FUTA-Q Imagination & Innovation

Technical Information

Vol.81

The Upgraded Clean Room for Medical Component Manufacturing

1. The cleanroom has been updated toward the new stage.

After five years of operating our cleanroom, we have completed the reconstruction and upgrade of the room in order for its clean environment to meet the demand for more reliable component supply of medical devices. Alcohol spray cleaning and microbial testing management inside the room are now available as well as cleanliness management using a particle counter. This establishes a reliable product supply system that complies with ISO 13485.

2. The exterior of the clean room

Pass box (max. length of 1.5m)

Handwashing sink, air dryer

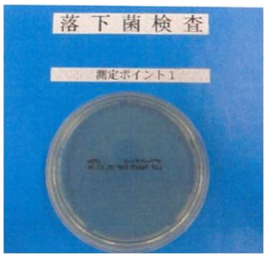
Inside the clean room

3. Sterilization and microbial testing (airborne, settled, and adherent microorganisms)

Microbial test results: "No microorganisms" were detected at all measurement points.

- Cleanroom microbial testing points
  For airborne microorganism: 22 places
  For settling microorganism: 22 places
  For adherent microorganism: 10 places

- Culture temperature: 30 - 35°C
  Culture time: 48 hours



The petri dish after bacterial fallout test

Pre-sterilization protective measures inside the room

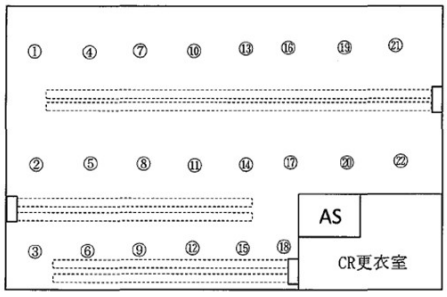
4. Cleanliness check

The cleanliness is measured at 22 points using the particle counter for a 0.5 μm particle. (complied with ISO 14644-1:2015)

Measurement result (August 2025):

Particle concentration of 20 - 140 (particles/CF)

While the official cleanliness level is ISO Class 7, we have confirmed an actural cleanliness level equivalent to ISO Class 6.



Area: 203 ㎡ (17.5 x 11.6 m)

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