

BIOTECHNOLOGY QUALITY MANAGEMENT SYSTEM

QUESTIONS AND ANSWERS

Biotechnology Regulatory Services

1. What is a quality management system?

A quality management system (QMS) explains how an organization manages its processes or activities to ensure the quality of a product or service. A QMS enables organizations to identify, measure, control, and improve the various core business processes, which ultimately leads to improved business performance.

International standards have been developed to measure quality and to provide organizations with a model to follow when setting up and operating a management system. This model incorporates the features on which experts in the field have reached a consensus as being the international state of the art.

Thus, the goal of an organization that operates using a QMS is to use processes that will help them meet the standards that the world views as acceptable when achieving quality.

A QMS functions correctly with four key features:

- effective planning,
- taking action based on the effective planning,
- checking the results of the planning and actions taken, and
- correcting nonconforming processes to achieve continual improvement.

2. How does a quality management system relate to biotechnology?

A quality management system (QMS) explains how an organization manages its processes or activities to ensure the quality of a product or service. A QMS enables organizations to identify, measure, control, and improve the various core business processes, which ultimately leads to improved business performance. The Biotechnology Quality Management System (BQMS) is a set of management processes that an organization conducting APHIS-permitted biotechnology research may use to facilitate compliance with APHIS regulations for the movement and field testing of regulated genetically engineered organisms.

3. How does compliance assistance play a role in the Biotechnology Quality Management System Program?

Compliance assistance is a service through which APHIS' Biotechnology Regulatory Services (BRS) will provide direct guidance to the regulated community on facilitating compliance with APHIS regulations as part of the Biotechnology Quality Management System (BQMS) Program. The BQMS Program will set forth an audit standard that provides a framework by which organizations can base their current regulatory practices. This standard will describe requirements for developing a BQMS that addresses vulnerabilities that may lead to compliance incidents. The critical processes involved with movement and environmental release of genetically engineered (GE) organisms may contain such vulnerabilities. APHIS BRS will furnish guidelines for developing, implementing, and monitoring the BQMS, and will assist the regulated community with understanding and conforming to the standard. A participant that wishes to voluntarily achieve BQMS certification will undergo third-party audits, which will validate the implementation and operation of a participant's BQMS. These audits will be conducted by USDA's Agricultural Marketing Service (AMS), or audit organizations that have been certified by AMS. After an audit, APHIS may consult with the participant to manage any identified non-conformity that could lead to a regulatory compliance incident. Participation in the BQMS program—with its external third-party audits and resulting certification—is voluntary and not a mandatory requirement for APHIS permittees.

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4. How does an organization develop a Biotechnology Quality Management System?

The Biotechnology Quality Management System (BQMS) is a set of management processes that an organization conducting APHIS-permitted biotechnology research may use to facilitate compliance with APHIS regulations. Organizations can develop a quality management system based on the BQMS standard, which will provide organizations with a model to make necessary quality improvements to address vulnerabilities that may lead to non-compliance with APHIS regulations. APHIS based the BQMS standard on international concepts for quality management systems.

A permitted organization will tailor its processes to strive for error-free movement and field testing of regulated genetically engineered (GE) plants. BQMS will initially focus on movements and field testing of regulated GE plants.

APHIS will use an audit standard within the Biotechnology Quality Management System (BQMS) that provides a framework by which participants can base their current regulatory practices. The standard is flexible enough to address the specific needs of the entire regulated community, including large corporations, small businesses, and academia. APHIS recognizes that the scope and scale of regulated research and that development ranges from academic researchers to large corporate organizations that utilize numerous cooperators and subcontractors. The audit standard will provide sufficient flexibility for any participant to develop a BQMS that suits their scope and scale of work while demonstrating their commitment to regulatory compliance.

APHIS BRS developed a series of technical guides that will be the foundation of the compliance assistance program. The technical guides will be made available to the entire regulated community regardless of whether an applicant chooses to develop a BQMS and voluntarily have a BQMS certified by a USDA third-party auditor. These guides will provide the regulated community assistance for:

- Developing a QMS that meets the BQMS standard,
- Writing Standard Operating Procedures,
- Conducting Internal Audits,
- Conducting Root Cause Analyses, and
- Identifying Critical Control Points.

5. What is the purpose of the Biotechnology Quality Management System pilot project?

In winter 2009, BRS launched a Pilot Development Project for its Biotechnology Quality Management System (BQMS) program to test the applicability of the BQMS standard and accompanying guidelines, and assist APHIS in further development of a quality program for its customers. APHIS' goal for the pilot project is to provide another avenue for continuous improvement for the BQMS program by obtaining feedback from participants on strengths and areas for improvement to the standard and the guidelines prior to full implementation of the program. Specifically, participants will test the feasibility of the BQMS standards and guidelines by developing and implementing quality management systems for their organizations that proactively manage regulated movements and field releases.