Poster

[P27-10] P27-10: Pharmacokinetics and pharmacogenetics

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[P27-10-9] In search of objective criteria for judging results of TDM proficiency tests

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Background

KKGT, section for TDM and toxicology of the proficiency testing organization SKML, founded in the Netherlands, is looking for a new way of evaluating the results for routine TDM performed by its participants, as well as exact criteria for a score and judgement. Proficiency testing can evaluate different assay methods and also the result of an individual lab for a certain determination. Especially the latter purpose needs high objectivity and should be generally acceptable, as auditors use these scores in their evaluation of a lab. Consensus values are often used in proficiency testing, determined retrospectively, after results are reported back. For endogenous compounds in serum often the only possibility is using (method-group-) consensus values.
KKGT has used weighed-in (spiked) values, as reference values for over 35 years. Dr. I.C. Dijkhuis, (Ph.D. thesis, Univ. of Leiden N.L., 1979) developed and validated this method including the liophylisation of the (calf)serum samples. It is in use by KKGT ever since.

Methods

A literature search learned that in the Vocabulaire International de Metrologie (VIM, 3d ed. published in 2012 by the Bureau International de Poids et Mesures), Maximum Permissible Measurement Error" is defined as: "Extreme value of measurement error with respect to a known reference quantity value, permitted by specifications or regulations…." (definition. nr. 4.26)
Now guidelines of the European Medicines Agency (EMA, 2011) and the practically identical guidelines of the US-FDA (2013) are available. These documents set requirements for maximum differences between the results from QC samples used in measurement procedures and the assigned reference value of that QC sample. These documents can be regarded as the "regulations" mentioned in VIM definition nr. 4.26.

Results

International guidelines from EMA/FDA, demand that the deviation from the nominal value that can be permitted in measurement results of TDM-proficiency tests, should be no greater than +/- 30%. This percentage reflects two times the standard deviation allowed by these documents and therefore equals the 95% confidence interval.

Conclusions

Deduction from official documents leads to a simple, clear and objective criterion for judging TDM proficiency tests.