

# How to Conduct Field Facility Inspections

Debra L. Green, RQAP-GLP  
Advantage Quality Services

NAICC Meeting, Memphis, TN  
January 30, 2008

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

[http://www.epa.gov/compliance/resources/policies/  
monitoring/fifra/sop/glp-c-01.pdf](http://www.epa.gov/compliance/resources/policies/monitoring/fifra/sop/glp-c-01.pdf)