USFDA Inspection Readiness & Quality Culture Excellence Masterclass 2026

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Date: 10th July 2026

Venue: Hyderabad, India

Delivered by:

Dr. Jennifer Huntington

(Former USFDA Inspector)

More Than Compliance:
Cultivating Inspection-Ready Enterprises Through Impactful Training, a Culture of Quality, and Mature Quality Management Practices

"Prepare Today for the Inspection You May Face Tomorrow."

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USFDA Inspection Readiness & Quality Culture Excellence Masterclass 2026

What Inspectors Really Look For:

- Cleaning Validation
- Investigations & CAPA Effectiveness
- QA Oversight
- Unannounced Inspections
- Quality Management Maturity

Gain firsthand perspective from a Former USFDA Inspector while exploring how leading organizations achieve inspection readiness by aligning robust quality systems, skilled personnel, and a deeply rooted culture of excellence.

Dr. Jennifer L. Huntington, DVM, MPH
Independent Consultant,
Strategic Compliance Consulting

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- **Experience**
  - A regulatory leader, mentor, international collaborator, decision-maker, and public speaker with 10 years of U.S. Food and Drug Administration (FDA) experience committed to the mission of the Agency, Office of Regulatory Affairs (ORA), and the Center for Drug Evaluation and Research (CDER).
  - GMP expert with 10 years of national and international inspection experience, performing complex inspections of international pharmaceutical manufacturing facilities to meet the needs of the organization.
  - Senior level drug expert as a GMP and Pre-Approval Investigator, Pharmacy Compounding Expert, Pharmaceutical Quality Systems Assessor, and Quality Management Maturity Assessor.
- **Expertise**
  - Dr. Huntington has extensive knowledge, experience, and is a subject matter expert (SME) in Current Good Manufacturing Practices (CGMP), Post-Market Assessments, and Technical Reviews of external FDA guidance prior to publication.
  - She provides GMP guidance/advice to the pharmaceutical industry, including working with firms to ensure corrective actions to FDA inspections and subsequent Warning Letter are implemented effectively to mitigate significant drug contamination risk factors.
  - She is a Subject Matter Expert providing efficient technical expertise in the areas of Cleaning Validation, Water System Qualification, Active Pharmaceutical Ingredients, and sterile and Non-sterile Finished Dosage Small Molecule Drug Products.
- **Education**
  - University of Florida Bachelor of Science in Agriculture
  - University of Florida College of Veterinary Medicine (DVM)
  - University of Florida, Masters Public Health (MPH)

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Learning Outcomes

By the end of this program, participants will be able to:

- ✓ Understand current USFDA inspection trends and regulatory expectations
- ✓ Strengthen Cleaning Validation programs using lifecycle and risk-based approaches
- ✓ Conduct scientifically sound investigations and effective CAPAs
- ✓ Enhance QA oversight across Manufacturing and Quality Control functions
- ✓ Improve employee competency and training effectiveness
- ✓ Build sustainable inspection readiness systems
- ✓ Prepare for announced and unannounced inspections
- ✓ Assess and improve Quality Management Maturity

Session: 1
Current USFDA Inspection Landscape

What is USFDA Focusing on Today?

- Recent inspection trends
- Top observations from Form 483s
- Common reasons for Warning Letters
- Data integrity expectations
- Quality Culture versus Documentation Compliance

Case Studies

- Real inspection examples
- Lessons learned from regulatory actions

Common USFDA Inspection Observations

1. Quality Management System (QMS)

- Inadequate Quality Unit oversight and authority
- Procedures not established, maintained, or consistently followed
- Deficient annual product quality reviews and complaint management

2. Documentation & Good Documentation Practices (GDP)

- Incomplete, inaccurate, or missing GMP records
- Batch records lacking required information
- Poor documentation of investigations and laboratory activities
- SOP deviations without appropriate justification or documentation
- Lack of appropriately documenting internal audits and deviation from internal audits

Common USFDA Inspection Observations

3. Investigations, Deviations & CAPA

- Failure to thoroughly investigate discrepancies, deviations, OOS, and failures
- Root cause investigations incomplete or unsupported
- Corrective and Preventive Actions (CAPA) ineffective or inadequately documented
- Lack of QA oversight of laboratory data and computerized systems for batch release

4. Laboratory Controls

- Laboratory controls not scientifically sound
- Test methods inadequately validated or verified
- Incomplete analytical data and poor data integrity practices
- Using in-house STDS when USP or other reputable sources are readily available
- Inadequate microbiological and component testing

Common USFDA Inspection Observations

5. Equipment, Facilities & Utilities

- Equipment not adequately designed, qualified, calibrated, or maintained
- Cleaning and sanitization procedures inadequate or not followed
- Facility maintenance deficiencies affecting GMP compliance
- Inadequate environmental monitoring and contamination control systems

