Bioquell®
Business Operations

Equipment Servicing & Maintenance
Plus Additional Service Offerings

ECOLAB®

GLOBAL EXPERTS IN CONTAMINATION CONTROL

Equipment Servicing & Maintenance Plus Additional Service Offerings

Comprehensive solutions to keep your equipment running smoothly, backed by our unmatched expertise and expanded service offerings.

> "We had such a great experience with the engineers deployed, would it be possible to request the same team again? Their knowledge and rapport with our internal team makes the process far easier"

Customer comment

STEP 1

Services usually performed before equipment installation

Ingress testing

- Testing customers' load items to ensure H_2O_2 does not permeate the outer packaging. This data will be required by all customers with respect to Annex 1 (please see back page)

Materials compatibility

- Testing materials such as cleanroom panels and coatings for compatibility when repeatedly exposed to H_2O_2

Bespoke systems document

- Needs to be completed and signed off ahead of an engineer attending site

Validation load testing

- Example loads to test cycle times and load configuration

STEP 2

Site services related to equipment installation

Installation qualification & operation qualification

- Installation and operational qualification testing / commissioning

Gassing cycle development

- Equipment and fixed room, completed by a validation engineer or member of the Bioquell Qube Elite team

Production qualification

- Running repeated validated cycles to prove they are still fit for purpose

Production re-qualifications

- Re-qualifying an existing production validated cycle using biological indicators

STEP 3

Post installation site services

Advanced operator training

- For customers who want an additional level of operator training to get the most out of their systems

Customer SOP assistance

- Completed after all validation site works and training has taken place

First line fix training

- Customer's engineering team to receive basic fault finding, alarms and component orientation, ideally electrically trained

Preventive maintenance of equipment

- Service and maintenance of all equipment based on the customer and regulatory requirements

Return to base investigation and repair

- Major overhauls, serious reported faults, and full testing, where it's not appropriate to repair or run tests on site

Regulatory Requirements

Annex 1 provides specific guidance for the production of sterile medicines.

The maximum time interval for requalification of grade A & B areas, is 6 months.

The maximum time interval for requalification of grade C & D areas, is 12 months.

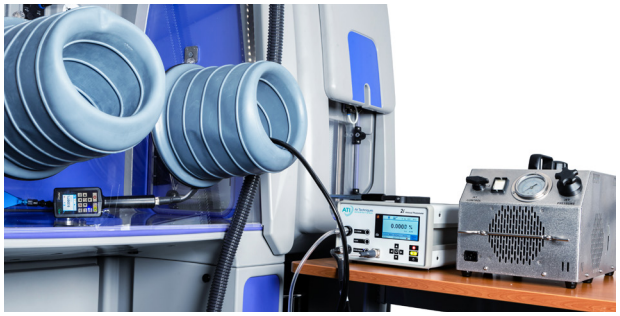
"The requalification of cleanrooms and clean air equipment (i.e. isolators such as the Qube) should be carried out periodically following defined procedures." 4.32

The requalification should include at a minimum the following:

- **Cleanroom classification** (total particle concentration)
- **Integrity test** of final filters
- **Airflow volume** measurement
- **Verification of air pressure difference** between rooms
- **Air velocity test** (Note: For grade B, C and D the air velocity test should be performed according to a risk assessment documented as part of the CCS. Even so, it is required for filling zones supplied with unidirectional airflow, e.g. when filling terminally sterilized products or background to grade A and RABS. For grades with non-unidirectional airflow, a measurement of recovery testing should replace velocity testing.)

Therefore, in summary, the qualification should include at the minimum:

Filter Integrity (DOP) testing, particle testing and airflow checks / calibration. These should be completed EVERY six months and after reactive breakdown visits which impact the pressure or airflow. Additionally, smoke visualization testing will be required on installation.



Filter Integrity (DOP) testing being performed on the Bioquell Qube

Please send your initial enquiries to bioquellusorders@ecolab.com or speak to your local Ecolab account manager.
For more information about Ecolab's Bioquell service offering please visit www.bioquell.com/businessoperations

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WORLDWIDE HEADQUARTERS
1 Ecolab Place
St. Paul, MN 55102
USA
www.ecolab.com/lifesciences

ECOLAB INC BIOQUELL HEADQUARTERS
702 Electronic Dr., Suite 200
Horsham, PA 19044
www.bioquell.com

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