



Lab Guidance Document

FROM DISCUSSION TO CONSENSUS

Outcomes

- ▶ Review the comments/suggestion from reviewers
- ▶ Make decisions regarding their level of relevance to the document
- ▶ Consensus on revisions
- ▶ Frame work to revise the document

This is for whom the document has been generated Keep this in mind as we go through the comments and suggestions

The main areas of attention in this document include personnel responsibilities in relation to IR-4 residue work, definitions and a significant section regarding lab operations with emphasis on sample handling and storage; sample processing; analytical method validation; sample analysis and extract storage; storage stability studies; communication with the study director; and the Analytical Summary Report. This document will provide guidance for contract labs and will be used as a training tool with regard to IR-4 analytical work.

But first a few question for you

- ▶ Was this the first time you read this document?
- ▶ Did you find it relevant to your work and what you are doing?
- ▶ Were there any surprises?
 - ▶ What were they?
- ▶ Did you find any omissions?
 - ▶ What were they?
- ▶ ON TO THE COMMENTS.....



Definition section

- ▶ Should we add a discussion of the e-QA system as used by the facility for
 - ▶ Audits
 - ▶ Archive for analytical reference methods (in the future)
- ▶ If this is going to be used by contract labs, is the addition of this information still relevant?

Standards, solutions and reagents

- ▶ How to handle non-GLP standards
- ▶ Extending the expiration date of solvents and reagents- How or do you?
- ▶ Determination of stability of solutions (stocks, intermediates and calibrations)



Method Development and Validation- Registrant involvement

- ▶ Approval for significant changes to the reference method must be requested from the SD, HQ gatekeeper and **registrant**.- When does the registrant need to get involved?
- ▶ Extraction – Other substitutions (from tissuemizer to shaker tray) should be discussed with **the registrant** and in consultation with the SD and the gatekeeper.-
- ▶ When does the registrant need to get involved?
- ▶

Method Development and Validation- other considerations

- ▶ What is considered a significant change from the working method-
 - ▶ when does the study director need to be informed?
 - ▶ What is that threshold?- a discussion we have often with our QA.
- ▶ (Sample Analysis and Extracts) – Add a statement regarding back-calculation to the curve for standard injections, retention time variation, peak response within the curve.
 - ▶ is this necessary or a requirement?
 - ▶ In what instances would this need to be included?
- ▶ What happens if we cannot meet the 70 to 120% range? A discussion of possible approaches to this conundrum should be included



Sample processing

- ▶ Guidelines for Sample Preparation for the use of preservatives during sample processing. For example, we must process all chlorothalonil samples in the presence of sulfuric acid?
- ▶ Any suggestions from the sample processing discussion that might be useful that have not already been covered or have changed



ASR Format

- ▶ Including preparation of every standard used in the study in the text vs. including standard preparation in appendix.
 - ▶ Does every standard need to be included? Is this a GLP requirement?
- ▶ Including so much detail in the chromatogram example table of contents.
 - ▶ How so? What can be eliminated?

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z
a b c d e f g h i j k l m n o p q r s t u v w
x y z

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z
a b c d e f g h i j k l m
n o p q r s t u v w x y z

Items that will simply be done- no discussion necessary.....

- ▶ Reference to the freezer advisory from 2014 is needed
- ▶ Remove the reference to satellite labs
 - ▶ None currently part of the IR-4 project
- ▶ Therefore remove reference to Regional Laboratory Coordinator as well
- ▶ Add footnote (1) to gatekeeper.
- ▶ Typo on page 11- "informaiton" instead of information
- ▶ Remove Dave Suderlund as reviewer and replace with new reviewers name

Thank you for your comments and discussion

