Slovenian Cleanroom Society

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International Conference

CLEANROOMS TODAY AND TOMORROW:

INNOVATION, SUSTAINABILITY, EXCELLENCE AND REGULATORY COMPLIANCE

30 – 31 MARCH 2026

BRDO PRI KRANJU, SLOVENIA

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Opening remarks

30 – 31 MARCH 2026

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ISCC 2026

JACA

International Symposium on Contamination Control

Harmonizing various fields beyond the Contamination Control

Tokyo, Japan, 2026

Organized by ICCCS and JACA

Nov. 11 – 13, 2026 Hachioji Tokyo, Japan

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Cleanrooms Advanced HVAC Design – Update on New ASHRAE Cleanroom Design Guide

Vincent Sakraida, Olsson

30 – 31 MARCH 2026
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Outline

- What is ASHRAE and TC9.11 Clean Space Committee?
- How TC9.11 Clean Space Committee is Leading the Way
- What Changes are Being Made to the ASHRAE Cleanroom Design Guide
- What Cleanroom Technological Changes are Being Made and Supported by TC9.11

Vincent A. Sakraida, PE, LEED AP

- Bachelor of Science in Mechanical Engineering, Georgia Tech 1982
- Performed Engineering, Construction, and Commissioning of Cleanrooms since 1987
- Chairman of ASHRAE TC9.11 Clean Space Committee
- Member of ISO 14644 Cleanroom Standard

What is ASHRAE and TC9.11 Clean Space Committee?

Vincent Sakraida, Olsson

ASHRAE is an international society of professionals in heating, ventilation, air conditioning, and refrigeration with over 50,000 members with members in 130 countries.

ASHRAE Mission is to advance human well-being through sustainable technology for the built environment.

ASHRAE Activities includes funding research projects, offering educational programs; and developing technical guides, design manuals, and standards.

ASHRAE®

Shaping Tomorrow's Built Environment Today

Slovenian Cleanroom Society

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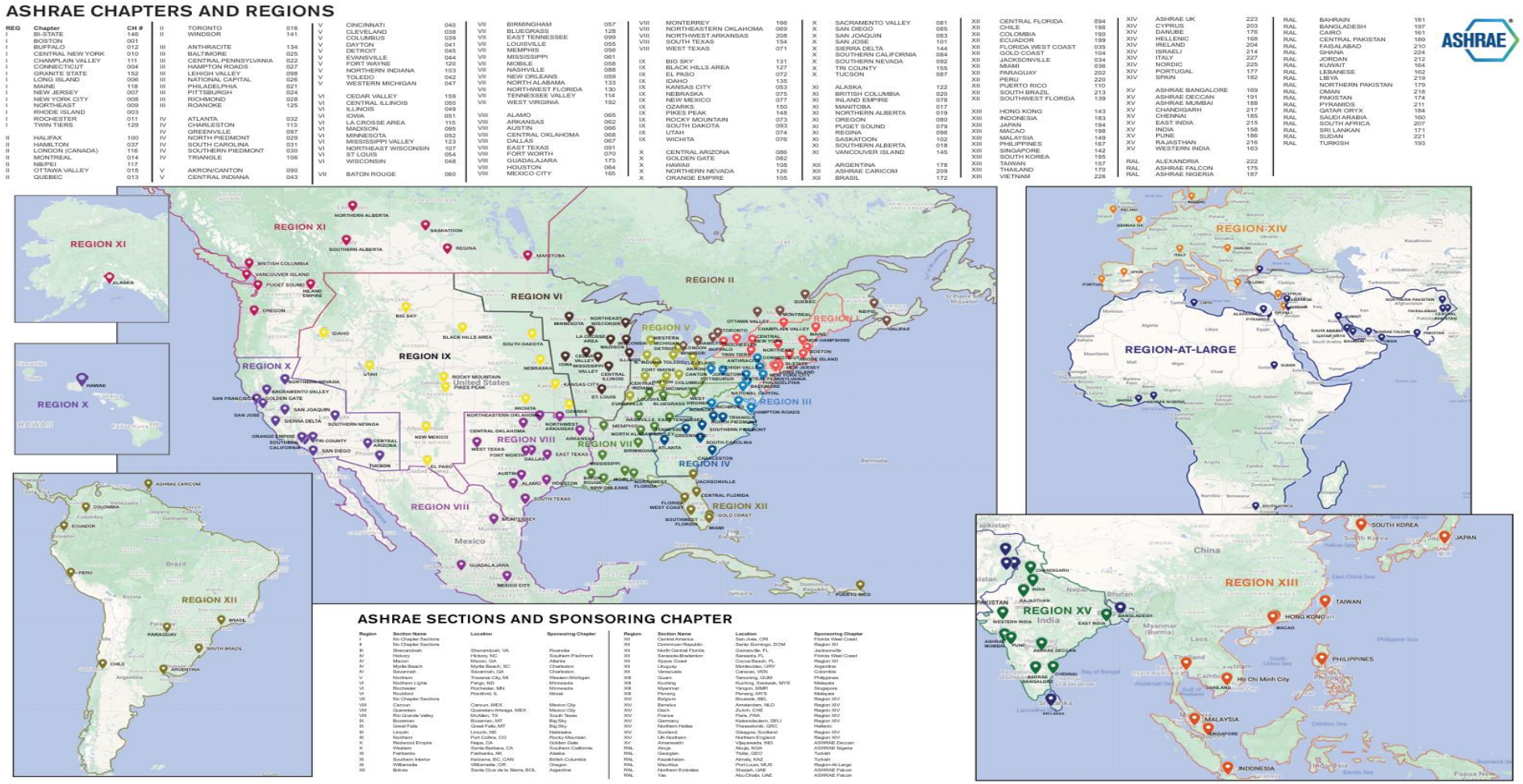


Cleanroom Advanced HVAC Design – Update on New ASHRAE Cleanroom Design Guide

Vincent Sakraida, Olsson

- TC9.11 Clean Spaces is one of 99 Technical Committees in ASHRAE:
  - TC9.11 Scope is HVAC system design for cleanrooms and clean spaces; including process, product and facility air conditioning, and related process ventilation for R&D, manufacturing, assembly, and testing.
- TC9.11 current Chair is Vincent Sakraida, HVAC and Mechanical System Engineer, and Distinguished Lecturer.
- TC9.11 membership includes Design Engineers, Experts, Vendors, Facility Engineers, and Academia.
- >250 participating ASHRAE members from across the globe.

