Halton Vita Cleanroom Design Guide

Enabling Wellbeing

Halton

Contents

1 Introduction

1.1 About this document

The purpose of this document is to provide guidelines for designing a Halton Vita Cleanroom system. It is meant to give you specifications and design guidelines as well as practical design examples with recommended advanced product options that you can use to plan and design a well-functioning cleanroom environment.

Users of this guide are assumed to have basic heating, ventilation and air conditioning (HVAC) and automation design knowledge.

NOTE: As all designs vary, this document only provides a general guideline. Therefore, close cooperation with Halton is recommended in order to ensure the best results.

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1.3 Summary of changes

Version	Date	Description
1.0	1 March 2021	First version.

1.4 Terminology

Term	Description
biosafety cabinet (BSC)	An enclosed, ventilated laboratory workspace for safe working with materials contaminated with (or potentially contaminated with) pathogens that require a certain biosafety level. There are several different types of BSC, defined by the degree of biocontainment required.
cleanroom	A space where particulate contamination has been reduced to a minimum and where environmental parameters such as pressure, temperature and humidity are carefully monitored and controlled.
fume cupboard	A ventilated enclosure in a laboratory, in which harmful volatile chemicals can be used or kept.
HEPA filters	High Efficiency Particulate Air (HEPA) filters

1.5 Contact information

For contact information, see www.halton.com.

2 Solution description

2.1 Overview

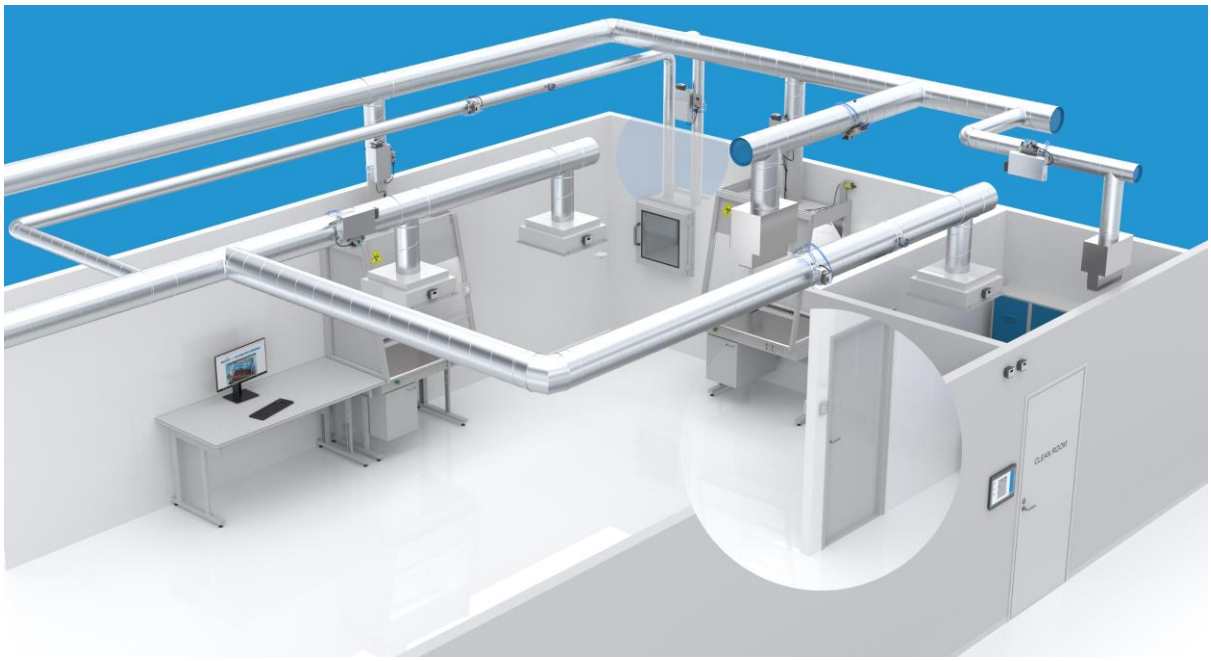


Fig. 1: Halton Vita Cleanroom system

Halton Vita Cleanroom is a total solution for demanding cleanroom spaces. It enables controlling and monitoring clean and safe conditions for professionals in medical and pharmaceutical cleanroom environments. The Halton Vita Cleanroom solution covers the total cleanroom life cycle from beginning to end as a total service.

Application areas

Hospitals, manufacturing plants, and research centres where cleanrooms are needed, such as:

- Hospital cleanrooms (laboratories, hospital pharmacies)
- Biosafety and microbiology cleanrooms
- Pharmaceutical and medical cleanrooms (medical devices, medical storage, medical manufacturing)
- Cleanrooms for university research and study
- Manufacturing cleanrooms (automotive, biotech, food industry, semiconductors)
- Agricultural cleanrooms
- Forensic cleanrooms
- Quality control cleanrooms

Key features

- A complete solution from Halton, your experienced all-in-one partner
- Accurate and reliable room pressure, cleanliness, and airflow control system

- Easy-to-use touch screen user interface
- Reliable, hygienic, and cleanable system components
- Continuous monitoring of all necessary parameters and events, both locally and remotely
- Enables energy savings as the air change rate can be reduced during unoccupied hours, for example, in the evenings or on weekends
- Compliant with the standards and guidelines set for cleanroom environments to guarantee the safety of the personnel and processes
- Start-up, environment validations, filter integrity tests and life cycle services

2.2 Operating principle

The Halton Vita Cleanroom system includes both a control system and a monitoring system, which brings synergy benefits (fast response time to maintenance requests, for example), as both independent systems are provided by one company, Halton.

Halton Vita Cleanroom Control

The Halton Vita Cleanroom Control system consists of a reliable room pressure and airflow control system, High Efficiency Particulate Air (HEPA) filters, and air diffusers specified for cleanroom environments. Air distribution is designed in such a way that it does not disturb the operation and processes in the room. Hygienic and cleanable system components are used to ensure clean and safe conditions both for the personnel working in the cleanroom and for procedures or processes that require specific environmental control.

The Halton Vita Cleanroom Control system guarantees safety and accurate ventilation control in the cleanroom environment, advanced sensor solutions, and a reliable alarm system.

The conditions in the cleanroom can be supervised and controlled by the medical and maintenance staff using easy-to-use touch screen interfaces.

The Halton Vita Cleanroom Control system adjusts the exhaust airflow of the fume cupboards and biosafety cabinets and controls the supply airflow, pressure and temperature. It ensures optimal air quality and comfort in the cleanroom.

Halton Vita Cleanroom Monitoring

To ensure safety, enabling reliable, continuous monitoring of all necessary parameters and events is of vital importance. The Halton Vita Cleanroom Monitoring system is an independent GMP-compliant monitoring system that can be linked to the Building Management System (BMS).

2.3 Offering

2.3.1 Basic control delivery

Value promise: Stable pressure conditions

Basic control delivery includes an independent system with the components needed for stable pressure and airflow control in the cleanroom space, data transfer to BMS, and easy-to-use room panels with local alarms for users.

Contents

- Room pressure and airflow control (VLR)
- Room panels and room pressure sensors (HTP, VPT)
- Biosafety cabinet or fume cupboard control, sensors and control panels (VLS, VSS, HTP)
- Start-up and commissioning

2.3.2 Halton delivery

Value promise: Ensured process safety and comfort to the staff

Halton delivery includes a holistic solution for cleanrooms. In addition to pressure and airflow control, it consists of HEPA filters integrated into supply air diffusers, the main supervisory panel (VSP) of the Halton Vita Cleanroom system, ensured HEPA filter integrity tests and validation measurements, as well as room-specific adjustments of supply airflow patterns to guarantee process safety and comfort to the staff. Parallel access to Halton Vita Cleanroom Control system and Halton Vita Cleanroom Monitoring system enhances system reliability and troubleshooting. The goal is to enable a smooth system delivery from the planning phase of the cleanroom project up until the start-up and whole life cycle of the cleanroom system.

Contents

- Room pressure and airflow control (VLR)
- Room panels and room pressure sensors (HTP, VPT)
- HEPA diffusers, adjusted flow pattern, filter pressure sensor (VHT)
- Biosafety cabinet or fume cupboard control, sensors and control panels (VLS, VSS, HTP)
- Halton Vita Supervisory Panel (VSP)
- System ECO mode control
- Halton Edge remote control for quick response in fault situations
- System wiring and connections
- Validation measurements
- HEPA filter integrity tests
- Cleanroom Monitoring system (CMS)
- Halton Design Support service
- Start-up and commissioning

- Halton Life Cycle services

2.4 Services

Halton Design Support

- Co-designing with the customer: defining the requirements and performance targets, matching the targets to an optimal solution.

- Halton Computational Fluid Dynamics (CFD) - Computational simulations are used for laboratory space design to ensure that the room air flow pattern does not interrupt the operation in the room. This way, safe working conditions are guaranteed already at the design phase.

- Possibility for full-scale mock-up and pre-verification tests for indoor environments conducted in Halton Innovation Hubs.

Halton Start-up

- Halton Vita solutions always include on-site commissioning to ensure the safety and functionality of the spaces and working conditions.

- Verifying and adjusting the optimal performance of room systems.

- Service personnel and end user training.

Halton Life Cycle

- Maintenance

Halton offers a maintenance agreement for installed systems. As part of this service, the Halton service team recalibrates and tests all the components and sensors to ensure continuous functionality of the spaces and working conditions.

- Halton Edge remote control (as part of a maintenance agreement)

Halton Connect is an IoT platform with an advanced cloud-based portal. It enables 24/7 remote monitoring of the solutions designed by Halton, allowing end-users to access useful information about system performance. It also provides vital information to Halton engineers so they can remotely and safely control all systems and their settings when required.

- Regular system functionality evaluation

2.5 Features of Halton Vita Cleanroom Control

2.5.1 Halton Vita Lab Room (VLR) features

Direct pressure control

Direct pressure control maintains the desired pressure level based on measurements from a room pressure sensor. This provides rigorous pressure control for spaces where safety requirements are high. The system is configured for positive or negative pressure depending on the type of laboratory.

Air change rate control (ACH)

Air change rate control is used to ensure the required air change rate in the room. The room controller maintains the air change rate at its minimum level when the total local exhaust airflow rate is low. During unoccupied hours, for example, in the evenings or on weekends, the air changes per hour (ACH) can be reduced to the ECO mode.

Temperature control

The temperature in the cleanroom can be controlled automatically.

The system monitors the room temperature using either a temperature sensor integrated into the room panel (HTP) or with an external temperature probe.

With the standard temperature control feature, the temperature is controlled by adjusting the airflow rate, while for the advanced temperature control, an additional heating or cooling element is required.

Cascade control

Cascade control is available for room pressure control applications. It combines the room pressure and room airflow controls by calculating the setpoint of the supply or exhaust airflow (depending on which one is controlling the pressure) from the measurement of the room pressure and the estimated airflow. This provides a faster control reaction time.

Control freeze

To avoid excessive loss of room pressure, the control can be frozen during the opening of the door.

Alarm

The room panel (HTP) indicates an alarm, both visually and acoustically, when the airflow or pressure value is below the predefined alarm range or when a door is open after a predefined delay time has passed.

Operating modes

- ECO mode

The ECO mode saves energy by setting the ventilation directly to the ECO adjusted position. The manual ECO mode allows the user to activate it. The feature is enabled and adjusted from the configuration menu. Reducing the air change rate (ACH) does not impact the pressure control.

The automatic ECO mode is an optional feature and requires an occupancy sensor or it can be controlled via the Building Management System (BMS).

- Manual mode

Manual mode allows the manual control of the exhaust and supply VAV damper positions during commissioning and maintenance. This mode is enabled from the configuration menu of the room panel (HTP) and protected by a password.

2.5.2 Halton Vita Lab Solo (VLS) features

Double sensor control for fume cupboards

The double sensor control feature maintains the face velocity at a predefined level and controls the sash movement to provide an exceptionally quick increase of the exhaust airflow. This feature is compatible with standard EN14175-6.

The face velocity is maintained at its setpoint (0.5 m/s by default) by proportionally controlling the exhaust airflow damper of the fume cupboard based on the measurement value of the velocity sensor.

