10th PT/EQA Workshop - Windsor 2023

Report from WGs 4A +4B

Comparison of synthetic vs real PT items

- Convenors:

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Workshop Demographics

- Number of participants = 21 / 23
- PT/EQA providers = 19 / 15
  - Clinical (4 / 1), Food (7 / 11), Environmental (5 / 10)
  - Products (1 x fuels, 1x cosmetics, 1 x medical products 1 x forensic)
- PT/EQA end-users = 3 / 10
- AB = 1 / 2

What is understood to be the meaning of real and synthetic PT items?

- "An item with measurand but with no matrix" "Simulated"

- "An item with measurand and matrix" "Natural"

- Rainbow/Continuum – synthetic samples with added matrix/parameters (e.g. viscosity); modified/treated (e.g. freeze-drying)

- Operationally defined – how it is analysed defines it.
- Virtual real test items

Based upon your experience, in which area of testing are synthetic PT items most useful?

- More dependent on analytes and test items than sector – though Industrial/product sectors may be easier to produce sufficient "natural" samples
- Where homogeneous samples can't be achieved naturally
- Lack of availability of analytes/levels in real world products
- Testing limits/concentrations of methods/regulations
- Where there are instability or transportation issues
- When degradation of analytes is a concern
- When the "true" value is especially important

What is the main reason(s) to use synthetic or real PT items?

- Deepening knowledge in the field – e.g., a synthetic sample can provide information about the extraction efficiency
- Assessing precision element (benefit of synthetic)
- Assessing extraction step/matrix interferent (benefit of real)
- 'Real' world samples don't have always have appropriate analytes or concentrations
- Economic – reasonable for necessary production levels
- Synthetic can provide increased level of control – can tailor a sample to the specific need
- But real sample can provide more confidence in end-to-end process

Can synthetic PT items provide a realistic challenge to assess the performance of a laboratory's routine work?

- It depends on the aim and purpose of the PT – needs to be clearly stated
- Need to "stress test" the system – ISO 15189/17043 requires PT providers to challenge across the range of an analyte and to provide items as close as possible to everyday samples
- Two areas of concern with synthetic: the handling of the sample (pre-analytical) and the second is ability to cheat the system/process (i.e., spikes)
- In most labs, the validation of methods are usually done with synthetic samples in reality
- Useful for looking certain measurement parameters – precision estimates / Not useful if looking for say – extraction efficiency

What are the challenges in preparing synthetic PT items that mimic, as far as possible, the properties of real samples?

- Matrix matching issues - Adding matrix, confounders, interferents to mimic real world challenges (e.g. extraction efficiency)
  - But this adds increased testing, potential for instability, adding contamination, and sometimes simply we don't know what to add (because we don't know always what is in real-world samples besides the measurand in question!
  - Adds additional risk in each step, source of errors
  - Tendency to over-complicate synthetic samples
  - But on the other hand, can provide an opportunity to simplify or control as well

- In clinical field, certain assays/test kits/devices respond differently to a matrix, so hard to produce synthetics that cover all devices.
- Making sure metabolites of interest are included
- Finding a "true" blank
- Working with very low concentrations
- Difficulty finding enough material to send to the participants
- Adding an additional handling step for participants that isn't reflective of normal lab practices