

Clinical translation of tissue-engineered medical products (TEMP) journey from bench to bed-side

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Tissue-engineered medical products (TEMPs) are rapidly growing as an advanced innovative therapeutics that can restore, repair and regenerate the cells and tissues to improve functionality. The driving force behind the rapid growth of TEMPs is unmet clinical need of organs and organ donors. Tissue engineering uses a novel interplay of cell and biomaterial and very efficiently brings life science and engineering concepts together. Presentation will illustrate process development of translating TEMP to clinical manufacturing with focus on regulatory requirements with a case study. Preclinical safety studies involving both *in vitro* and *in vivo* using small and large animal models that help find solutions to key research questions will be discussed. Ethical issues in clinical studies with regards to use of cells and tissues, their sources, donor consent, as well as clinical trials will be addressed. TEMPs are regulated as drugs, biologics, devices, or combination products by the US Food and Drug Administration (FDA). Institutional and government levels regulatory issues must be addressed prior to the translation of TEMPs to clinic. The presentation will highlight the regulatory issues for tissue engineered medical products that assures quality, safety and efficacy. Presentaion will also discuss how Regenerative Medicine Advance Therapy (RMAT) also called 21st Century Cures Act will help fasten the translation process of TEMP.

Biography

Sita Somara has completed her Ph.D from SK University, India and Post-doctoral studies from University of Michigan, Ann Arbor. She was appointed as Assistant Professor at Wake Forest Institute for Regenerative Medicine in 2011. She has been served as Investigator in NIH-funded and private foundation projects. In 2014, she joined Regenerative Medicine Clinical Center as Lead Process Development Scientist to pursue her passion for Translational Medicine. She has since led and managed TEMP project in highly regulated environment developing cell-based products, tissue-engineered products and cell/tissue banking in GLP and GMP. She has authored FDA submissions from PPIND, PIND and IND specifically CMC sections. She has published more than 25 peer-reviewd publications in reputed journals. She has recently been appointed as a Committee Member of "Legal and Regulatory Affairs Committee: North America" of International Society of Cellular Therapy (ISCT).

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