Based on the change of the sash position measured by the sash position sensor, the control is accelerated by directly driving the position of the exhaust airflow damper according to the characteristic curve.

Dual position control for biosafety cabinets

When the biosafety cabinet is in use, the dual position control feature controls the airflow rate to a predefined maximum level based on the signal emitted by one of the following:

- On/off switch (contact switch at the lower part of the fume cupboard)
- Two-step (min/max) airflow control of the fume cupboard
- A local exhaust unit using a limit switch or a 2-position switch
- Dry contact from the biosafety cabinet

When the biosafety cabinet is in standby mode, the airflow rate is adjusted to a predefined minimum level.

The two-step switch allows the system to detect when the sash is closed:

- Sash closed / Switch closed = Min airflow rate setpoint
- Sash open / Switch open = Max airflow rate setpoint

The switch then adapts the damper position or frequency to maintain the airflow setpoint and sends the exhaust flow rate and controller state to the room controller.

2.6 Features of Halton Vita Cleanroom Monitoring

The Halton Vita Cleanroom Monitoring system, empowered by Vaisala viewLinc™, enables the monitoring of clean and safe conditions for professionals in medical and pharmaceutical cleanroom environments. With this monitoring system, Halton and Vaisala cooperate to ensure a seamless project delivery and life cycle service.

The Halton Vita Cleanroom Monitoring system provides reliable, continuous monitoring, measurement, and recording of particles, humidity, dewpoint, temperature, pressure, and several other parameters.

Continuous environmental monitoring is necessary for GMP-compliant production. The Halton Vita Cleanroom Monitoring system is a validated system that fulfils the requirements set for cleanroom monitoring systems (CMS, EMS) by the EU GMP regulations and various certification bodies.

Cleanrooms and other critical environments require high performance environmental measurements to operate consistently and within specifications. The Halton Vita Cleanroom Monitoring system reduces the risk of out-of-specification conditions and helps in keeping cleanrooms audit-ready and compliant.

3 Specification

3.1 Cleanroom control system: System diagram

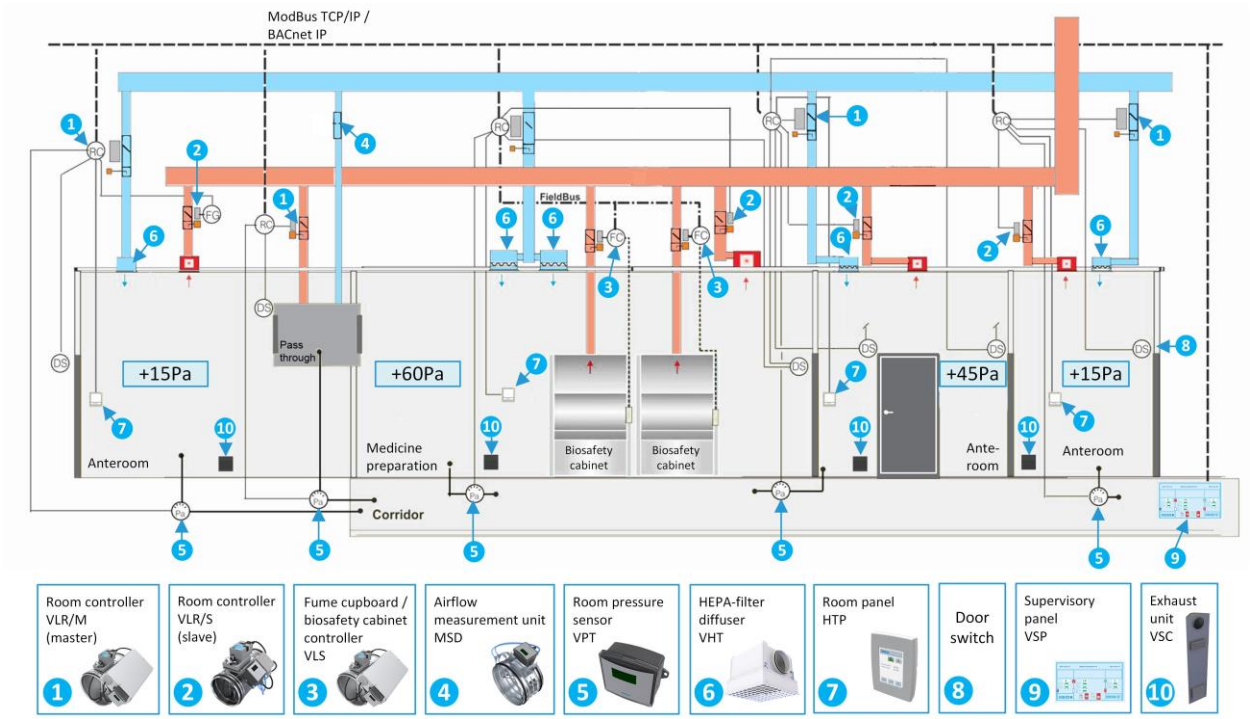


Fig. 2: Cleanroom control system: System diagram

No.	Component
1	Room controller VLR/M (master)
2	Room controller VLR/S (slave)
3	Fume cupboard or biosafety cabinet controller VLS
4	Airflow measurement unit MSD
5	Room pressure sensor VPT
6	HEPA diffuser VHT
7	Room panel HTP
8	Door switch
9	Supervisory panel VSP
10	Exhaust unit VSC

3.2 Cleanroom control system: Functions

3.2.1 Pressure control of cleanroom (VLR)

Room pressurisation (main space)

The room controller (VLR/M), equipped with a fast actuator, controls the room pressurisation so that the desired room differential pressure between the room and the reference space is achieved, based on feedback from the room pressure sensor (VPT).

The local exhaust air flow rates are controlled demand-based. The room supply airflow is controlled based on the measurement value of the room pressure sensor by controlling the actuator of the room controller (VLR/M) so that the room pressurisation is maintained at its setpoint, either at negative or positive pressure.

The room controller (VLR/S) maintains the air exchange at its minimum level when the total local exhaust airflow rate is low. As the room temperature rises above the setpoint, the general exhaust airflow rate is proportionally increased up to the defined maximum flow rate to reach the desired room temperature.

The VLS controllers of the fume cupboards or biosafety cabinets send the exhaust airflow rate via a field bus to the room controller (VLR/M). Additionally, the airflow rates of the local exhaust units are measured using a measurement unit (MSD) and they are connected to the room controller (VLR/M). Respectively, when fume cupboards or local exhaust units are used and the exhaust airflow rate is higher than the minimum ventilation rate, the general exhaust airflow rate is decreased.

Room pressurisation (other spaces)

The room pressurisation of other spaces is handled in the same way as in the main space.

The desired room air change rate is achieved by using balancing dampers for maintaining a constant supply airflow rate. For monitoring purposes, the supply airflow rate is measured with a measurement unit (MSD).

Control function when a door is open

When a door to a room opens, the door interlock system sends the door switch indication to the room controller (VLR/M) which freezes the pressure control, but allows the control of the airflow. When the door is closed, the pressure control is resumed after a predefined delay time (5 seconds by default).

Instead of a door interlock system, separate door switches can be used.

When the room pressure is lower than the setpoint and the predefined delay time has passed, a pressure alarm is initiated. The alarm is indicated on the room panel (HTP).

3.2.2 Airflow control of fume cupboards (VLS)

To keep the face velocity constant, the exhaust airflow rate is controlled by using a fume cupboard controller (VLS) equipped with a fast actuator and by using the reference measurement value of the velocity sensor as feedback.

The fume cupboard controller (VLS) maintains the face velocity at its setpoint (0,5 m/s by default) by proportionally controlling the exhaust airflow damper of the fume cupboard based on the measurement value of the velocity sensor.

Based on the change of the sash position measured by the sash position sensor, the control function is accelerated by directly driving the position of the exhaust airflow damper of the fume cupboard according to the characteristic curve.

Operating modes

The face velocity setpoint can be shifted by changing the operating mode of the fume cupboard to the economy mode (ECO) or the boost mode (MAX).

The ECO and MAX modes can be activated on the control panel (HTP) of the fume cupboard.

The ECO mode (the face velocity defined as 0,3 m/s, for example) can also be activated by using an occupancy sensor, when a predefined delay time has passed and the sensor has not detected movement in the vicinity of the fume cupboard.

Settings

The face velocity measurement value and setpoint are displayed on the on the control panel (HTP) of the fume cupboard.

The following settings can be adjusted on the control panel (HTP) of the fume cupboard:

- Face velocity
- Setpoints for basic, ECO and MAX operating modes
- Activation of ECO and MAX operating modes
- Face velocity high and low alarm limits
- Shut-off control
- Switching lighting on or off (if enabled)

Alarm

When the face velocity is lower than the alarm limit or the sash position is higher than the predefined maximum position and a predefined delay time has passed, an alarm is initiated. The alarm is indicated on the control panel (HTP) of the fume cupboard.

3.2.3 Airflow control of biosafety cabinets (VLS)

When the biosafety cabinet is in use, the dual position control feature controls the exhaust airflow rate to a predefined maximum level based on the signal emitted by one of the following:

- On/off switch (contact switch at the lower part of the fume cupboard)
- Two-step (min/max) airflow control of a fume cupboard
- A local exhaust unit using a limit switch or a 2-position switch
- Dry contact from the biosafety cabinet

The minimum airflow rate is used when the biosafety cabinet is in standby mode.

The two-step switch allows the system to detect when the sash is closed:

- Sash closed / Switch closed = Min airflow rate setpoint
- Sash open / Switch open = Max airflow rate setpoint

The switch then adapts the damper position or frequency to maintain the exhaust airflow setpoint and sends the exhaust flow rate and controller state to the room controller.

The exhaust airflow measurement value and setpoint are displayed on the control panel (HTP).

When the total airflow rate is lower than the alarm limit and a predefined delay time has passed, an alarm is initiated. The alarm is indicated on the control panel (HTP).

3.2.4 Room panel (HTP)

Local functions

The room panel (HTP) is used for viewing and managing the system data. It has an overall view of the room data and two password-protected views for the cleanroom and service personnel.

The overall view shows both the room pressure setpoint and the actual value, as well as the actual room air temperature.

The following settings can be modified on the room panel (HTP):

- Room operating modes
- Room pressurisation setpoints (negative or positive pressure)
- Room minimum air change rate and basic/ECO/MAX operating mode setpoints
- Maximum general exhaust airflow rate in the cooling mode
- Room air temperature setpoint
- Shut-off control of the supply airflow control damper

Operating modes

In addition to the basic operating mode, the general exhaust airflow control may use the setpoints for the economy mode (ECO) and boost mode (MAX).

The ECO and MAX modes can be activated on the room panel (HTP).

The ECO mode (the general airflow rate set to 30% of the basic value, for example) can also be activated by using a motion detector when, after a predefined delay time, the sensor has not detected movement in the room.

Alarms

The room panel (HTP) indicates alarms both visually and acoustically. Users can cancel the acoustic alarm from the room panel (HTP), but the visual alarm (red blinking light) is not turned off until the reason for the alarm is cancelled.

The alarm limits and delay times are configured during the start-up. They can be later adjusted using the room panel (HTP).

The following alarms are indicated on the room panel (HTP):

- Pressure alarm
  - Initiated when the pressurisation is lower than the low limit or higher than the high limit and a predefined delay time has passed.
  - Not initiated when a door is open.
- Airflow rate alarm
  - Initiated when the measured airflow rate is lower than the low limit or higher than the high limit and a predefined delay time has passed.
- Room temperature alarm
  - Initiated when the measured value is lower than the low limit or higher than the high limit and a predefined delay time has passed.
- HEPA diffuser differential pressure alarm
  - This alarm concerns either the supply or exhaust HEPA diffuser (VHT) or both.
  - Initiated when the measured pressure difference is lower than the low limit or higher than the high limit and a predefined delay time has passed.
  - Two separate filter pressure drop measurements that can be connected to the filters of either the supply or exhaust HEPA diffuser (VHT).
  - Both measurements have their own alarm limits.
- Door open alarm
  - Initiated when a door is open for a period longer than a predefined delay time.
  - Each door has its own predefined delay time, configured during the start-up.

