GERMAN

LabConCert

LABORATORY CONSULTING CERTIFICATION

www.labconcert.de

HT GROUP

GERMAN
LabConCert
LABORATORY CONSULTING CERTIFICATION

Material air locks in GMP laboratories

Requirements, types, use cases, FATs and SATs

Fabio Blaha, Till Manthey

Material air locks in GMP laboratories

Overview

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

1. Function of material air locks in GMP laboratories
2. General requirements
3. Types
4. Use cases and planning requirements
5. FATs and SATs in the qualification process


HT GROUP

Material air locks in GMP laboratories

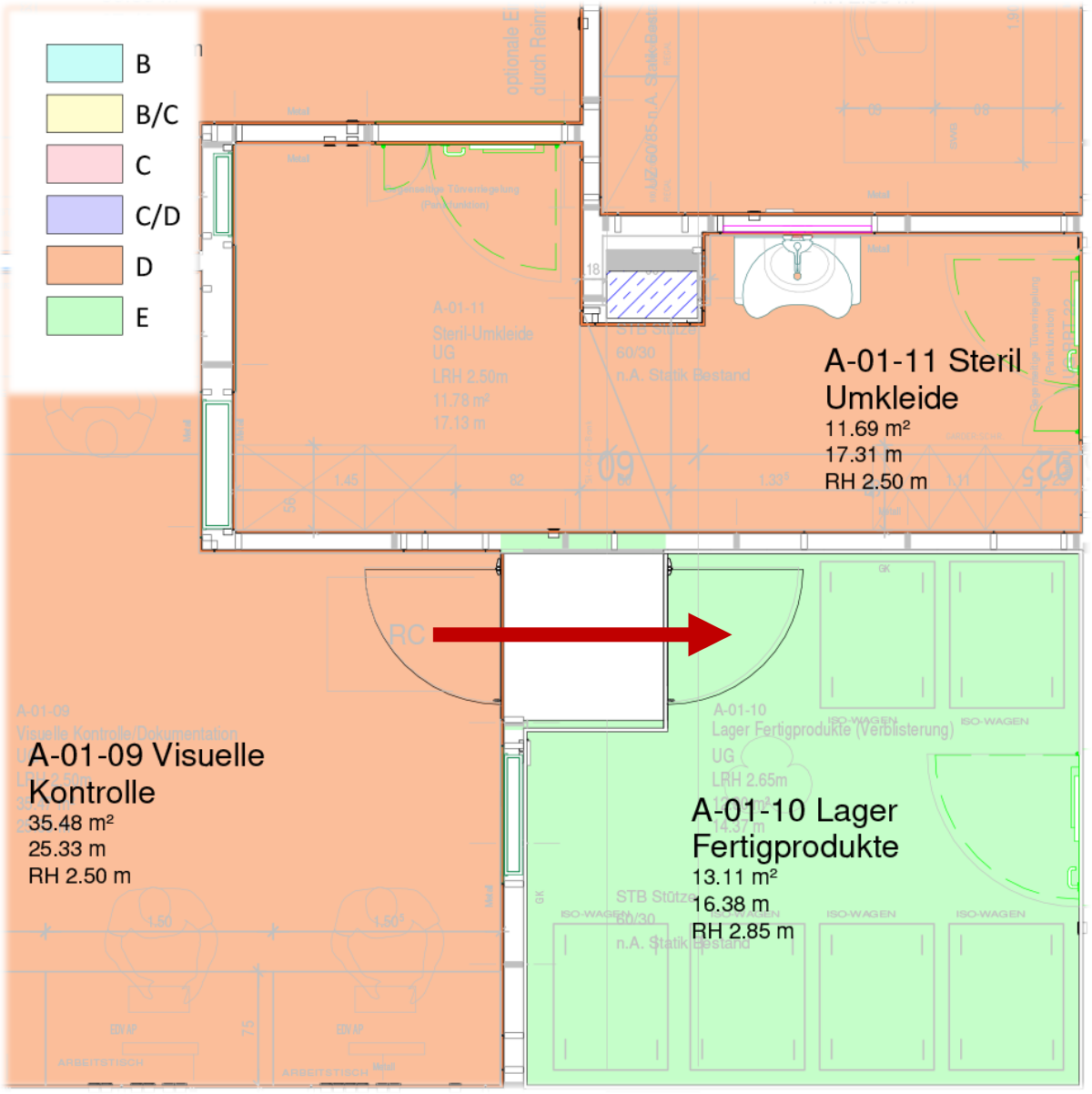
1. Function of material air locks in GMP laboratories

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- Bringing in / bringing out of material
- Maintenance of clean room classes, product protection
- Separation of personnel and material flow
- Time saving

  - depending on the use case, there's no need for an additional person to lock into the clean room area
  - material can be brought in from outside the respective clean room grade

The product can be brought out, personnel does not need to leave the clean room area (grade D).