6. Manufacturing Process Controls

- Lack of validated manufacturing processes
- Inadequate in-process controls and process monitoring
- Master production and batch records not properly controlled
- Computerized systems inadequately controlled or validated
- Lack of QA oversight during production activities

Common USFDA Inspection Observations

7. Sterility Assurance & Contamination Control

- Inadequate aseptic processing procedures
- Insufficient validation of sterile manufacturing processes
- Weak contamination control strategy and environmental monitoring
- Deficient cleaning validation for sterile operations
- Inadequate smoke studies

8. Materials Management

- Inadequate identity testing of incoming components
- Supplier qualification and Certificate of Analysis (CoA) verification weaknesses
- Improper storage conditions for raw materials and finished products

Common USFDA Inspection Observations

9. Stability Program

- Stability program absent or not consistently followed
- Stability-indicating analytical methods inadequate
- Stability data insufficient to support product shelf life

10. Personnel & Training

- Inadequate GMP training programs
- Personnel qualifications not adequately documented
- Training effectiveness not demonstrated or periodically assessed
- Poor documentation of remedial or CAPA training

Common FDA 483 Observations

Across industries, the most frequently cited Form 483 issues in 2025 included:
Pharmaceuticals (21 CFR Part 211):

- **211.22(d):** Quality Unit procedures not adequately established or followed
- **211.192:** Inadequate investigation of deviations or failures
- **211.100(a):** Absence of adequate written procedures for production and process control
- **211.160(b):** Laboratory controls not scientifically sound
- **211.67(a/b):** Cleaning, maintenance, and equipment deficiencies
- **211.68(b):** Weak governance of computerized systems

Why Companies Receive Form 483s

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Indicative Root Causes

- Weak Quality Culture
- Inadequate QA Oversight
- Poor Investigation Practices
- Ineffective CAPA Systems
- Data Integrity Gaps
- Weak Management Engagement
- Lack of Risk-Based Decision Making

Key Message

USFDA is assessing the effectiveness of your Quality System, not merely the existence of SOPs.

Why Companies Receive Form 483s

The FDA does not assess compliance based solely on documented policies and procedures (SOPs);

- It evaluates whether those procedures are consistently implemented in day-to-day operations.
- Inspectors focus on actual practices and expect firms to demonstrate that personnel follow established procedures.

For example,

If a Good Documentation Practices (GDP) SOP specifies that all GMP documents must be issued, reconciled, archived, and destroyed exclusively by the Quality Assurance (QA) department, but inspectors observe shredders and sticky notes distributed throughout the facility, this may indicate inadequate control over GMP documentation.

Even if no GMP documents are found in the shredders, the FDA may cite the firm for inadequate quality oversight because the observed practices are inconsistent with the documented procedure.

2026 Warning Letter Trends

#	OBSERVATION	RECENT USFDA OBSERVATION (2026)	HOW TO PREVENT
1	**DATA INTEGRITY** ALCOA+ principles not followed, data manipulation or backdating.	Warning Letter | Feb 2026 Data integrity issues in laboratory records and chromatographic data.	✓ Implement ALCOA+ principles ✓ Ensure audit trails & secure systems ✓ Regular data integrity training
2	**INADEQUATE INVESTIGATIONS** Failure to investigate OOS, OOT, deviations thoroughly.	Warning Letter | Jan 2026 Inadequate investigation of OOS results in API manufacturing.	✓ Follow cGMP & SOPs ✓ Use root cause analysis tools ✓ Ensure CAPA implementation
3	**INADEQUATE TRAINING** Insufficient training of employees on procedures and GMP.	Warning Letter | Mar 2026 Employees not adequately trained on aseptic processing & GMP.	✓ Define training matrix ✓ Ensure initial & ongoing training ✓ Document & evaluate effectiveness

2026 Warning Letter Trends

4	**RECORDS & REPORTS** Incomplete, unclear or inaccurate documentation in records.	Warning Letter | Feb 2026 Incomplete batch manufacturing and testing records.	✓ Review records for accuracy ✓ Ensure timely documentation ✓ Implement QA review & approval
5	**POOR FACILITY CONDITIONS** Issues with cleanliness, maintenance and facility design.	Warning Letter | Apr 2026 Poor maintenance of HVAC system in sterile manufacturing area.	✓ Follow preventive maintenance ✓ Monitor environment regularly ✓ Ensure facility cleaning programs
6	**QUALITY CONTROL FAILURES** Failure in testing, method validation or analytical procedures.	Warning Letter | Mar 2026 Analytical method validation found inadequate.	✓ Validate all analytical methods ✓ Use qualified instruments ✓ Review & approve test results
7	**MATERIAL MANAGEMENT** Issues with receipt, storage, labeling & inventory control.	Warning Letter | Feb 2026 Improper labeling & storage of raw materials.	✓ Follow GMP for material handling ✓ Use proper labeling & segregation ✓ Conduct regular inventory checks

