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Note d'application

Minimizing Errors Through Standardization of GXP And R&D Laboratory Measurement Processes

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Ce document est une note d'application et ne contient pas de section détaillée concernant l'expérimentation.

Abstract

This application brief describes about the Waters SDS solution represents a standardized interface for interacting with common electronic measurement devices (***e.g.***, balances, pH meters, titrators, ***etc.***) that can eliminate wasted effort in re-transcribing instrument readouts, improve laboratory productivity, and improve data quality by eliminating transcription errors.

Introduction

Electronic balances, pH Meters, titrators, ***etc***. constitute standard equipment for most analytical laboratories. Traditionally, analysts operate these electronic devices manually and transcribe results into a paper SOP form or paper notebook. The manual transcription of these results is both a common source of error and inherently inefficient due to the redundancy of effort. A 1996 study indicates that the median laboratory transcription error

rate is approximately 1–3% and may be as high as 39%.[1] Laboratories implementing Lean Six Sigma and adhering to GxP regulations seek to standardize processes to eliminate errors and maintain consistent quality.

A straightforward procedure for reducing errors and maintaining document consistency while working with electronic devices such as balances and pH meters, involves connecting these electronic devices, directly to electronic SOP forms or notebooks; spreadsheets; and instrument acquisition system sample lists. This approach works to reduce manual transcription errors and standardizes data handling to reduce variability, thus addressing the major tenants of Lean Processes; ***i.e.***, eliminating waste, improving workflows, and improving quality.

The Waters® Serial Device Support (SDS) solution serves as a standardized electronic interface between common electronic devices and electronic documentation systems, as well as instrument acquisition systems and spreadsheets. For example, the Waters SDS can be utilized to interface with an electronic balance and the NuGenesis® SDMS Intelligent Procedure Manager (an electronic SOP workflow and documentation system). Figure 1 highlights recording a weight measurement from an electronic balance into an electronic SOP form via the Waters SDS application interface.

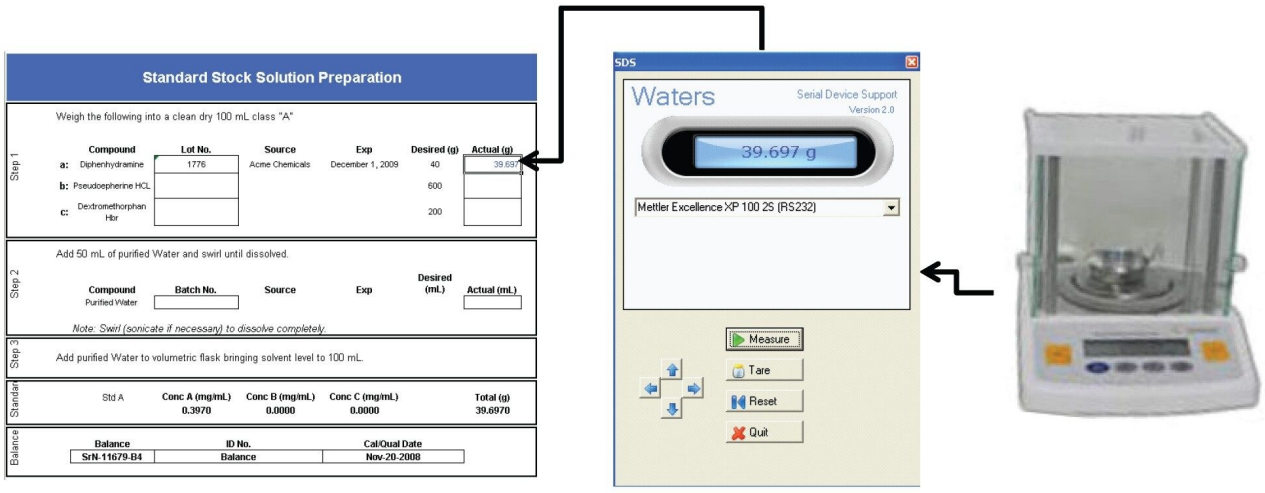

Figure 1. The SDS solution electronically captures and directly transfers a balance measurement into an electronic SOP form. The SDS Application can electronically initiate a measurement.

Results and Discussion

Using the Wat Ers Serial Device Support

The Waters Serial Device Support (SDS) solution interfaces with electronic devices that utilize a RS232 serial port interface. The SDS interface sends a command to the electronic device initiating a measurement (other commands may include tare and device reset). After the device conducts the measurement, a data stream is sent back to the SDS interface. The SDS application then parses the incoming data stream for relevant information (a configurable option) and sends the appropriate information to the receiving application. Figure 1, illustrates using the SDS to perform a balance measurement and then passing the information into an electronic SOP form.

