

# **Tissue Biofabrication—Next Wave of Science Discovery and Technology Innovation in Biomedical Engineering**

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Creation of highly organized multicellular constructs or organoids will revolutionize tissue engineering and regenerative medicine by enabling the production of personalized tissues and organs for patient-tailored transplantation. With the advent of stem cell biology and the discovery of the reprogramming of patient-specific cells into induced pluripotent stem cells (iPSCs), the previously unthinkable production of personalized tissues is now within reach. The conventional wisdom for producing tissue products of interest has been to differentiate and mature stem cells stepwise into desired tissues and organs. These approaches are less controllable and present challenges in scale-up and/or scale-out. Since individual patients respond to therapeutic interventions differently due to genetic differences and disease states, cellular treatments need to be tailored to individual patients. This concept of precision medicine shifts the emphasis from mass production of uniform biomedical products to high-volume, small-scale production of customized tissue products that have a short shelf life. Precision medicine presents significant challenges to existing biomanufacturing technologies, including product formulation preservation, testing and tracking, quality control, regulatory pathways, and supply chains. These limitations have made it virtually impossible to manufacture tissues and organs at an industrial scale, which is critical to the success of regenerative medicine and tissue engineering. The manufacturing of tissues and organs at high volume or in a more controlled fashion requires revolutionizing current stem cell technologies, and necessitates breaking new ground. The development of these new technologies could quickly lead to better medical treatments with broad impacts as well as the birth of an entirely new class of biomanufacturing industry. This lecture will provide an overview on this emerging field and identify the paths to move forward to establish the discipline and accompany industry.