For information on the room panel (HTP) component, see Cleanroom panels (HTP, VSP).

3.2.5 Supervisory panel (VSP)

The supervisory panel (VSP) displays the cleanroom conditions in two views: overall view and room view. The supervisory panel (VSP) is typically located at the main entrance of the cleanroom or in the personnel anteroom where users can easily see the conditions of the cleanroom to ensure safety when entering the cleanroom. The service personnel can use the supervisory panel (VSP) also for adjusting the cleanroom system.

The room controllers (VLR) are connected to the local supervisory panel (VSP) via an Ethernet communication bus by using Modbus TCP/IP or BACnet/IP. The measurement values of the room, fume cupboards, and biosafety cabinets as well as the active alarms are displayed on the supervisory panel (VSP).

The essential setpoints and operation values of the room, fume cupboards and biosafety cabinets can be adjusted from the supervisory panel (VSP).

Fume cupboards and biosafety cabinets are connected to the room controller (VLR) using an RS-485 field bus.

The status information and all measurement values are connected to trend monitoring and they are arranged in groups by the space.

The space layout drawing and the status information and measurement values of the related spaces are connected to the graphics on the supervisory panel (VSP).

For information on the supervisory panel (VSP) component, see Cleanroom panels (HTP, VSP).

3.2.6 Building Management System (BMS) connection

The following protocols are used for the Building Management System (BMS) connection: Modbus RTU, Modbus TCP/IP or BACnet/IP.

NOTE: With the supervisory panel (VSP), Modbus TCP/IP or BACnet/IP are used.

The following information is transmitted to the BMS:

- Total airflow rates (supply and exhaust)
- Room pressure rates
- Difference setpoint and alarm of supply and exhaust airflow rate
- Operating status of fume cupboards (in use/not in use/ECO/MAX)
- Fume cupboard alarms
- Fume cupboard and biosafety cabinet airflow rate

3.2.7 Faultless performance guarantee

To ensure safe and faultless system performance in all situations, the Halton Vita Cleanroom system can be equipped with redundant pressure controllers or a rotary actuator with a fail-safe position.

Redundant control is used especially at laboratories that handle bacteria and viruses. In spaces like this, exhaust fans are typically made redundant.

Redundant pressure control has two independent room controllers (VLR) controlling the pressure. If the main room controller (VLR) fails, the redundant room controller (VLR) continues to maintain the adjusted pressure level in the room.

In case of a power outage or fault situation, the rotary actuator with a fail-safe position adjusts the damper to a predefined position to guarantee the needed pressure in the room.

3.3 Cleanroom control system: Components

3.3.1 Overview of components

The configuration of the Halton Vita Cleanroom Control system varies according to the application. For an overview of the components included in different configurations, see figure Overview of cleanroom control system components.

Fig. 3: Overview of cleanroom control system components

For information on the components of the Halton Vita Cleanroom Control system, see the sections below.

For further information on the Halton Vita Cleanroom system, see www.halton.com or the Halton HIT Design tool or contact Halton sales.

3.3.2 Controllers (VLR, VLS)

Component	Description
Room controller VLR/M (master) 	• Circular room controller for room pressure and airflow control *Products:* • Halton Vita Lab Room VLR + VFH (galvanised steel) • Halton Vita Lab Room VLR + VFI (stainless steel AISI 316L)
Room controller VLR/M (master) 	• Rectangular room controller for room pressure and airflow control *Product:* • Halton Vita Lab Room VLR + VKR (galvanised steel)
Room controller VLR/S (slave) 	• Circular room controller for room pressure and airflow control • Used as a slave controller with master room controller VLR/M *Products:* • Halton Vita Lab Room VLR + VFH (galvanised steel) • Halton Vita Lab Room VLR + VFI (stainless steel AISI 316L)

Component	Description
Fume cupboard or biosafety cabinet controller VLS 	• Circular fume cupboard controller for exhaust airflow control of fume cupboards and biosafety cabinets *Products:* • Halton Vita Lab Solo VLS + VFC (galvanised steel) • Halton Vita Lab Solo VLS + VFN (stainless steel AISI 316L) • Halton Vita Lab Solo VLS + VFP (PVC or PPS)

Damper/controller features and options

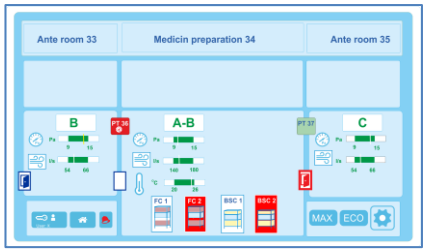
Feature	Description		
Material options	• Galvanised steel or stainless steel AISI 316L/PVC/PPS • Option: antibacterial finishing		
Measurement type	• Differential pressure measurement using orifice (VFC, VFN), cross-tube (VFH, VFI, VFP/Y, VKR) or Venturi (VFP/V)		
Fast actuator		LMQ24A-SR HI	NMQ24A-SR HI
	Running time 90°	1,9 s / 2,5 s	4 s
	Torque	4 Nm	8 Nm
	Sizes	100-250	315-500
Control cabinet	• Galvanised steel • Integrated into the control damper. Option: separate control cabinet.		
Airflow measurement	• Pressure sensor PELH 2500-N • Default range 0…200 Pa, changeable > 0…100 Pa or 0…500 Pa • Display for measurement value • Inaccuracy +/- 3 Pa, automatic zero calibration		
Airflow controller (VLC)	• Communication: Modbus RTU, Modbus TCP/IP or BACnet/IP • Exhaust unit communication to room controller: field bus RS-485		
Transformer 230/24 VAC	• Power supply for controller, actuator, and sensors • Capacity: 32 VA. Options: 60 VA and 120 VA. • Option: no transformer, when centralised 24 VAC power supply for all units		
Installation	• Safety distance 3x D from flow disturbances		

3.3.3 Air diffusers (VHT, VSC)

Component	Description
HEPA diffuser (VHT) 	• Radial, swirl or low turbulent flow pattern • Air supply through adjustable nozzles or perforated front panel (for vertical air supply or exhaust) • Can be installed flush with the ceiling or the wall • Lockable nozzles that allow easy cleaning without changing the nozzle setting • Designed to be equipped with a HEPA filter with foamed polyurethane (PUR) gasket. • E10, H13 and H14 class standard and high airflow HEPA filters available • Antimicrobial epoxy-polyester powder paint finishing to prevent microbial growth • Easy filter change through the front panel • Test probe for measuring the filter pressure loss • Test probe for measuring particle concentration above the filter • Pressure difference transmitter to inform the user when to change the filter (optional) • Available in three sizes with two different types of duct connection *Product:* Halton Vita VHT HEPA diffuser

Component	Description
Exhaust unit (VSC) 	• Includes two Halton Vita VSG exhaust grilles, a vertical air duct and a duct spigot for horizontal exhaust ductwork connection • One third (1/3) of the exhaust air flows through the upper grille and 2/3 through the lower grill • Three different duct connection sizes covering a wide airflow range • Standard heights at 100 mm intervals (3000–4300 mm) • Stainless steel grilles equipped with stainless steel mesh fluff separators • Front panel of the grille is easy to remove and clean. • Front panel of the grille can be sterilised in an autoclave. • Option: Single grille (lower grille) • Option: Special configurations with different airflow distribution ratios • Option: Available also without the metal mesh fluff separator • Option: Custom unit heights according to room design *Product:* Halton Vita VSC Exhaust unit

3.3.4 Cleanroom panels (HTP, VSP)

Component	Description
Room panel (HTP) 	• End-user and service personnel user interface for room pressure control • Allows controlling end-user functions, configuring parameters, and carrying out maintenance functions • Shows active alarms • 3,5” resistive touch screen user interface that can be used with gloves on *Product*: Halton Vita HTP touch panel
Control panel (HTP) 	• End-user and service personnel user interface for controlling fume cupboards and biosafety cabinets • Allows controlling end-user functions, configuring parameters, and carrying out maintenance functions • Shows active alarms • 3,5” resistive touch screen user interface that can be used with gloves on *Product*: Halton Vita HTP touch panel
Supervisory panel (VSP) 	• Local monitoring station that gathers information from controllers located in other system components • Displays system status and shows active alarms. • 15” capacitive touch screen user interface that can be used with gloves on *Product:* Halton Vita VSP supervisory panel

3.3.5 Measurement units and sensors

Component	Description
Airflow measurement unit (MSD) 	• Airflow measurement unit for circular ducts • Contains a measurement element and a pressure transmitter with a liquid-crystal display (LCD) *Product:* Halton MSD airflow measurement unit
Adjustment and measurement unit (PRA) 	• Damper for balancing the airflow between exhaust units *Product:* Halton PRA adjustment and measurement unit
Occupancy sensor 	• An optional sensor that detects occupancy inside the room and activates the ECO mode when the room is unoccupied *Product:* Halton HOS-OE1 occupancy sensor
External temperature sensor 	• Temperature sensor for measuring the duct temperature *Product:* PT 1000 temperature sensor

Component	Description
Room pressure sensor (VPT) 	• Room pressure sensor used for measuring overpressure or underpressure in the room • The measurement is transmitted to the room controller (VLR), to ensure the correct pressure control in the room. *Product*: Halton VPT room pressure sensor
Filter Pressure Sensor (HDP-PE) 	• Filter pressure sensor used for measuring the pressure difference of the filter • The measurement is transmitted to the room controller (VLR). If the pressure difference is higher than the predefined alarm limit, an alarm is initiated. *Product:* Halton HDP-PE differential pressure sensor

3.4 Cleanroom control system: Scope of delivery and project responsibilities

NOTE: This is a Halton recommendation. If agreed with Halton, the scope of the delivery can be modified.

3.4.1 Materials and installation

Code	Material	Installation	Cabling	Wiring connections
1.1	Airflow control dampers, duct installation VLS, VLR	HVAC	EL	EL
1.2	Airflow measurement unit MSD			
1.3	Supply and exhaust HEPA diffuser VHT equipped with filters			
2.1	Sash position sensor	Halton or, if agreed, fume cupboard supplier	EL	EL
2.2	Velocity sensor			
2.3	Motion detector of fume cupboard			
2.4	Fume cupboard control panel HTP			
3.1	Room panel HTP	EL	EL	EL
3.2	Field bus RS-485			
3.3	Automation bus • Modbus RTU > RS-485 • Modbus TCP/IP or BACnet/IP > Ethernet			
3.4	Local exhaust units			
3.5	Airflow measurement sensor MSD			
3.6	Room pressure sensor VPT			
3.7	Duct pressure sensor MSS			
3.8	Door switches			

HVAC = HVAC contractor
EL = Electrical contractor

3.4.2 Preconditions for commissioning and start-up

During the commissioning and start-up phase, the general power supply must be turned on and the ventilation (exhaust and supply) must be stabilised and available for adjustments by Halton Services. All spaces must be cleared and in function. There may not be leakage points in the constructions of the rooms or ductwork (referring to local regulations and/or Halton recommendations), other than planned in the specifications. All doors and windows must be closed.

All installations of Halton products and components must be done according to installation instructions specific to the project, product or component. All necessary operational parameters and setpoint data must be provided in Excel format by the customer (a template in Excel format is provided by Halton in advance). All sensor locations (including sensor holes, springs**,** and mounting brackets) must be designed in advance in co-operation with the customer. Halton does not undertake power connections exceeding 24 V, unless otherwise agreed in writing in advance.

All drawings and documentation listed below must be delivered to Halton prior to the implementation of any services on site and Halton must be allowed to copy selected parts of it with the purpose of fulfilling the contract:

- Ventilation plan drawings
- Automation operation and wiring diagrams
- Automation operation descriptions (specification in case descriptions are not included in the operation diagrams)
- Airflow balancing report

The following operations must be completed before the commissioning and start-up tasks listed in chapter *Commissioning and start-up* (each task is described in the component-specific installation instructions):

- Installation of all systems and components affecting the Halton Vita Cleanroom system operation, including but not limited to supply and exhaust air handling units and general power supply
- Installation of supply and exhaust units
- Installation of constant airflow units
- Installation of airflow control dampers for fume cupboards and biosafety cabinets
- Installation of supply airflow control dampers
- Installation of general exhaust airflow control dampers
- Installation of constant air flow dampers for space-specific local exhaust units
- Installation of room and fume cupboard controllers
- Marking and identification of units and controllers
- Functionality testing and performance verification of all systems and components affecting the Halton Vita Cleanroom system operation, including but not limited to supply and exhaust air handling units and general power supply
- Preliminary balancing of the ventilation system

- Verification of duct pressure adjustment functionality on constant-pressure zone level

Some of the tasks listed above may be carried out by Halton in case this has been agreed upon in writing between Halton and the customer prior to implementation of any services on site.