Material air locks in GMP laboratories

2. General requirements

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- 4.5 In cleanrooms and critical zones, all exposed surfaces should be smooth, impervious and unbroken in order to minimize the shedding or accumulation of particles or micro-organisms.
- 4.7 Materials used in cleanrooms, both in the construction of the room and for items used within the room, should be selected to minimize generation of particles and to permit the repeated application of cleaning, disinfectant and sporicidal agents where used.
- 4.12 Airlocks should be flushed effectively with filtered air to ensure that the grade of the cleanroom is maintained. The final stage of the airlock should, in the “at rest” state, be of the same cleanliness grade (viable and total particle) as the cleanroom into which it leads.
- 4.13 For pass-through hatches and airlocks (for material and personnel), the entry and exit doors should not be opened simultaneously. For airlocks leading to the grade A and grade B areas, an interlocking system should be used. For airlocks leading to grade C and D areas, a visual and/or audible warning system should be operated as a minimum. Where required to maintain area segregation, a time delay between the closing and opening of interlocked doors should be established.

EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Annex 1: Manufacture of Sterile Medicinal Products

Material air locks in GMP laboratories

2. General requirements

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- Metal surfaces: stainless steel 1.4301
- Glass windows: safety glass
- Lip seal: EPDM, possibility to pull it out to clean it
- Joint filler: cleanroom silicone
- H14 filter (supply): testable for integrity and leakage (in acc. with ISO 14644)
- Test connections for differential room pressure test: available
- Interlocked access: it is not possible to open both doors at the same time (electro-mechanical interlock)
- Flushing time, during which it is not possible to open any of the doors: settable by user via display
- Optical indicator (LED) for status showing at minimum: red (cannot open), green (can open) and blue (door open for too long)
- Doors: with emergency button to open the door
- Door hinges: adjustable in three dimensions
- Programmable (e.g., flush time)
- Service access
- Optional:
    - LED light for inside the material air lock
    - H14 filter (exhaust): testable for integrity and leakage (in acc. with ISO 14644)
    - Interface to BMS
    - Interface instrumentation and control engineering
    - perforated insertion compartments

Material air locks in GMP laboratories

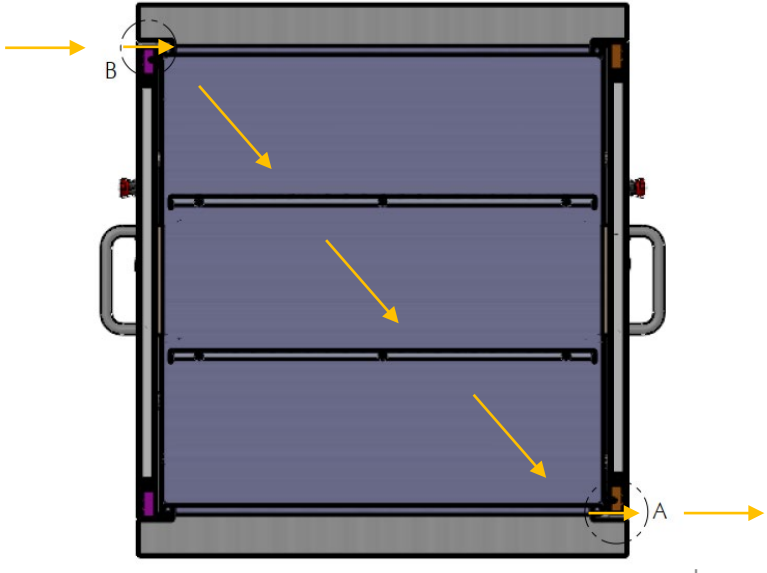
3. Types

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- Passive
  - ➢ Ventilation via differential pressure between the adjacent rooms
  - ➢ Both doors with undercut