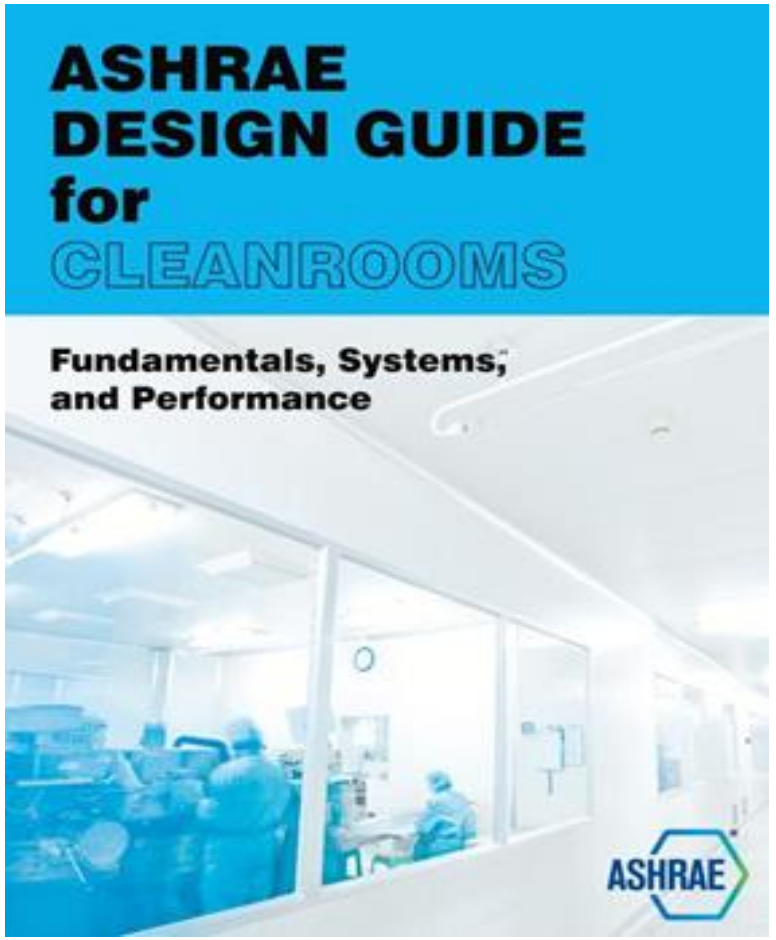
How TC9.11 Clean Space Committee is Leading the Way

Cleanroom Advanced HVAC Design – Update on New ASHRAE Cleanroom Design Guide

Vincent Sakraida, Olsson

ASHRAE TC9.11 – Leading the Way!

- Update to Chapter 19 Clean Spaces in "***ASHRAE HVAC Applications Handbook***", expected late 2026 - Editor Conor Murray
- New 2nd Edition "***ASHRAE Design Guide for Cleanrooms: Fundamentals, Systems, and Performance***" expected in 2027 (1st Ed 2018) - Editor Wei Sun
- Published Numerous Articles in ASHRAE Journal by Phil Naughton and Kishor Khankari



ASHRAE TC9.11 – Leading the Way!

- International Lectures by TC9.11 Distinguished Lecturers.
  - Conor Murray, Don Colliver, Kishor Khankari, Mitch Swan, Vincent Sakraida, Wei Sun
  - Bahrain, Bangladesh, Canada, Egypt, Greece, India, Ireland, Lebanon, Maylasia, Nigeria, Oman, Pakistan, South Korea, Sri Lanka, United Arab Emirates, United States, and many more countries

ASHRAE TC9.11 – Leading the Way!

- Promoting and Participating in ISO Standards – in particular ISO 14644
  - Phil Naughton was ASHRAE Delegate to ISO 14644 for 25 years.
  - Vincent Sakraida is Present ASHRAE Delegate to ISO 14644 for past 3 years.
  - Conor Murray is Head of Delegation for Ireland ISO 14644.
  - Wei Sun is Member of US TAG and Active Participant in ISO 14644 – Part 16.


INTERNATIONAL STANDARD

ISO 14644-4
2022

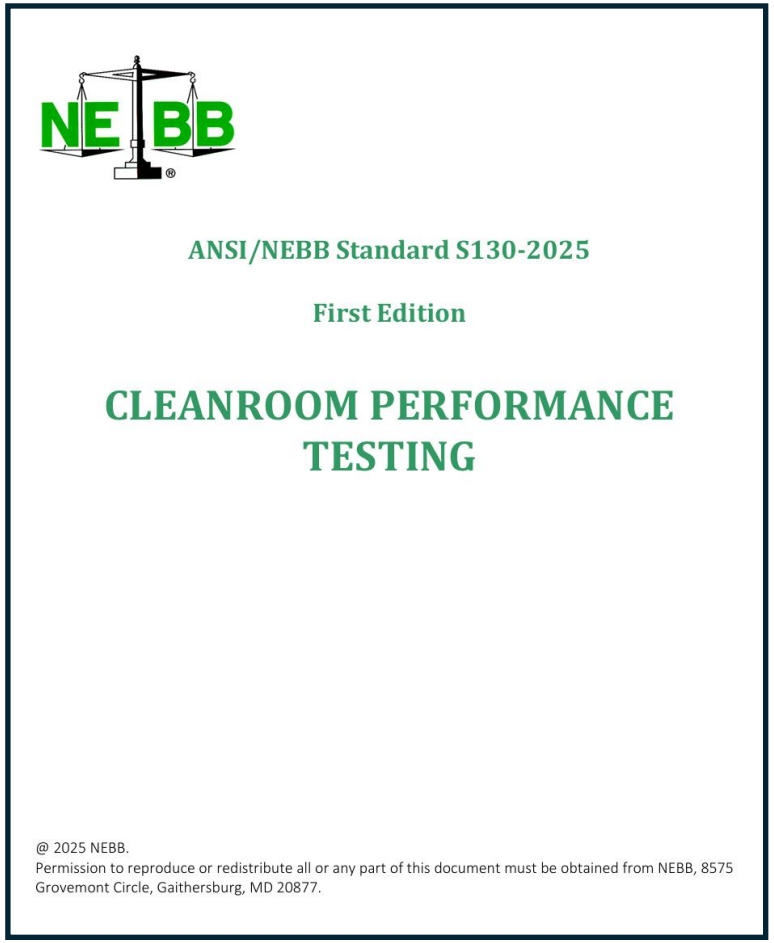
Edition 3
2022-06

Cleanrooms and associated controlled environments
Part 4: Design, construction and start-up

ISO

ASHRAE TC9.11 – Leading the Way!

