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Editorial

Class three medical devices—as classified by the FDA—are generally life saving devices which require stringent engineering and pre-clinical studies prior to use in human subjects. Prosthetic heart valves fall into such a category, and have been in clinical use since 1960. Today, approximately half a million prosthetic heart valves are implanted annually worldwide. International standards are developed for medical devices such as prosthetic heart valves to ensure patient safety. For the record, there has been an international standard for prosthetic heart valves since the late 1970 s, namely ISO 5840. International standards for medical devices are revised approximately every three to five years. The ISO 5840 standard is currently undergoing a major revision. The current standard has three parts which address both surgical and transcatheter heart valve replacement devices. The level of engineering rigor that is required for pre-clinical testing has increased over the years. Unfortunately, an international standard is limited in the level of technical details it can provide. Therefore, peer reviewed state-of-the-art papers, published in scientific literature are referenced in international standards as a way to convey these particulars.

The first two articles in this issue of CVET address state of the art engineering techniques—*in vitro* and *in silico*—both of which study the detailed fluid dynamic characteristics of these devices and their potential to damage platelets and red cells and cause thromboembolic complications. The third paper in this issue addresses the new, emerging area of transcatheter mitral valve replacement (TMVR) devices and evaluates the necessary functional requirements using a combination of state-of-the-art engineering (*in vitro* and *in silico*) and pre-clinical techniques.