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Workshop
Method Validation in Analytical Sciences
Current practices and future challenges

Gent, 9-10 May 2016

Report from WG 3

Validation of qualitative and semi-quantitative methods

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Validation of qualitative and semi-quantitative methods

How to validate methods where data cannot be handled by normal statistics (e.g. PCR)

- Moderator:
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Suggested questions

- What type of qualitative / semi-quantitative methods are you interested in validating?
- What are the different approaches applied in different fields?
- What are the performance criteria used to validate qualitative / semi-quantitative methods?
- What are the documents available for guidance?
- How do you decide about the extent of validation needed?
- Examples of special approaches for planning and data treatment (when the normal approaches are not applicable – e.g. in terms of statistics for the data treatment)

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Actual questions

- What does ‘qualitative’ mean?
- What does ‘semi-quantitative’ mean?

- What’s different about ‘qualitative’ validation?
  - What special problems does it present?
- ... and what stays the same?
  - What does it have in common with any other method validation?

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What does 'qualitative' mean?

- Qualitative
  - Classification (a category, not a number)
  - Examples: Yes/No, Present/Absent, Identity

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What does 'semi-quantitative' mean?

- Ordinal scales
  - Absent/Low/Med/High
- 'Binned'
  - 0-10, 10-100 ...
- Quantitative with large uncertainty
- Discussion: Hard to find *purely* semiquantitative examples; often quantitative *expressed* semiquantitatively

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What's different about 'qualitative' validation?

- What special problems does it present?
  - Not a number:
  - Results can be counted but not summarised to average, standard deviation etc.
  - This has considerable implications for size of experiments,

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… and what stays the same?

- General concepts apply:
  - Detection capability
  - Ruggedness
  - Selectivity/specificity
  - Accuracy (agreement with reference/true value)
  - Precision (result can be reproduced under repeatability/reproducibiiity conditions
- … but these all have quite different interpretation in qualitative context

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Any other comments?

- Screening methods do not have the same requirements when included in a larger confirmation process
- Uncertainty is difficult to express
  - Probabilities/response rate not very reliable
- Traceability applies to test conditions
  - Unclear whether one can be 'traceable' to a reference library

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Any other comments? (cont)

- Qualitative validation needs a *lot* more observations
- Need to find a balance between 'enough to detect problems' but not so large to go out of business