2026 Warning Letter Trends

8	**CHANGE CONTROL** Changes implemented without proper approval or documentation.	Warning Letter | Jan 2026 Major changes implemented without change control system.	✓ Implement robust change control SOP ✓ Assess impact & document changes ✓ Approval before implementation
9	**CAPA EFFECTIVENESS** CAPA not effective or not verified for closure.	Warning Letter | Apr 2026 CAPA system not effective in preventing recurrence.	✓ Ensure root cause based CAPA ✓ Verify effectiveness before closure ✓ Trend & review CAPA data
10	**MANAGEMENT OVERSIGHT** Lack of management involvement in quality systems.	Warning Letter | Mar 2026 Management did not ensure compliance with cGMP.	✓ Strengthen management oversight ✓ Conduct management reviews ✓ Promote quality culture

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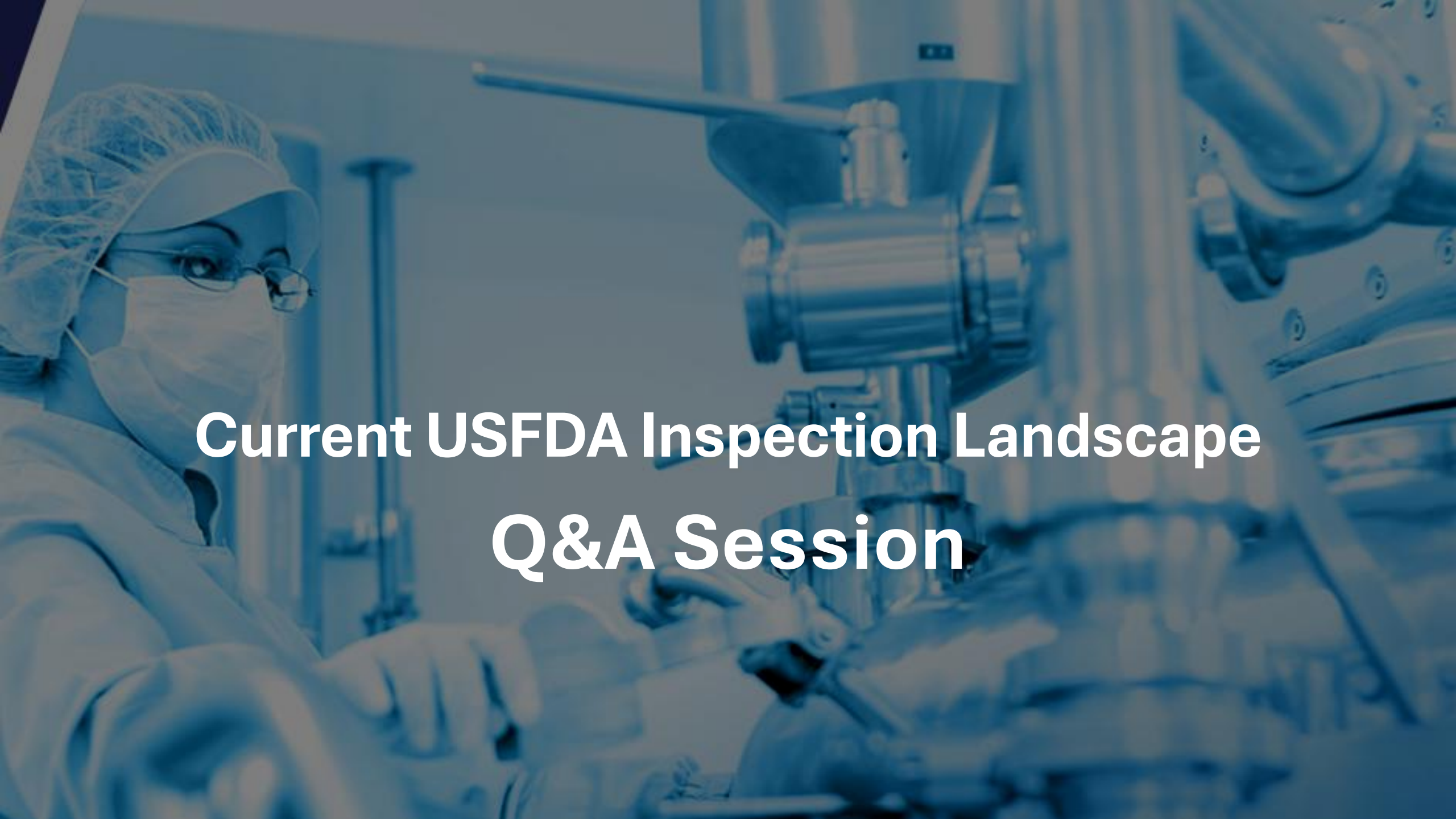
FDA Inspection Insight

Majority of FDA observations arise not because procedures are absent, but because established procedures are not consistently implemented, documented, monitored, or effectively governed by the Quality Management System and Quality Assurance Unit.



