



SPONSOR'S



2





One Sponsor's Guide to CRO Facility Inspections

Kimberly Brown

Syngenta Crop Protection, LLC

January 18, 2024


2024 NAICC Annual Meeting and Ag Pro Expo

San Antonio, TX


Syngenta Process

COI


APPROV


2023 FIELD FACILITY INSPECTION – CHECKLIST


GENERAL INFORMATION			
Inspection Date:		Inspection End	


2023 ANALYTICAL FACILITY INSPECTION – CHECKLIST

GENERAL INFORMATION			
Inspection Date:		Inspection End	


2023 PROCESSING FACILITY INSPECTION – CHECKLIST

GENERAL INFORMATION			
Inspection Date:		Last EPA Inspection Date:	
QAU Auditor's Name:			
Facility Name:			
Facility Address:			
Office Phone:			
Name of Contact Person:			


2023 ANALYTICAL & TOXICOLOGY FACILITY INSPECTION – CHECKLIST

GENERAL INFORMATION			
Inspection Date:		Inspection End Date (if applicable)	
Last EPA Inspection Date:	<input type="checkbox"/> N/A	Last FDA (GLP) Inspection Date:	<input type="checkbox"/> N/A
QAU Auditor's Name:			
Facility Name:			
Facility Address:			

Signature

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REVISIONS AND APPROVALS

Challenge



**Arranging
multiple
inspections in
one week**



**Allowing time to
travel from one
site to another**



**Good grief,
not there**



**Hooray, my
favorite
place to go**



**Good grief,
not Syngenta
again**



**Best day ever
– Syngenta
QA is coming!**



via One Day At A Time on GIPHY



This email is to confirm that My Favorite CRO located in Favorite City, Favorite State has been scheduled for a GLP facility inspection on Thursday, October 26th, with a proposed start time of 8:30 am.

In advance of the inspection, please provide the following documents by October 16th:

- **SOP Index**
- **Master schedule**
- **Most recent EPA inspection closeout letter (if available)**

The facility inspection will include a tour and review of documentation including, but not limited to, the following items:

- 1. Standard Operating Procedures (SOPs)**
- 2. Curriculum Vitae (CVs) for management, lab staff and QA personnel**
- 3. Training records and job descriptions for management, lab staff and QA personnel**
- 4. Facility Floor plan/Site map**
- 5. Test System care, receipt, identification, handling, and accountability**
- 6. Test/Reference substance receipt, storage, and accountability**
- 7. Equipment and associated records**
- 8. Sample identification, storage, and accountability**
- 9. Procedures for the Quality Assurance Unit**
- 10. Computer records, if applicable**
- 11. System validation documentation**
- 12. Work and administrative areas**
- 13. Archives/records storage and retention policy**

If you have any questions or concerns regarding this facility inspection, please feel free to contact me at (000) 111-2222 or via email.

