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Disparities Versus Similarities; WHO Good Practices for Pharmaceutical Quality Control Laboratories and ISO/IEC 17025:2017: International Standards for Quality Management Systems in Pharmaceutical Laboratories

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Abstract : Medicines regulatory authorities expect pharmaceutical companies and contract research organizations to seek ways to certify that their laboratory control measurements are reliable. Establishing and maintaining laboratory quality standards are essential in ensuring the accuracy of test results. 'ISO/IEC 17025:2017' and 'WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL)' are two quality standards commonly employed in developing laboratory quality systems. A review was conducted on the two standards to elaborate on areas on convergence and divergence. The goal was to understand how differences in each standard's requirements may influence laboratories' choices as to which document is easier to adopt for quality systems. A qualitative review method compared similar items in the two standards while mapping out areas where there were specific differences in the requirements of the two documents. The review also provided a detailed description of the clauses and parts covering management and technical requirements in these laboratory standards. The review showed that both documents share requirements for over ten critical areas covering objectives, infrastructure, management systems, and laboratory processes. There were, however, differences in standard expectations where GPPQCL emphasizes system procedures for planning and future budgets that will ensure continuity. Conversely, ISO 17025 was more focused on the risk management approach to establish laboratory quality systems. Elements in the two documents form common standard requirements to assure the validity of laboratory test results that promote mutual recognition. The ISO standard currently has more global patronage than GPPQCL.

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