E41 EPA, GLP, and USP vs. Forensic Science: Where is the Commutability? Why Are There no Standardized Methods Across All of Forensic Science?

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After attending the presentation, attendees will appreciate the difference between the highly regulated world of analytical chemistry in the Good Laboratory Practices (GLP) and the Environmental Protection Agency (EPA) regulated environment, as well as USP guidelines versus the largely unregulated world in forensic science where there is no overarching oversight.

This presentation will impact the forensic science community by bringing into focus the discussion on the need for validated, standardized methods in forensic science with the prize not simply being proper metrology, but instead commutability.

Commutability is the hallmark of all measurement science and is particularly important in analytical chemistry at large. Commutability is the feature of being comparable across borders and universal over all time. It's goal is to set up a scheme so that a test of an unknown results in the same qualitative identification and a quantitative estimation regardless of where the testing happens (geographically and environmentally) and through all of time (this year, next year or 100 years later). Using appropriate and traceable standards/reference materials during calibration combined with using validated and standardized methods provides for commutability.

Since the mid 1980s, the Environmental Protection Agency (EPA) has pushed the forefront of standardizing assays and methods in testing then delivering validated and standardized methods for all laboratories to us throughout the United States and in the world. Shortly thereafter, the Food and Drug Administration (FDA) developed GLP whereby a method has to be proven as valid, standardized, and then is accepted and used throughout industry for a particular purpose. The United States Pharmacopeia (USP) has published a stringent set of guidelines that govern the validation and standardization of methods. These validation procedures include testing to determine:

1. Accuracy (Bias)
2. Precision (Calibration)
3. Specificity (Degree of Selectivity)
4. Limit of detection
5. Limit of quantitation
6. Linearity and range
7. Ruggedness
8. Robustness

Put basically and simply, a validated method means that there has been some sort of rigorous method of testing of the instructions of the assay and its calibration procedure to produce data that shows and proves that the method is suitable for its intended purpose.

A true validation study much like the ones found in GLP and EPA regulated environments are consistently missing in the world of forensics. Therefore, the true commutability of any measurement reported in the forensic world can be questioned. There is a high degree of variability in the world of forensics. Not so in GLP and EPA worlds.

Contrast this with the world of forensics. For example, blood ethanol analysis by way of Headspace Gas Chromatography using a Flame Ionization Detector (HS-GC-FID) is a routine method of analysis and perhaps the most frequently run forensic assay in the US today. Yet, unlike EPA, GLP, or USP methods, there are no standardized methods, instrumentation or assays developed and implemented in the testing world. Some laboratories conduct ethanol determinations by enzymatic assay, others use direct liquid injection on packed columns by way of GC-FID. Still others use single column GC-FID. One laboratory runs GC-FID with MS. Not all laboratories use dual column HS-GC-FID. Those that do run dual column HS-GC-FID some consciously decide not to quantitate on two columns. What constitutes a batch as well as what constitutes proper quality control is never uniform among laboratories. Acceptance criteria vary in a seemly arbitrary way. Should there be blanks between unknowns? Should inorganic salt be used? How much dilution should be performed by way of ISTD? And the list goes on and on showing a great amount of variance between and among laboratories to the point that the core question remains: where is the commutability of the number generated USP, VIM 3, and TAM sense of the word.

GLP, EPA, Commutability

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