**Functional Specification (FS)**

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Change index

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# Purpose

In the specifications, the potential supplier describes **whether** and **how** the requirements of the specifications will be implemented.

# Detailed requirements for individual rooms (room conditions) are defined in the room book and attached to this document (see Appendix 1).

# Area of application

This specification describes the requirements for the affected premises [including RR monitoring ] for [location, e.g. building] at [customer name, address] .

# Terms and abbreviations

## Definitions

**Water qualities**

|  |  |
| --- | --- |
| **Name / Abbreviation** | **use** |
| HEPA filter | Highly efficient Particulate filter (High efficiency particulate air filter) |
| Information (data) | e.g. numbers, texts, images, videos or audio files |
| Product quality | GMP-critical product specifications (e.g. according to the “Design History File”) |
| Process component | Element that is relevant to the process, such as the temperature or humidity in the room. |

## 

## Abbreviations

|  |  |
| --- | --- |
| **Expression /** **abbreviation** | **Explanation** |
| DQ | Design qualification |
| FMEA | Failure Mode Effects Analysis​ |
| GMP | Good Manufacturing Practice |
|  |  |
|  |  |

# Functional Specification (functional description)

Qualification is carried out using a risk-based approach. The qualification procedure and regulatory classification are finally described in the system-specific Qualification Master Plan (QMP) . Based on a GMP relevance analysis (Doc ID GMP-I\_GRA\_GEB\_O2; Oxygen, GMP-I\_GRA\_GEB\_PW; Purified Water and GMP-I\_GRA\_GEB\_DL; compressed air) the media systems were classified as GMP-relevant.

The user requirements were classified according to their relevance (GxP or safety/economic efficiency) and criticality (necessary/optional).

Whether the functional descriptions in the FS were “fulfilled” or “not fulfilled” is documented with a “Y” (Yes) or an “N” (No).

How the requirements are implemented is described in the new column below the “old” “Description” column so that you can understand what the original requirement was.

GxP-relevant points must be considered in the qualification process; safety/economically relevant points must be considered by the engineering/operator. Requirements classified as "necessary" must be implemented; for points classified as "optional," implementation may be waived.

In the "URS#" column of this URS, direct requirements are assigned a number. This number consists of the chapter number of the URS and a sequential number.

## 4.1 Technical standards

The design and implementation of the affected media (generation, storage and distribution) must comply with the relevant local, regional and national regulations (European Union, USA) and correspond to the state of the art.