The service delivery schedule is determined together with the customer when the offer has been accepted. Halton must be informed about the status of the technical commissioning of the building in order to schedule the ordered services.

3.4.3 Commissioning and start-up

Task	Implementation
Software download of control panels and controllers	Halton
Setpoint configuration for controllers	
Operation tests of fume cupboards and biosafety cabinets	
Operation tests of room controllers and related components	
Minimum and maximum airflow rate verification	

3.5 Cleanroom monitoring system: Functions

The Halton Vita Cleanroom Monitoring system enables the monitoring of clean and safe conditions for professionals in medical and pharmaceutical cleanroom environments.

Continuous environmental monitoring is necessary for GMP-compliant production. The Halton Vita Cleanroom Monitoring system is a validated system that fulfils the requirements set for cleanroom monitoring systems (CMS, EMS) by the EU GMP regulations and various certification bodies.

Cleanrooms and other critical environments require high performance environmental measurements to operate consistently and within specifications. The Halton Vita Cleanroom Monitoring system reduces the risk of out-of-specification conditions and helps in keeping cleanrooms audit-ready and compliant.

The Halton Vita Cleanroom Monitoring system provides reliable, continuous monitoring, measurement, and recording of particles, humidity, dewpoint, temperature, pressure, and several other parameters.

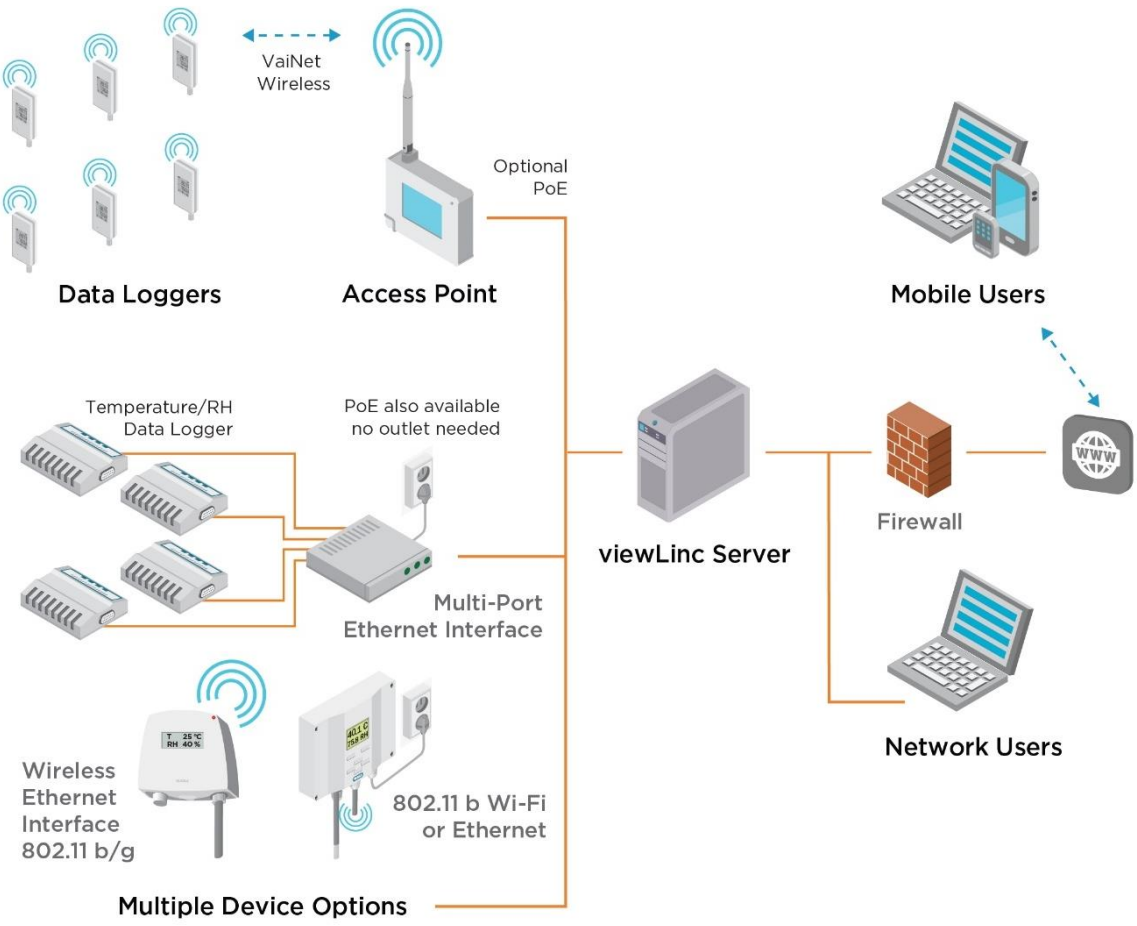


Fig. 4: Halton Vita Cleanroom Monitoring system, empowered by Vaisala viewLinc™

The Halton Vita Cleanroom Monitoring system provides the following:

- Real-time data trending and complete data protection
  - Logging of all necessary environmental parameters
  - Connected with Ethernet or wireless
  - Gap-free data acquisition
  - Redundant recording running parallel to control systems

- Flexible alarming and automated reporting
  - Graphical user interfaces for data monitoring
  - Mobile-optimised user interface for smartphones and tablets
  - Browser-based access
  - Custom reports on demand

3.6 Cleanroom monitoring system: Scope of delivery

Halton provides a turnkey solution of the Halton Vita Cleanroom Monitoring system in cooperation with Vaisala. The solution includes a Vaisala viewLinc™ monitoring server, data loggers, all necessary sensors (temperature, humidity, room pressure, number of particles), installation qualification (IQ), operation qualification (OQ), system start-up, and life cycle services.

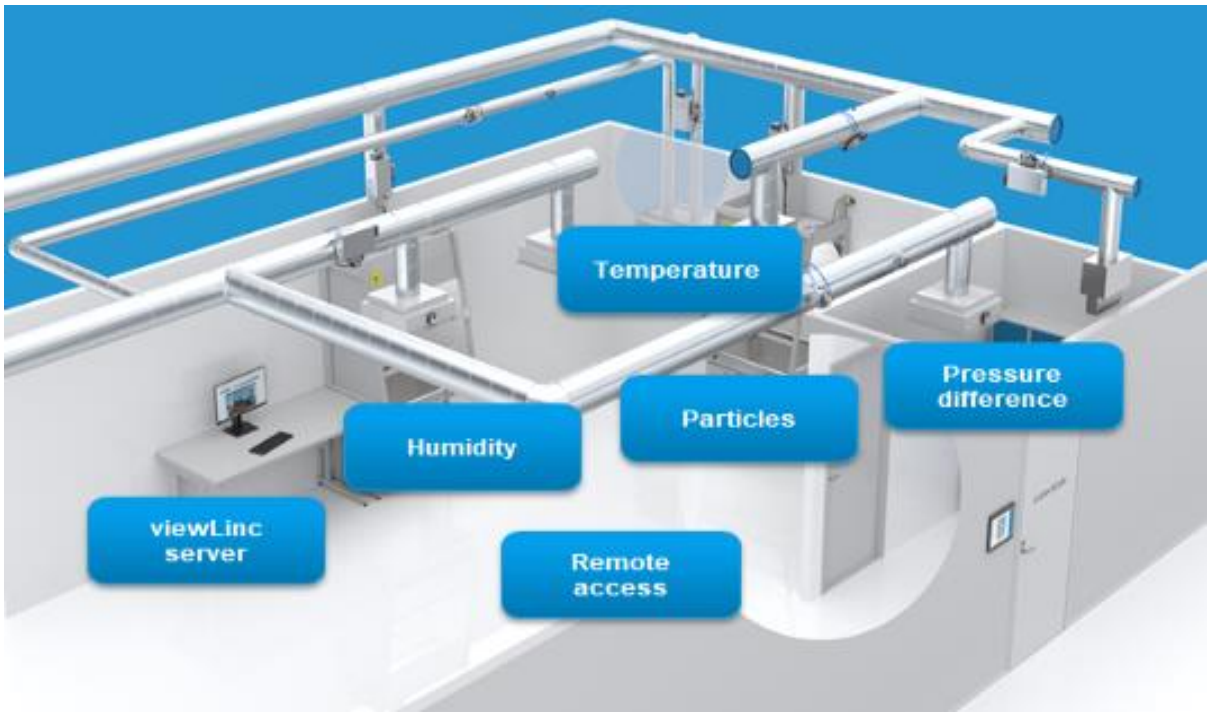


Fig. 5: Halton Vita Cleanroom Monitoring system delivery

Services

- Project management support
- Design support
- Installation or installation supervision
- Start-up and commissioning
- Life cycle maintenance agreement, yearly sensor calibration, and system test
- Qualification process
- ICH-compliant calibration options

Project responsibilities

Task	Implementation
Installation of sensors, data loggers, and vacuum pumps	Halton
Cabling and wiring connections of sensors, installation of vacuum tubes	
Operation tests and pre-calibration of sensors	
User training	
Life cycle maintenance and yearly sensor calibrations and system tests	

4 Design guidelines

4.1 Design process

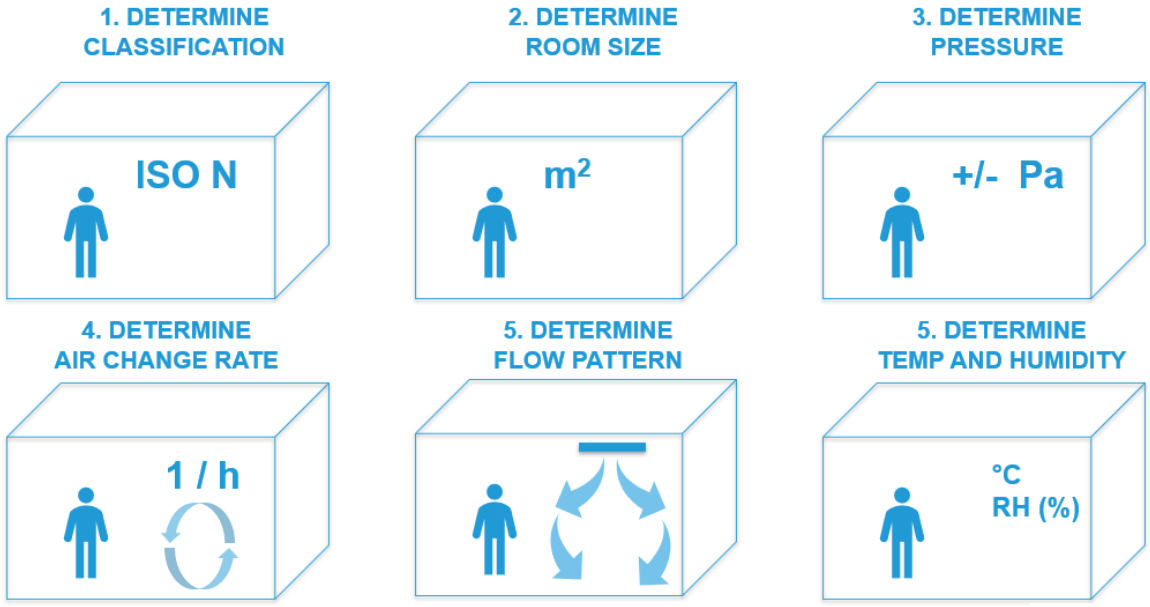


Fig. 6: Cleanroom design process

No.	Design process phase
1	Determine classification
2	Determine room size
3	Determine pressure
4	Determine air change rate
5	Determine flow pattern
6	Determine temperature and humidity

4.2 Determining the classification

The classification of your cleanroom affects all other components, from the wall material to your HVAC system. Cleanrooms are classified by the maximum number of particles of various sizes that are allowed in the air of the room. Each industry and institution varies as to the required classification.

