

Biotechnology Quality Management System Update

**BRS Stakeholder Meeting
December 1, 2010**

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Biotechnology Quality Management System Update



- **Mission:**

- To provide support for the voluntary adoption of a BQMS to improve the management of an organization's domestic research and development of regulated GE organisms.

- **Goals:**

- Provide clarity and expectations of regulatory responsibilities to the regulated community.
- Provide compliance assistance to the regulated community to facilitate compliance with 7 CFR part 340.



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- Pilot project concluded in 2009
- 2010 activities included:
 - Pilot project evaluation
 - Evaluation of comments received on 2009 *Federal Register* notice
 - Development of program documents
 - Audit standard, checklists, and guidelines
 - Program development tools
 - Operational procedures



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- Publication of *Federal Register* notice in July 2010 soliciting interest in next class
- Second class began in September 2010
- Two classes planned for 2011
 - February (class is full)
 - August
- Utilizing an open enrollment approach for future classes



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- More information available on BRS website:
- http://www.aphis.usda.gov/biotechnology/news_bqms.shtml