



QMS SERVICES FOR PHYTOSANITARY TREATMENT



Building Compliant, Efficient and Effective Quality Systems.

Quantum EBX provides comprehensive services to design, implement, and support robust Quality Management Systems (QMS) for facilities that perform phytosanitary irradiation. We ensure your QMS meets international (ISPM) and national (USDA APHIS) requirements, establishing a foundation for operational excellence and facilitating safe trade.

KEY QMS SERVICE AREAS

QMS DESIGN & IMPLEMENTATION

We develop comprehensive quality systems aligned with phytosanitary treatment requirements, including:

- **Quality Manual:** Defining the scope of phytosanitary treatments, policies, objectives, system structure, and process interactions relevant to facility approval and operation.
- **Procedure Development (SOPs):** Crafting detailed operational and support procedures covering all necessary QMS functions for phytosanitary irradiation.
- **Work Instructions (WIs):** Creating clear, task-specific instructions for consistent execution of treatment and handling protocols.
- **Documentation & Record Keeping:** Establishing systems for document control, record management (including treatment records, dosimetry, calibration, maintenance), and traceability as required.
- **Risk Assessment:** Integrating risk assessment related to treatment efficacy and process deviations.

COMPLIANCE & AUDITING

We provide comprehensive audit programs and certification support to help you organization meet requirements, including:

- **ISPM 18 & USDA APHIS Compliance:** Gap analysis of existing documentation to determine compliance with international and national phytosanitary standards.
- **Internal Audit Programs:** Guidance for establishing, managing, and conducting internal audits to verify compliance and maintain effectiveness.
- **Certification/Approval Support:** Guiding you through the facility certification and approval process, including documentation preparation and support during regulatory audits.

619.842.1099



QUANTUMEBX.COM



INFO@QUANTUMEBX.COM





QMS SERVICES FOR PHYTOSANITARY TREATMENT



KEY QMS SERVICE AREAS

IRRADIATOR OPERATIONS & COMPLIANCE PROCEDURES

Developing specific, compliant procedures integrated within your QMS for phytosanitary irradiation:

- **Irradiator Qualification & Maintenance**
 - » Procedures for Installation Qualification (IQ) and Operational Qualification (OQ) demonstrating capability to meet treatment specifications.
 - » Support for IQ/OQ protocol execution and reporting.
 - » Procedures for routine maintenance and calibration ensuring consistent operation.
- **Treatment Process Control & Monitoring**
 - » Procedures for irradiator operation specific to phytosanitary treatments, including critical parameter control (e.g., speed, beam settings) and monitoring.
 - » Development of procedures for dose mapping (PQ) to identify minimum dose locations for specific commodities/load configurations.
 - » Procedures for routine process monitoring and ensuring the required minimum absorbed dose (D_{min}) is achieved.
- **Commodity Handling & Integrity**
 - » Procedures for commodity receipt, staging, loading/unloading, segregation (treated vs. untreated), and secure packaging/handling post-treatment to prevent re-infestation.
- **Dosimetry System Integration**
 - » Procedures for dosimetry system selection, calibration, measurement, reader verification, and routine use according to relevant standards.
 - » Support for dosimetry system implementation, uncertainty assessment, and software validation.
- **Treatment Verification & Documentation**
 - » Procedures for reviewing processing records, verifying achievement of required dose, and generating required phytosanitary treatment documentation/certificates.



619.842.1099

QUANTUMEBX.COM

INFO@QUANTUMEBX.COM





QMS SERVICES FOR PHYTOSANITARY TREATMENT



KEY QMS SERVICE AREAS

PROCESS IMPROVEMENT & VALIDATION

We optimize your QMS through validation, risk assessment, and continuous enhancement initiatives, including:

- **QMS Enhancement:** Reviewing and optimizing existing QMS documents and processes for phytosanitary compliance and efficiency.
- **CAPA Systems:** Supporting the development and implementation of effective Corrective and Preventive Action systems for treatment deviations or QMS nonconformities.
- **Process Validation Support:** Providing expertise and documentation support for dose mapping and ongoing process verification.
- **Risk Assessment:** Assisting with risk assessments for key processes like treatment deviations, change control, and corrective actions.

TRAINING & PERSONNEL QUALIFICATION

We provide targeted training and develop role definitions to ensure staff are qualified and compliant with relevant standards, including:

- **Targeted Training:** Delivering training programs covering relevant ISPMs, national regulations (e.g., USDA 7 CFR Part 305), QMS procedures, dosimetry, irradiator operation, commodity handling, and documentation requirements for phytosanitary treatments.
- **Role Definition & Qualification:** Defining roles, responsibilities, and qualification criteria for personnel involved in phytosanitary irradiation operations.

ONGOING QMS SUPPORT

We provide sustained support to ensure ongoing compliance, operational excellence, and continuous improvement of your QMS, including:

- **Management Review Facilitation:** Assisting with the preparation and execution of effective Management Reviews focused on phytosanitary compliance.
- **Sustained Compliance:** Offering tailored support for ongoing compliance, internal audits, responses to audits, and adaptation to revised standards or regulations.
- **Supplier Management:** Implementing robust purchasing controls and supplier selection/assessment processes where applicable.

619.842.1099



QUANTUMEBX.COM



INFO@QUANTUMEBX.COM





QMS SERVICES FOR PHYTOSANITARY TREATMENT



RELEVANT STANDARDS

- **ASTM 51261:** Standard Practice for Calibration of Routine Dosimetry Systems for Radiation Processing
- **ASTM 52628:** Standard Practice for Dosimetry in Radiation Processing
- **Codex Alimentarius:** As relevant for food commodities:
 - » General Standard for Irradiated Foods (CODEX STAN 106)
 - » Code of Practice for Radiation Processing of Food (CAC/RCP 19)
- **ISPM 18:** Requirements for the use of irradiation as a phytosanitary measure
- **ISO 14470:** Food Irradiation - Requirements for the Development, Validation and Routine Control of the Process of Irradiation Using Ionizing Radiation for the Treatment of Food
- **USDA 7 CFR Part 305:** Phytosanitary Treatments (or equivalent national regulations)

CONTACT US TODAY

TO LEARN MORE ABOUT HOW QUANTUM EBX CAN HELP YOU
WITH YOUR PHYTOSANITARY QMS NEEDS.



619.842.1099

QUANTUMEBX.COM

INFO@QUANTUMEBX.COM