EU Good Manufacturing Practice (GMP)

Good manufacturing practice (GMP) describes the minimum standard that a medicines manufacturer must meet in their production processes, according to the European Medicines Agency (EMA). The EMA coordinates inspections to verify compliance with the standards and plays a

key role in harmonising GMP activities at European Union (EU) level. National competent authorities are responsible for inspecting manufacturing sites located within their own areas.

According to *EU GMP Annex 1: Manufacture of Sterile Medicinal Products*, cleanrooms are classified into four grades (A-D) according to the ISO cleanliness class they comply with. The ISO cleanliness classes define different levels of contamination, depending on the amount of particles allowed in the space, per cubic meter. See Table 1: EU GMP cleanroom grades versus ISO 14644 cleanliness classes.

Grade (EU GMP)	Cleanliness class (ISO)
A	ISO 5
B	ISO 7
C	ISO 8
D	No control

Table 1: EU GMP cleanroom grades versus ISO 14644 cleanliness classes

ISO classes (ISO 14644)

Standard "Cleanrooms and associated controlled environments" (14644) of the International Organization for Standardization (ISO) specifies the classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones. The following table describes the maximum concentration limits (particles/m^3 of air) for particles equal to and larger than the considered sizes shown below.

ISO classification number	Max. concentration limits (particles/m^3)					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000
NOTE: Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining classification level.						

Table 2: Selected airborne particulate classes for cleanrooms and clean zones (ISO 14644-1)

4.3 Determining the pressure levels, air change rates, and air flow patterns

At this phase, you determine the needed pressure level, air change rate, and air flow pattern for the different spaces based on the cleanroom classifications.

Usually, grade A is implemented in a laminar fume cupboard or biosafety cabinet.

The airflow rate is based on particle levels, the number of personnel, and the amount of process emissions.

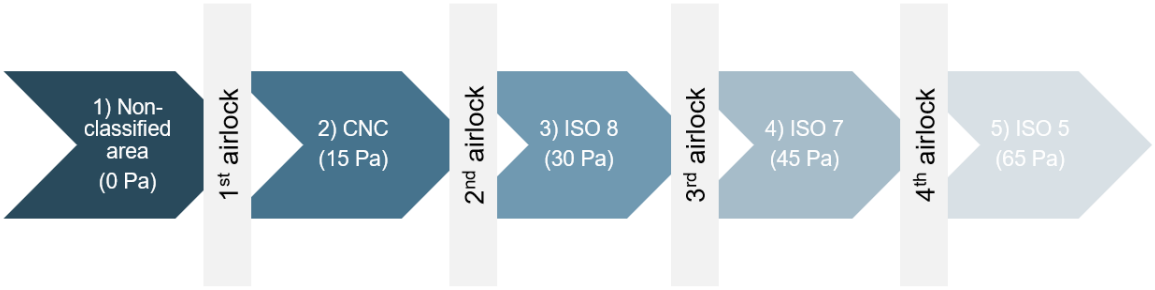


Fig. 7: The pressure differences between the different ISO classes

CNC = clean non classified

Grade (EU GMP)	Cleanliness class (ISO)	Air Changes per Hour (ACH)	Flow
A	ISO 5	25 …400	turbulent or laminar
B	ISO 5-7	15 …40, typically: 40	turbulent
C	ISO 8	10 …25, typically: 25	turbulent
D	No control	5 …20, typically: 15	turbulent

Table 3: Design guidelines according to EU GMP Annex 1

4.4 Determining the temperature and humidity levels

When working with sensitive materials or processes, controlling temperature and humidity in the cleanroom space is vital. While typical temperature standards for cleanrooms state 20-24°C, you need to consider the specifics of your application as well as any conditions that may affect that number, such as a large number of people in the space or equipment that emits a lot of heat.

Typically, the range for the relative humidity (RH) in a cleanroom is 45-60% RH. However, this requirement may vary based on the specimens or tests used in the cleanroom.

5 Design examples

5.1 Halton Vita Cleanroom system for a hospital pharmacy

5.1.1 Introduction

Hospital pharmacies choose, prepare, store, and dispense medicines and medical devices for patients, doctors, nurses, and other healthcare professionals. Most of the actions need to be inspected by the authorities and therefore GMP-compliant cleanrooms are required.
A competent authority is to ensure compliance with contemporary requirements of safety, quality and efficacy.

The Halton Vita Cleanroom system provides stable conditions in the cleanroom area controlling the room pressure, airflow, temperature, and airflow patterns.

A cleanroom system for a hospital pharmacy could consist of the following, for example:

- Positive pressurisation of spaces
- Cleanroom classes according to Good Manufacturing Practices (GMP)
    - GMP D +10…20 Pa
    - GMP C +35 Pa
    - GMP B +50 Pa
    - GMP A-B +65 Pa
- Pass-through cabinets
    - A-B >< C +50 Pa
    - D >< corridor +35 Pa
- Fume cupboard in the large distribution hall
- Two biosafety cabinets in both medicine preparation rooms
- Pressure control by exhaust air control dampers
- Constant supply air from proportionally balanced ductwork

5.1.2 Example layout

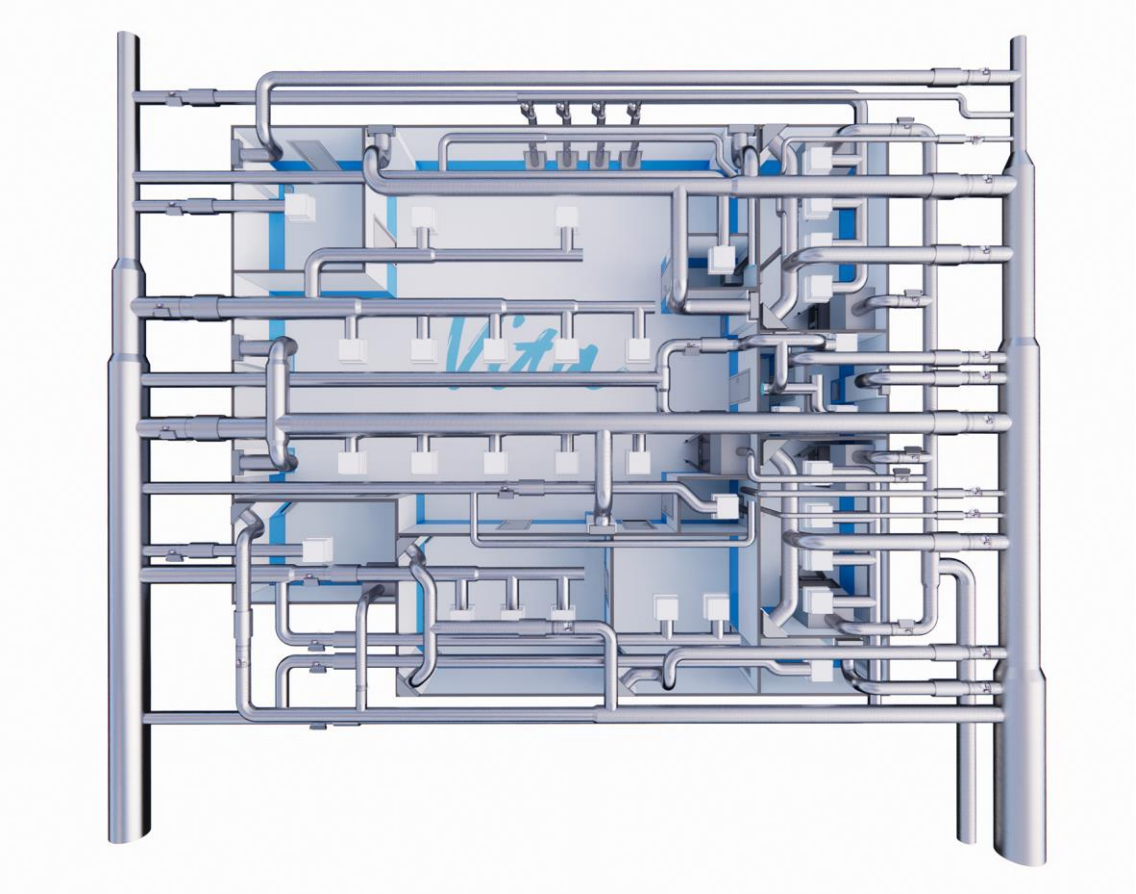


Fig. 8: Halton Vita Cleanroom system for a hospital pharmacy, top view

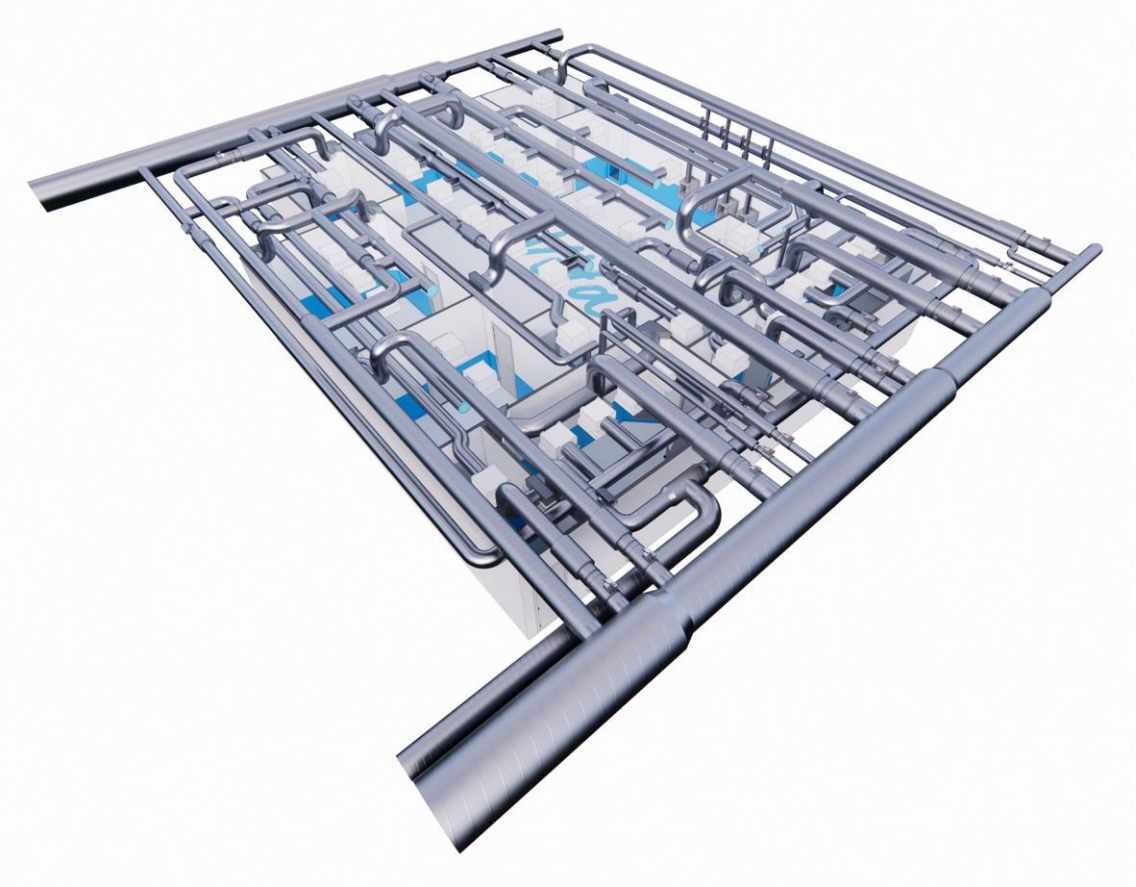


Fig. 9: Halton Vita Cleanroom system for a hospital pharmacy, corner view

5.1.3 Cleanroom spaces and components

Medicine and material stock

Design criteria

- Room area: 13 m^2
- Room height: 2.6 m
- Room volume: 34 m^3
- GMP grade: D
- Room pressure: Δp = +20 Pa
- ACH: 20 1/h
- Airflow rate: qv = 240 l/s (864 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 250, v = 4.9 m/s, Δptot = 11 Pa, Lw = 34 dB (A)	Room pressure controller
VLR/S	VLR + VFH 250, v = 4.9 m/s, Δptot = 11 Pa, Lw = 34 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	2x VHT/S-600, à qv = 120 l/s, Δptot = 98 Pa, Lw = 16 dB (A)	Supply air diffuser with HEPA filter
VSC	VSC/A-315-3000-2, qv = 240 l/s, Δptot = 27 Pa, Lw = 26 dB (A)	Exhaust unit, corner model

