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Toxicology of polymeric biomaterials: A regulatory approach

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Polymeric biomaterials are widely used in clinical applications such as for drug delivery, tissue engineering, bio-medical sensing, skin grafting, medical adhesives etc. Polymeric biomaterials are chosen for different applications depending on their properties. They act as substitutes for soft and hard tissues in the body. The objective of the toxicological studies of polymeric materials, intended for the fabrication of medical devices, is to investigate the potential biological hazards by careful observations for unexpected adverse reactions or events in humans during clinical use of the medical devices. The toxicity/biocompatibility evaluation of polymeric materials assesses the risk of adverse health effects due to normal use and likely misuse of a device. Adverse health effects could result from exposure to the materials from which a device is made; preclinical assessment of the toxic potential of such materials or components is needed to minimize the potential hazard to the patient. It was well aware that the medical device comprises several components made from different materials; the ideal procedure from a toxicological point of view would be, to evaluate extracts of the components separately. However, in some situations this is not practical, and extracts of the whole device may be used instead. The amount of leachable substances released to the extraction media is related to the surface area and thickness of the product to be extracted. The range of potential biological hazards is wide and may include; short term effects (like acute toxicity, irritation, sensitization, haemolysis and thromobogenicity) and long term effects (such as sub chronic and chronic toxicity, sensitization, genotoxicity, carcinogenicity and effects on reproduction including teratogenicity). Due to the diversity of medical devices, it is recognized that not all the tests identified in a category will be necessary or practical for any given device. It is indispensable for testing that each device shall be considered on its own merits. The details of the toxicity assays will be discussed during the presentation.

Biography

Mohanan P V is working as a Scientist & Head, Toxicology Division, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST). He has Postdoctoral experience from the University of Tsukuba, Japan and Doctoral degree from the University of Kerala. As a toxicologist at SCTIMST with more than 28 years of experience, he has been intimately associated with all the medical devices/technologies developed at SCTIMST. As a Scientist, he has established his own area of research and pursued them with several externally funded projects as Principal Investigator. He has made significant contributions for the development of medical device industry and medical device regulations in India, and India getting GLP membership in OECD countries. He is the senior most GLP Inspector (DST, New Delhi) of the country and a Certified Biological Safety Specialist. He received several national and international awards and honors like, certificate of appreciation from the Hon. Minister of Science and Technology, Govt. of India for the contribution to India getting full adherent status on GLP from OECD, JSPS Fellowship, JSPS Bridge Fellowship, Country Correspondent for the World Library of Toxicology, Senior Toxicologist Fellowship from IUTOX, USA. He was the Secretary General of Society of Toxicology, India and presently he is the General Secretary of Indian JSPS Alumni Association. He is a Fellow of Society of Toxicology, Fellow of Society of Applied Biotechnology and Fellow of Academy of Sciences for animal welfare. He has authored 137 peer reviewed full papers, 4 book chapters, edited 3 books and 4 conference proceedings.

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