Typical Implementation Strategy

Utilizing the SDS solution in small laboratory applications involves connecting a computer serial port (COM1/COM2) to the RS232 interface on the electronic measuring device. However, in most laboratory applications, connecting a single computer to a single balance can become cost prohibitive. Hence, typical implementations connect the measurement device RS232 serial port to a serial-to-ethernet device; thus allowing communication to many electronic devices by a single computer, via the network. The SDS seamlessly provides access to a selection of available devices by use of a pulldown menu list (as shown in Figure 2), and also manages the connection logistics so that multiple users cannot access the same device concurrently during a measurement.

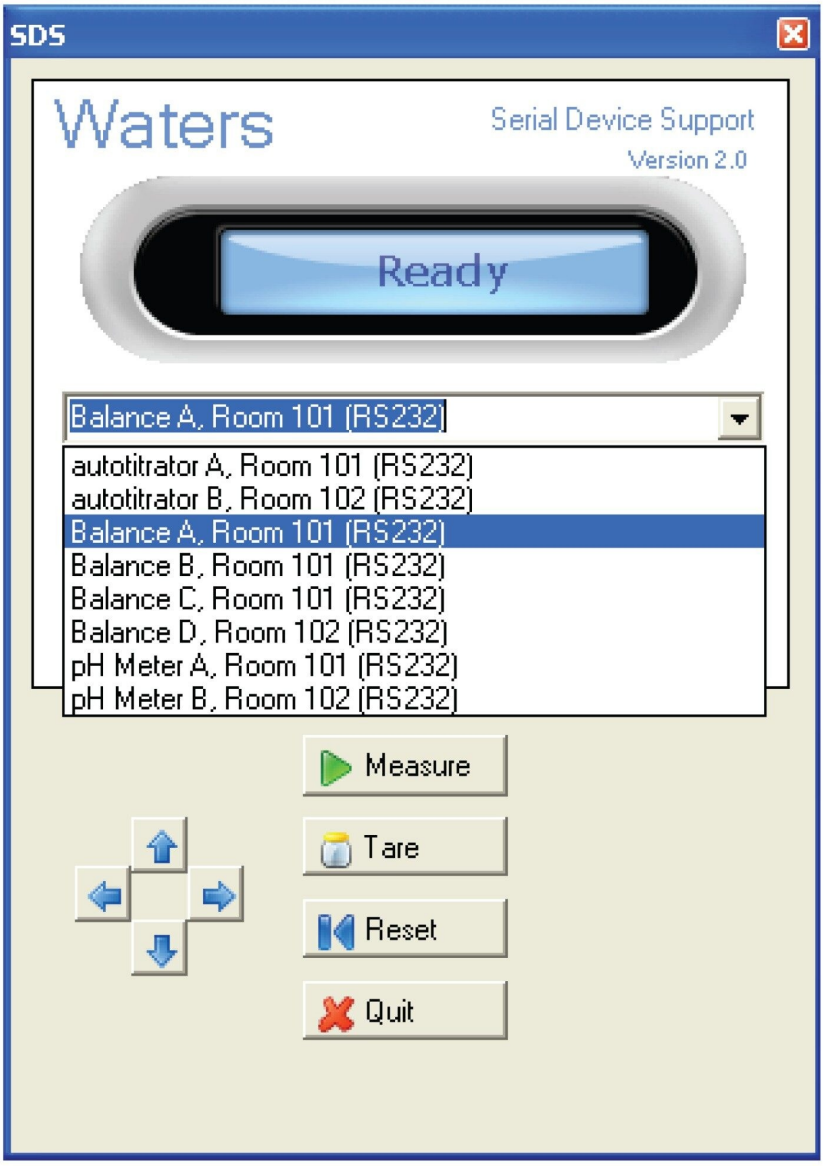

Figure 2. Drop-down menu lets the analyst select the desired small electronic device.

Conclusion

Many sources of error exist in both GxP and R&D Laboratories. Standardizing laboratory processes provides a feasible way to minimize laboratory errors during routine measurements. The Waters SDS solution represents a standardized interface for interacting with common electronic measurement devices (***e.g.***, balances, pH meters, titrators, ***etc.***) that can eliminate wasted effort in re-transcribing instrument readouts, improve laboratory productivity, and improve data quality by eliminating transcription errors. The SDS solution directly addresses the three major tenets of Lean Process: Improvements (eliminate waste, improve workflows, and improve quality) and serves to improve business efficiency and project/product quality.

References

1. M Khoury, L Burnett, and M A Mackay. "Error Rates in Australian Chemical Pathology Laboratories", *MJA*. 165: 128–130, 1996.

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NuGenesis SDMS <https://www.waters.com/waters/nav.htm?cid=513068>

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