## Requirements

### 4.2.1 General requirements

| **URS#/#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| **GMP room book** | | | |
| 4.2.1 | Number and size, including labelling of rooms, as well as specification of zone status for clean rooms and material hatches, including airlock systems | GxP, necessary | N |
| 4.2.1-1 | Number and size of cleanrooms according to GMP room book **(Appendix 1)** | GxP, necessary | J |
| 4.2.1-2 | Identification of rooms with room number and room name **(Appendix 1)** | GxP, necessary | J |
| **Zone status and transitions** | | | |
| 4.2.1-3 | Zone status of clean rooms according to GMP room book **(Appendix 1)** :   * CNC * RRK D * RRK C * Transition CNC to RRK D * Transition RRK D to RRK C | GxP, necessary | J |
| 4.2.1-4 | Zone status material pass-through between E20 and E 21:   * RRK C | GxP, necessary | J |
| 4.2.1-5 | Access from one cleanroom class (RRK) to the next higher RRK is via locks  The lock corresponds to the higher RRK  **(Appendix 1)** | GxP, necessary | J |
| 4.2.1-6 | Spatial separation within the lock is achieved by barriers ( sit -over bench or floor markings) | GxP, necessary | J |
| **Flows (material, personnel flow)** | | | |
| 4.2.1-7 | Separation of material and personnel flow: Through material and personnel locks, as well as material pass-throughs | GxP, necessary | N |
| 4.2.1-7 | Spatial separation of material and personnel flow:   * Materials are introduced and removed via material lock * Within production areas, materials can be transferred via material hatches * Persons will enter and leave the cleanroom via personnel locks | GxP, necessary | J |
| 4.2.1-8 | Biological waste (solid material) is discharged via autoclaves | GxP, necessary | J |
| **Clean room conditions** | | |  |
| 4.2.1-9 | Cleanroom conditions of the individual rooms including warning limits according to the GMP room book ( **Appendix 1** ):   * Pressure * pressure difference * temperature * Humidity * discontinuous monitoring for particles and microbiology | GxP, necessary | J |
| 4.2.1-10 | Pressure difference between room zones is measured by means of “empty pipe” instead of “side room” | GxP, necessary | J |
| **flow** | | |  |
| 4.2.1-11 | Flow direction in the room is from the critical to the less critical area | GxP, necessary | J |
| 4.2.1-12 | Non-laminar, low-turbulence flow must be ensured | GxP, necessary | J |
| 4.2.1-13 | Clean room conditions in the locks correspond to the higher RRK  ( **Appendix 1** ) | GxP, necessary | J |
| 4.2.1-14 | The cleanroom conditions must be monitored and maintained (monitoring) | GxP, necessary | J |
| **Maintenance/Repair** | | |  |
| 4.2.1-15 | Systems must be maintainable | GxP, necessary | N |
| 4.2.1-15 | The system must be serviceable. In particular, the system components requiring maintenance must be accessible (if possible from outside the RR). | GxP, necessary | J |
| 4.2.1-16 | Inspection hatches are provided for maintenance between the suspended ceiling and the building slab (plenum) | GxP, necessary | J |
| 4.2.1-17 | Interchangeability of wall modules: The wall and ceiling modules should be installed so that they are individually accessible and easily replaceable. | GxP, necessary | J |
| **calibration** | | |  |
| 4.2.1-18 | Sensors must:   * calibrated ( factory calibration ) * recalibratable (calibration preferably in installed state or simple disassembly) | GxP, necessary | J |
| **Control panel** | | |  |
| 4.2.1-19 | Control panel for monitoring cleanroom parameters. | GxP, necessary | N |
| 4.2.1-19 | Control panel for monitoring the cleanroom parameters is provided in the entrance area in the wall GMP1\_E.03 | GxP, necessary | J |

### Environmental conditions/interfaces

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.2-1 | Construction site: Building GMP-I is [location] | GxP, necessary | J |
| 4.2.2-2 | Cleanroom/ventilation system interface:  terminal HEPA filters (specification H14) including scan certificate | GxP, necessary | J |
| 4.2.2-3 | In personnel locks, lint separators must be provided in the exhaust air | GxP, necessary | N |
| 4.2.2-3 | During the project, a change in the technical solution was made, the lint separator | GxP, necessary | J |
| 4.2.2-4 | The material hatch is actively ventilated (clean room class C) | GxP, necessary | J |
| 4.2.2-5 | Cleanroom/ventilation system interface:  Extraction arm in process room 4, connected to central extraction system | GxP, necessary | J |
| 4.2.2-6 | Cleanroom/ventilation system interface:  LF-Zone- Digestorium with own supply and exhaust air | GxP, necessary | J |

#### Media supply

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.2.1-1 | The following media connections in clean rooms **( Appendix 2)** :   * compressed air * oxygen * Purified Water (PW ) | GxP, necessary | J |
| 4.2.2.1-2 | Media (for technical supply/operation of plants/systems) such as cooling water and compressed air are available | Security, necessary | J |