airflow

clean side



less clean side


HT GROUP

Material air locks in GMP laboratories

3. Types

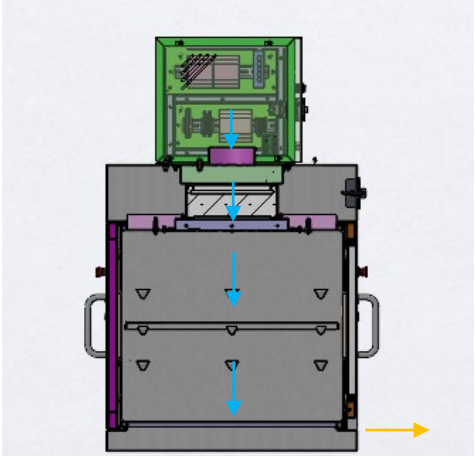
GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- Semi-active, only supply air

  - ➢ Supply air only (connection via air pipe on top)
  - ➢ H14 filter in supply air
  - ➢ Door to the less clean side with undercut (outward airflow, airflow direction to the less clean side)

supply air
exhaust air

clean side



less clean side

Material air locks in GMP laboratories

3. Types

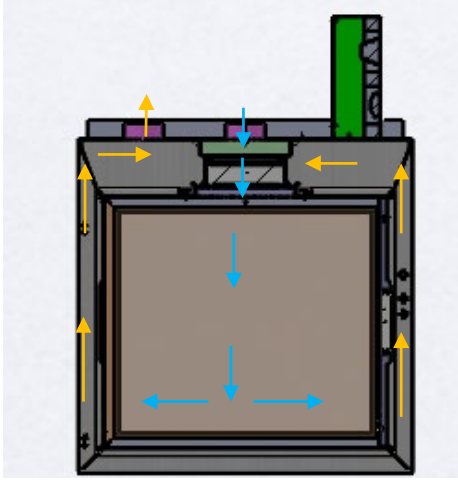
GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- Semi-active, supply and exhaust air

  - Supply and exhaust air (connection via air pipe on top)
  - H14 filter in supply air
  - H14 filter in exhaust air optional (e.g., when working with some hazardous material)
  - Both doors sealed
  - Air flow via inner perforation

supply air
exhaust air

clean side



less clean side

Material air locks in GMP laboratories

3. Types

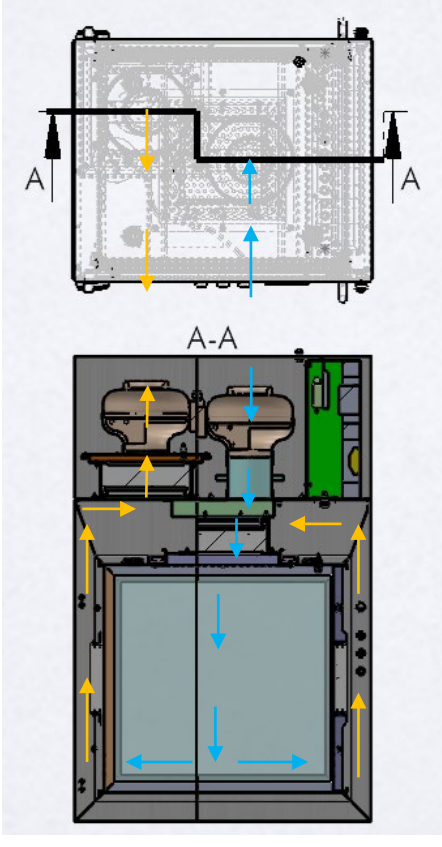
GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- Active, independent air supply

  - Supply and exhaust air (no connection to HVAC system, integrated fans for air flow and pressure control)
  - H14 filter in supply air
  - H14 filter in exhaust air optional (e.g., when working with some hazardous material)
  - Both doors sealed
  - Air flow via inner perforation

supply air
exhaust air

clean side



less clean side


HT GROUP

Material air locks in GMP laboratories

3. Types

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- Trolley
  - Accessible for trolleys
  - Possible as passive, semi active and active air lock


bi BOX
Blechfertigung
Blechfertigung

Material air locks in GMP laboratories

4. Use cases and planning requirements

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- 4.11 The transfer of materials, equipment, and components into the grade A or B areas should be carried out via a unidirectional process. [...] The removal of items from the grade A and B areas (e.g. materials, waste, environmental samples) should be carried out via a separate unidirectional process.
- 4.12 Wherever possible, airlocks used for personnel movement should be separated from those used for material movement.
- 4.14 Cleanrooms should be supplied with a filtered air supply that maintains a positive pressure and/or an airflow relative to the background environment of a lower grade under all operational conditions and should flush the area effectively.

EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Annex 1: Manufacture of Sterile Medicinal Products

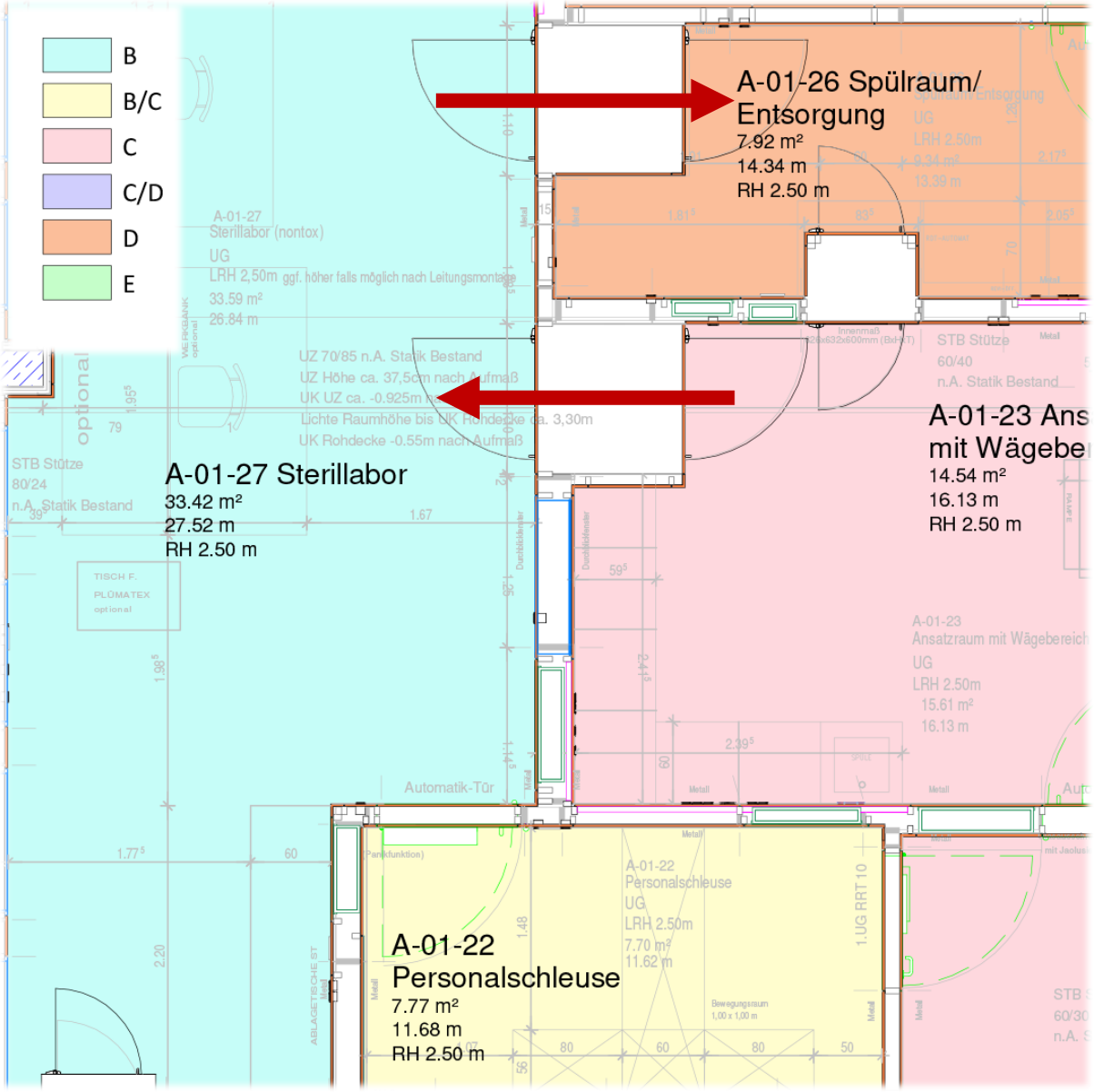
Be careful: usually, material air locks should not jump a clean room class (e.g., D to B).

