

Technical QA Audit Report¹ on the IPEC project titled,
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EXPERIMENTAL DESIGN

Has the Protocol been validated in the literature?

Has the protocol been validated in your laboratory?

Has data from the protocol been compared with values from other laboratories

Has the protocol been validated with multiple positive or negative controls

Does the protocol have criteria for a positive response?

Has the variability in the protocol been determined within an experiment and between experiments?

Has a statistician reviewed the experimental protocol?

COMMENTS:

SAMPLES

Do the samples have a unique ID and date associated with the labeling?

Are the labels properly identified with the PI and laboratory?

Are the labels capable of withstanding storage conditions

Have the location and number of the samples been documented for future reference?

Have the storage life and conditions of the samples been determined? If so, have they been documented?

Is there a chain-of-custody associated with the samples? If so, does it list the name(s), room numbers and Phone Numbers of those involved?

Have the samples been properly prepared for disposal? If so, are they in the proper containment?

Has the appropriate paperwork/documentation for disposal of samples been completed?

COMMENTS:

CONTROLS

Are there negative controls involved in the planned experiment?

Are there positive controls involved in the experiment?

Are there duplicates involved in the experiment?

Are the duplicates performed the same each time?

Are there multiple doses involved in the experiment?

Are the multiple doses processed the same way each time?

Are there spike samples if using a GC or other analytical equipment?

¹ Adapted from Schladweiler, M. and T. Hughes "Quality Control (Qc) Checklist For Research Studies,"; Experimental Toxicology Division (ETD); NHEERL, ORD, U.S. EPA, RTP, NC

Are the spike samples recorded for reference?

Are there replicates involved with the experiment?

If using replicates, are they properly documented and validated?

COMMENTS:

CHEMICALS

Are there chemicals being used?

Have the chemicals undergone analysis for purity?

Do the chemicals have an expiration date?

Are the chemicals stored in the proper environment?

Are there biochemicals being used?

Do the biochemicals have an expiration date?

Are solutions being prepared for the experiment?

Is the date, solution recipe and pH being put on the prepared solution for reference?

Are culture media involved in this experiment?

Is there an expiration date for the culture media?

COMMENTS:

EQUIPMENT

Balances/pH Meter

Are a pH meter and/or a balance being used for the experiment?

Has the equipment been checked for accuracy by an outside agency?

Has the equipment been validated before coming to the facility, and has this been documented?

Is the equipment under a maintenance agreement?

Is the equipment operating properly under normal conditions?

Is the equipment being cleaned/maintained, and has this been documented?

Is the equipment being calibrated before and after use, and has this been documented?

If so, is it on a regular basis? ____ ____ ____ (Eg. every day, every week, monthly or quarterly)

COMMENTS:

REPLICATION

Is there replication within the experiment?

Is there replication outside the experiment?

Is there replication in a series of experiments?

Is the replication on a day to day basis?

Is the replication on a week to week basis?

COMMENTS:

STATISTICS

Will statistical assistance be needed for the experiment?

Is a statistician being used prior to an experiment starting (reviewing

protocol)?

Is a statistician being used during an experiment (reviewing data and suggesting changes in the protocol)?

Is statistician being used after an experiment is completed (analyzing data)?

During the experiment, are standard software packages being used to analyze the data and is this documented?

After the experiment, are standard software packages being used to analyze the data, and is this documented?

During the experiment, are specialized software packages being used to analyze the data, and is this documented?

After the experiment, are specialized software packages being used to analyze the data, and is this documented?

COMMENTS:

DATA MANAGEMENT

Are notebooks being used for the experiment?

Are data being recorded in the notebooks being written in black ink?

Are the notebooks being checked, signed and dated for accuracy and validation by someone other than the person writing in the notebooks?

Are PDA's being used for the experiment?

Are the PDA's capable of downloading the data onto a hard drive for backup?

Is an outside person validating the data collected on the PDA's?

Is there specific computer hardware needed to execute the experiment?

Does the computer hardware come validated and is this documented?

Is there specific computer software needed to execute the experiment?

Is there specific computer software needed to analyze data from the experiment?

Does the computer software come validated and is this documented?

COMMENTS:

RECORDS

Are data files kept for the experiment?

Do the data files have a unique ID and date associated with them?

Are the data files validated by someone other than the person filling them out?

Are the data files filled out using black ink pens?

Are the data files generated from using a PDA?

Are notebooks being used to keep records?

Do the notebooks have a unique ID and date associated with them?

Are the data recorded in the notebooks reviewed by someone other than the person writing them?

If using notebooks and data files, do they have the same unique ID

and date as in the experiment?

Are e-mails associated with the planning, execution, and analysis of the experiment retained?

Are e-mails printed out and kept with the other data files and notebooks (mandatory by EPA record rules)?

Are computer files kept for the experiment?

Do the computer files have a unique ID and date as in the experiment?

Do the computer files have the same ID and date as the notebooks and data files (if applicable)?

Are soft copies (such as floppy, Zip disk, CD or DVD) of the computer files kept?

Are hard copies of the computer files kept?

Is there one person in charge of all the data, files and notebooks?

Will the data & computer files along with the notebooks ever be transferred to a different location than where they are being stored now?

When the time comes to archive, are all notebooks, data & computer files organized for archiving (master file)?

Has it been at least 3 years after publication so that the data can be archived?

COMMENTS:

Actions to be taken:

Respond to comments above, as required.

Overall comments and additional suggestions for improvement

Signature

Date
