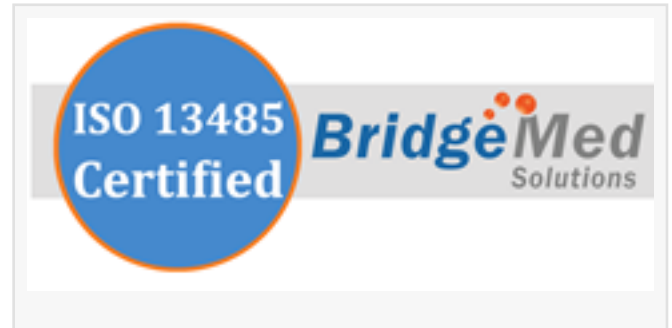


BridgeMed Solutions Receives ISO 13485 Certification for Medical Device Industry

ISO 13485 Certified, Enhancing BridgeMed Solutions' Contract Manufacturing Services in Heart Valve Industry

IRVINE, CA, USA, May 16, 2018 /EINPresswire.com/ -- Irvine, CA – May 16, 2018 – Christopher Williams, Biologist at [BridgeMed Solutions](#), announced that the company is an ISO Certified 13485 facility that meets the stringent quality management regulations required for the prestigious designation.



The [ISO 13485 certification](#) is earned by companies that have demonstrated the ability to consistently meet the highest level of quality and safety standards in the medical device industry, customer and regulatory requirements, and service and delivery. BridgeMed Solutions has amply demonstrated its ability to meet the highest industry standards and best practices.



By obtaining ISO 13485 certification, we now offer enhanced contract manufacturing services to our clients by manufacturing heart valves for FIH (First In Human) implantation and clinical trials,”

*Tara Kupumbati, PhD.,
President and CEO of
BridgeMed Solutions Inc.*

BridgeMed Solutions is a multifaceted company that provides in-house [contract manufacturing](#) of porcine and bovine pericardium tissue patches for use within the heart valve industry and transcatheter heart valve services. The company’s team of tissue engineers, PhD scientists and stent experts also works with clients to provide consulting services, research and development, and facility setup and transfer services.

The company has the skill, experience and expertise to manage every product stage, whether the project requires acquiring tissue or valve production. BridgeMed Solutions provides services encompassing disease monitoring, tissue traceability, viral inactivation studies, anti-calcification treatments, and optimal sewing techniques. The quality-centered company is committed to working with approved suppliers and meeting all regulatory requirements.

BridgeMed Solutions assists and collaborates with a wide variety of companies around the globe. The company’s services are particularly beneficial and cost effective for small and startup medical device companies that may not have their own capabilities to compete with industry leaders such as Edwards Lifesciences and Medtronic Inc. End-to-end integrated services are provided, enabling each client to have access to the innovative services and products they require for success from concept to the manufacturing stage.

The ISO 13485 certification received by BridgeMed Solutions is proof of the company’s dedication to the highest level of quality management in its manufacturing and all related services. The certification also indicates that the company is responsive to the latest changes in technology, utilizing those

improvements to ensure the highest level of service for each client.

About BridgeMed Solutions

BridgeMed Solutions is the leading contract manufacturing organization (CMO) in the transcatheter heart valve area. The company produces custom transcatheter aortic valve (TAVR), transcatheter mitral valves (TMVR), and transcatheter tricuspid valves from scratch per client requirements. The company provides highly-qualified in-house consultants to address areas that include biocompatibility, sterilization, viral inactivation qualification, QMS, regulatory submissions and FIH studies.



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