BQMS User Orientation

Last Modified:

The BQMS Program repository contains user-friendly question and answer formatted guidelines customized to jumpstart or complete self-certifying quality management practices.

The repository was designed to assist BQMS Program users interested in developing a documented quality management system to facilitate compliance with the APHIS regulations for the import, interstate movement, and field release of organisms developed using genetic engineering in complying with regulations found at 7 CFR part 340.

Users may develop, implement, and maintain a BQMS within their organization to manage the environmental release, movement and field release, of regulated GE organisms. Specifically, organizations:

- Work to identify critical control points in the organization's processes for working with regulated GE organisms,
- Develop or revise standard operating procedures that address critical control points,
- Properly train personnel on standard operating procedures,
- Undergo self-certification to determine effectiveness of the organization's quality management system, and
- Become an organization participating in the BQMS Program.

Biotechnology Quality Management Support Module Templates

APHIS developed the compliance assistance modules below to better meet the needs of universities, small businesses and large companies alike in following areas:

Document Control

- Document Control (47.76 KB)
- Record Control (43.19 KB)

Internal Controls

- Competence Awareness and Training Procedure (44.7 KB)
- Management Review Meeting Form (42.1 KB)

BQMS Critical Control Points

- Site Selection Planning (37.94 KB)
- Storage (42.14 KB)
- Transport, Movement, and Import (44.11 KB)
- Environmental Release Planning and Monitoring (44.33 KB)
- Post-harvest Handling and Transfer (46.65 KB)
- Devitalization and Final Disposition (41.57 KB)
- Potential Regulatory Compliance Incidents (40.71 KB)
- Reporting Form for Potential Regulatory Compliance Incidents (37.46 KB)

Process Improvements

- Internal Audit (47.31 KB)
- Corrective Action (45.14 KB)
- Preventive Action (46.5 KB)
- CAR PAR Form (53.51 KB)

Still have questions, comments or suggestions? Contact us via email: BRS.BQMS@usda.gov

Disclaimer: *This material is provided as a generalized guide for your organization's quality management practices relevant to your obligations under APHIS regulations found at 7 CFR part 340. Use of these modules and its content does not guarantee that the user's activities are in compliance with 7 CFR part 340, and it does not eliminate the user's obligations under any other statute or regulation. If your organization wishes to use formal quality management systems, it is best to rely on qualified quality management professionals.*

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