### Structural requirements

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.3-1 | Building envelope is not outer shell (double shells, if RR closes to the outside, room in room system) | GxP, necessary | J |
| 4.2.3-2 | Rooms and joints should be able to withstand the planned overpressure cascade | GxP, necessary | J |
| 4.2.3-3 | be finished in white ( RAL 9010) | GxP, necessary | J |
| 4.2.3-4 | For RR walls with window elements, double-glazed (frameless) laminated safety glass panes must be integrated flush into the frame | GxP, necessary | J |
| 4.2.3-5 | Doors with windows in the upper area are used | GxP, necessary | J |
| 4.2.3-6 | Doors are opened electronically.  Double doors have a holding mechanism. | GxP, necessary | N |
| 4.2.3-6 | High-speed doors are opened electronically.  Double doors have a holding mechanism.  Doors must be opened manually. | GxP, necessary | J |
| 4.2.3-7 | Emergency lights must be installed in the grid lights or on the cleanroom ceiling | GxP, necessary | J |
| 4.2.3-8 | Appropriate blackout blinds should be provided on the exterior of the windows. These should be wind-resistant. | Security, necessary | J |
| 4.2.3-9 | Ceiling lights must be flush mounted and sealed/sealed with suitable plastic (e.g. silicone) | GxP, necessary | J |
| 4.2.3-10 | Ventilation: Tightness class of duct network at least class C according to DIN EN 1507 for square air ducts and DIN EN 12237 for round air ducts | GxP, necessary | J |
| 4.2.3-11 | Flow-optimized channel routing (avoid too many bends) | GxP, necessary | J |
| 4.2.3-12 | All cables (electrical, media) must be laid in the wall elements (cavity of the walls)  Alternatively, selective media columns are permitted | GxP, necessary | J |
| 4.2.3-13 | Media feedthrough ( mousehole ) is available at the intended position: Transition  Process room 4 GMP1\_E.16 to process room 2 GMP1\_E.20 in the quantity 3 pieces  - Diameter 4-6 inches  - Installation height 950 mm FBK  Process room 1 GMP1\_E.15 to process room 2 GMP1\_E.20 in the quantity 1 piece  - Diameter 4-6 inches  - Installation height 950 mm FBK | GxP, necessary | J |
| 4.2.3-14 | Media penetrations from wall to ceiling (cable/pipe) must be sealed airtight and flush. | GxP, necessary | J |
| 4.2.3-15 | Impact protection must be installed at relevant locations (e.g. material lock). | Security, necessary | J |
| 4.2.3-16 | Extractor arm in the process room GMP1\_E.16 mounted on the cleanroom wall and connected to the exhaust air system of the central air handling unit | GxP, necessary | J |
| 4.2.3-17 | LF zone/ digestorium in the process room GMP1\_E.15 with connection to the air handling unit for supply air as 75% fresh air and 100% exhaust air via HEPA 14:   * Internal area size (usable area) is 2.3 m length, 0.7 m depth, 1 m height * 6 sockets in the interior, side entry / connections for hoses * Walls : glass/ transparent * LF housing made of stainless steel * LF zone is open in operating condition (without panes) with air barrier through the air flow * Interface: Communication with the air handling unit via potential-free contact (when the unit is switched on, the air handling unit receives a signal that more air should be provided in the room and vice versa) | GxP, necessary | J |
| 4.2.3-18 | The cleanroom wall and wall elements axis A-1; A-2, on the insertion opening must be removable for insertion area " ~~2000 mm x 1250 mm\*"~~ 2000 mm x 2250 mm and resealable (magnetic coupling) and sealed after insertion. | GxP, necessary | J |

#### Drawings and plans

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.3.1-1 | Preparation and delivery of production drawings, P&I flow diagrams, circuit diagrams, ceiling grid drawings including lighting, topology of the cleanroom monitoring system (PDF and DWG format) for RR and HVAC  Uniform component identification in P&ID and in the drawings. | GxP, necessary | J |

