Fall 10-21-2015

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APPLYING PRACTICES FROM THE MEDICAL DEVICE INDUSTRY TO ENSURE PATIENT SAFETY OF SINGLE-USE PRODUCTS IN THE BIOTECHNOLOGY INDUSTRY

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Key Words: Biocompatibility, toxicology, ISO 10993, risk assessment, hazard assessment

Biocompatibility (i.e., the quality of not having toxic or injurious effects on biological systems) requirements for single-use products in the biotechnology industry can vary depending on point of use. For example, single-use syringes are considered a combination medical device and thus require assessment according to the ISO 10993 standards with test ranging from acute systemic toxicity to genotoxicity to sensitization. Processing equipment (e.g., reaction vessels, tubing, filters, chromatography columns) in contrast, generally requires a USP Class VI designation (a battery of in vivo tests consisting of acute systemic toxicity, intracutaneous reactivity, and muscle implantation) with rigorous requirements for leachates. The USP Class VI Plastic test was developed to test drug containers and is designed to evaluate the biological reactivity of various types of plastic materials *in vivo*, while the ISO 10993 tests addresses biological hazards of medical devices (and their materials of construction) based upon duration and route of exposure. As the use of disposables in biopharma production continues to increase, a primary focus of these new, and often cutting-edge, products is patient and drug safety. During their life-cycle (i.e., manufacture to end-use) single-use products in the biotechnology industry come in contact with processing equipment, packaging components, and delivery systems that might transfer small amounts of chemicals that can negatively impact cell growth and product titers, or even compromise drug safety. It is thus critical that both the materials of construction and the product contact surfaces used during production are appropriate for the intended end-use of the single-use device. Specific examples of material selection, biological and chemical (i.e., extractable/leachable) study selection, and subsequent risk assessments will be presented and discussed.