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Stability Testing of Drug Eluting Stents

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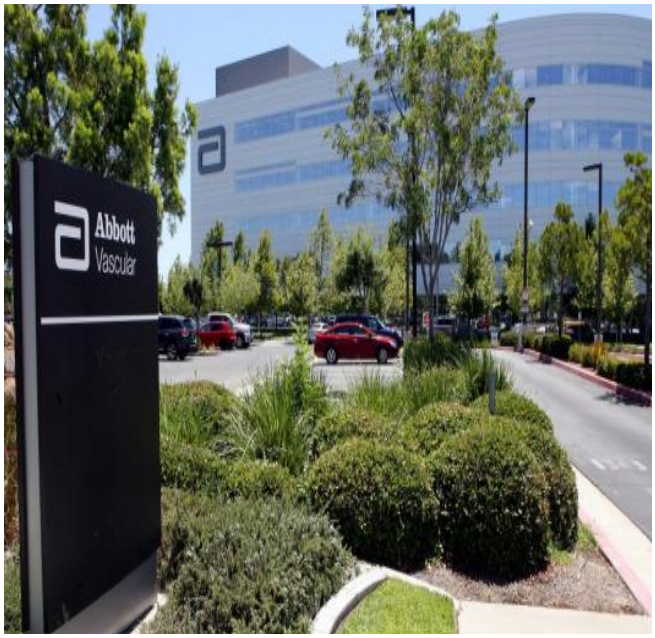
ABSTRACT :Stability testing of drug eluting stents (DES) is performed to provide evidence on how the quality of the product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, and to support the establishment of product shelf life or expiration dating period and recommended storage conditions. Stability studies are critical for ensuring the maintenance of product quality, safety and efficacy throughout the shelf life, and together with testing performed to demonstrate that the functionality of the stent and delivery system (i.e., mechanical performance), coating integrity and package integrity have not degraded over the requested shelf life are considered as pre-requisite for the acceptance and approval of any DES product.FDA draft guidance recommends that the stability studies of DES be conducted in a planned way following the guidelines issued for stability testing by ICH, WHO and/or other agencies. However, these regulatory guidelines are mainly designed to address stability studies that need to be conducted to determine the shelf life of pharmaceutical products.There is currently no clearly established regulatory basis or information in the scientific literature on how to conduct the stability testing of DES.This presentation attempts to discuss key points to consider when designing the stability studies to be performed during the DES lifecycle, as well as some other important aspects related to the stability testing of DES



5. 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.

Publication: **1**.Long-term safety of an everolimus-eluting bioresorbable vascular scaffold and the cobalt-chromium XIENCE V stent in a porcine coronary artery model.
2.A sensitive high-throughput HPLC assay for simultaneous determination of everolimus and clobetasol propionate
3.A novel accelerated in vitro release method for biodegradable coating of drug eluting stents: Insight to the drug release mechanisms.
4.Setting acceptance criteria for validation of analytical methods of drug eluting stents: Minimum requirements for analytical variability.
5.Analysis of non-covalent aggregation of synthetic hPTH (1-34) by size-exclusion chromatography and the importance of suppression of non-specific interactions for a precise quantitation.

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