Current USFDA Inspection Landscape

Q&A Session

Session: 2
Cleaning Validation – Inspector Expectations

Equipment Cleaning and Cleaning Validation

Common Deficiencies Observed by USFDA

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Cleaning

The FDA mandates that equipment used in drug manufacturing must be cleaned, maintained, and sanitized at appropriate intervals to prevent contamination and ensure product safety.

Key Requirements

- Cleaning and Maintenance Procedures
- Validation of Cleaning Processes
- Record Keeping
- Cross-Contamination Prevention

Cleaning and Maintenance Procedures

According to 21 CFR 211.67, written procedures must be established and followed for the cleaning and maintenance of equipment used in drug manufacturing.

- These procedures should include:
  - Assignment of responsibility for cleaning and maintenance.
  - Maintenance and cleaning schedules, including sanitizing schedules where appropriate.
  - Detailed descriptions of the methods, equipment, and materials used in cleaning operations.
  - Procedures for removing previous batch identification and protecting clean equipment from contamination prior to use.
  - Inspection of equipment for cleanliness immediately before use

Validation of Cleaning Processes

Cleaning procedures must be validated to ensure they effectively remove residues from equipment surfaces.

- This includes:
  - Ensuring that residues (active ingredients, cleaning agents) are adequately removed during product changeovers.
  - Documenting cleaning validation studies to demonstrate that the cleaning process consistently meets predetermined specifications.
  - Performing Clean Hold Time Studies, Dirty Hold Times Studies, and Campaign Studies

Record Keeping

Records must be maintained for all cleaning, sanitizing, and inspection activities.

This includes documentation of maintenance and cleaning schedules, as well as any inspections performed.

Cross-Contamination Prevention

The FDA emphasizes the importance of preventing cross-contamination between different drug products.

This includes ensuring that equipment is properly cleaned between different production runs, especially when dealing with potent compounds.

Cross Contamination Studies and Risk Assessment are being required by the FDA

Cleaning Validation – Why It Fails

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Typical Deficiencies

- Worst-case selection not justified
- Inadequate sampling plans
- Poor recovery studies
- Inappropriate residue limits
- Inadequate equipment design assessment
- No lifecycle monitoring

Common USFDA Question

"How do you know your cleaning process remains in control today?“

“Did you perform a risk assessment for sample type and swab locations?”

Worst Case Product Selection

- Potency,
- Toxicity,
- Solubility and
- Cleanability.

HBEL and PDE Concepts

Health-Based Exposure Limits (HBEL) and Permitted Daily Exposure (PDE) are used in the selection of worst case product should a firm choose this method.

Some firms may opt to perform cleaning validation for all products.

FDA is ok with either as long as there is a risk assessment when new products are introduced.

Sampling Strategies

An effective sampling strategy combines representative swab and rinse sampling, based on scientific rationale and risk assessment, to provide reliable evidence that equipment has been cleaned to established acceptance criteria.

Common FDA Inspection Deficiencies

- Sampling locations not scientifically justified.
- Reliance solely on rinse sampling without supporting rationale.
- Failure to sample worst-case or hard-to-clean locations.
- Inadequate number of sampling points.
- Sampling procedures not validated or consistently followed.

Recovery Studies

A cleaning validation result is only as reliable as the sampling method used. Recovery studies provide the evidence that the method can effectively detect and quantify residues remaining on equipment surfaces, ensuring confidence in cleaning verification results.

Common FDA Inspection Deficiencies

- Recovery studies not performed before cleaning validation.
- Recovery studies conducted on only one surface material.
- Recovery factor not applied to analytical results.
- No scientific justification for low recovery values.
- Recovery studies not repeated following significant method or equipment changes.

Visual Cleanliness

Visual cleanliness is the first line of verification, while analytical testing provides objective evidence that cleaning acceptance criteria have been achieved. Together, they provide greater assurance of effective cleaning and contamination control.

Common FDA Inspection Deficiencies

- Equipment released based solely on visual cleanliness.
- No documented visual inspection procedure.
- Inadequate lighting during inspections.
- Difficult-to-access areas not inspected.
- No evidence of inspector training or qualification.

Cleaning Validation Deficiencies

The most common FDA 483 citation for cleaning validation are lack of clean and dirty hold time studies, lack of disinfectant residue testing during validation, not updating the worst-case drug product when new products are introduced.

Cleaning Validation Case Study

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Scenario

- Multi-product oral solid dosage manufacturing facility
- Shared equipment used for Product A and Product B
- Validation completed three years ago
- Recent FDA inspection identifies significant deficiencies

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Cleaning Validation – Inspector Expectations

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Q&A Session

Interactive Discussion

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Session: 3 Investigations & CAPA Management

“What Makes an investigation adequate? Using the correct tools to perform root cause analysis.

“What ensures a CAPA is appropriate? CAPA Effectiveness.