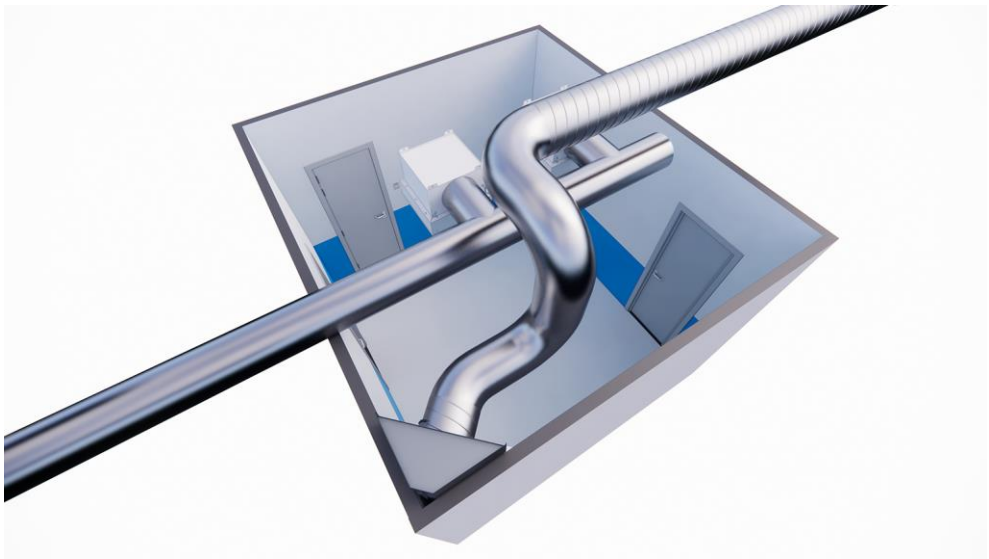


Fig. 10: Medicine and material stock

Distribution preparation

Design criteria

- Room area: 20 m^2
- Room height: 2.6 m
- Room volume: 52 m^3
- GMP grade: D
- Room pressure: Δp = +20 Pa
- ACH: 25 1/h
- Airflow rate: qv = 360 l/s (1300 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 315, v = 4.6 m/s, Δptot = 5 Pa, Lw = 30 dB (A)	Room pressure controller
VLR/S	VLR + VFH 315, v = 4.6 m/s, Δptot = 5 Pa, Lw = 30 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	3x VHT/S-600, à qv = 120 l/s, Δptot = 98 Pa, Lw = 16 dB (A)	Supply air diffuser with HEPA filter
VSC	2x VSC/A-315-3000-1, à qv = 180 l/s, Δptot = 23 Pa, Lw = 24 dB (A)	Exhaust unit, corner model

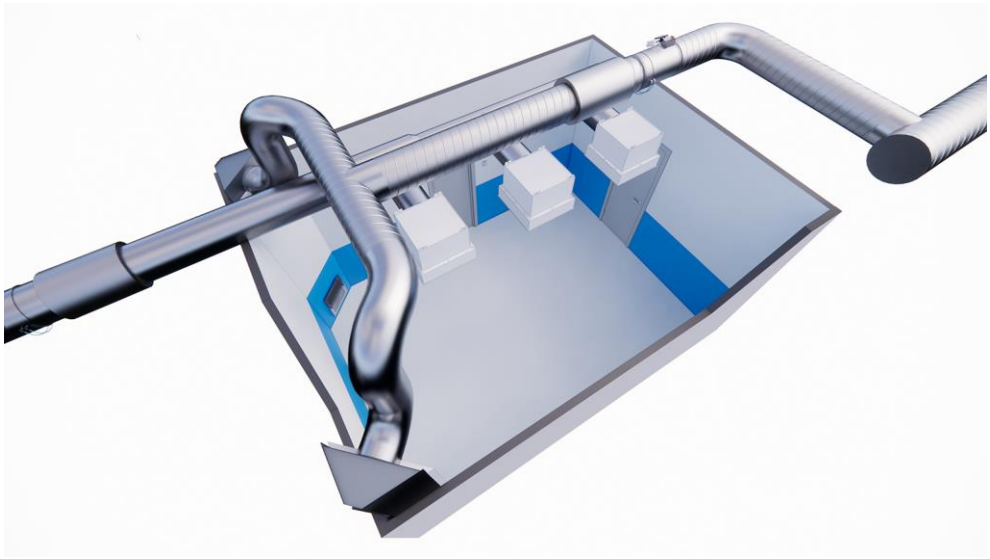


Fig. 11: Distribution preparation

Equipment room

Design criteria

- Room area: 9 m^2
- Room height: 2.6 m
- Room volume: 23 m^3
- GMP grade: D
- Room pressure: Δp = +15 Pa
- ACH: 23 1/h
- Airflow rate: qv = 145 l/s (520 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 200, v = 4.6 m/s, Δptot = 9 Pa, Lw = 33 dB (A)	Room pressure controller
VLR/S	VLR + VFH 160, v = 3.7 m/s, Δptot = 7 Pa, Lw = 29 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	VHT/S-600, qv = 145 l/s, Δptot = 120 Pa, Lw = 25 dB (A)	Supply air diffuser with HEPA filter
VSC	VSC/A-315-3000-1, qv = 75 l/s, Δptot = 7 Pa	Exhaust unit, corner model
MSD	MSD-160, qv = 70 l/s	Airflow measurement unit

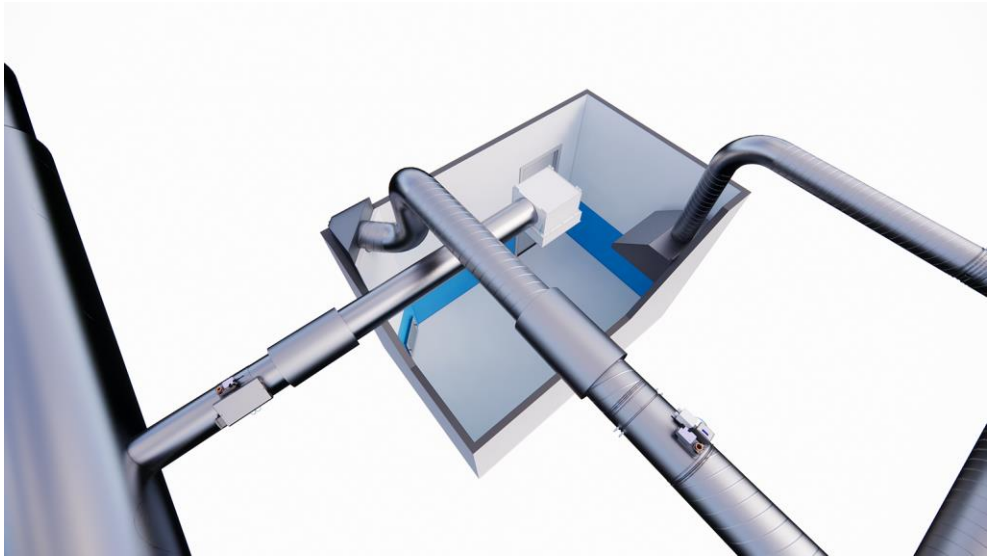


Fig. 12: Equipment room

Distribution

Design criteria

- Room area: 103 m^2
- Room height: 2.6 m
- Room volume: 268 m^3
- GMP grade: D
- Room pressure: Δp = +20 Pa
- ACH: 27 1/h
- Airflow rate: qv = 2020 l/s (7270 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 500, v = 5.1 m/s, Δptot = 7 Pa, Lw = 34 dB (A)	Room pressure controller
VLR/S	VLR + VFH 500, v = 5.1 m/s, Δptot = 7 Pa, Lw = 34 dB (A)	Room pressure controller
VLR/M	VLR + VFH 500, v = 5.1 m/s, Δptot = 7 Pa, Lw = 34 dB (A)	Room airflow controller
VLR/S	VLR + VFH 500, v = 5.1 m/s, Δptot = 7 Pa, Lw = 34 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	12x VHT/S-600, à qv = 168 l/s, Δptot = 141 Pa, Lw = 29 dB (A)	Supply air diffuser with HEPA filter
VSC	6x VSC/B-400-3000-1, à qv = 336 l/s, Δptot = 32 Pa, Lw = 31 dB (A)	Exhaust unit, wall model
VLS	VLS + VFC 250, qv = 200 l/s (720 m^3/h), v = 4.1 m/s, Δptot = 31 Pa, Lw = 41 dB (A)	Fume cupboard controller
VSS		Sensor package for fume cupboard
HTP		Control panel for fume cupboard

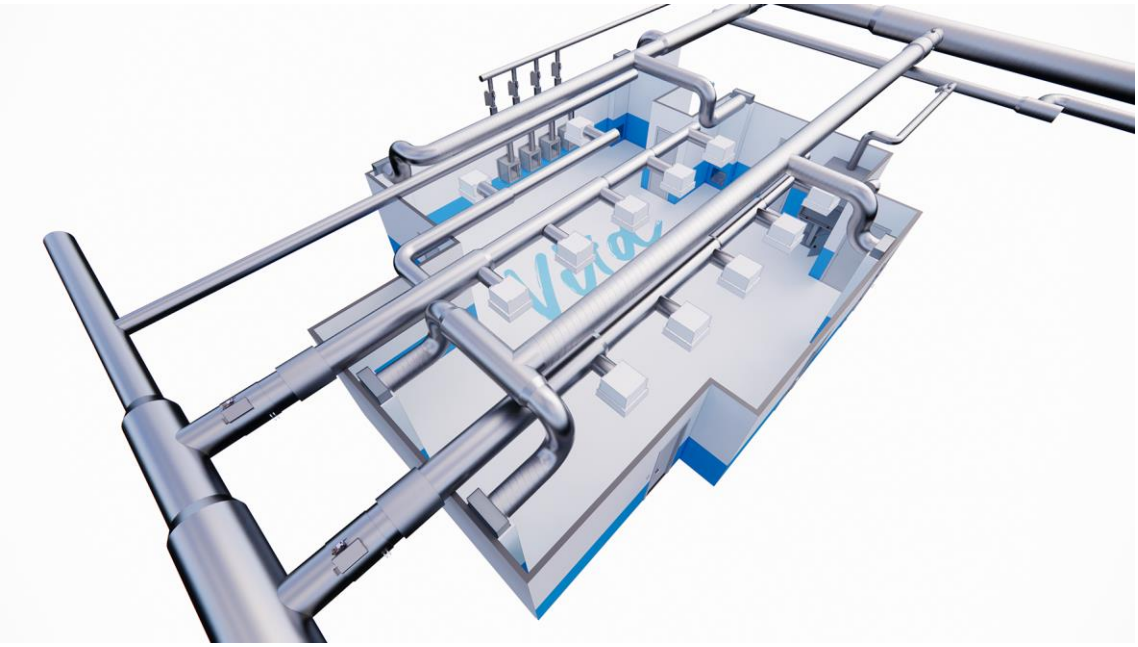


Fig. 13: Distribution

Medicine preparation 1

Design criteria

- Room area: 13 m^2
- Room height: 2.6 m
- Room volume: 34 m^3
- GMP grade: A-B
- Room pressure: Δp = +65 Pa
- ACH: 69 1/h
- Airflow rate: qv = 645 l/s (2320 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 400, v = 5.1 m/s, Δptot = 7 Pa, Lw = 34 dB (A)	Room pressure controller
VLR/S	VLR + VFH 400, v = 5.1 m/s, Δptot = 7 Pa, Lw = 34 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	4x VHT/S-600, à qv = 160 l/s, Δptot = 134 Pa, Lw = 28 dB (A)	Supply air diffuser with HEPA filter

