How to Conduct Field Facility Inspections

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Why conduct field facility inspections?
Because it is expected!

Sponsor

EPA (160.15)
Get Ready

• Arranged in advance (confirmation email).

• List Documents for inspection records.
  (Sanitized) Copy of Master Schedule, SOP Index including QA SOPs,
  Facility Floor Plan, Organization Chart at minimum

• List records you review.
  SOPs, CV/Training Records, Job Descriptions, Equipment Logs, Facility Logs
Beginning the Inspection

Tour Facility

Review Documentation
Focus on GLPs

Subparts
B, C, D, E, F, G, and J
Subpart B
Organization and Personnel

Review Org Chart, Master Schedule, CV/Training Records, Job Descriptions
Subpart C Facilities

Observe facility for:
Adequate Space
Housekeeping
Facility Records
Security
Subpart D Equipment

Adequate Design

Maintenance and Calibration
Subpart E
Test Facility Operation

Review SOPs
Adequacy
Adherence
Subpart F
Test, Control, Reference Substances

Characterization

Documentation of Storage and Handling
Subpart G
Protocol / Conduct of Study

Fully Signed Copy of Protocol and Amendments at Field Site

Data Collection
Subpart J
Record Storage & Retrieval

Reports
Study Data
Facility Records / Archive
Conclude Inspection

Inspection Report

Exit Interview
Keys to Successful Inspections

Preparation

Communication

Requirement vs Preference
EPA Facility Inspection SOP