Investigation Expectations

Elements of a Robust Investigation

- Timely initiation
- Data collection
- Scientific evaluation
- Root cause determination
- Impact assessment
- Corrective action
- Effectiveness verification

Question

"Would another investigator reach the same conclusion?"

Weak vs Strong Root Cause Analysis

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Weak

- Human Error
- Lack of Attention
- Procedure Not Followed

Strong

- Why did the system allow the error?
- Training effectiveness?
- Procedure complexity?
- Process design flaws?
- Management oversight gaps?

Focus

Find system failures—not people to blame.

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Building Scientifically Sound Investigations

- Deviation management
- OOS investigations
- OOT investigations
- Complaint investigations
- Laboratory investigations
- Impact assessments
- *I am seeing a fear of opening deviations or investigations. Investigations are being performed without proper documentation. Firms are immediately jumping to CAPA without the appropriate root cause analysis.*

Investigation Types

- Lab investigations
- Out-of-Specification investigations
- Out-of-Trend investigations
- Deviation investigations
- Complaint Investigations

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Root Cause Analysis Tools

- 5 Why Analysis
- Fishbone (Ishikawa) Diagram, 6M
- Fault Tree Analysis
- Human Error Investigation Models
- Failure Mode and Effects Analysis (FMEA)

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Human Error Investigations

The FDA currently tracks this in FAR and BDPR submissions.

High rates of Human error root cause is a trigger for failed or inadequate investigations.

Impact Assessment

Patient, product and regulatory risk.

Impact assessments are often too narrow.

Look at how upstream deviations can affect downstream operations.

Microbial contamination investigations often fail in this regards.

Sometimes historical searches for similar issues are so narrow, they do not appropriately identify negative trends.

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CAPA Fundamentals

Corrective Action: Reacting to an existing problem.

Preventive Action: Proactively identifying potential risks.

CAPA Effectiveness

Why CAPAs Fail

- Symptom correction
- Poor root cause
- Weak implementation
- No effectiveness verification

Effective CAPA Framework

- Issue
  → Root Cause
  → Action
  → Verification
  → Sustainability

Regulatory Case Study

Observation

Recurring deviations over 18 months

Company's Response

Repeated retraining

FDA Assessment

Root cause investigations are inadequate CAPAs are ineffective

Lesson

Training alone rarely addresses systemic causes.

Session:
Investigations & CAPA Management

Q&A Session

Interactive Discussion

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Session-4: QA Oversight

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QA Oversight in Manufacturing

- Shop-floor quality presence
- Process monitoring
- Batch review effectiveness
- Risk escalation
- Quality decision making

QA Oversight in QC Laboratories

- Data review expectations
- Audit Trail reviews
- Analyst qualification
- Laboratory controls
- Data Integrity monitoring

Common FDA Expectations

- Independence of the Quality Unit
- Escalation and decision-making authority
- Quality metrics review

QA Oversight in Manufacturing

Inspector Expectations

QA should:

- Be visible on shop floor
- Review critical operations
- Assess GMP behavior
- Escalate quality risks
- Ensure compliance culture

Warning Sign

QA becomes a documentation reviewer instead of a quality leader.

QA Oversight in QC

Critical Areas

- Data review
- Audit trail review
- Instrument controls
- Laboratory investigations
- Analyst qualification
- Method adherence

Common Finding

Lack of a robust review of QC laboratory data and electronic computerized systems.

Electronic Data Integrity

Data integrity is demonstrated not only through compliant software but also through compliant user behavior. During inspections, FDA investigators evaluate whether electronic systems, user access controls, audit trails, SOPs, and day-to-day practices collectively ensure the authenticity, integrity, and traceability of GxP data.

Metadata and robust access controls are essential components of laboratory data integrity. They ensure that electronic records are attributable, traceable, secure, and reliable, providing confidence in analytical results and supporting regulatory compliance.

Common Inspection Deficiencies

- Shared or generic user accounts.
- Password sharing among personnel.
- Audit trails not enabled or routinely reviewed.
- Excessive administrator privileges without justification.
- Inadequate documentation of user access management.
- SOPs that do not reflect actual system use or operational practices.
- Incomplete metadata preventing reconstruction of activities
- Failure to investigate data integrity events

Electronic Data Integrity

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Good Practices

- Implement unique user IDs for every authorized user.
- Enforce strong password and account management policies.
- Restrict administrator access to authorized personnel.
- Review audit trails for critical GxP records using a documented, risk-based approach.
- Train personnel on data integrity expectations and system security.
- Periodically verify that actual practices match documented procedures.