Preparation



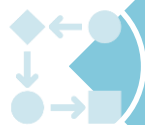
Facility Checklist



Organization & Personnel



QAU



Test Facility SOPs



General Facility Information



Test, Control & Reference
Substance/Storage

Facility Checklist



Frozen/Cold Storage



Balance/Weight Facilities



Facility/Laboratory Equipment



Computer Systems



Archives

Challenge





FIELD

ANALYTICAL

**Field
Equipment**

SOPs

**Laboratory
Equipment**

Computer

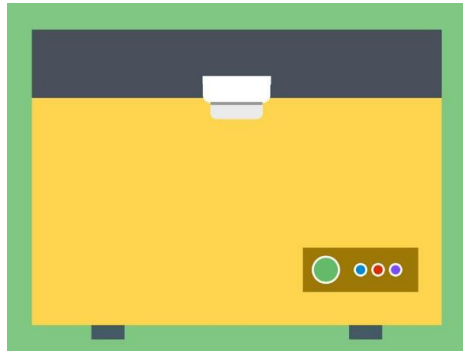
SOPs





Test/Reference
Substance

Sample
Storage



Equipment

Archives





SOPs

CVs & TRs

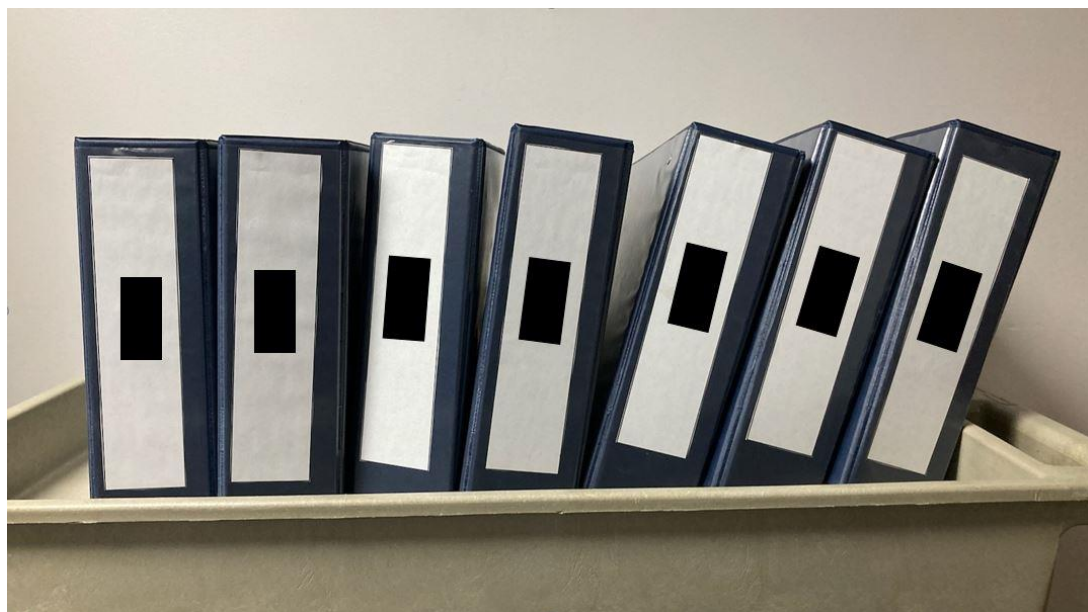
Active Study File

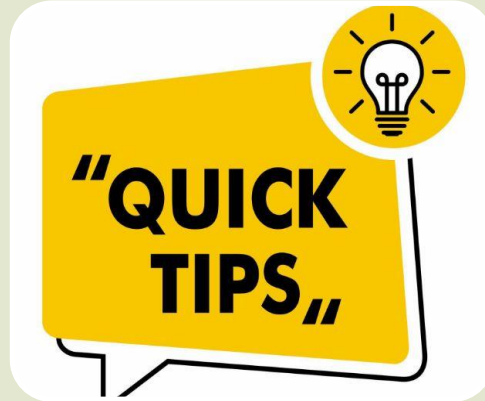
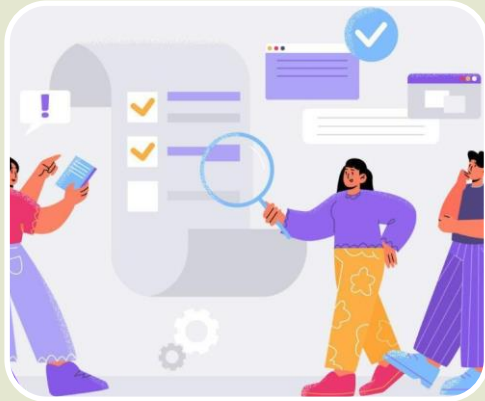
Equipment Records

Field Research Site



Analytical Laboratory





Compliance

Suggestions

Findings

Challenge





**Issue Facility
Inspection Report**

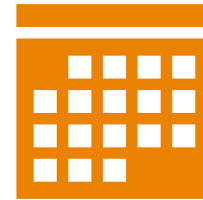


**Follow up
Questions**



**Send as pdf in
email**

**If findings, request
response in 30
calendar days**



**File report in QAU
records**

**Update CRO
Facility Inspection
Smartsheet**



