USDA APHIS Biotechnology Quality Management System Program (BQMS Program)

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USDA APHIS BRS
BQMS Program Concept

7 CFR part 340

Enforcement
Inspection
Assistance

REGULATORY COMPLIANCE
BQMS Program Concept

Opportunities
straight ahead
BQMS Program from Development to Delivery

- Meet the needs of the regulated community;
- Accountable to the public
BQMS Program from Development to Delivery

- **BQMS Concept**: Sep-07
- **2008 Farm Bill**: May-08
- **BQMS Program Pilot**: Jan-09
- **Assess Feedback**: Oct-09
- **Solicit Participation**: Jul-10
- **BQMS Program Roll Out**: Sep-10

*Date Markers:
- 9/20/2007
- 9/30/2007
- 9/30/2010
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BQMS Program from Development to Delivery
The APHIS BQMS Program

- **Mission:**
  - To provide support for the voluntary adoption of a BQMS to improve the management of an organization’s domestic R&D 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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- **Standard:**
  - Best practices

- **Guidelines:**
  - Step-by-step
  - What to consider
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- Class workshops
- One-on-one
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- A positive impact on the regulated community.
The APHIS BQMS Program: Outcomes

Bar chart showing outcomes of the APHIS BQMS Program:
- Audit Process: Strongly Agree
- Compliance Assistance Visits: Strongly Agree
- Increased Education and Awareness: Strongly Disagree
- Better Management: Strongly Disagree
The APHIS BQMS Program: Outcomes

- Operational Continuity
- Process Consistency
- Efficiency
- Document Control
- Record Control
- Best Practices

Levels:
- Strongly Agree
- Neutral
- Strongly Disagree
The APHIS BQMS Program

▪ Testimonials:
  ▪ “I can not imagine the ag biotech regulatory compliance industry without this type of assistance/guidance program, it is the last piece of the puzzle.”
Testimonials:

“Participation really helped me understand the value of QMS in biotechnology, because it brings good management practices to the organization in conducting regulated field trials.”
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Additional Information and Resources: