GeminiBio
Empowering cell culture and process liquid workflows

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USP Class VI Compliance STATEMENT

GeminiBio utilizes single use materials in their manufacturing process as well as final product containers (tubes, bottles, and bags). Materails used in these applications meet the USP Class VI testing requirements identified in USP General Chapter 88, *Biological Reactivity Testing in Vivo*. In this USP Chapter, testing certifies that components passed three different administration route toxicology tests systemic injection, intra-cutaneous, and implantation demonstrating:

1. There was no mortality or evidence of systemic toxicity from the extracts injected into the specimen.
2. There was no evidence of significant irritation from extracts injected intracutaneously into the specimen.
3. There was no evidence of significant reaction to product material implanted into the specimen's live tissue over the course of a minimum of 120 hours (5 days).

GeminiBio's raw material suppliers are qualified prior to use and monitored for performance in accordance with defined procedures. GeminiBio relies on the accuracy of the information provided by the vendors/suppliers of the materials as well as responses to audit information from the GeminiBio Quality department when assessing compliance with USP <88> and approval for use.

Robert Perry

Chief Scientific Officer

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