But in many laboratories, material air locks actually jump a clean room class. That is mostly for two purposes:

1. Bringing out waste
2. Bringing out product

In many cases, this makes a lot of sense to save time.

Please discuss this with your authorities first, and be extra careful in the case of hazardous materials handled.



Material air locks in GMP laboratories

5. FATs and SATs in the qualification process

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- FAT (factory acceptance test):
  - testing “in the factory” – making sure it meets the specification before shipping
- SAT (site acceptance test):
  - testing “on site” – making sure it meets the specification when installed and integrated (i.e., including the interfaces with BMS/monitoring/HVAC and physical interfaces like walls, joints …)

Material air locks in GMP laboratories

5. FATs and SATs in the qualification process

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- Principle with regard to FATs and SATs:

  - Do not do it outside of the planned qualification activities
  - Do include formal requirements on the FATs and SATs (e.g., on the test plan, roles, supervision of testing) in the VMP (validation master plan)
  - Do make sure that the URS requirements are tested in the FATs and SATs → traceability matrix
  - Do make sure that the requirements of EudraLex - Volume 4, Annex 15 (Qualification and Validation) are adhered to
  - Only then it is possible to use the FATs and SATs for IQ test points → no double testing necessary

Material air locks in GMP laboratories

5. FATs and SATs in the qualification process

GERMAN LabConCert
LABORATORY CONSULTING CERTIFICATION

- What to check before approval of the FATs and SATs:

  - A SOP that determines the procedure is available.
  - A proof of the necessary competence of the personnel involved in the FATs and SATs is available.
  - A test description is available.
  - The test plan includes the applicable requirements (GMP, URS, manufacturer's specification)
  - Test results can are comprehensible (i.e., relevant markings and notes in drawings and in the test report)
  - The relevant annexes of the test report are available (e.g., drawings, wiring diagram, material certificates, filter certificates, user instructions, cleaning instructions, maintenance instructions)

- The documents are kept in digital form and as originals → GMP – Give More Paper

Version	1.0
Datum	24.04.2023
Seite	8 / 15

P220068-FAT-PP-003					
Prüftätigkeit	Prüfkriterium	Referenz	Erfüllung	Datum	Unterschrift
Sichtprüfung	Die Anpressvorrichtung für den Zuluftfilter ist vorhanden.	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
	Hinweis: Sichtprüfung ohne eingebauten H14-Filter	FAT-PP-003-Anhang01	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
Sichtprüfung, Abgleich mit Filterzertifikat	Die Materialdurchreiche ist mit einem H14-Filter für die Abluft ausgestattet.	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
Sichtprüfung	Der Abluftfilter ist unbeschädigt.	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
Sichtprüfung	Das Filtergehäuse für die Abluft ist mit Reinraumsilikon abgedichtet	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
Sichtprüfung	Die Anpressvorrichtung für den Abluftfilter ist vorhanden.	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
	Hinweis: Sichtprüfung ohne eingebauten H14-Filter	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
Sichtprüfung	Die Türen sind dichtschließend und flächenbündig (mit äußeren Kanten) eingesetzt.	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
Sichtprüfung	Die Türdichtungen sind intakt und so eingebaut, dass sie bei Türschließung leicht eingedrückt werden.	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
Sichtprüfung	Hinweis: Prüfung mit einem Blatt Papier	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	
Funktionsprüfung	Die Türen lassen sich vollständig und leichtgängig öffnen.	26. APR. 2023	☒ ja ☐ nein ☐ N/A	26. APR. 2023	

Schleuse_Teilaktiv_DIN_L_Göppingen_MAL03

FAT-PP-003-Anhang01

26. APR. 2023

German LabConCert GmbH
Christoph-Sturm-Str. 25-29
91161 Hilpoltstein
Germany
info@labconcert.de
+49 (0) 9174 9765527

www.labconcert.de

GERMAN
LabConCert
LABORATORY CONSULTING CERTIFICATION