SWGDRUG Recommendations, Version 6.1

Public Comments and SWGDRUG Responses

SWGDRUG Recommendations (Version 6.1) was posted for a public comment period from January 16 to March 29, 2013. SWGDRUG received 19 responses (15 affirmative, 4 negative) which included the following comments. The comments have summarized or edited for brevity. Comments that did not offer suggested changes were not addressed. Each comment was considered by the Reference Material and Editorial subcommittees and responses are below in red.

1. Several comments referred to sections Part IVA 6.2.3, 6.2.4 and 6.2.6.3 regarding assessing the matrix, stability, and homogeneity for reference materials. Response - The requirements for stability, matrix and homogeneity assessments have been removed.

2. We have also collected several comments regarding the verification of standards as explained in section IVA.6.2.6. We do not agree that standards obtained from ISO accredited suppliers should be trusted based on their documentation. Laboratories have received inappropriately labelled standards in the past, and it was only through our policy of obtaining a confirmatory spectrum on every standard that we discovered the mistake. Response – this is a minimum requirement, no change.

3. It would be a substantial use of our time and resources to obtain quantitative data for these standards, and often times, we obtain them in quantities of less than 10 mg, so it would be a drain on the supply itself. We are also concerned that this would substantially increase the paperwork necessary for maintaining a drug standards collection while following ISO guidelines. Response – only reference materials from an ISO Guide 34 and ISO 17025 accredited providers are exempt from assessing the purity if used for quantitative analysis.

4. IVA 6.2.6.2.2 the list seems to indicate that qNMR and UV-Vis methods don't need to be validated, and that you don't need RM to quant with UV-Vis. Response – Section was edited for clarity.

5. Recommend IVA 6.1.4 ...appropriate blanks or reference materials... Response – SWGDRUG intentionally included controls.

6. Section IVA 6.1.4: Missing commas - "...blanks, controls, or..." Response – Agree, correction made.

7. Section IVA 6.1.6.3: Missing comma - "...data are available, structural elucidation..." Response – Agree, correction made.

8. Section IVA 6.2.6.3: missing comma - "...case sample), then the chemical identity..." Response – Agree, correction made.

9. Section 6.2.7: missing commas - "...with an expiry date, one should be..." AND "...is fully used, then the material can..." Response – Agree, correction made.

10. IVA6.1.4 text says "(see 6.3)" not sure what that references. Response - Agree, the reference was removed.

11. IVA 6.1.6.3 "...the impact on the interpretation of the reported results assessed." Recommend providing an example of how this circumstance would be reported. For example: "The reported substance was confirmed by structural elucidation. A reference material was not available for comparison. Response – An example was considered but deemed not necessary.

12. IVA 6.2.9 Recommend eliminating space in "sub- divided" Response - Agree – correction made.

13. IVA 6.2 "fulfil" is misspelled. Response – No change was made.

14. IVA 6.2.1 Recommend rewording to eliminate excess words: "SWGDRUG recommends laboratories have a process for demonstrating reference materials are fit for purpose." Response – Agree – edited for clarity.

15. Section IIIB 3.8 Recommend adding ".2" and Qualitative Analysis" to "(see Part IVC - Uncertainty) to make it very clear that quantitative UME and qualitative uncertainty are different. Response – Agree – updated link.

16. IVA 6.2.1 and 6.2.2 - Recommend clarifying the requirements. Difficult to determine the correlation between recommendations, shalls, and shoulds. It would seem that if it is necessary to assess reference materials, that a process would also be required. Response – Agree – edited for clarity.

17. IVA 6.2.2.2 Recommend requiring the completion of assessments prior to or alongside casework. If it meets the recommendations to do it after, how long after is ok? Response – Agree – edited for clarity.

18. IVA 6.2.3 What do you mean by assessing matrix and homogeneity of RMs? Can it be as simple as "appear to be"? Seems like a great deal of work, particularly for small amounts of expensive RMs. Response - Agree – the requirements for stability, matrix and homogeneity assessments have been removed.

19. 6.2.3 and 6.2.4 Recommend parallel wording of the two paragraphs. Response – Agree – edited for clarity.

20. Section IVB.2.3: Reads "The validation documentation and operating protocol..." Recommendation to read "The validation documentation and/or operating protocol..." With the current verbiage, more frequent use of RMs will require a change to the validation documentation. This may affect certain RMs (i.e. weights) and not others (i.e. drug solutions) because the increased use serves as a more conservative intermediate function check. Thus, validation

may be unaffected. Response – Section addresses initial validation – no change made.

21. Finally, we would like to comment on section IVA.6.2.7 regarding expiration dates for drug standards. A minority of our vendors issue expiration dates, and of those that do, some list the date on the bottle while others list it on the shipping invoice. The majority of our standards collection does not have a manufacturer issued expiration date. We feel it would be an inappropriate use of resources to evaluate the entire collection to issue arbitrary expiration dates, and it would be creating a cycle that would require more documentation and unnecessary use of standards when those arbitrary expiration dates pass. These standards are primarily used for GCMS and FTIR analysis. This technique allows us to make a determination of their suitability at the time of use, every time it is used. We feel this constant evaluation is a much more practical and economical policy as compared to setting arbitrary expiration dates. Response – Agree, edited for clarity and added section 6.2.7.2.

22. Page 6: in d) paragraph, Journal of Chromatography A, Analytical Bioanalytical Chemistry could be also added? Response – Section II.5.d is not intended to be an inclusive list – no change made.

23. Page 10: about the Sampling guidelines from ENFSI, why didn't you use the most recent reference which is the Joint guidelines of United Nations Office on Drugs and Crime and ENFSI Drugs WG, UNITED NATIONS New York, 2009? Response – Agree, changes made.