Quality Planning: Principles and Practices

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The harmonization of laboratory test results is a major issue in medical laboratories today. Tests such as HbA1c and INR highlight the difficulties, but even simple tests such as glucose are of concern today with widespread testing sites that employ different measurement technologies. Medical laboratories need a careful plan for managing the analytical quality of their testing processes to *verify the attainment of the intended quality of test results*, as required by ISO 15189.

This presentation describes a plan for Analytical Quality Management that integrates many critical steps such as the definition of quality requirements, selection of measurement procedures to assure traceability, validation of measurement procedures to assure performance, design of statistical QC procedures to verify the attainment of the intended quality of test results, and development of an Analytic QC Plan on the basis of a risk analysis of the laboratory testing process. The sigma-performance of a measurement procedure is a key metric for developing an objective and quantitative Analytic QC Plan and Analytic Quality System. Use of the CLSI C24A3 Sigma-metrics QC Selection Tool facilitates the choice of control rules and the number of control measurements to assure that SQC procedures provide a safety net for catching or detecting medically important errors. Risk analysis provides a new approach for customizing and optimizing the control mechanisms for a testing process, but a properly designed SQC procedure is still fundamental for analytical quality management.

Guidance for risk analysis is provided by ISO 14971 and 22367 and CLSI EP18A3 and EP23P. In particularly, CLSI EP23P prescribes the use of risk analysis for developing a QC Plan on the basis of a manufacturer's built-in controls, the prioritization of risks, and the identification of additional controls to be implemented by the laboratory. Unfortunately, the proposed risk analysis methodology utilizes qualitative rankings of occurrence and severity and neglects detection altogether, even though its intended purpose is to identify control mechanisms and evaluate the residual risks of the proposed QC Plan. A more quantitative approach that makes use of a 3-factor risk model that includes detection is both possible and practical, but will require some education and training to master the Failure Modes and Effects Analysis tool (FMEA) that is new to most medical laboratories.

Finally, the ongoing measurement of quality and performance (EQA), as well as ongoing monitoring of failures (FRACAS), are essential parts of the Analytic Quality System and provide the driving force for corrective and preventive actions (CAPA) and continuous quality improvement (CQI). It is essential that the plan for Analytical Quality Management incorporates and integrates all of these tools to effectively manage the quality of laboratory testing processes.