

*Control, Validate, Qualify*

PRODUCTION PREMISES, PROCESSES  
AND EQUIPMENT

# CONTROLS & VALIDATION



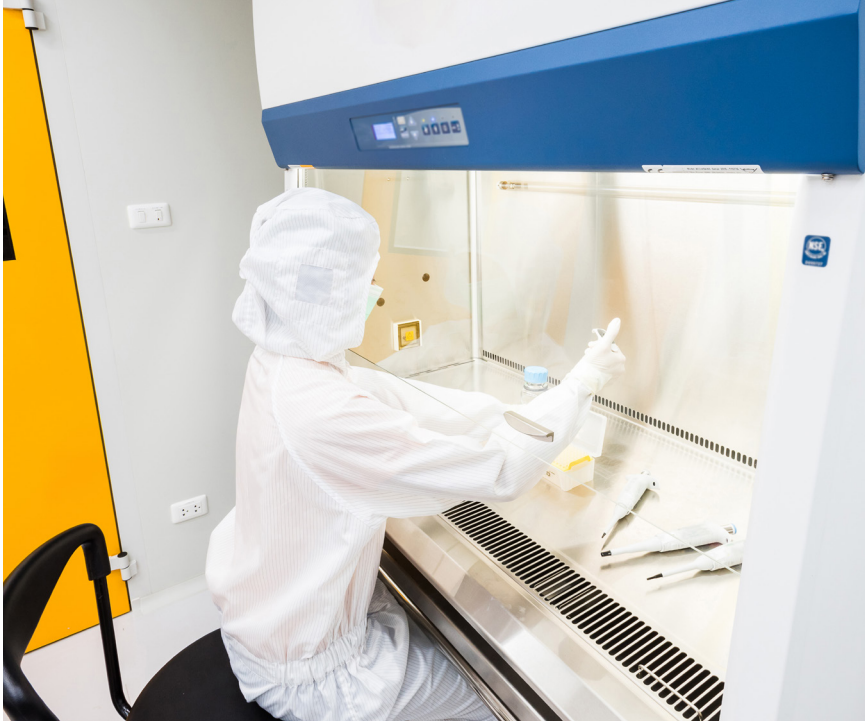
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## CHARACTERIZATION CLEAN ROOMS AND CONTROLLED ENVIRON- MENTS

(COFRAC accreditation)

### References:

ISO 14644, EN 12469...



### Equipment and positions concerned:

Sampling and weighing boxes, preparation and manufacturing areas, laminar or unidirectional flow hoods, PSM, extractors, isolators, glove boxes, operating theaters, L2, L3, L4 containment zones, utility networks, etc.

### Tests that can be carried out:

- Particle counts
- Recovery time
- Air volume flow rate
- Hourly renewal rate
- Filter leak detection ("Emery")
- Differential pressure
- Air flow visualization
- Aerobiocontamination
- Surface biocontamination
- Laminarity
- Temperature and relative humidity
- Leak testing of premises
- Deliverable: A Test Report

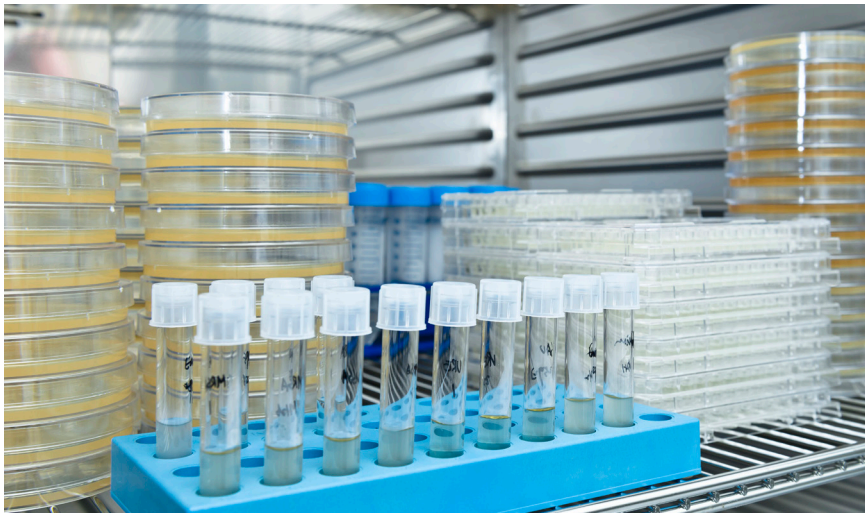
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## THERMOSTATIC ENCLOSURES

(COFRAC accreditation)

### References:

FDX 15-140, CEI 60068



### Equipment and positions concerned:

Thermostatic and climatic chambers, stability chambers, cold rooms, refrigerators, freezers, ovens, CO2 incubators, storage warehouses, -80°C chambers, nitrogen storage units, water baths, etc.

