All bioanalytical (BA) LC-MS/MS labs strive to provide quality data in a timely manner. One important means of assuring adequate quality is performing quality control (QC) checks on the data and laboratory procedures. Traditionally, QC is performed after data has been acquired, with errors identified and addressed after they occur. At that point, issues can only be resolved by resource-intensive investigative processes. Both of these options are undesirable and impact productivity and efficiency in the bioanalysis laboratory. The present study was undertaken to identify options for overcoming this retrospective analysis in current QC processes. Incorporating QC checks into the workflow prevents re-work or written justification.

**ABSTRACT**

Methods

The electronic lab notebook (ELN) solution, E-Workbook Suite (IDBS, Bridgewater, NJ) was configured to support several BA laboratory workflows. In addition to providing an audit-tracked and paperless environment, the ELN was specifically configured to detect deviations from SOPs and approved BA methods.

- A Balance Check workflow was created to enforce QC processes in the instrument standardization and verification steps. The ELN system was used to register balances and weight sets, along with their associated parameters (range, calibration expiration date, etc.). The template was configured to alert the user to any QC violations during the process of balance verification.

- A Common Reagents workflow was created to support preparation of common laboratory reagents and stock solutions. The system was used to detect and record possible SOP deviations. Specifically, the ELN-based workflow was utilized to preemptively identify:
  - Lapsed reagent expiration dates
  - Use of incorrect reagents
  - Erroneous calculations of analyte parameters, such as purity constraints or dilution factors

- ELN-based templates contained embedded laboratory and business rules to prevent most potential laboratory errors from occurring each ELN template was validated before use, incorporating business and scientific rules to ensure that the task could be consistently and completely recorded in an error-free manner, making post-analysis QC redundant. The validated ELN functionality allowed ‘audit by exception.’ As a result, the system prevented the real-time use of expired reagents by checking the database to confirm that it was approved for use in the analytical method and was not expired. Failure to rectify either deviation prevented the analyst from proceeding with the method. This approach was extended to the use and control of equipment, standards, methods, document templates, and general lab processes, enabling faster QC audits and final reporting.

**RESULTS**

System registers whether measurements are captured directly from the instrument.

Query for valid COA records return analyte data and enforces a valid balance check record.

**CONCLUSIONS**

The utility of an ELN in supporting common bioanalytical laboratory processes was successfully tested.

Once configured within the system, each workflow produced no auditable findings and supported the hypothesis that QC processes can indeed be incorporated during real time operations.