Session:
QA Oversight

Q&A Session

Interactive Discussion

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Session-5:
Managing USFDA Inspections

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01

How to Prepare and Perform During an Inspection

02

Mock Inspection Scenarios

03

Common Mistakes Made During Inspections

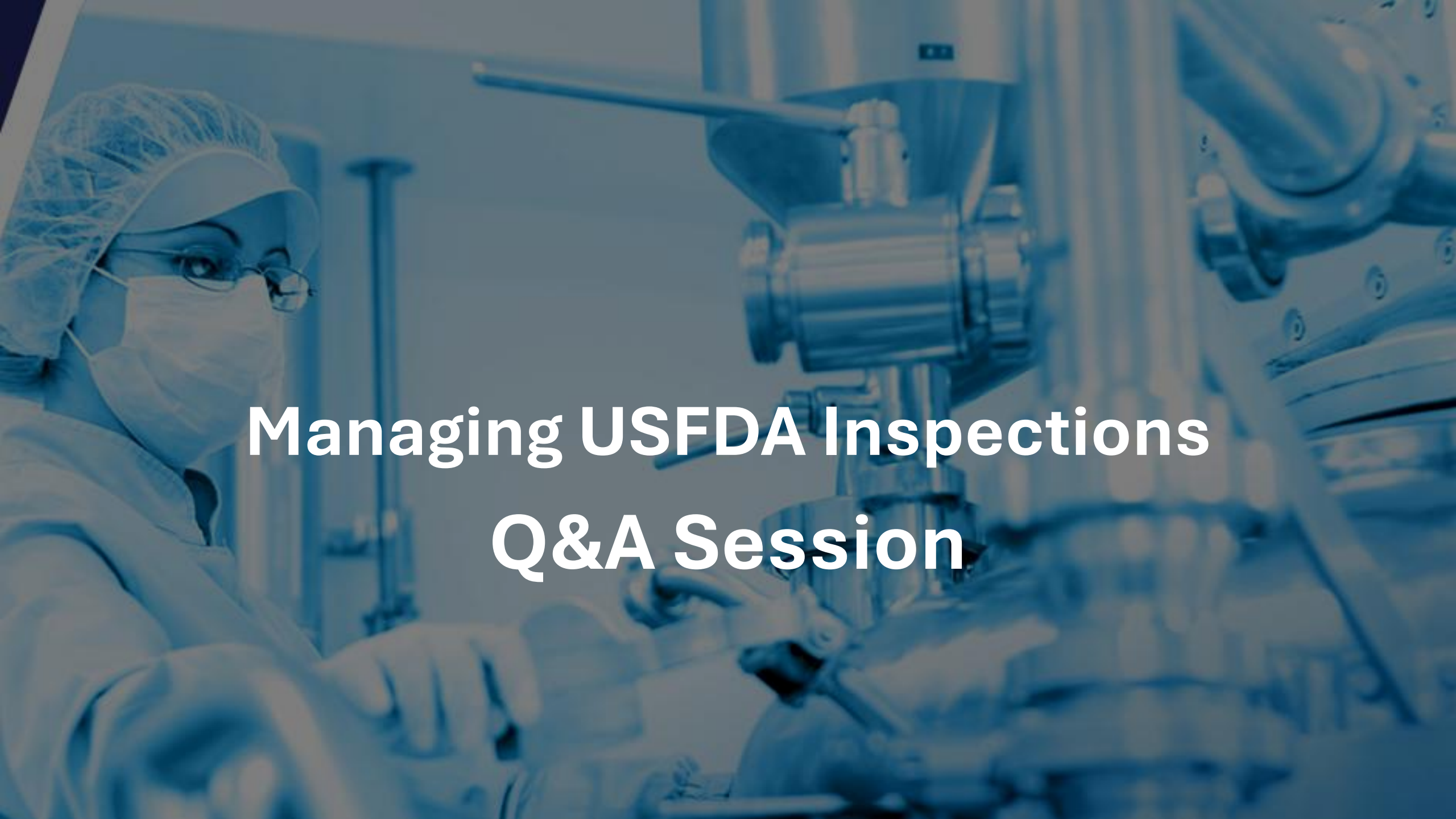
Pre-Inspection Activities

Inspection Planning

- Practice Unannounced FDA arrivals

Establishing Roles and Responsibilities

- Front Room responsibilities
  - Liaisons/Escorts
  - Scribes
  - Document management personnel
- Back Room responsibilities
  - Subject Matter Expert preparation
  - Document managers
- Leadership involvement
  - Establish a communication system



Managing USFDA Inspections

Q&A Session

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Session-6: Unannounced Inspection Preparedness

Building a Readiness Program

- **SOP Framework**
- **Preparedness Plan**
- **Team Structure**
- **Inspection Readiness Checklist**

Unannounced Inspection Preparedness

Establishing an Inspection Response Framework

- Inspection Management SOP
- Escalation procedures
- Communication plans
- Inspection response teams

First 30 Minutes of an Inspection

- Leadership notification
- Document control
- Team activation
- Inspection room preparation

Inspection Readiness Checklist

Building a sustainable state of readiness

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Unannounced Inspection Focus

- Production Activities
- Equipment Checks
- Laboratory Assessment
- Data Integrity Assessment

Unannounced Inspection Preparedness

Q&A Session

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Session-7:

Quality Management Maturity

- Moving from Compliance to Excellence
- Future of Regulatory Inspections

Building a Sustainable Quality Culture

Leadership Responsibilities

- Set expectations
- Lead by example
- Encourage transparency
- Promote learning
- Reward quality behaviors

Culture Equation

Quality Culture = Values + Behaviors + Accountability

Management Review

Management Review is more than a compliance requirement - it is a leadership responsibility. Effective leadership engagement transforms quality data into strategic decisions, drives continual improvement, and ensures the Pharmaceutical Quality System remains effective, compliant, and aligned with business objectives and patient needs.