#### Material/Surfaces

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.3.2-1 | Hygienic Design:   * Smooth, crack-free, dense, easy-to-clean/disinfect surfaces * Gaps, sharp edges and dead spaces must be avoided * Coves for wall and machine connections must be made and flush * easy to clean | GxP, necessary | J |
| 4.2.3.2-2 | Flooring:   * anti-slip * conductive * lower Particle abrasion | GxP, necessary | J |
| 4.2.3.2-3 | Interior material pass-throughs easy to clean | GxP, necessary | J |
| 4.2.3.2-4 | Surfaces are resistant to the cleaning and disinfection agents used by [company] (alcoholic solvents) | GxP, necessary | J |
| 4.2.3.2-5 | Seals:   * must be abrasion and ageing resistant and, if possible, UV-resistant * must not release particles and plasticizers | GxP, necessary | J |
| 4.2.3.2-6 | Fittings/machine connections, LF zone and extraction arm in the RR must be made of stainless steel (at least 1.4301) | GxP, necessary | J |
| 4.2.3.2-7 | Lubricant:   * must be at least food grade (proof example according to NSF-H1 conformity) * TSE certified (free from materials of animal origin) | GxP, necessary | J |
| **furnishing furniture** | | |  |
| 4.2.3.2-8 | Furniture must be flush with the ceiling or sloped at 25°-30°. Furniture should conform to " hygienic design." | GxP, necessary | J |
| 4.2.3.2-9 | Furniture should be made of stainless steel | GxP, necessary | J |

#### Performance data

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.3.3-1 | Ventilation **(Appendix 1)** :   * Supply air * exhaust air * Air volumes | GxP, necessary | J |
| 4.2.3.3-2 | Air exchange corresponds to RRK | GxP, necessary | J |
| 4.2.3.3-3 | Fresh air ratio 100% in all cleanrooms | GxP, necessary | J |

### Safety requirements

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.4-1 | Mutual locking of the locks is necessary | GxP, necessary | J |
| 4.2.4-2 | A mutual lock is necessary for the material pass-through | GxP, necessary | J |
| 4.2.4-3 | Lock doors and high-speed doors must be equipped with an emergency switch | GxP, necessary | J |
| 4.2.4-4 | Storage room GMP1\_E.12 should be access controlled | GxP, necessary | J |
| 4.2.4-5 | Precautions must be taken against the intrusion of insects and other animals (Pest Control) | GxP, necessary | J |
| 4.2.4-6 | All electrical and EMSR components used must comply with the respective environmental requirements in terms of their protection class to ensure safe system operation | Security, necessary | J |

### Process requirements

#### Material flow IN

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.5.1-1 | Materials:   * Storage of materials in the central external warehouse * Transport to the GMP-I building * Delivery via GMP1\_E.07 * Introduction via material locks into the respective production rooms * Transfer between production rooms via material hatch | GxP, necessary | J |
| 4.2.5.1-2 | Outer packaging materials:   * No wood in GMP-I buildings (pallets either stainless steel or plastic) * no cardboard boxes in GMP-I | GxP, necessary | J |

#### Material flow OUT

|  |  |  |  |
| --- | --- | --- | --- |
| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| 4.2.5.2-1 | Storage of material/product in storage room GMP1\_E.12 | GxP, necessary | J |
| 4.2.5.2-2 | Materials:   * Application above Material lock * Transport to warehouse * Storage equipment in the storage room * Transport and handover e.g. to customer via GMP1\_E.07 (after QC approval) | GxP, necessary | J |
| 4.2.5.2-3 | Separate flows of materials and product | GxP, necessary | J |

#### persons

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.5.3-1 | Number of persons in locks according to GMP room book **(Appendix 1)** | GxP, necessary | J |
| 4.2.5.3-2 | A clothing concept is defined **(Appendix 3)** | GxP, necessary | J |

### Functional requirements

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.6-1 | Lock locking: Automatic locking and display system. | GxP, necessary | N |
| 4.2.6-1 | Lock locking:  Normal state: all doors are unlocked, lock control display “green”  Door opening: Opposite door locks automatically, lock control display “red” | GxP, necessary | J |
| 4.2.6-2 | Release of lock locking after parameterized time or after reaching specified RR conditions) | GxP, necessary | J |
| 4.2.6-3 | Opening lock doors in case of fire alarm | Security, necessary | J |
| 4.2.6-4 | Lock doors and high-speed gates trigger an alarm if they are opened for too long | GxP, necessary | J |
| 4.2.6-5 | Monitoring room conditions: triggering alarms  Normal state: no alarm  Freeze/delay time: no alarm Overshoot/undershoot: alarm (acoustic or visual) | GxP, necessary | J |

