[redacted]	[redacted] ENGINEERING STANDARD	
[redacted] FACILITY STANDARDS DOCUMENT SECTION: HVAC DESIGN FOR CLEAN ROOMS & SUPPORT AREAS	EFFECTIVE DATE	[redacted]
	REVISION	[redacted]

Table of Contents:

1.0 Purpose

To define design basis, key parameters, configuration, control methodology, and consumable (spare) parts for HVAC systems supporting Clean Room Manufacturing within the [redacted] facility. This guideline is to be applied to new construction projects within [redacted]; it is to be applied to renovation projects to the extent that its use is feasible without requiring a full replacement of the HVAC system.

2.0 Definitions

3.0 References

- [redacted] Environmental Monitoring Site Policy
- FDA Guidance to Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice
- EudraLex: The Rules Governing Medicinal Products in the European Union, Volume 4: EU guidelines to Good Manufacturing Practice – Medicinal Products for Human and Veterinary Use,
  - Annex 1: Manufacture of Sterile Medicinal Products
  - [redacted]
- USP General Information Chapter <1116>
- [redacted]
- ISO 14644: Cleanrooms and Associated Controlled Environments
  - Part 1: Classification of air cleanliness by particle concentration
  - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
  - Part 3: Testing Methods
  - Part 4: Design, Construction and Start-Up
- [redacted]
- ISPE Baseline Guide,
  - Volume 1: Active Pharmaceutical Ingredients
  - Volume 2: Oral Solid Dosage Forms
  - Volume 3: Sterile Product Manufacturing Facilities
- ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC)