

Customer Temperature Benchmark Specification

Customer Information

Customer Name: BioSyn Pharmaceutical Manufacturing

Customer ID: CUST-PH-3291

Industry: Pharmaceutical Manufacturing

Location: Research Triangle Park, North Carolina

Facility Overview

BioSyn operates a GMP-certified pharmaceutical manufacturing facility specializing in temperature-sensitive biologics and vaccine production. The facility spans 75,000 square feet across multiple controlled environment zones.

Temperature Benchmarks

Normal Operating Range

Production Floor Temperature: 20°C - 22°C (68°F - 72°F)

Manufacturing processes require precise temperature control to maintain product integrity and comply with FDA regulations. All production batches are validated against environmental conditions including temperature logs.

Critical Thresholds

- **Lower Warning Threshold:** Below 19°C (66°F)
- **Upper Warning Threshold:** Above 23°C (73°F)
- **Production Halt Required:** Outside 18°C - 24°C (64°F - 75°F)

Monitoring Requirements

Temperature monitoring occurs at:

- Clean room production areas
- Material staging zones
- Quality control laboratories
- Cold storage transition areas

Sensor readings are collected every 30 seconds. Any excursion outside normal range requires documentation in batch records and investigation within 24 hours.

Regulatory Compliance

Temperature data is retained for 7 years per FDA 21 CFR Part 211 requirements. All deviations are reported through the quality management system with formal corrective action procedures.

Zone-Specific Requirements

The normal operating range of 20°C - 22°C applies specifically to active production zones. Adjacent support areas may operate at different specifications not covered in this benchmark document.