### Monitoring

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.7-1 | Display of clean room conditions on PAL GMP1\_E.11 (e.g. pressure difference) | GxP, necessary | J |
| 4.2.7-2 | Delay time/freeze for alarm available (by briefly opening lock doors | GxP, necessary | J |
| 4.2.7-3 | Specified pressure difference monitoring between different cleanroom classes must be present and continuously monitored | GxP, necessary | J |
| 4.2.7-4 | The system must be able to trigger alarms when warning limits and alarm thresholds are violated | GxP, necessary | J |
| 4.2.7-5 | Pressure difference monitoring must trigger an alarm | GxP, necessary | J |
| 4.2.7-6 | Monitoring documents including monitoring data must be easily accessible to users (detection via signal lamp and acknowledgement via control computer) | GxP, necessary | J |
| 4.2.7-7 | Data (monitoring) is recorded and archived | GxP, necessary | J |
| 4.2.7-8 | Data must be protected from manipulation by unauthorized persons and loss (within the organization as well as during transmission) | GxP, necessary | J |
| 4.2.7-9 | Data must be readable for the entire retention period (up to 30 years) | GxP, necessary | J |
| 4.2.7-10 | Temperature control via averaging of individual rooms, unless otherwise stated | GxP, necessary | J |
| 4.2.7-11 | Trends: Day and month accurate display and evaluation possible | GxP, necessary | J |
| 4.2.7-12 | An overview of maintenance and fault messages in the system must be presented; this includes in particular warning and alarm messages | GxP, necessary | J |

#### Requirements for security and access and authorization controls

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.7.1-1 | The software program system must be protected by physical access control and changing password rules | GxP, necessary | J |
| 4.2.7.1-2 | The system must provide several levels of security depending on the user's responsibilities  (Applies to RRM only) | GxP, necessary | J |
| 4.2.7.1-3 | Audit trail: generation and reliability. | GxP, necessary | N |
| 4.2.7.1-3 | The system must generate an audit trail | GxP, necessary | J |
| 4.2.7.1-4 | Fail-safe operation including data storage via UPS (uninterruptible power supply) | GxP, necessary | J |

#### Backup and recovery requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| 4.2.7.2-1 | The system must have backup and recovery ­functionality. An emergency program for this must be documented. | GxP, necessary | J |

#### Data Integrity Requirements

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.7.3-1 | The system generates electronic records as defined in 21 CFR 11, EU-GMP Annex 11 and other pharmaceutical IT regulations | GxP, necessary | J |
| 4.2.7.3-2 | Electronic data is archived via interface in the in-house server | GxP, necessary | J |

#### Hardware requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| 4.2.7.4-1 | Standard hardware components from well-known manufacturers must be used | GxP, necessary | J |

#### Software requirements

| **URS#** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.7.5-1 | Standard software components from well-known manufacturers must be used (e.g. Microsoft Windows, Microsoft SQL database) in accordance with GAMP requirements | GxP, necessary | J |
| 4.2.7.5-2 | Security patches and updates are installed by the maintenance technician during inspection/maintenance | GxP, necessary | J |

### Documentation and training requirements

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.8-1 | The complete documentation must be in German | GxP, necessary | J |
| 4.2.8-2 | The documentation must be delivered in one copy in paper form (filed in DIN A4 folders including table of contents) and on a data storage device (USB stick) | GxP, necessary | J |
| 4.2.8-3 | An overview list of all submitted supplier documents must be submitted to the client. | GxP, necessary | J |
| 4.2.8-4 | Uniform labeling of all components and parts in all documents | GxP, necessary | J |
| 4.2.8-5 | All fittings/tapping points must be clearly marked according to the flow diagrams | GxP, necessary | J |
| 4.2.8-6 | Version control of all manufacturer documents must be ensured by means of a change history | GxP, necessary | J |
| 4.2.8-7 | All documents must be finalized by the time of acceptance (SAT) | GxP, necessary | J |
| 4.2.8-8 | EC declaration of conformity for all components of the scope of delivery | GxP, necessary | J |
| 4.2.8-9 | CE marking | GxP, necessary | J |
| 4.2.8-10 | Initial calibration of the sensors | GxP, necessary | J |
| 4.2.8-11 | Functional description | GxP, necessary | J |
| 4.2.8-12 | Initial hygiene inspection according to VDI 6022 for ventilation | GxP, necessary | J |
| 4.2.8-13 | Recommendations/instructions including manufacturer's schedules regarding maintenance/repair  Excluded are inspection openings (maintenance-free) | GxP, necessary | J |

