GeminiBio
Empowering cell culture and process liquid workflows

Gemini Bioproducts, LLC
920 Stillwater Rd, Suite 130
West Sacramento, CA 95605
(800) 543-6464
https://geminibio.com/

cGMP Compliance STATEMENT

Background:

Title 21 CFR Part 820, known as the Quality System Regulation (QSR), established by the Food and Drug Administration (FDA), outlines current good manufacturing practice (cGMP) requirements for the quality management system of applicable medical device manufacturers. Compliance with these regulations is intended to ensure that medical devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.

ISO 13485 is a standard that outlines the development, implementation, and maintenance of a quality management system (QMS) for medical device manufacturers and suppliers. It is recognized globally as a benchmark for quality management in the medical device sector that is focused on QMS effectiveness and meeting regulatory and customer requirements.

GeminiBio Statement:

GeminiBio has established a quality management system (QMS) that authorizes and governs the creation of other quality-related documentation. The QMS is based on cGMP regulations of Title 21 CFR Part 820 and principles of ISO 13485:2016.

The Quality Policy is documented to reflect GeminiBio's commitment to the following Quality Objectives:

- Complying with Title 21 CFR 820
- Complying with ISO 13485:2016
- Evaluating the Effectiveness of the Quality Management System
- Maintaining and Continuously Improving Our Quality, Compliance, and Safety Systems

Robert Perry

Chief Scientific Officer

16JUN2025