K41 Uncertainty of Blood Alcohol Concentration (BAC) Results as Related to Instrumental Conditions: Optimization and Robustness of BAC Analysis Parameters

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After attending this presentation, attendees will learn the concepts and practices of the quality-by-design approach to analytical method development to ensure both optimal and robust method conditions. Specifically applied to the analysis of Blood Alcohol Concentration (BAC), this approach will be used to determine optimal chromatographic and headspace conditions to yield a robust set of method parameters with determination as to how these parameters affect both detection limits and uncertainty. Finally, the presentation will extend these concepts to the two most common types of headspace samplers used for BAC analysis: pressurized loop systems and volumetric systems.

This presentation will impact the forensic science community by providing a better understanding of how the major instrument parameters affect both detection limits and uncertainty of headspace gas chromatographic analyses, specifically for BAC analysis. This approach can, and should, be used for many applications in analytical laboratories to ensure that the instruments are operated in a manner that allows for normal variations to occur without an impact to the final determinations. In short, if proper robustness experiments have not been conducted, it is possible the normal daily variance in instrument parameters could cause non-compliance or a lack of determinative value control, which may not be measured by normal system Quality Control (QC) samples. For this reason, robustness experiments should be common in the initial method validation of analytical measurements.

Analysis of blood alcohol concentration is a routine analysis performed in many forensic laboratories. This analysis commonly utilizes headspace-sampling, followed by Gas Chromatography combined with Flame Ionization Detection (GC/FID). Studies have shown several “ideal” methods for instrumental operating conditions which are intended to yield accurate and precise data. Given that different instruments, sampling methods, application-specific columns, and parameters are often utilized, it is less common to find information on the robustness of these reported conditions. A major problem can arise when these “ideal” conditions may not also be robust, thus producing data with higher-than-desired uncertainty or inaccurate results.

The goal of this research is to incorporate the principles of Quality By Design (QBD) in the development of BAC instrument parameters, thereby ensuring that minor instrumental variations, which occur as a matter of normal work, do not appreciably affect the final results of this analysis. This presentation will discuss both the QBD principles as well as the results of the experiments which allow for determination of “ideal” instrumental conditions. Additionally, method detection limits will also be reported in order to determine a reporting threshold and the degree of uncertainty at the common threshold value of 0.08g/dL. Finally, differences between pressurized loop headspace systems and volumetric headspace systems will be discussed, comparing and contrasting these two different types of analytical instruments.

Blood Alcohol Concentration, Robustness, Optimization

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