

Test Your GLP Knowledge

GLP GAME SHOW

Your Host: **Valen Straub**



RULES

- ❖ Everyone has an opportunity to answer the question
- ❖ Questions consist of True or False, Multiple Choice and Short Answer with a few ‘Brain Teasers’ mixed in
- ❖ The first person spotted raising their hand will be called upon to answer the question (*please do not shout out answers*)
- ❖ If the answer is correct that person will be awarded a scratch off ticket
- ❖ Prizes will be awarded at the end of the game to those having ‘PRIZE WINNER’ on their scratch off ticket

GOOD LUCK!!!

Example:

What does EPA stand for?

**Environmental Protection
Agency**

What does FIFRA stand for?

**Federal Insecticide, Fungicide
and Rodenticide Act**

*True or False: Printouts of emails
must be signed and dated by the
person printing it and kept with the
study records?*

True

A record that describes the reporting structure and where you can find the positions for all job descriptions is called?

- A. Curriculum Vitae
- B. Master Schedule
- C. Training Record
- D. Final Report
- E. Organizational Chart

*What individual is responsible for
the overall conduct of a study?*

Study Director

*True or False: Training Records
should contain ‘verification’ of
training documentation*

True

The ‘entity’ to which the test substance is applied in a study is called?

- A. Carrier
- B. Batch
- C. Test System
- D. All the Above
- E. None of the Above

*A planned change, revision, or
addition to the protocol*

Amendment

BRAIN TEASER

Sponsor QA goes out to conduct a critical phase inspection of a harvest sample. The protocol specifies that the samples to be harvested are mature tomatoes. When the QA arrives at the plot and starts reading the protocol they realize that the tomatoes that are being harvested are green and not red as expected. What should happen next?

True or False: Dated, historical copies of job descriptions of employees that have left the company can be permanently removed from the archives.

False

The 'last date' on which data is collected directly from the study is called ?

- A. Study Termination Date
- B. Experimental End Date
- C. Cancellation Date
- D. Data Collection Date
- E. Experimental Termination Date

BRAIN TEASER

The protocol for a GMO field trial says to do the trial under GLP.

The protocol requires 2 trait specific herbicide applications (applied at v2-v3 and then at v6) and list the application rate at 22 fl oz. product/A tank mixed with AMS at 2.5% v/v. Sprayer output should be 5-20 GPA. The plots are to be monitored for phytotoxicity after each application. The first application was applied at 22.29 fl oz. product/A (101.3% the protocol rate) and showed no phyto. The second application was applied at 23.41 fl oz product/A (106.4% the protocol rate) and there was some yellowing of the leaves. Since the protocol does not provide an acceptable range (i.e., +/- 5% or 95% to 105%) for the application, do these applications require a protocol deviation?

*Written guidelines for operation of
equipment or completion of a
procedure*

Standard Operating Procedures (SOPs)

True or False: When collecting ‘data’ by an automatic system the person entering the data does not have to be identified.

False

Who is responsible in assuring that there is a Quality Assurance Unit (QAU)?

- A. Principal Investigator
- B. Test Facility Management
- C. Study Director
- D. Sponsor QA
- E. Contract QA

What is the date the protocol is signed by the study director called ?

Study Initiation Date

*True or False: Published literature
can supplement SOPs?*

True

Who is responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods practices, records and controls are in conformance with the GLP regulations?

Quality Assurance Unit

True or False: QAU have the responsibility to write all SOPs.

False

*Who is responsible in assuring that
original raw data is retained?*

Sponsor

*Who is responsible in assuring that
the facility is in compliance with
GLPs?*

Test Facility Management

BRAIN TEASER

During a QA audit of the second application to a soybean trial with a hand boom, the PFI trips/stumbles/falls during the third of 4 passes. The trial data (including the application verification calculation) is being recorded in an electronic notebook. What steps should be taken by the PFI?

*Who is responsible for authorizing a
‘deviation’?*

Study Director

True or False: 'Freezers and refrigerators' are considered equipment

True

Which of the following are QAU Responsibilities?

