at Xavier MedCon
- 3/30/17 – MDIC Case for Quality Forum
- 7/20/17 – MDIC Case for Quality Forum
- 9/25/17 – Case for Quality update at the MedTech Conference
- 10/10/17 – CDRH Public Meeting on the Case for Quality

Project activities

- Maturity Model
 - Following the 2016 pilot, continued refining the metrics, enrollment criteria, and appraisals necessary for the Maturity Model to be used in the CDRH Quality program
- Product Quality Outcomes Analytics
 - Expand use of hospital, registry and patient-reported data for use in the Analytics dashboard
- Operational support for the CDRH voluntary quality program
 - Enroll at <http://mdic.org/cfq/enroll>

More details at: <http://mdic.org/CFQ>



Today:

- Study
- Monitor
- Measure vs Plan

2018:

- Broaden and sustain?
- What else?





Thank you to our Steering Committee

- Steve Binion, BD
- Sean Boyd, CDRH
- Sarah Deeghan, Johnson & Johnson
- Joe DuPay, CVRx
- Jennifer Kelly, CDRH
- Jackie Kunzler, Baxter
- Luann Pandy, Medtronic
- Bill Murray, MDIC
- Joe Sapiante, Hologic
- Francisco Vicenty, CDRH