- Collaboration with other international organizations – ICCCS
- Collaboration with other international industry organizations – including IEST, ISPE, PDA, and NEBB.
  - Wei Sun is Chairman of NEBB Cleanroom Performance Testing Standard and Past President of IEST.
  - Vincent Sakraida is Contributor and Voting Member of NEBB Cleanroom Performance Testing Standard.


NEBB

ANSI/NEBB Standard S130-2025

First Edition

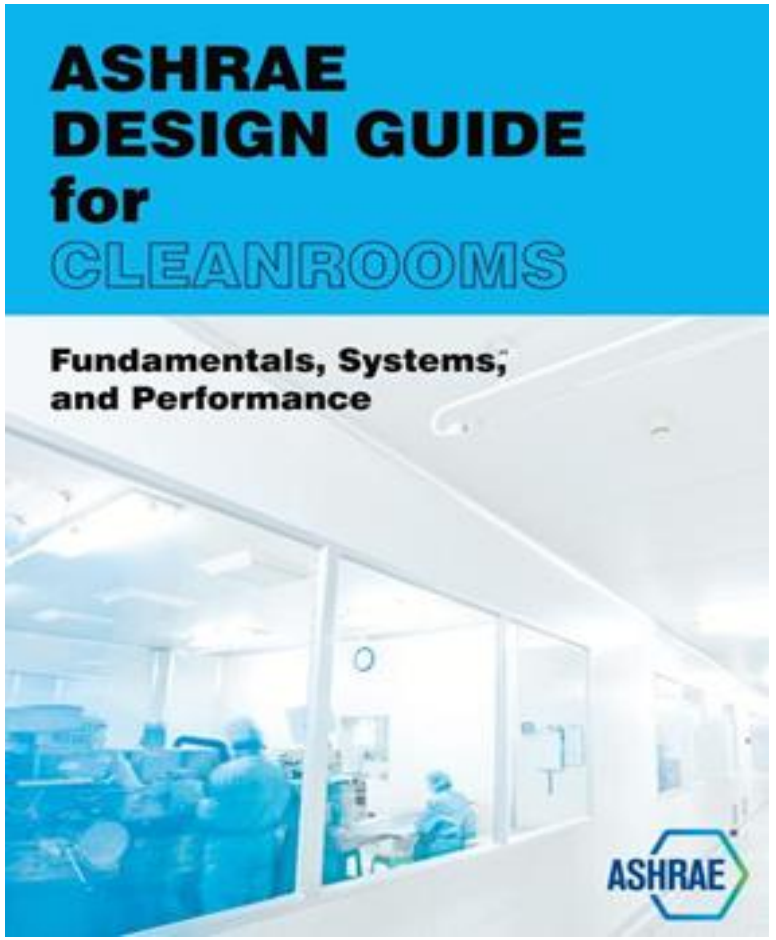
CLEANROOM PERFORMANCE TESTING

What Changes are Being Made to the ASHRAE Cleanroom Design Guide

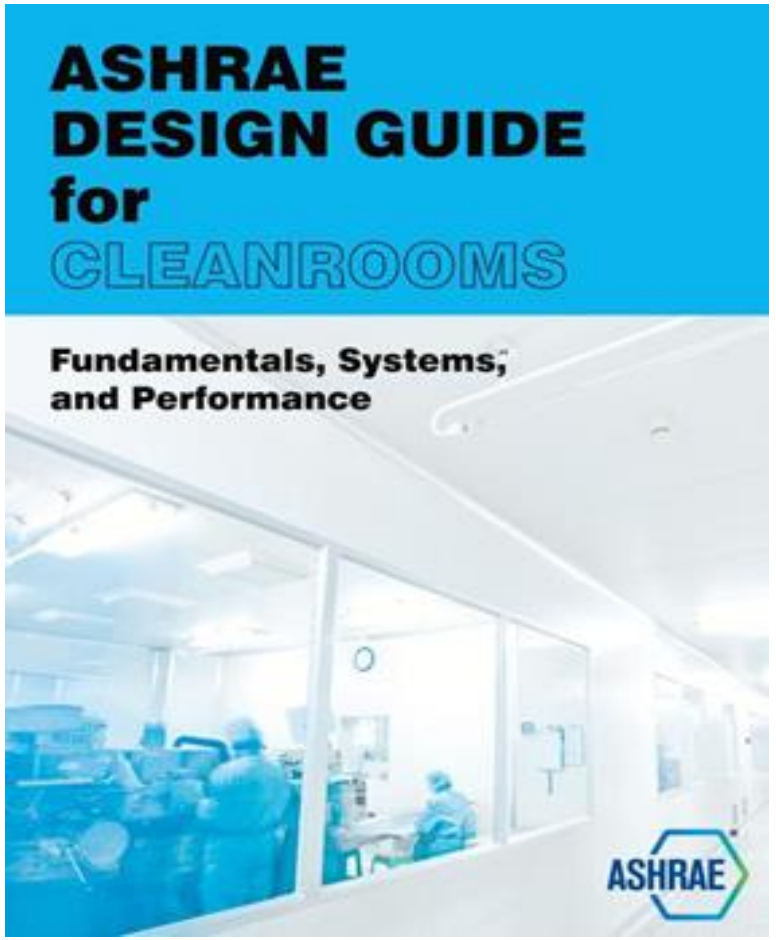
Cleanroom Advanced HVAC Design – Update on New ASHRAE Cleanroom Design Guide

Vincent Sakraida, Olsson

- Cleanroom Design Guide First Edition is a Single Volume that Included:
  - Cleanroom Fundamentals
  - Cleanroom Design and Environmental Control Systems
  - Cleanroom Testing, Certification, Commissioning, and Qualification
  - Cleanroom Design is Select Industries
- Book Contained 426 Pages which is Utilized by Design Professionals, Operators, and as a University Textbook.
- ASHRAE Requested TC9.11 to Provide a Second Edition.



- Cleanroom Design Guide Second Edition will Expand the Content that will Require the Cleanroom Design Guide to be Split into Two Volumes with a Total of 600 Pages.
- Volume 1 will Include Fundamentals, Design, Construction, Analysis, Monitoring & Control.
  - Volume 1 will Include Cleanroom Construction and Cleanroom Contamination Monitoring Sections.
- Volume 2 will Include Applications, Testing, Qualification, Operation & Maintenance.
  - Volume 2 will Include Cleanroom Operation and Maintenance.