#### Lists

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.8.1-1 | Spare parts list with storage recommendations | GxP, necessary | J |
| 4.2.8.1-2 | Wear parts list | GxP, necessary | J |
| 4.2.8.1-3 | Warning and alarm list (list and explanation of all alarm functions and error messages depending on the operating status including system response (light, horn, shutdown)) | GxP, necessary | J |
| 4.2.8.1-4 | Parameter list  A separate parameter list is not necessary for the components of the air handling unit (H14 filter, swirl outlets and floor extraction) | GxP, necessary | J |
| 4.2.8.1-5 | Component list | GxP, necessary | J |
| 4.2.8.1-6 | Filter lists | GxP, necessary | J |
| 4.2.8.1-7 | Measuring device list | GxP, necessary | J |
| 4.2.8.1-8 | A measuring point plan must be created | GxP, necessary | J |
| 4.2.8.1-9 | A calibration specification list for relevant measuring points with description and acceptance criteria must be created | GxP, necessary | J |
| 4.2.8.1-10 | A maintenance schedule must be created | GxP, necessary | J |

#### Electrical documentation

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.8.2-1 | A cable list/MSR list must be created | GxP, necessary |  |
| 4.2.8.2-2 | A circuit diagram must be available in “ as-built ” version | GxP, necessary |  |

#### Operator documentation

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.8.3-1 | Logbooks must be present or, if not initially present, created | GxP, necessary | J |
| 4.2.8.3-2 | Technical data sheets or manuals must be provided | GxP, necessary | J |
| 4.2.8.3-3 | Instructions for operation/safeguarding/maintenance:   * building hygiene (e.g. cleaning instructions, functioning pest control system) * of the rooms (maintenance, repair, calibration, operation) and clean room conditions (monitoring) | GxP, necessary | J |

#### Material quality

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.8.4-1 | For materials that come into contact with the product, at least tool certificates 2.2 are required | GxP, necessary | J |
| 4.2.8.4-2 | Declarations of conformity according to 21 CFR 177 for product contact surfaces | GxP, necessary | J |
| 4.2.8.4-3 | Material certificates seals  Does not apply to RRM because no product-contacting seals or sensors are installed and no material certificates are required. | GxP, necessary | J |
| 4.2.8.4-4 | Filter certificates (H14) | GxP, necessary | J |
| 4.2.8.4-5 | Leak test/filter leak test | GxP, necessary | J |

#### Training requirement

| **URS# /#FS** | **Description** | **Classification** | **Fulfilled** |
| --- | --- | --- | --- |
| 4.2.8.5-1 | Initial operator training must be provided | GxP, necessary | J |

# Cited or relevant documents

GMP-I\_GRA\_RR GMP-Relevance Analysis Systems Cleanroom

GMP-I\_GRA\_RR\_MS GMP relevance Analysis Systems Cleanroom Monitoring

EU-GMP Part II Basic requirements for active substances used as starting materials

and Annices

VDI 6022 Indoor air technology, indoor air quality

21 CFR Title 21 of Code of Federal Regulations

AMWHV Medicinal Products and Active Substances Manufacturing Ordinance

EU-GMP Part II Basic requirements for active substances used as

and Annices starting materials

# Attachments

GMP-I\_RR\_URS A1 GMP room book

GMP-I\_RR\_URS A2 Media connections in RR

GMP-I\_RR\_URS A3 Clothing concept