



America's Blood Centers[®]
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NEWS RELEASE

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America's Blood Centers to Host Medical Device Data Systems (MDDS) Workshop

Workshop to take place January 15-16 in the Washington, DC area.

WASHINGTON (December 5, 2013) — [America's Blood Centers](http://www.AmericasBlood.org) is set to host an unprecedented Medical Device Data Systems (MDDS) Workshop on January 15-16, 2014 at the DoubleTree by Hilton Silver Spring in the Washington, DC area. This workshop will review recently issued MDDS requirements and discuss their effects on blood centers and other impacted healthcare institutions, as well as provide direction on implementation of the Food and Drug Administration guidance requirements. Participants will learn what an MDDS is; the regulatory requirements for their development, validation and approval; and how to navigate FDA device inspections and development in a quality systems environment.

Although the FDA issued its final rule reclassifying MDDS to Class I, the lowest of the three regulatory classifications which are based on the level of control necessary to assure the safety and effectiveness of the device, in 2011, the impact of this change is just being felt in blood centers, hospitals, and other areas where medical devices are used. Because of this, all health care industry professionals involved in the development or use of MDDS are encouraged to attend and participate.

"The FDA's requirements for MDDS are now in force and there are many questions within the healthcare industry including what is and what isn't considered an MDDS and what organizations must do to meet the new requirements," said Ruth Sylvester, Director of Regulatory Services for America's Blood Centers. "The most common misconception is 'it doesn't apply to us'; however, the MDDS requirements apply to any organization using a medical device including blood centers, hospitals, radiology centers, and facilities providing medical services."

Registration information for industry professionals can be found at: <http://www.cvent.com/d/n4qmbh/1Q>. Manufacturers and vendors interested in participating should contact Abbey Nunes at anunes@americasblood.org or (202) 654-2980.

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About America's Blood Centers

Founded in 1962, [America's Blood Centers](#) is North America's largest network of community-based, independent blood programs. Recognized by the U.S. Congress for its critical work in patient care and disaster preparedness and response, the federation operates more than 600 blood donor centers providing half of the U.S., and a quarter of the Canadian blood supply.

These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.