What Cleanroom Technological Changes are Being Made and Supported by TC9.11

Cleanroom Advanced HVAC Design – Update on New ASHRAE Cleanroom Design Guide

Vincent Sakraida, Olsson

Demand Control Ventilation

- Cleanrooms are designed for highest particulate generation. High particulate generation time frames are typically only several hours a day resulting in opportunities to save energy by variable airflow to maintain cleanliness class.
- Reducing airflow saves substantial fan energy!!!!
  - Fan Affinity Law for Power

$$P_2/P_1 = (CFM_1/CFM_2)^3$$

$$P_2 = P_1 (CFM_1/CFM_2)^3$$

Energy savings is cube of CFM reduction

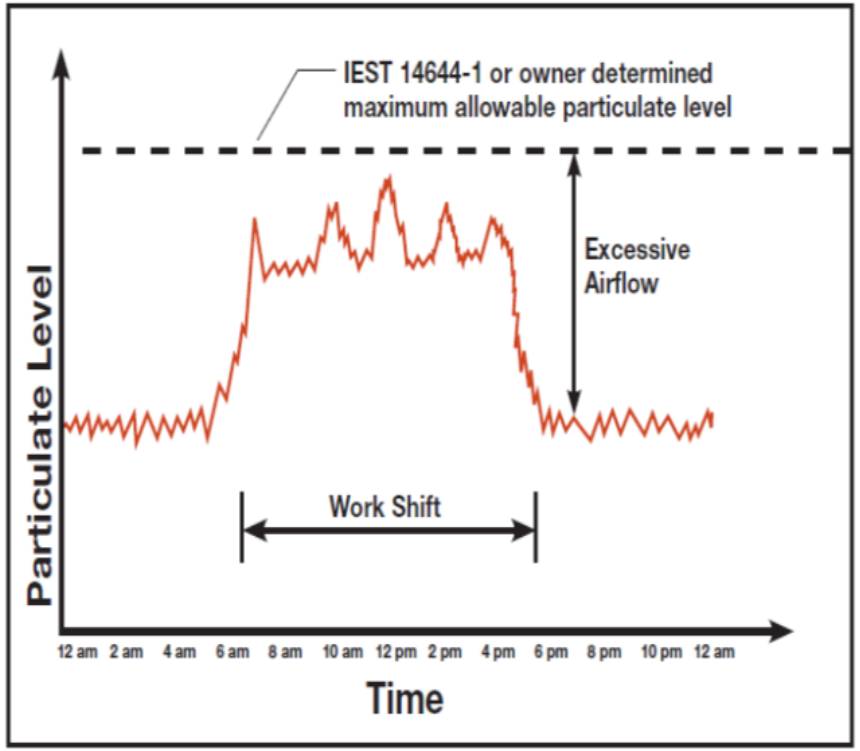


FIGURE 1. Cleanroom particulate levels with constant airflow.

Demand Control Ventilation

- Example: normal operation is 1,000 CFM airflow can be reduced to 750 CFM.

$$P_2 = P_1 (750/1{,}000)^3$$

$$P_2 = 0.42\ P_1$$

A 25% reduction in airflow saves 58% in energy.

Demand Control Ventilation

To ensure stable cleanroom space pressurization during variable supply and return airflow and to determine the minimum supply and return airflows based upon cleanroom configuration and HVAC system capabilities. The testing will include:

- Determining the total space infiltration or exfiltration airflow.
- Determining the minimum cleanroom supply and return airflows that will maintain the space-pressurization set point.
- Observing the cleanroom static-pressure stability during modulating airflows.
- Tuning supply and return airflow rate-of-modulation to keep the cleanroom static pressure near set point.

Supply Air Calculations

- There is Extensive Cleanroom Testing Data that Many Cleanrooms are Operating at Cleanliness Classification Levels Cleaner than Designed. ISO 8 Cleanrooms were Testing Out at ISO 7 or ISO 6.
- The Air Change Rate Tables Lack the Ability to Include All the Necessary Variables to Accurately Determine the Required Cleanroom Air Change Rate.

ISO Class	Air Changes Per Hour	Ceiling Coverage
ISO 1	500-750	80-100%
ISO 2	500-750	80-100%
ISO 3	500-750	60-100%
ISO 4	400-750	50-90%
ISO 5	240-600	35-70%
ISO 6	150-240	25-40%
ISO 7	60-150	15-25%
ISO 8	5-60	5-15%

Supply Air Calculations

- And More Important than Air Change Rate, the HVAC System Design has a Substantial Impact on Containing and Removing Contamination within a Cleanroom. There are Two Calculations that will Determine whether a Cleanroom will meet its prescribed Cleanliness Classification. They are:
  - Air Change Effectiveness (ACE)
  - Contamination Removal Effectiveness (CRE)

Supply Air Calculations

- Air Change Effectiveness (ACE) Index is Defined by ANSI/ASHRAE 129 – 1997 as the Relation between Nominal Time Constraint and Age of Air at a Specific Location.

- $$ACE = \frac{\text{Air Change Rate at Measuring Location}}{\text{Overall Air Change of Cleanroom}}$$

- With Perfect Air Mixing, the ACE Index is 1. If Less Clean Air than Average, the ACE Index will be Below 1. If More Clean Air than Average, the ACE Index will be Above 1.

Supply Air Calculations

- Contamination Removal Effectiveness (CRE) Index is the Effectiveness of Supply Air in Diluting Particle Contamination and is Calculated as follows:

- $$CRE = \frac{\text{Concentration of Contamination at Exhaust}}{\text{Average of Concentration in Cleanroom}}$$

- With Perfect Air Contaminant Removal Effectiveness, the CRE Index is 1. The Lower the CRE is Below 1, the Less Effective the Contaminant Removal is.

Supply Air Calculations

The Important Information that Needs to be Collected to Perform the Supply Air Calculations are:

- Particulate Generation Sources and Generation Locations
- Particulate Generation Rate and Variability
- Generated Particulate Sizes
- Cleanroom Configuration (H x W x L)
- HVAC System Design, Filtration, and Humidification
- Cleanroom Supply Air and Return Air Configuration

Supply Air Calculations

What are **Sources** of Particulate Generation

- People, Activity Level, Movement Types
- Extent of Gowning
- Type of Gowning Materials
- Cleaning Products
- Raw Materials/Products
- Consumables (Wipes, Paper)
- Operating Equipment

Supply Air Calculations

What are **Sources** of Particulate Generation

- Surface Area of Ceiling, Walls, and Floors
- Type of Ceiling, Walls, and Floor Finishes
- Infiltration from Adjoining Spaces
- Packaging (Bags, Tapes, Adhesive)
- Utilities (Compressed Air, Water, Gases)
- Doorways, Pass-Thru, Openings
- Outdoor Make-up Air

Questions?

Thank you for your attention!

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Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

Pier Angelo Galligani, Techniconsult Firenze

Andrea Daviddi, Techniconsult Firenze

30 – 31 MARCH 2026
BRDO PRI KRANJU, SLOVENIA

INTRODUCTION – Speaker Presentation

Pier Angelo Galligani

President and Co-founder of Techniconsult, a group of companies supporting the Life Sciences industry from design to maintenance.

techniconsult group

Education & Experience: Holds an MSc in Mechanical Engineering with over 40 years of industry experience.
Core Expertise: Specializes in HVAC applications, pharmaceutical processes and plants, clean systems, contamination control, and validation.
Industry Engagement: Active member of technical societies including UNI, AICARR, ASHRAE, ISPE, AFI, and PHSS.
Key Leadership Positions: Former President of ASCCA (Italian Cleanroom Society) and Italian delegate to ISO/TC 209 WG13 (energy efficiency in cleanroom) and WG4 (cleanroom Design, Construction and start-up).

Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

Pier Angelo Galligani, Techniconsult Firenze

INTRODUCTION – Speaker Presentation

Andrea Daviddi

CDE Manager for Techniconsult Group

techniconsult group

Role & Experience: over 20 years of experience between digital design, engineering, and new technologies.
Technical Background: Computer science, workflow optimization, data management, BIM.
Key Achievement: Led the transition to ISO 19650–compliant Common Data Environments.
Project Scope: CDE management, R&D support and digital tool integration for complex industrial and biotech projects.
Strategic Focus: Drives digital transformation from design to execution, standardizing processes and enabling scalable technology adoption.

Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

Pier Angelo Galligani, Techniconsult Firenze

INTRODUCTION – Foreword (1/3)

Why do we talk about Engineering Controls and Smart HVAC Design?

- **Today's projects** are increasingly **complex**, **innovative**, and **demanding** in terms of both **schedule** and **cost**.
- In addition to **performance** and **regulatory compliance**, **environmental sustainability** is becoming a key challenge, as many projects involve **significant energy consumption** and use of **natural resources**.
- As a result, design **risks increase**, making it essential to adopt **tools capable of controlling**, **mitigating, or eliminating them** — the so-called **engineering controls**.

INTRODUCTION – Foreword (2/3)

- We will briefly review the evolution of these approaches, highlighting **both innovative and established technologies** that share a **common objective**:
  anticipating real operating conditions and **reducing project risks**, thus enabling "**smart projects**".
- Practical examples will be presented in the design of **new facilities** and controlled-contamination GMP environments.
- Many of these techniques can also provide significant benefits for **existing facilities**, when applied to optimization activities (i.e.: process simulation*, energy simulation*, CFD) or to troubleshooting (i.e.: CFD).

* While not covered in today's presentation due to time constraints, it remains a relevant concept in smart design.

INTRODUCTION – Foreword (3/3)

AUTODESK Forma

In 2021 Techniconsult transitioned to Autodesk Forma (former Autodesk Construction Cloud) as its main project information management platform.
It was chosen for the flexibility given by the integration with Revit and third party applications through its APIs.

