

17JUL2020 PACT Web Seminar – Q&A Session

The following questions were asked during the PACT web seminar Q&A session but were not able to be answered live during the web seminar. For other questions and answers, please listen to the audio recording posted on the PACT website.

1. Does each ISO-7 clean room in a multi product facility need dedicated AHU's/HVAC's?

Answer: No, one AHU can service multiple ISO 7 suites. In fact both negative and positive pressured suites can be supplied by the same AHU.

2. For cell therapy processing, did you do the processing in separate suites or one open room?

Answer: For 361 minimally manipulated products they are done in one open room where there are multiple BSCs and work stations.

3. Do you do test method qualification or validation for Phase I?

Answer: The FDA Phase 1 guidance document does not directly address test method qualification or validation but says the following regarding testing:

“Laboratory tests used in manufacturing (e.g., testing of materials, in-process material, packaging, drug product) should be scientifically sound (e.g., specific, sensitive, and accurate), suitable and reliable for the specified purpose. You should perform tests under controlled conditions and follow written procedures describing the testing methodology. You should maintain records of all test results, procedures, and changes in procedures.”

For most tests we would use kits from qualified vendors and include the appropriate recommended controls (i.e., endotoxin and mycoplasma pcr). In some situations it may be appropriate to demonstrate precision and accuracy when initially setting up the test. For a specific lot release test for identity that we had to develop ourselves (i.e., flow cytometry phenotype) we would incorporate positive and negative control cells. To validate a new sterility test method we would have a more rigorous approach that included specificity and sensitivity.

4. If a small biotech company wants to setup a clean room 200sq ft for autologous cell therapy, what is the pricing and operation cost you can estimate?

Answer: A rough estimate to build ISO7 space is \$1,000/square feet in the USA. So, this will calculate to \$200,000. Having said that it will likely cost more considering the non-movable fixed items you will need whether you are planning on building one suite or multiple suites. In comparison, Non ISO7 workspaces cost approximately \$300 per square feet.

5. Did your cryopreservation area require special or different ventilation specifications?

Answer: No special ventilation was required. Liquid nitrogen pumped in via vacuum piping from adjacent mechanical space where the bulk tanks are housed.