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Challenges in setting acceptance criteria for validation of analytical methods of combination products

Analytical methods used in the characterization of combination products must be sufficiently accurate, specific, sensitive and precise to ensure quality and reliability of the results, which in turn are crucial for ensuring quality, safety and efficiency of the products. Method validation is the process of proving that an analytical method is acceptable for its intended purpose. Validation is primarily concerned with the identification of the sources of the potential errors in the method and their quantification. It describes in mathematical and quantifiable terms the performance characteristics of a method. Performance is strongly connected with both the requirements and the design of the individual analytical procedure. Consequently, the analyst has to identify relevant parameters, which reflect the routine performance of the given analytical procedure, to design the method validation studies accordingly and to define acceptance criteria for the results generated. Setting acceptance criteria for the analytical methods used in the characterization of combination products is however much more complex than usually described. Criteria that are too wide may lead to unnecessary and incorrect out-of-specification (OOS) cases, resulting in bad reject decision for the 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 drug eluting stents (DES). The findings of this study point towards what levels of precision and accuracy are needed, in other words, what is the magnitude of the allowable total error from all possible effects (both systematic and random) in an assay method, in order to to achieve the level of performance required for the methods applied routinely for the evaluation of the total loaded dose of DES as part of lot release/ stability testing

Biography

Marika Kamberi holds a double major in chemical engineering and biochemistry. She received her PhD from Oita University in Oita, Japan and completed postdoctoral studies at Stanford University in Palo Alto, California. Dr Kamberi has over 25 years of pharmaceutical experience/medical devices with increasing levels of responsibility across functional disciplines, including analytical R&D, bioanalytical, pre-clinical research, quality control and stability. She is currently the director of Analytical Chemistry for Medical Devices of Abbott, a worldwide premier medical device organization. Marika is author/co-author of more than 50 papers published in peer-reviewed journals, conference proceedings, and book chapters, and of 15 US/EU patents.

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