- A. Maintain copies of protocols for all studies for which it is responsible
- B. Sign the Compliance Statement
- C. Designate a Study Director before the study is initiated
- D. Inspect studies at intervals adequate to ensure the integrity of the study
- E. A and D only

The first date the test substance is applied to the test system is called?

Experimental Start Date

True or False: QA does not need to maintain a copy of the ‘Master Schedule’?

False

Brain Teaser

The Sponsor Company had a seed treatment field processing study that needed to be started quickly in order to make this year's growing season for soybeans. The study director called the seed treatment lab to let them know the treatment rate for the seeds and the seeds were treated on June 3rd, and the seeds were shipped to the field that same day. The SD signed the protocol on June 4th and sent it to the field that same day. The seeds were received on the 4th and planted on the 5th of June. Is this acceptable under GLP or does there need to be an exception listed on the compliance statement for this study?

*True or False: the Test Substance in a
seed study is the pesticidal
substance?*

True

*True or False: A study can be
started without an approved
protocol?*

False

The study director signed/dated the protocol on 12 July 2012; the sponsor signed/dated on 05 July 2012. The dosing solutions were made and the test system was given their respective doses on 15 July 2012. When was the study initiated?

12 July 2012

*True or False: Historical files of SOPs
and all revisions do not need to be
retained (archived)?*

False

*True or False: Test substance should
be stored in original container?*

True

BRAIN TEASER

Contract facility QA typically sends separate inspection reports to SD and SDM. Sponsor QA tells contract QA that this is not acceptable for their company and that the inspection report should be sent only to sponsor QA. What should be done?

What steps must be followed when making a change to raw data? (more than one answer may apply)

- A. Single line through, insert correct information
- B. Use white-out and then correct the error
- C. Add reason for change (error code)
- D. Initial and date change/correction
- E. Tear the page out and start all over again, this time use pencil so you can erase if you make a mistake

*True or False: ‘Reference substance’
is another word for ‘test substance’?*

False

Whose responsibility is it to ensure that the ‘Facility’ is in compliance with GLPs?

- A. Test Facility Management
- B. Quality Assurance
- C. Principal Investigator
- D. Landowner
- E. Study Director

*True or False: In an 'Analytical Study'
positive, negative controls are
acceptable methods to control bias?*

True

In a corn seed trial what needs to be listed on the Master Schedule as the Test Substance?

Corn or All the events (gene names)?

All the events

*When you ‘calibrate’ a piece of equipment,
which of the following is true?*

- A. Clean the equipment to remove any dirt
- B. Compare it against a similar piece of equipment
- C. Throw it away and buy a new one
- D. Use of materials with known or certified values
(usually involves adjustments)
- E. All of the above

*True or False: A ‘microorganism’ can
be considered a ‘Test system’?*

True

What is a written and approved document that describes the study's content?

Protocol

True or False: Archives must have systems for orderly storage and expedient retrieval?

True

Your test substance has arrived, which of the following ‘logging-in’ procedures does not apply?

- A. Leave the test substance in the package and store it in your desk drawer
- B. Check the condition upon receipt and document
- C. Document the ‘amount received’ and ‘date received’
- D. Document the physical description
- E. Document the amount and number of containers received

BRAIN TEASER

The study director at sponsor tells contract facility principle investigator (PI) that only 1 out of their 3 studies needs to have a QA inspection and states which study to inspect. What should be done?

True or False: Original (study specific) data must be retained by the Principal Investigator

False

When a study director needs to be replaced, who is responsible for naming a new study director?

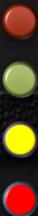
- A. Environmental Protection Agency
- B. Sponsor
- C. Quality Assurance
- D. Test Facility Management
- E. Principal Investigator

THANK YOU!!!

YOU WERE WONDERFUL!

**GLP GAME
SHOW**

Your Host: ***Valen Straub***



Prizes Donated By:

Grand Prize: Renee Daniel

*Other prizes: NAICC
LABServices, ICMS*

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