

OPERATORS AS SOURCES OF ERROR – IMPROVED EFFICIENCY THROUGH PIPETTING TECHNIQUE TRAINING

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Data integrity and confidence in assay results are critical measures of a laboratory's quality system. No matter which tests or assays are performed, robust and trustworthy results must be the highest priority for any laboratory, especially in forensics-related assays, where the results may have to hold up in court. In the material presented herein, the focus is primarily on operator pipetting and pipetting technique when using manual, hand-held pipettes. Though pipetting is sometimes considered a mundane, routine task in the laboratory, where everyone *thinks* they are good at pipetting, we show that poor operator technique can be universal but can be overcome with technique training. Because pipetting poorly can inadvertently, unknowingly and severely impact assay results, it is of imperative importance that pipetting is taken seriously in the laboratory.

Many regulatory bodies have established guidelines designed to help laboratories achieve and maintain good quality practices, while providing a sense of confidence in the quality of work performed at an accredited facility. Not meeting quality standards is an expensive failure for any laboratory. Questionable and unreliable results may lead to several consequences. Of particular relevance to calibration and testing laboratories, as well as medical and reference laboratories are: ISO 17025, ISO 15189, ISO 15195, as well as FDA regulations on cGLP and cGMP. All of these guidelines place a strong emphasis on operator competency, its assessment and documentation.

In one facet of this presentation, we discuss a case study where the goal was to assess the proficiency pertaining to pipetting skills of professionals who use pipettes daily in quality control processes in their companies. In brief, it is clearly evident that several pipette users delivered liquid volumes, which would exceed even the most liberal tolerance limits for accuracy and precision in any SOP.

In the best case scenario, tests and assays will have to be repeated, incurring labor and material costs, which can be quite substantial. If questionable or incorrect results have been released, consequences are usually much more severe and costly, and can include misdiagnosis, poor patient outcomes, and significant legal challenges by affected parties.