Public Workshop - Division of Cardiovascular (DCD) 30-Day Notices and Annual Reports Workshop, August 28, 2012

U.S. Food & Drug Administration

The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Division of Cardiovascular Devices (DCD) 30-Day Notice and Annual Report." This workshop will be co-sponsored with Advanced Medical Technology Association (AvaMed). The purpose of this workshop is to discuss details of the reporting requirements for both 30-Day Notices and Annual Reports for cardiovascular devices.

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Date, Time and Location

This workshop will be held August 28, 2012, beginning at 8:00 am – 5:00 pm at the following location:

FDA White Oak Campus
10903 New Hampshire Avenue
Building 31 Conference Center (Great Room, Sections B&C)
Silver Spring, MD 20993

- FDA Campus Information [5]

The workshop will be webcasted.

Draft Agenda Topics

- The role of risk assessment in evaluating manufacturing changes
- Equipment/software changes
- Moves/relocations
- Supplier changes
- Submission types and conversions
- Best practices for submissions

Registration to Attend the Workshop

Registration will be available soon.

Contact Us

For questions regarding workshop content please contact:

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Links:
[1] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#date
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