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Analytical challenges in method development for drug eluting stents

Drug eluting stents (DES) have become a standard of care for the treatment of symptomatic atherosclerotic coronary artery disease. DES combine drug and device components, and are therefore combination products within the meaning of section 503(g) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 353(g). Analytical methods used in drug eluting stents analysis must be sufficiently accurate, specific, sensitive and precise to ensure quality and reliability of the results, which in turn are crucial for ensuring the quality, stability, safety and efficiency of DES. There are numerous challenges to overcome when developing analytical methods for the DES products. The low levels of the active substance(s) loaded on the DES and their poor water solubility, low levels of other analytes of interest (residual solvent, monomer content, lactic acid, oligomers, and antioxidants) and the presence of polymer(s) in the sample matrix make the selection of sample pretreatment, detection mode and the development of separation conditions extremely difficult. Limited guidance is available on how to achieve an appropriate consideration of the analytical variability in analytical methods used to monitor the quality of the DES products over the shelf-life and set the appropriate method validation acceptance criteria to maintain the method capability and demonstrate its suitability for the intended purpose.

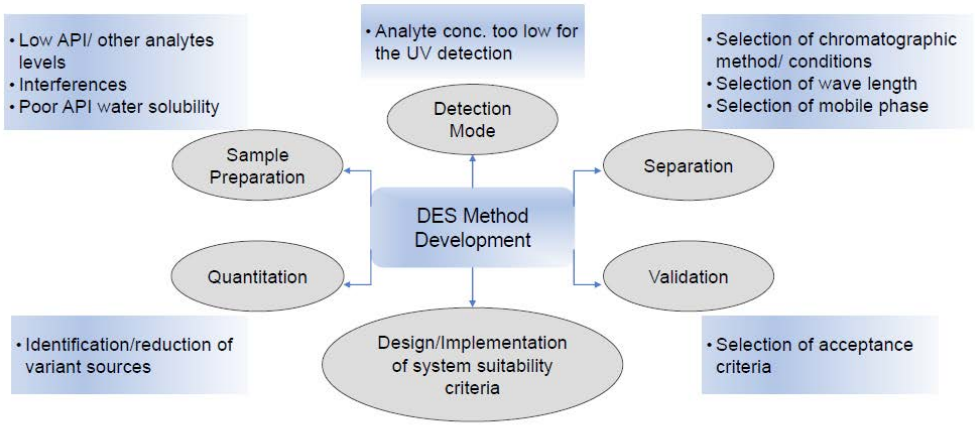

Fig 1. Analytical method development challenges for drug eluting stents (DES).

Biography

Marika Kamberi completed her PhD at Oita University in Oita, Japan and Post-doctoral studies at Stanford University in Palo Alto, California. She holds a double major in Chemical Engineering and Industrial Chemistry. She has over 25 years of Pharmaceutical experience 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, Bioanalytical, Stability at Abbott Vascular Inc., Santa Clara, California, a worldwide premier medical device organization. She is author/co-author of more than 50 papers published in peer-reviewed journals, conference proceedings, and book chapters, and of 10 US patents.

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