



LABFISH

CLINICAL TRIAL SUPPLIES

WE ARE DEDICATED TO QUALITY –
SUPPLIES FOR CLINICAL TRIALS

TOPIC

EXPLANATION SHEET INSTALLATION QUALIFICATION / OPERATION QUALIFICATION (IQ/OQ)



APPLICATION EXAMPLE: REFRIGERATORS

→ CORRECT STORAGE CONDITIONS

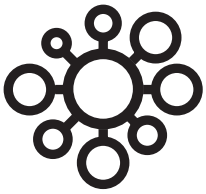
During some clinical trials, correct storage conditions at the sites may be particularly critical. This applies particularly to highly temperature sensitive IMPs which only tolerate short periods of temperature deviations before running risk of changing or losing their activity.

→ RISK

Incorrect storage may lead to grave consequences:

- If noticed, very expensive medication may need to be replaced
- Replacement medication may not be readily available and patients already recruited may fall out of the trial
- If noticed too late, usually very valuable obtained data may render useless
- If not noticed, the obtained data may be incorrect and jeopardize the trial outcome

These kinds of IMPs require a maximum of confidence in the correct temperature conditions inside the refrigerator which requires a **careful Installation Qualification / Operation Qualification (IQ/OQ)** at the location where the refrigerator will be used.



EXPLANATION SHEET - INSTALLATION QUALIFICATION / OPERATION QUALIFICATION (IQ/OQ)

IQ/OQ



→ TO DO'S

INSTALLATION QUALIFICATION (IQ)

During the IQ phase, a number of parameters are checked, including the refrigerator's identity, location, integrity, correct installation, and settings as well as the completeness of documents.

OPERATION QUALIFICATION (OQ)

- The essential component of the OQ is a 24 hour temperature mapping with a simulated door opening event.
- To simulate a realistic situation, the refrigerator is usually loaded with dummy packets of the IMP.
- For the temperature mapping, usually nine calibrated precision temperature data loggers are placed into the refrigerator: four in each corner of the top layer, one in the middle and four in each corner of the bottom layer thereby spanning the complete volume of the storage area.
- After 24 hours,, the temperature data is retrieved and evaluated.

After the refrigerator has passed the IQ/OQ, it is ready to be used for storing the IMPs. The storage temperature of course needs to be continuously monitored with a calibrated temperature data logger.

SERVICES



→ SERVICES

USER TRAINING

An IQ/OQ process usually includes a user training to ensure that the users operate the refrigerator correctly. The training includes

- operating the refrigerator
- loading the refrigerator, with particular emphasis on the maximum load and best distribution
- trouble-shooting
- what to do in case of an instrument malfunction



IQ/OQ DOCUMENT SERVICE

LABFISH provides the full service for drawing up IQ/OQ documents. Usually, this is done in close collaboration with the customer's QA department and considers the customer's individual requirements.

MORE APPLICATIONS: CENTRIFUGES

INSTALLATION QUALIFICATION / OPERATION QUALIFICATION (IQ/OQ) SERVICE: CENTRIFUGES

While IQ/OQ is more common for refrigerators, some application also call for IQ/OQ procedure for centrifuges which LABFISH also offers as an on site service.