Component	Sizing	Description
VSC	2x VSC/A-400-3000-1, à qv = 323 l/s, Δptot = 30 Pa, Lw = 30 dB (A)	Exhaust unit, corner model
VLS	2x VLS + VFC 200, à qv = 150 l/s (540 m^3/h), v = 4.8 m/s, Δptot = 38 Pa, Lw = 44 dB (A)	Biosafety cabinet controller

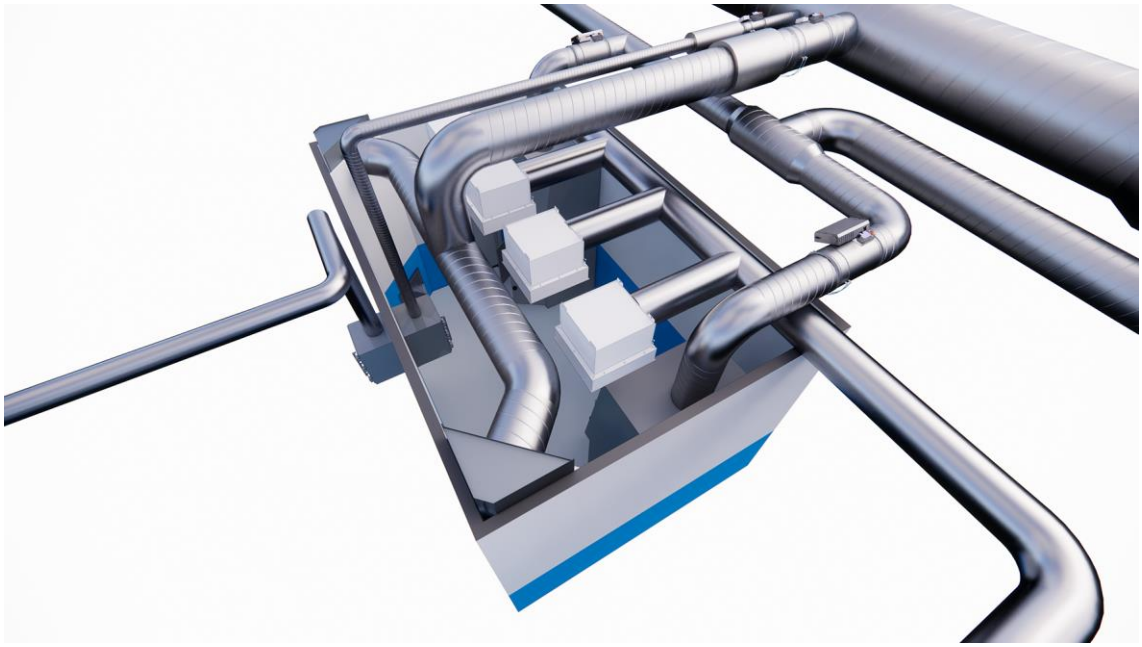


Fig. 14: Medicine preparation 1

Medicine preparation 2

Design criteria

- Room area: 13 m^2
- Room height: 2.6 m
- Room volume: 34 m^3
- GMP grade: A-B
- Room pressure: Δp = +65 Pa
- ACH: 69 1/h
- Airflow rate: qv = 645 l/s (2320 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 400, v = 5.1 m/s, Δptot = 7 Pa, Lw = 34 dB (A)	Room pressure controller
VLR/S	VLR + VFH 400, v = 5.1 m/s, Δptot = 7 Pa, Lw = 34 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	4x VHT/S-600, à qv = 160 l/s, Δptot = 134 Pa, Lw = 28 dB (A)	Supply air diffuser with HEPA filter
VSC	2x VSC/A-400-3000-1, à qv = 323 l/s, Δptot = 30 Pa, Lw = 30 dB (A)	Exhaust unit, corner model
VLS	2x VLS + VFC 200, à qv = 150 l/s (540 m^3/h), v = 4.8 m/s, Δptot = 38 Pa, Lw = 44 dB (A)	Biosafety cabinet controller

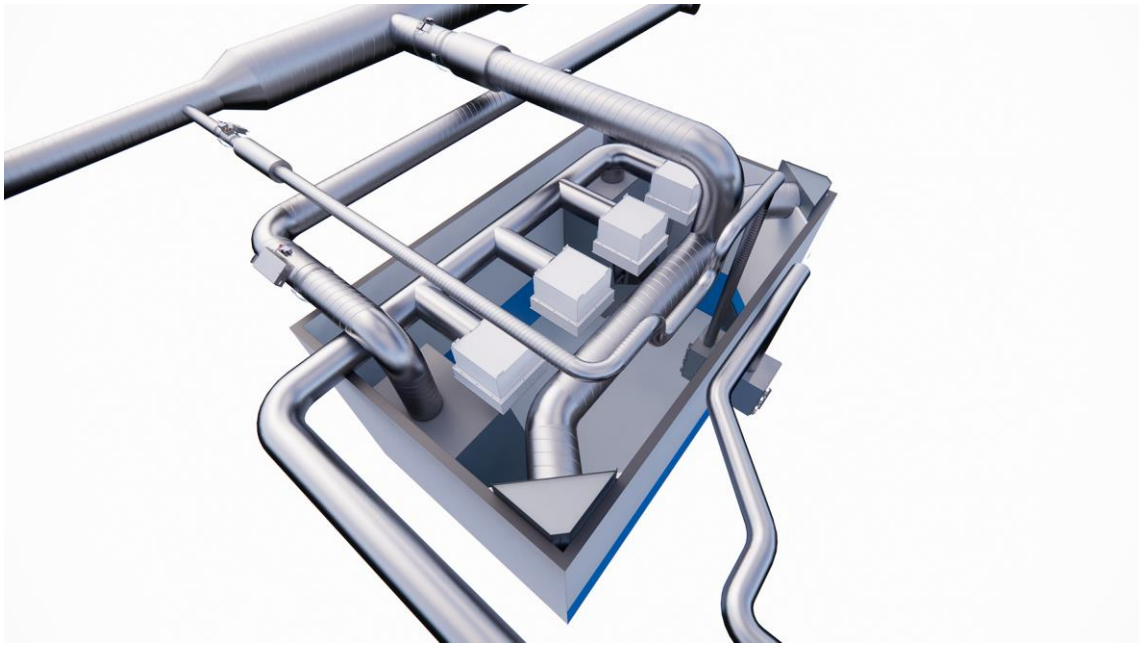


Fig. 15: Medicine preparation 2

Anteroom, class C

Design criteria

- Room area: 2.5 m^2
- Room height: 2.6 m
- Room volume: 6.5 m^3
- GMP grade: C
- Room pressure: Δp = +35 Pa
- ACH: 45 1/h
- Airflow rate: qv = 80 l/s (290 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 160, v = 4.0 m/s, Δptot = 8 Pa, Lw = 30 dB (A)	Room pressure controller
VLR/S	VLR + VFH 160, v = 4.0 m/s, Δptot = 8 Pa, Lw = 30 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	VHT/S-600, qv = 80 l/s, Δptot = 64 Pa	Supply air diffuser with HEPA filter
VSC	VSC/B-315-3000-1, qv = 80 l/s, Δptot = 7 Pa	Exhaust unit, wall model

Fig. 16: Anteroom, class C

Anteroom, class B

Design criteria

- Room area: 4 m^2
- Room height: 2.6 m
- Room volume: 10.4 m^3
- GMP grade: B
- Room pressure: Δp = +45 Pa
- ACH: 73 1/h
- Airflow rate: qv = 210 l/s (756 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 250, v = 4.3 m/s, Δptot = 9 Pa, Lw = 31 dB (A)	Room pressure controller
VLR/S	VLR + VFH 250, v = 4.3 m/s, Δptot = 9 Pa, Lw = 31 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	VHT/S-600, qv = 210 l/s, Δptot = 180 Pa, Lw = 35 dB (A)	Supply air diffuser with HEPA filter
VSC	VSC/B-315-3000-1, qv = 210 l/s, Δptot = 31 Pa, Lw = 29 dB (A)	Exhaust unit, wall model

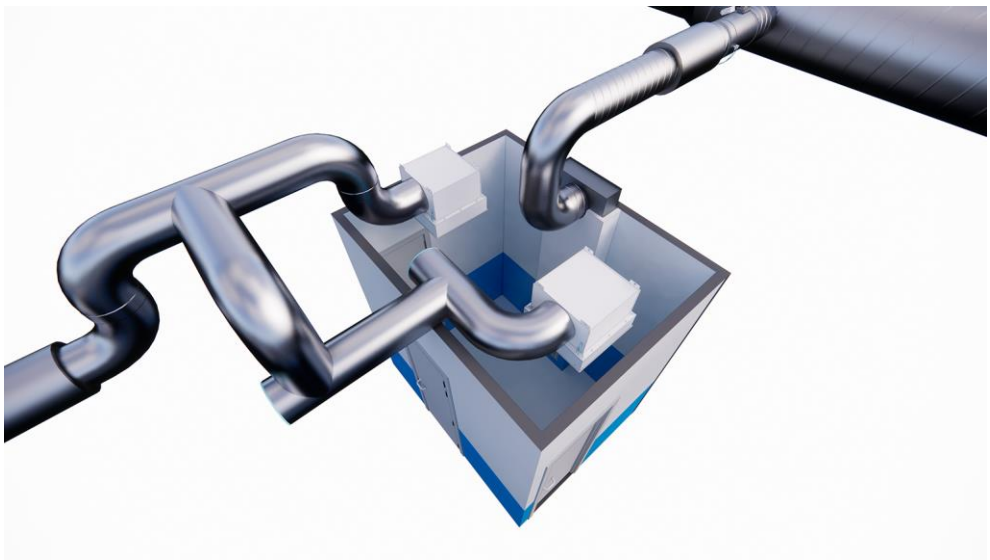


Fig. 17: Anteroom, class B

Airlock 1, class C

Design criteria

- Room area: 2.5 m^2
- Room height: 2.6 m
- Room volume: 6.5 m^3
- GMP grade: C
- Room pressure: Δp = +35 Pa
- ACH: 28 1/h
- Airflow rate: qv = 50 l/s (180 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 125, v = 4.1 m/s, Δptot = 16 Pa, Lw = 34 dB (A)	Room pressure controller
MSD	MSD-125, qv = 50 l/s	Airflow measurement unit
VPT		Room pressure sensor
HTP		Room panel
VHT	VHT/S-600, qv = 50 l/s, Δptot = 39 Pa	Supply air diffuser with HEPA filter
URH	URH-125	Exhaust unit

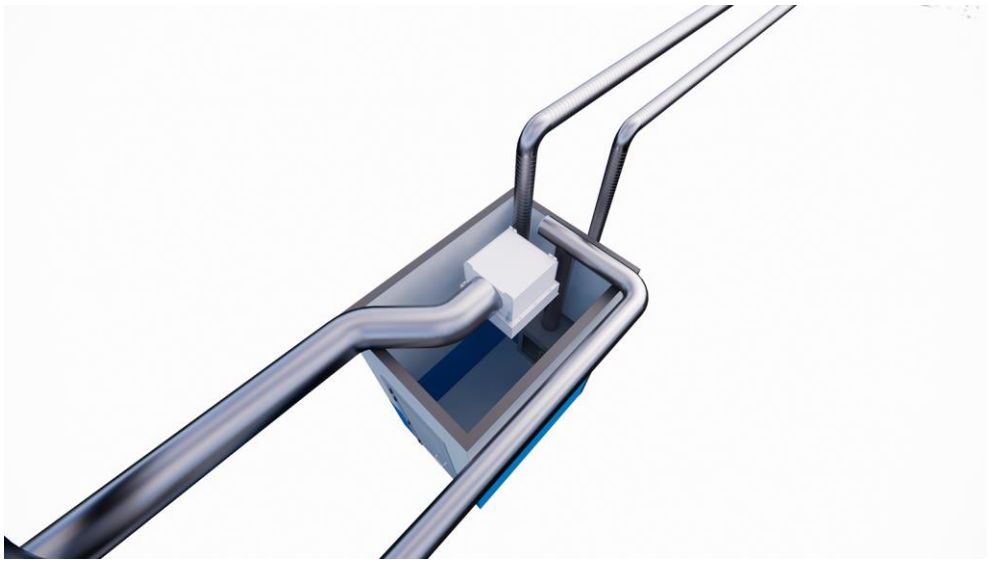


Fig. 18: Airlock 1, class C

Airlock 2, class C

Design criteria

- Room area: 2.5 m^2
- Room height: 2.6 m
- Room volume: 6.5 m^3
- GMP grade: C
- Room pressure: Δp = +35 Pa
- ACH: 28 1/h
- Airflow rate: qv = 50 l/s (180 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 125, v = 4.1 m/s, Δptot = 16 Pa, Lw = 34 dB (A)	Room pressure controller
MSD	MSD-125, qv = 50 l/s	Airflow measurement unit
VPT		Room pressure sensor
HTP		Room panel
VHT	VHT/S-600, qv = 50 l/s, Δptot = 39 Pa	Supply air diffuser with HEPA filter
URH	URH-125	Exhaust unit

