

Setting acceptance criteria for validation of analytical methods of drug eluting stents: Minimum requirements for analytical variability

Marika Kamberi Abbott, USA

A ccuracy and reliability of the analytical results are crucial for ensuring quality, safety and efficacy of drug eluting stents (DES). Method validation is the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use. Results from method validation can be used to judge the quality, reliability and consistency of analytical results. Validation of analytical methods includes the identification of the performance parameters relevant for the given procedure, the definition of appropriate acceptance criteria and the appropriate design of the validation studies. Achieving an appropriate consideration of the analytical variability in assay procedures and setting acceptance criteria for analytical validations is however much more difficult than usually described. Criteria which are too wide may lead to unnecessary and incorrect out-of-specification (OOS) cases, resulting in bad reject decision for products. This study concentrates on analysis, through simulation, of the relation of method variability with specification limits for the total loaded dose of the active substance on the DES. The findings of this study point what levels of precision and accuracy are needed, in other words what is the magnitude of the allowabletotal errorfrom all possible effects (both systematic and random) in an assay method in order to achieve the level of performance required for the methods applied routinely for evaluation of the total loaded dose of DES as part of lot release/stability testing. Important in this context is Process Sigma concepts.

marika.kamberi@av.abbott.com