Common Management Deficiencies

Management reviews conducted only to satisfy procedural requirements.

Senior management not actively involved in quality decisions.

Quality metrics not reviewed or trended.

Repeat deficiencies discussed without effective action.

CAPAs remain open without management escalation.

Inadequate documentation of decisions and follow-up actions.

Management Review

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Best Practices

Conduct reviews at planned intervals using a structured agenda.

Focus on trends and risk-based decision-making rather than isolated events.

Use dashboards to monitor quality performance and business impact.

Track action items to completion and verify effectiveness.

Integrate quality objectives into business strategy and operational planning.

Quality Culture & Quality Management Maturity

Understanding Quality Culture

- What inspectors observe beyond SOPs
- Leadership influence on compliance
- Employee engagement and ownership
- Transparency and issue escalation

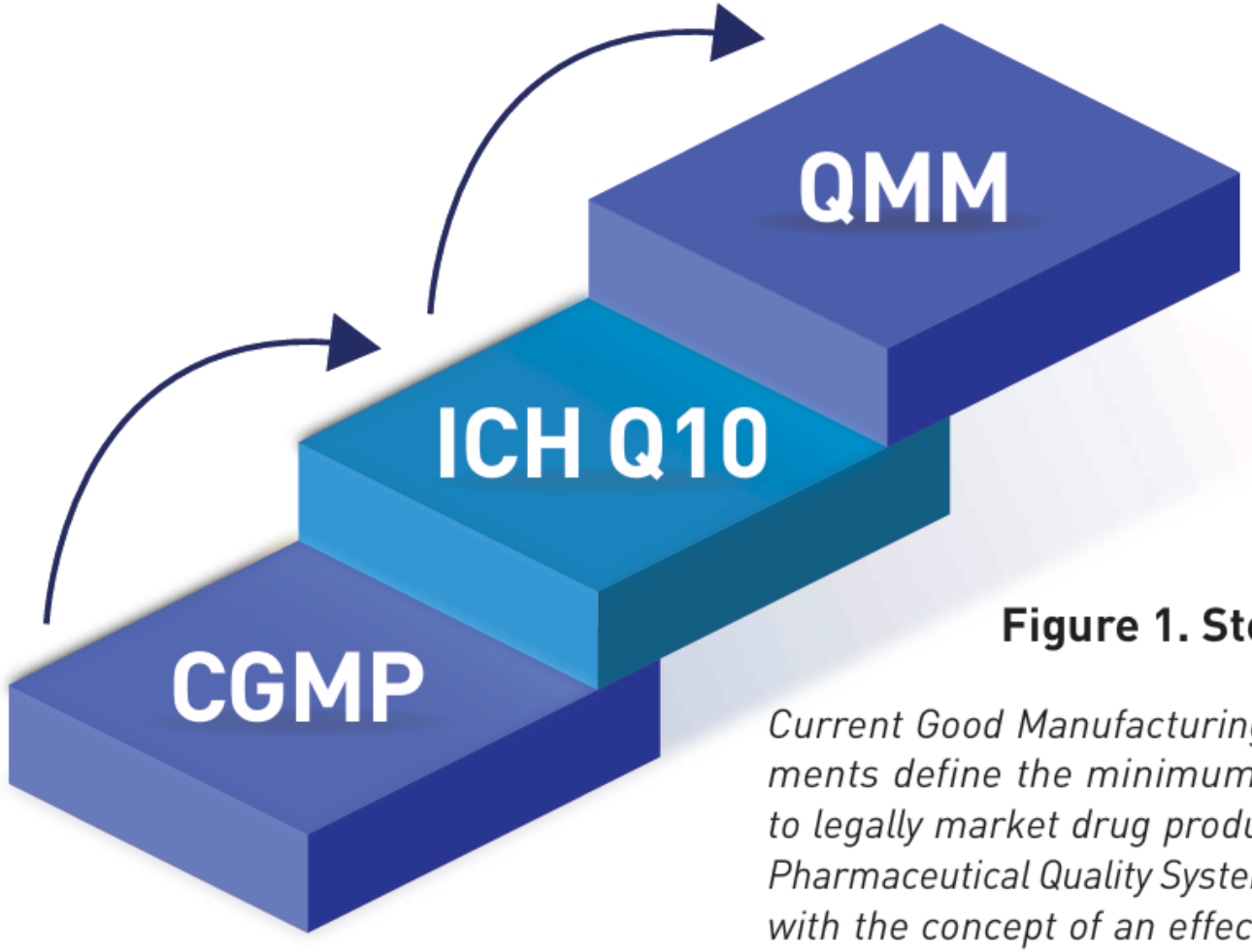

Figure 1. Steps to QMM

Current Good Manufacturing Practice (CGMP) requirements define the minimum manufacturing standards to legally market drug products in the US. The ICH Q10 Pharmaceutical Quality System guidance augments CGMP with the concept of an effective pharmaceutical quality system over the lifecycle of a product. QMM requires, in part, thoroughly implementing the concepts of ICH Q10 to promote continual improvement.