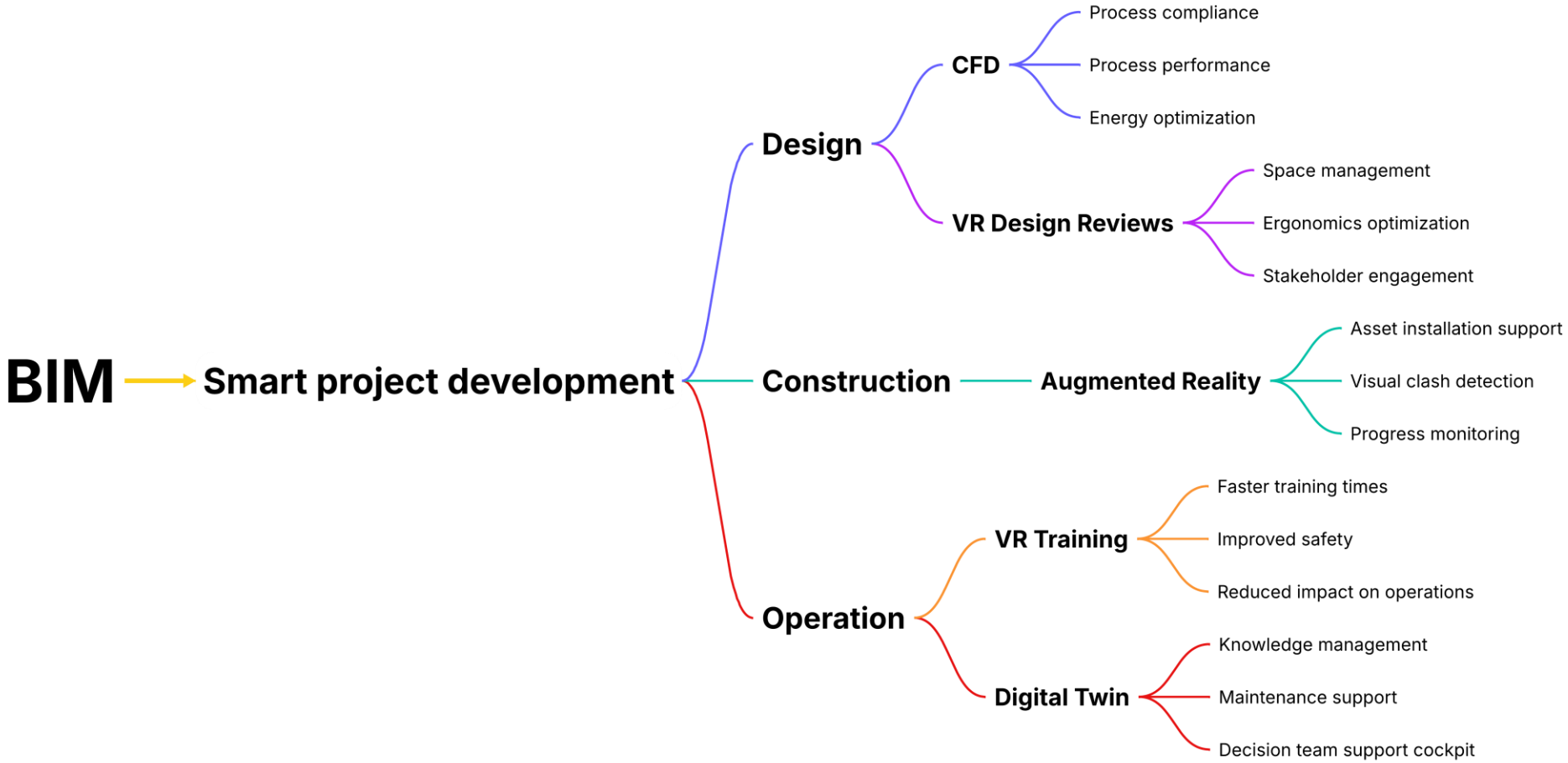
GAMMA AR

Augmented Reality software leveraging the Autodesk APIs for two way data comunication.
Models can be updated in mere seconds, progress data and issues are syncronized with the platform.

Workshop XR

Virtual Reality software developed internally by Autodesk, used for VR Design Reviews.
A review session can be created instantly and issues created are syncronized with the platform.

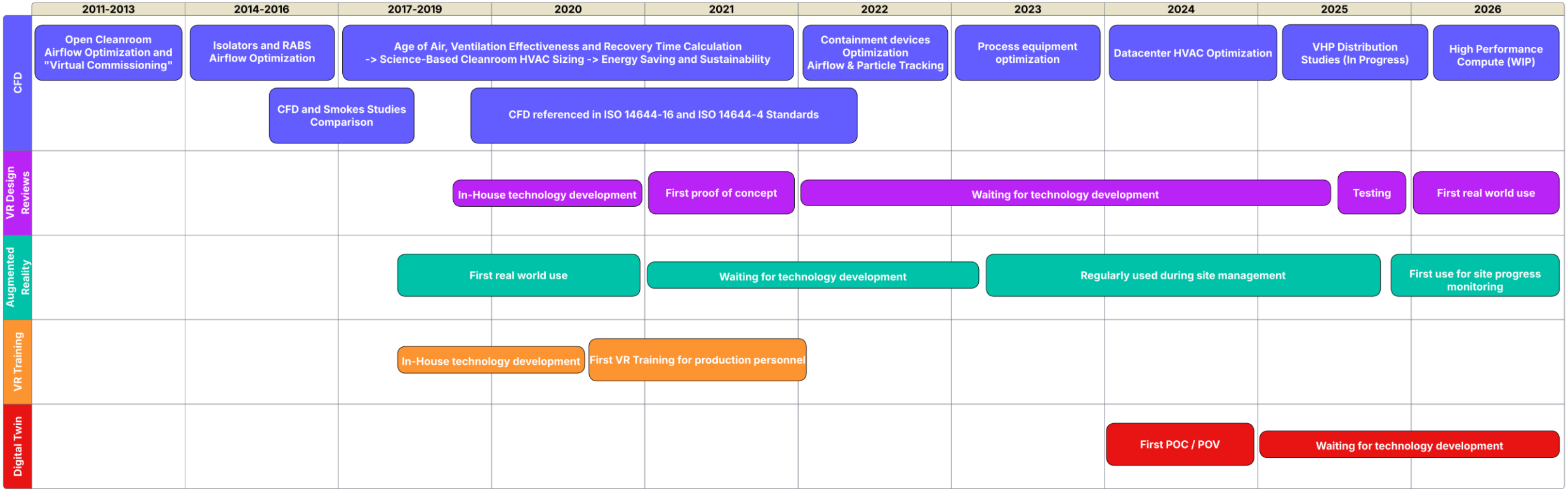
INTRODUCTION – Smart Project development



Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

Pier Angelo Galligani, Techniconsult Firenze

INTRODUCTION – Technology Adoption Timeline



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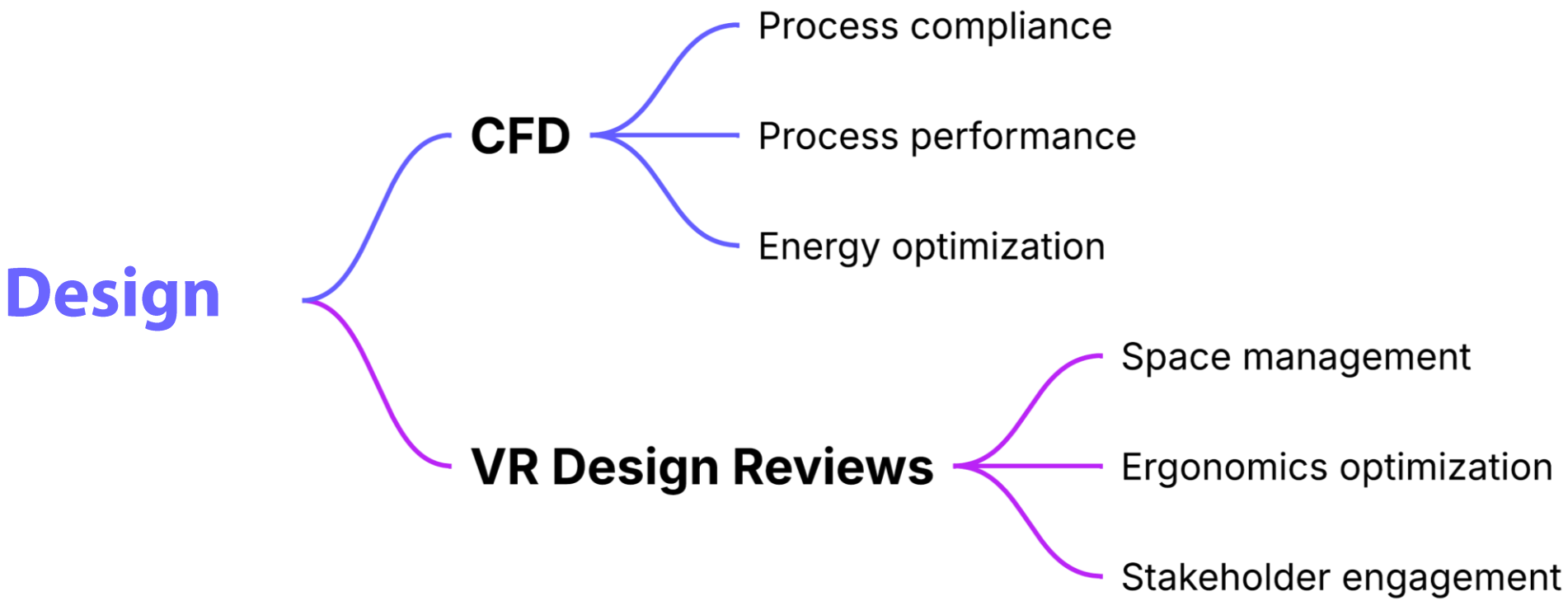

Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

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COMPUTATIONAL FLUID DYNAMICS – General (1/3)

CFD and cleanroom technology

- **CFD** was adopted within the company many years ago; its strong potential and wide range of applications quickly recognized internally → **creation of a dedicated in-house SME team** and use of multiple simulation software tools.
- End clients are strongly interested and often **drive CFD adoption in major and highly complex projects**.
- Like **VR**, **CFD** (and other simulation techniques, i.e. **process and energy simulation**) enable early prediction of system behavior and performance, allowing critical issues and design errors to be identified before construction, thus avoiding costly and time-consuming corrections during the execution phase.
- **Application of CFD at design stage** gives detailed information on airflow patterns inside the cleanroom, allowing to optimize the design and to **achieve more effective and efficient installations**

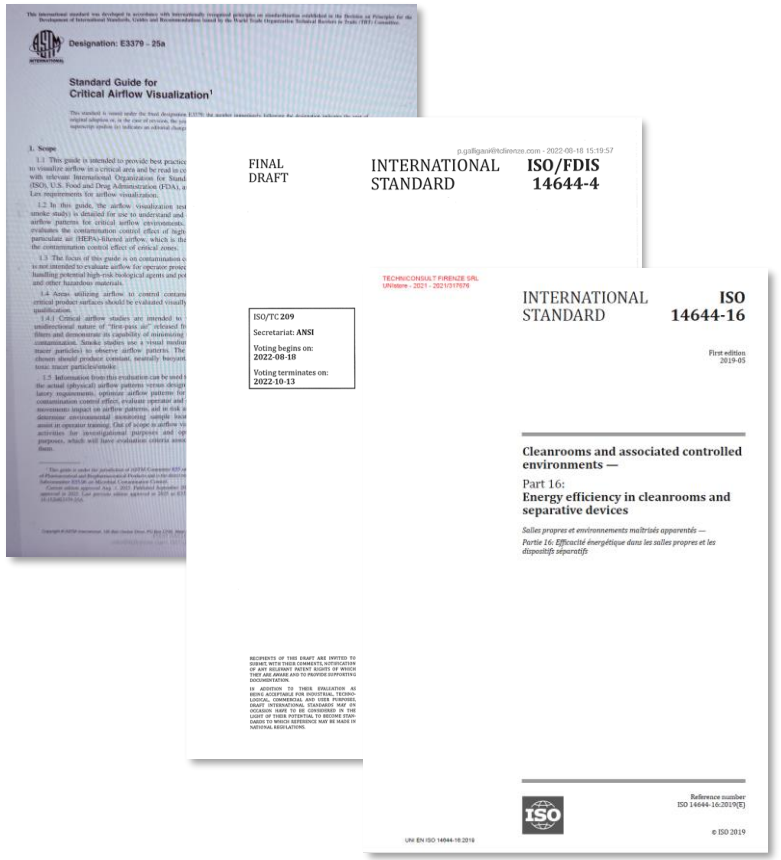
COMPUTATIONAL FLUID DYNAMICS – General (2/3)

- **CFD enables the identification of areas with poor cleanroom performance** (i.e.: areas with low **Ventilation Effectiveness (ε)** values, no flux, high/low air velocity, unidirectional airflow disrupted by eddies, backflow from less-clean areas to cleaner ones, possible " first-air " contamination before it reaches the areas to be protected, etc.).
- **CFD enables the modeling of contamination sources at "worst case" locations** in order to assess their impact on critical locations for the process (**particle tracking technique**).
- **CFD** simulations can help obtain the **optimal selection and location of diffusers and return-air grilles/airwalls** by predicting the **airflow patterns** and calculating the **Ventilation Effectiveness in critical areas.**
- The following slides present selected **CFD** application examples that **helped guide the design of cleanroom projects** in the life sciences sector, **ensuring GMP compliance**, **improving performance and reducing energy consumption**.

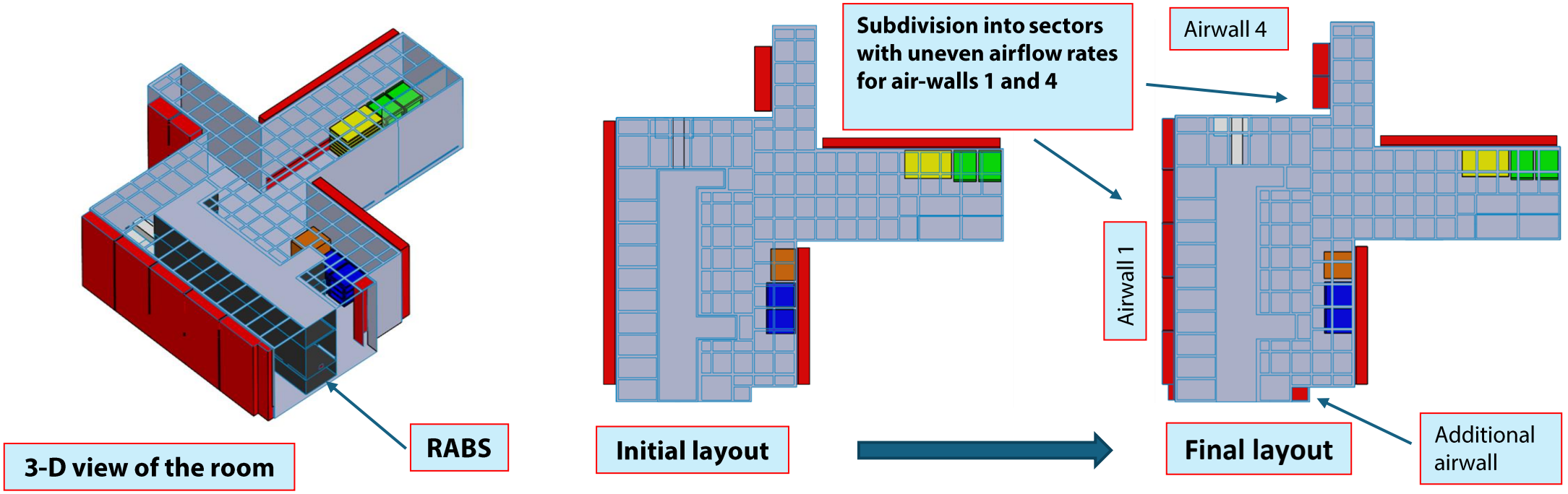
COMPUTATIONAL FLUID DYNAMICS – General (3/3)

