1. **Purpose**

This document defines the policies and procedures for controlling and sustaining the required infrastructure and work environment necessary to meet the needs of the organization.

1. **Scope**

This procedure applies to the infrastructure and work environment requirements that do or can potentially impact the quality of products and/or services provided.

1. **General** 
   1. **Definitions –** N/A
   2. **Responsibilities**

**Operations** – Operation is responsible for the implementation and sustaining of the requirement specified in this procedure

**Quality** – Quality is responsible for ensuring compliance with the procedures specified in this document.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** – Operations and Quality management shall be trained on this procedure and the training documented.
  4. **Record Management** – Operations manages and maintains infrastructure and work environment records
  5. **Reference Documents and Materials**

**21 CFR 820 FDA** Quality System Regulations

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**ISO 13485** – Medical Device Quality Management Systems

1. **Infrastructure**

Operations, with supports from other departments, shall continuously evaluate infrastructure requirements and ensure adequate facilities, equipment, and services for the organization.

* 1. **Facilities**

The facilities shall provide the organization with sufficient capacity, storage, organization, and utilities necessary to complete the business’s objectives. Facilities shall comply with all applicable building codes and status.

[Will differ based upon the manufacturing requirements]

* 1. **Equipment**

The company shall provide the equipment necessary for employees to complete their duties. All equipment utilized in the manufacturing of product shall be qualified for the application and validated, if applicable

* 1. **Service**

Services shall be contracted to ensure the company employees maintain sufficient services to complete directed tasks. These services include, but are not limited to:

| * General Housekeeping | * Telecommunications |
| --- | --- |
| * Electrical | * HVAC |
| * Plumbing | * Pest Control |
| * Maintenance & Repair |  |

1. **Work Environment**

Operations, with supports from other departments, shall create and maintain an environment that supports the goals and objectives of the organization.

* 1. **Environmental Conditions**

The company shall provide a work environment under the following guidelines:

| * Temperature – 68 to 76°F | * Water – Tap and Drinking Water |
| --- | --- |
| * Relative Humidity – 20 to 60% | * Cleaning Agents – least toxic surface cleaners, hand soaps, etc. |
| * Lighting – Suitable to perform duties |
| * Noise Level – below 85 dB |

Any environmental conditions critical to the quality of products or services shall be monitored. Visual and/or physical identifier shall designate any controlled/restricted areas.

* 1. **Health, Cleanliness, and Personnel Attire**

The dress code and personnel hygiene requirements are maintained within the Employee Handbook. Additionally requirements may apply to the manufacturing of specific medical products. Employees with infectious conditions are banned from manufacturing or working with medical devices meant for distribution.

* 1. **Contamination Control**

The company is a provider of clean, non-sterile products. [Will differ from company to company]. To prevent contamination of product, the company has implemented appropriate controls to limit the potential for contamination. These controls include but are not limited to the following.

| * General Housekeeping | * PPE (Personnel Protective Equipment) |
| --- | --- |
| * Access Restrictions | * Flooring Options |
|  |  |

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0022 |  |  | Initial release of the Infrastructure and Work Environment Controls |