Building a Sustainable Quality Culture

- Leadership commitment
- Employee empowerment
- Quality metrics
- Continuous learning
- Recognition systems

FDA Expectations on Quality Risk Management (QRM)

1. Systematic and Risk-Based Approach
FDA expects QRM to be integrated into the **Pharmaceutical Quality System (PQS)** and to support decision-making across the product lifecycle. It should address both manufacturing quality issues and broader product availability risks.

2. Alignment with ICH Q9(R1)
The FDA's Q9(R1) guidance revises the 2006 version to clarify formality in QRM work, improve risk-based decision-making, and reduce subjectivity in risk assessments. It emphasizes:

- **Principles and tools** applicable to different aspects of pharmaceutical quality.
- **Integration** of QRM outputs into validation master plans and control strategies.

FDA Expectations on Quality Risk Management (QRM)

3. Use of Appropriate Risk Tools
FDA-regulated environments (pharma, biotech, medical devices) expect the use of recognized risk management tools such as:

- **Failure Mode and Effects Analysis (FMEA)**
- **Hazard Analysis and Critical Control Points (HACCP)**
- **Fault Tree Analysis (FTA)**
  These tools should be selected based on the nature of the risk and the process.

4. End-to-End QRM Process
FDA expects a structured process from **risk identification** through **assessment, control, review, and monitoring** .

This ensures risks are not only identified but also mitigated and reviewed over time.

FDA Expectations on Quality Risk Management (QRM)

5. Integration with CAPA
QRM is expected to feed into **Corrective and Preventive Action (CAPA)** systems, creating a closed-loop improvement process that addresses root causes and prevents recurrence.

6. Compliance with 21 CFR Part 820 (Medical Devices)
For device manufacturers, QRM expectations are embedded in the QMSR, which requires a quality management system appropriate to the device's risk profile, including risk-based oversight and CAPA verification.

FDA Expectations on Quality Risk Management (QRM)

Practical Implications

- **Documentation**: Maintain clear records of QRM activities, including risk assessments, mitigation actions, and reviews.
- **Training**: Ensure personnel understand QRM principles and the selected tools.
- **Inspection Readiness**: Be prepared to demonstrate that QRM is integrated into quality systems and supports compliance with GMP/device regulations.
- In summary, FDA expects QRM to be a **formal, integrated, and risk-based component** of quality systems, aligned with ICH Q9(R1), and applied consistently across product development, manufacturing, and post-market activities to protect patient safety and ensure regulatory compliance

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- Organizations that invest in mature quality management reduce the cost of poor quality, improve operational performance, strengthen supply reliability, and create lasting value for patients and the business

- The FDA's enforcement priorities from 2023–2026 consistently show that most Warning Letters arise from systemic weaknesses—not isolated GMP errors. The strongest protection against regulatory action is a mature Pharmaceutical Quality System supported by effective leadership, robust quality culture, sound science, and continual improvement.

Emerging FDA Focus Areas (2025–2026)

Recent inspection and enforcement activity indicates increasing attention to:

- Quality Management Maturity
- Digital Quality Systems
- Data Governance
- AI-enabled computerized systems (with appropriate validation)
- Supply Chain Resilience
- Knowledge Management
- Risk-based decision making
- Continuous improvement

These topics complement traditional CGMP expectations rather than replace them.

Ask Your Leadership Team?

- Would our current Quality System withstand an FDA inspection today?
- Are we preventing problems or reacting to them?
- Which of these Warning Letter trends are present in our organization?
- Which three improvements would most reduce our regulatory and business risk?

Quality Management Maturity

Q&A Session

Key Takeaways

Five Questions Every Site Must Answer

- Are our investigations scientifically sound?
- Are our CAPAs truly effective?
- Is QA providing meaningful oversight?
- Are we prepared for an inspection tomorrow?
- Is our quality system mature or merely compliant?

Open Q&A

Interactive discussion with Dr. Jennifer

Topics include:

- Current inspection challenges
- Regulatory expectations
- Participant-specific questions
- Best practices from industry leaders

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Final Thought

"Inspection readiness is not an activity performed before an audit; it is the outcome of a mature quality culture practiced every day."

Thank You

Contact

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