### Tests that can be carried out:

- Control of measuring chains
- Characterization / Thermal verification, hygrometry (mapping, thermo-mappings)
- Door opening test
- Indication error, display deviation...
- Inertia test
- Deliverable: A Test Report

## 3

## THERMAL PROCESSES

### Equipment and positions concerned:

#### Production equipment:

- Manufacturing equipment and processes (dry, liquid and pasty forms) and biotechnology
- Production and distribution of water, steam
- Freeze-dryers
- NEP/SEP, CIP/SIP, Washers-disinfector, measuring chains...

#### Sterilization equipment:

- Autoclaves
- Ovens
- Tunnels
- Measuring chains...

### References:

ISO 17665, EN 285,  
ISO 13408, ISO 20857...



### Tests that can be carried out:

- Metrological control
- Biological validation and depyrogenization
- Mapping / Thermo-mapping and homogeneity
- Characterization
- Validation of sterilization efficiency
- Bowie-Dick Test
- Alarm Test
- Vacuum resistance
- Sterilizing value Fo/Ft
- Soiling test
- Record scrolling speed
- Cycle optimization
- Load definition
- Deliverable: A Test Report

## 4

## QUALIFICATION OF CONTAINMENT EQUIPMENT

### Equipment and positions concerned:

Laboratory fume hoods, chemical hoods, air recycling fume hoods, Etraf, glove boxes, mobile air sensors (or articulated arms), ventilated cabinets, boas.

### References:

EN 14175, NFX 15-211, NFX 15-206



### Tests that can be carried out:

- Visual checks
- Frontal air speeds / extract air volume flow
- Air flow visualization
- Ambient settings
- Pressure loss
- SF6 containment test, air renewal efficiency
- Test HEPA filtration system integrity
- Teston chemical filtration
- Deliverable: A Test Report

## 5

## ENERGY OPTIMIZATION FOR AIR HANDLING UNITS

### Equipment and positions concerned:

Storage unit, air handling control, clean room, ventilation network.



### Tests that can be carried out:

- Audit of existing installation
- Consultancy: definition of ways to optimize energy consumption
- Set-up and implementation of control and monitoring services for controlled environments
- Assistance in interpreting results and implementing action plans

## 6

## QUALIFICATION GAS NETWORKS

### Facilities concerned:

Nitrogen, compressed air, oxygen

### References:

ISO 8573, GMP, European Pharmacopoeia, NF EN 7396...



### Tests that can be carried out:

- Biocontamination
- Pollutant CO, CO<sub>2</sub>, NO<sub>x</sub>, SO<sub>2</sub>
- Deliverable: a test report
- Determination of oil and oil vapor content
- Determination of moisture content
- Particle counting down to 0.1µ

## 7

## SMOKE TEST AIR FLOW VISUALIZATION

### Facilities concerned:

Non-unidirectional airflow rooms, isolators, unidirectional airflow stations (horizontal and vertical unidirectional airflow hood, vertical unidirectional airflow blower ceiling, blower wall, microbiological safety station), fume cupboard or air extractor or chemical hood.

### References:

Annex 1 GMP, CGMP, EN ISO 14644-3



### Objectives:

- Understand the benefits of flow visualization testing and how to carry it out
- Understand the different acceptance criteria
- Analyze video results
- Produce a filmed aeraulic diagram
- Identify critical points

# A NETWORK AT THE SERVICE OF OUR CUSTOMERS

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## OUR MEANS

As a third party, Intertek provides advice, expertise, technical audits, diagnostics, help with problem solving and guarantees compliance with established rules (specifications, technical monographs, regulations, etc.) for all services provided.

Our technical centers are made up of qualified personnel enabling responsiveness and adaptation to customers and their needs..

**COPENHAGUE**

**LILLE**

**HEUDEBOUVILLE**

**PARIS**

**STRASBOURG**

**NANTES**

**ORLÉANS**

**BÂLE**

**CLERMONT  
FERRAND**

**GENÈVE**

**LYON**

**BORDEAUX**

**TOULOUSE**

**MONTPELLIER**

**MARSEILLE**



## QUALITY ASSURANCE SYSTEM

Testing in strict compliance with standards and reference documents. Complete test reports, written under Quality Assurance, consisting of the following elements:

- Analysis of results (excluding Cofrac)
- Comparative summary tables between specifications and results obtained
- Operating conditions of the tests and protocols
- Sampling plans for measurement points
- Test results recording sheets, all measurements taken (before and after readjustment) allowing complete traceability
- List of devices used

## OUR COFRAC CERTIFICATION



CHARACTERIZATION  
& VERIFICATION OF  
THERMOSTATIC ENCLOSURES

Cofrac Accreditations Program  
122-2

Available scope on  
[www.cofrac.fr](http://www.cofrac.fr)

ROOM CHARACTERIZATION  
CLEAN AND CONTROLLED ENVIRONMENT

Cofrac Accreditations No. 1-1077 (Heudebouville  
Agency) No. 1-1893 (Lyon Agency)

Available scope on  
[www.cofrac.fr](http://www.cofrac.fr)






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