directly contact product contact surfaces.

3.7 Heating, Ventilation and Air Conditioning Systems (HVAC)

Systems made up of mechanical, air filtration and electrical devices to create and maintain specific levels of temperature, humidity, pressure differentials and airborne cleanliness for designated environments.

3.8 High Efficiency Particle Air Filter (HEPA)

Filters designed to provide air that is 99.97% particle free for particles 0.3∝m and larger, reduce microbial air contamination and provide a uniform velocity of air along parallel flow lines.

3.9 House Steam

Steam produced from potable, softened or deionized water with a distribution system made of iron or steel and treated with additives to minimize corrosion and only used in applications with non-product contact.

3.10 Utility System

Basic site or building services (power, water, etc.) required to operate a pharmaceutical facility.

4 Responsibilities

4.1 Line Management

The Line Management of R&D in conjunction with Engineering & Facilities at each site is responsible for:

- Ensuring that the utility systems of the respective facility are adequately designed, installed, qualified and maintained to meet cGMP and business requirements.

4.2 R&D Quality Management

R&D QA is responsible for:

- Ensure that appropriate systems are in place to operate a pharmaceutical facility.

- Approving plans, protocols and final reports relating to the installation, qualification and use of the utilities associated with the development, manufacture, quality control and storage of API, intermediates and investigational products.

5 Guideline

