

Is It Time to Rethink the Way We Approach IQC and EQA?

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IQC has evolved over time and practice to become an essential component of laboratory process control. Stop/go decisions are made based on the results of well trialled rules using highly defined material. However, patient based real time quality control (PBRTQC) models have been around for many years and have recently been investigated as alternatives because:

- Sometimes other controls are unavailable or impractical.
- Patient results might detect an issue that other forms of QC cannot because of commutability issues.
- The state of the testing process can be assessed between the times of routine control-based QC, which may be run infrequently.
- There is little cost.

EQA is a process designed to independently:

- assess the performance of methods,
- provide feedback, often to Regulators, of individual laboratory performance
- assess of method robustness to clinically relevant interference
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These two processes, IQC and EQA, are often conducted independently, except when IQC results may be reviewed following a failed EQA report. However, looking at these two processes in this way loses much of the power of EQA, it can be more than just a regulatory exercise.

The development of better techniques and middleware to allow the practical application of PBRTQC has led to a rethinking of conventional QC, and the relationship between IQC and EQA.

In this presentation we will consider PBRTQC and how it could be used in conjunction with IQC or indeed instead of it. The information that can be gathered from some forms of EQA will also be described in terms of understanding of assay stability and capability. A model of integrating IQC/PBRTQC and EQA will also be described.

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