alma brainy

Clause 6 - Resource Management

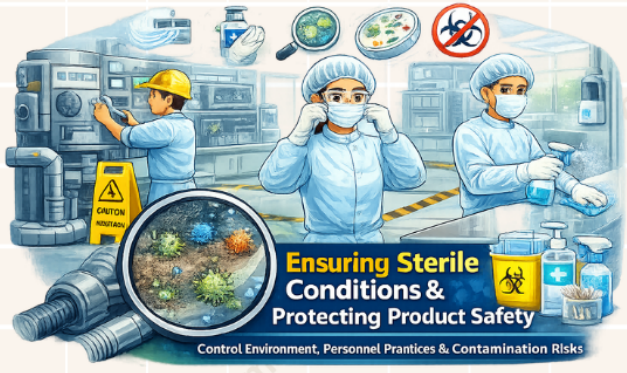
Knowing ISO13485

Provide and maintain facilities, equipment, utilities, and services needed to ensure product quality and prevent mix-ups.

Ensure personnel are competent based on education, training, skills, and experience to perform work affecting product quality.

Provide training, evaluate effectiveness, and ensure employees understand their role in achieving quality objectives.

Establish maintenance requirements and intervals to ensure equipment and environment do not negatively impact product quality.



Control environmental conditions, personnel practices, and contamination risks to protect product safety — especially for sterile devices.