# Operators as Sources of Error – Improved Efficiency through Pipetting Technique Training

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## Introduction

Data integrity and confidence in 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.

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. 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.

## Factors Influencing Data Integrity

Quality of laboratory data is affected by many parameters in several areas, among them:

- instrumentation
- reagents and samples
- procedures for assays and tests
- operator competency

It is commonly recognized and accepted that all instruments and equipment used in a laboratory must be suitable for the intended purpose, and must be regularly calibrated to ensure proper functionality.

Great care is usually exercised in developing appropriate standard operating procedures (SOPs) for all assays. These commonly address proper sample preparation and sample handling methods, purity of reagents, as well as specifying tolerance limits for the instruments to be used.

Despite all of these technical specifications, proper qualification and competency requirements for the individuals performing the assays and operating the instruments are easily overlooked. It is not uncommon that laboratories have no procedure in place to monitor and record a technician's proficiency and competency in specific skills.

Particularly in an economic environment, in which continuously increasing workloads need to be accomplished with decreasing available resources, it is easy to become negligent about full operator qualification.

## Regulatory Framework

A set of international and national guidelines and regulations addresses a multitude of specific details of instrument calibration and maintenance to insure proper functionality. Yet, most of these regulations do not specifically address the topic of operator competency.

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.

Generally, operators of instruments are required to demonstrate education, training, and experience relevant to the tasks they are performing. Several regulations also stipulate "Demonstrated Competency" and require the assessment of relevant skills.

Despite proper education, training and experience, skill levels may vary significantly, as the following case study demonstrates.

## Case Study

The aim of this study was to assess the proficiency pertaining to pipetting skills of professionals who use pipettes daily in quality control processes in their companies.

A total of 54 quality control technicians from four major biopharmaceutical companies participated in this study. All technicians had the appropriate education, training, and had plenty of experience - many have held their job for well over one decade.

To assess their pipetting skills, scientists from ARTEL visited the laboratories and provided an ARTEL PCS® Pipette Calibration System, reagents, and a calibrated pipette. Every participant used the same pipette, which was known to perform accurately. Each participant pipetted ten repetitions of 5 µL employing the same pipetting technique as used for every-day work. The average of these 10 repetitions is plotted as individual data point in **Figures 1** and **2**. The pipetted volumes were evaluated for their precision and accuracy, as shown in the plots.

Data obtained from this set of skills assessment are shown in **Figure 1**. 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. Most participants showed inaccuracy and imprecision values, which may not be tight enough, depending on the specific SOP.

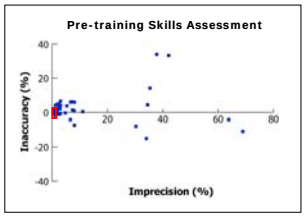


**Figure 1.** Pre-training pipetting skills assessment, using individuals' every-day pipetting technique.

After the initial skills evaluation, all QC technicians received pipetting technique training following the ARTEL Method™ to standardize their pipetting technique. After the training, their skills were evaluated again, based on the same protocol as before.

These post-training results are shown in **Figure 2**. Pipetting performance improved so significantly, that most results fell within, or very close to, the pipette manufacturer's specifications for this particular set volume of the pipette, as denoted by the red box in the figures.

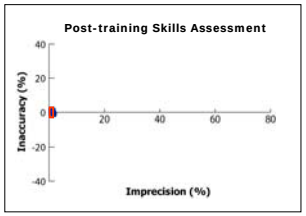


**Figure 2.** Post-training pipetting skills assessment, using a standardized pipetting technique.

## Reasons for Poor Pipetting Performance

Reasons for poor operator competency are as varied as the types of laboratories in which they work.[1] The most common reasons are:

1. High staff turnover
2. Insufficiently trained and inexperienced staff is recruited, requiring on-the-job training
3. Even experienced staff may have:
   - adopted sloppy techniques over time
   - never received formal pipetting training
4. Reduction in workforce requires staff to take on new tasks for which they may not be properly qualified
5. Perceived lack of convenient skills assessment methods leaves potential competency deficiencies undetected

## The Cost of Poor Pipetting Technique

Regardless what the reason for poor pipetting technique is, the consequences may be significant.

Pipettes are high-precision devices, which are used to deliver exact amounts of reagents to an assay or reaction mixture. These liquid delivery steps directly determine the concentrations and ratios of the components in the assay, and thereby influence the reaction kinetics.

The outcome of an assay or test is usually directly dependent on the relative concentrations of all components within its mixture. Altering these ratios may lead to erroneous test results and false conclusions based on those results.

Inconclusive results require repeated tests within the laboratory, adding to the materials and personnel costs of the lab, causing delay of other analyses and potentially leading to missed deadlines for delivering results and/or testimony reports.

In case the assay error is not noticed as part of the lab's QC strategy, and based on the type of test and type of laboratory, releasing erroneous results may have very significant financial and legal consequences.

## Conclusions

The use of handheld pipettes in a laboratory is ubiquitous, and most commonly, not much thought is given to performing the task of pipetting.

The presented case study is representative for a large number of training classes administered by the authors. Those results clearly demonstrate the need to train users of pipettes in the proper technique, as mundane as this may sound. Many participants of technique training classes are very experienced individuals, yet their specific pipetting skills had never been evaluated and improved.

Proficient operators employing a standardized pipetting technique reduce errors and thereby increase the efficiency of a laboratory at every level. Regular skills assessments and their proper documentation are an important part of a comprehensive QC process, and facilitate a laboratory's compliance with regulatory requirements by proving "Demonstrated Operator Competency."

Regular skills assessment and training for operators (of any instrument) should be considered in the same way as implementing regular calibration cycles for instruments. Strengthening every aspect in a laboratory's quality system directly translates into increased data integrity and confidence in the obtained test results.

Reference:
[1] Vaccaro, W. *American Laboratory News* **2007**, *39 (17)*, 16-17.



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