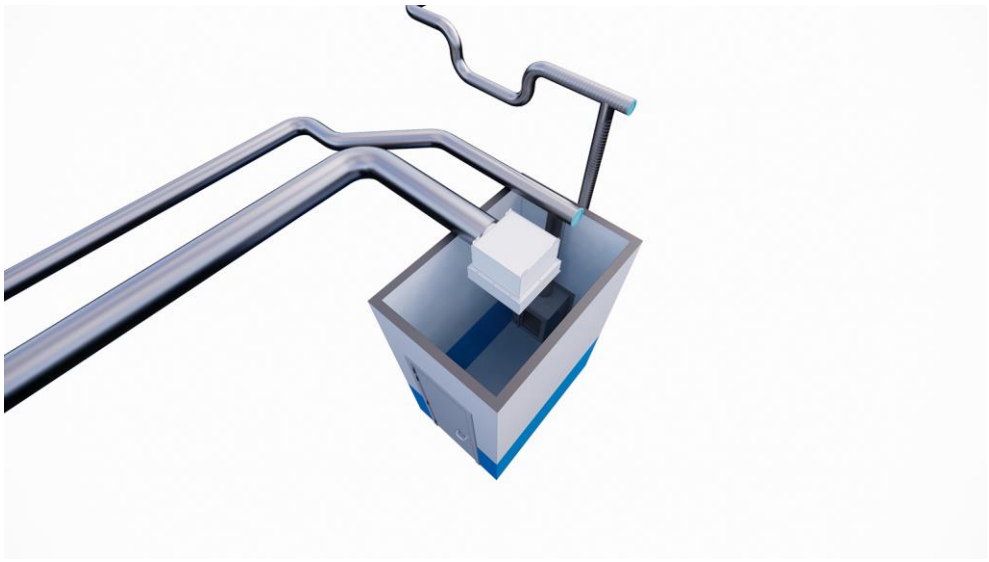


Fig. 19: Airlock 2, class C

Material airlock, class D

Design criteria

- Room area: 4 m^2
- Room height: 2.6 m
- Room volume: 10.4 m^3
- GMP grade: D
- Room pressure: Δp = +15 Pa
- ACH: 21 1/h
- Airflow rate: qv = 60 l/s (216 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 160, v = 3.0 m/s, Δptot = 4 Pa, Lw = 23 dB (A)	Room pressure controller
VLR/S	VLR + VFH 160, v = 3.0 m/s, Δptot = 4 Pa, Lw = 23 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	VHT/S-600, qv = 60 l/s, Δptot = 47 Pa	Supply air diffuser with HEPA filter
VSC	VSC/A-315-3000-1, qv = 60 l/s, Δptot = 7 Pa	Exhaust unit, corner model

Fig. 20: Material airlock, class D

Anteroom, class D

Design criteria

- Room area: 10 m^2
- Room height: 2.6 m
- Room volume: 26 m^3
- GMP grade: D
- Room pressure: Δp = +15 Pa
- ACH: 17 1/h
- Airflow rate: qv = 120 l/s (432 m^3/h)

Design

Component	Sizing	Description
VLR/M	VLR + VFH 200, v = 3.8 m/s, Δptot = 6 Pa, Lw = 28 dB (A)	Room pressure controller
VLR/S	VLR + VFH 200, v = 3.8 m/s, Δptot = 6 Pa, Lw = 28 dB (A)	Room airflow controller
VPT		Room pressure sensor
HTP		Room panel
VHT	VHT/S-600, qv = 120 l/s, Δptot = 98 Pa, Lw = 16 dB (A)	Supply air diffuser with HEPA filter
VSC	VSC/B-315-3000-1, qv = 120 l/s, Δptot = 10 Pa, Lw = 15 dB (A)	Exhaust unit, wall model

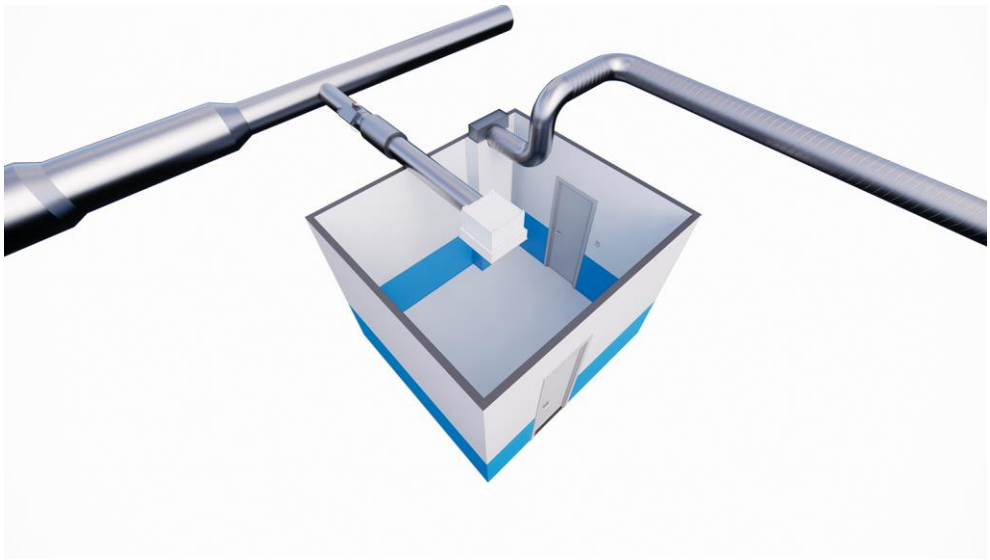


Fig. 21: Anteroom, class D

Pass-through cabinets

Design criteria

- GMP grade: D
- Room pressure: Δp = +15 Pa
- Airflow rate: qv = 15 l/s (53 m^3/h)

Design

Space/Component	Sizing	Description
Pass-through cabinet 1		
VLR/M	VLR + VFH 100, v = 1.9 m/s, Δptot = 5 Pa, Lw = 21 dB (A)	Room pressure controller
VPT		Room pressure sensor
HTP		Room panel
Pass-through cabinet 2		
VLR/M	VLR + VFH 100, v = 1.9 m/s, Δptot = 5 Pa, Lw = 21 dB (A)	Room pressure controller
VPT		Room pressure sensor
HTP		Room panel
Pass-through cabinet 3		
VLR/M	VLR + VFH 100, v = 1.9 m/s, Δptot = 5 Pa, Lw = 21 dB (A)	Room pressure controller
VPT		Room pressure sensor
HTP		Room panel
Pass-through cabinet 4		
VLR/M	VLR + VFH 100, v = 1.9 m/s, Δptot = 5 Pa, Lw = 21 dB (A)	Room pressure controller
VPT		Room pressure sensor
HTP		Room panel
Pass-through cabinet B-D		
VLR/M	VLR + VFH 100, v = 1.9 m/s, Δptot = 5 Pa, Lw = 21 dB (A)	Room pressure controller
VPT		Room pressure sensor
HTP		Room panel
Pass-through cabinet B-D		
VLR/M	VLR + VFH 100, v = 1.9 m/s, Δptot = 5 Pa, Lw = 21 dB (A)	Room pressure controller
VPT		Room pressure sensor
HTP		Room panel

5.2 Halton Vita Cleanroom system for a biosafety laboratory

Typically, a biosafety laboratory is isolated from the surrounding building and has a high negative pressure, which guarantees that any biological agents stay in the laboratory.

Each biosafety laboratory has a certain biosafety level (BSL) ranging from 1 to 4, based on the level of containment.

The Halton Vita Cleanroom system provides safe and stable conditions by controlling the pressure difference and air change in the laboratory as required. The Halton Vita Cleanroom system is up to level BSL-3.

A typical cleanroom system for a biosafety laboratory consists of the following:

- Negative pressurisation of spaces
- A room inside the room, protected from the surrounding area with cleanroom elements
- Pass-through cabinets
- Autoclaves
- 2 fume cupboards
- 1 biosafety cabinet and storage cabinet
- Pressure control with exhaust air control dampers. The pressure controllers are usually made redundant.
- Constant supply air from proportionally balanced ductwork

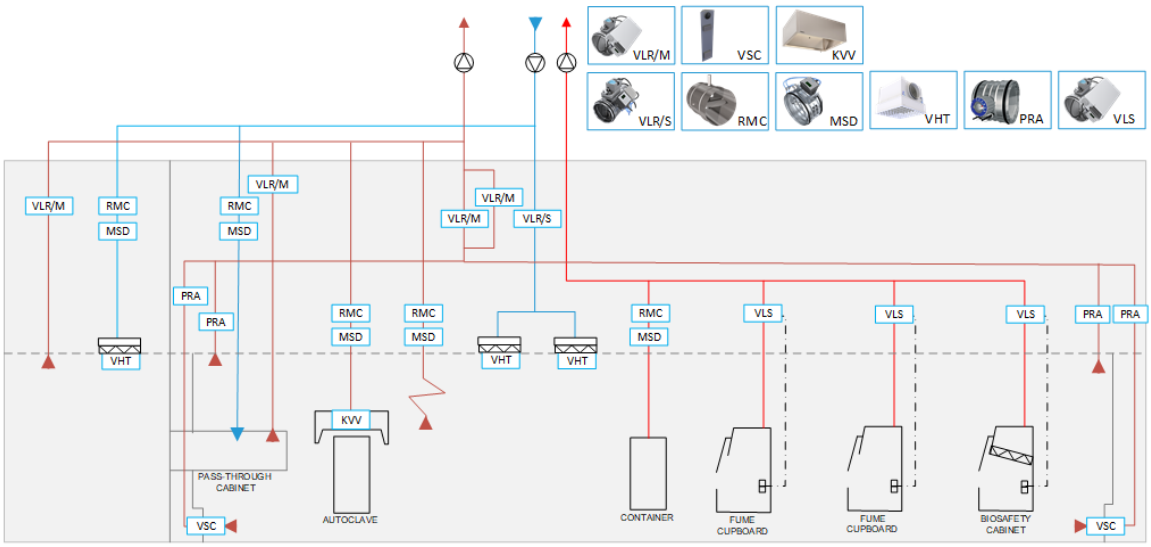


Fig. 22: Halton Vita Cleanroom system for a biosafety laboratory

For examples of product selections, see chapter *Halton Vita Cleanroom system for a hospital pharmacy*.

6 Reference data

6.1 Standards and guidelines

The relevant standards for the design of a Halton Vita Cleanroom system apply to the following:

- Cleanrooms
- Fume cupboards
- Laboratories

National and international standards and guidelines are the basis for system design. These standards do not constitute the law, but represent the state of the art and are the basis for expert opinions in case of damage.

NOTE: Make sure you follow the standards and guidelines applicable to your own country.

Standards and guidelines that apply to cleanrooms

- ISO 14644-1:2015, Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
- ISO 14698-1:2003, Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
- EU Directives 2003/94/EC and 91/412/EEC, European Union Guidelines to Good Manufacturing Practice (GMP): Medicinal Products for Human and Veterinary Use

Standards and guidelines that apply to fume cupboards

The national fume cupboard standards are harmonised into European standard EN 14175, parts 1-7.