CFD in the technical standards: some examples

- **ISO 14644-16**. Initially, strong resistance emerged against including **CFD** in the standard, due to concerns it might become a regulatory requirement and because its cost was (incorrectly) perceived as excessive. The final version of the standard nevertheless includes several useful references to its application.
- **ISO 14644-4.** In the last revision of the standard, the importance of **CFD** use was clearly recognized and significantly more space was dedicated to describing its benefits in cleanroom technology.
- **ASTM - E3379 - 25a**. The most recent standard on smoke studies in critical environments describe **CFD** as an useful **DQ** tool to anticipate and resolve potential design issues, while emphasizing the importance of the verification of the model and that only (in situ) real smoke studies can support **GMP** process validation. **CFD** application for existing CR is also mentioned.

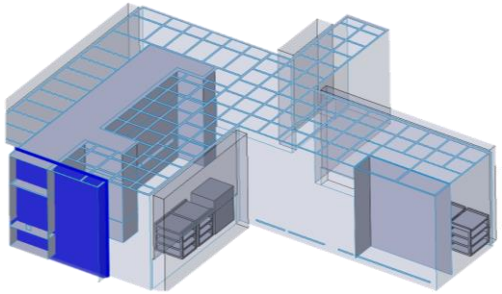


CFD – Example #1 – ASEPTIC FILL-FINISH LINE INSIDE AN OPEN RABS - (1/4)

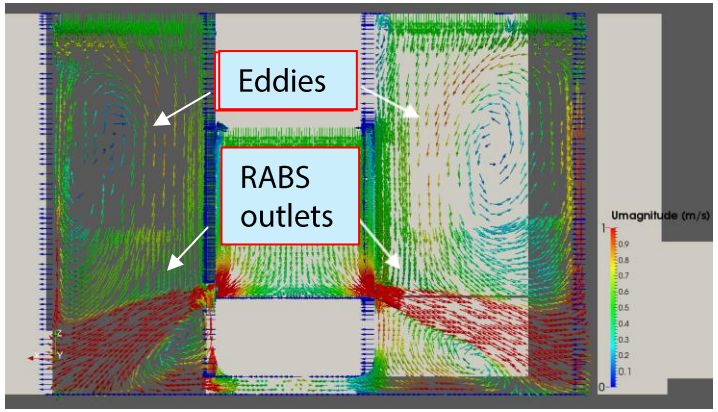


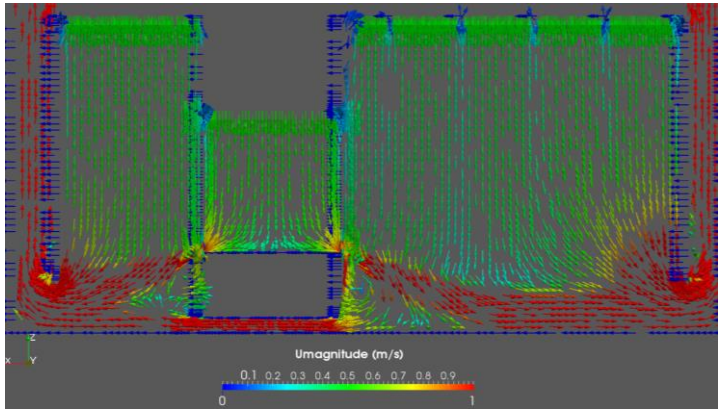
- Aseptic filling line inside an open RABS, room ceiling with HEPA filter full coverage
- **Problem:** high quantity of air coming from the RABS and the HEPA ceiling to be returned to the HVAC system → preliminary CFD analysis of airflow patterns inside the room → **difficulty to balance the system, risk of eddies**
- **Corrective actions and optimization** of flows via the introduction of an additional air-wall and the sectorizing of two air-wall → **virtual balancing of the return airflow rates**

CFD – Example #1 – ASEPTIC FILL-FINISH LINE INSIDE AN OPEN RABS - (2/4)



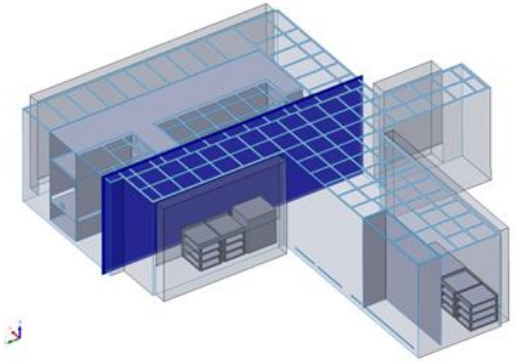
Cross section 1





Before corrective actions

After corrective actions



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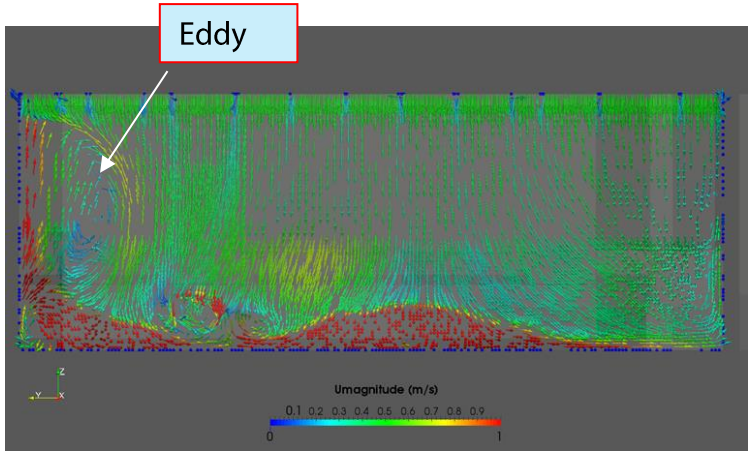
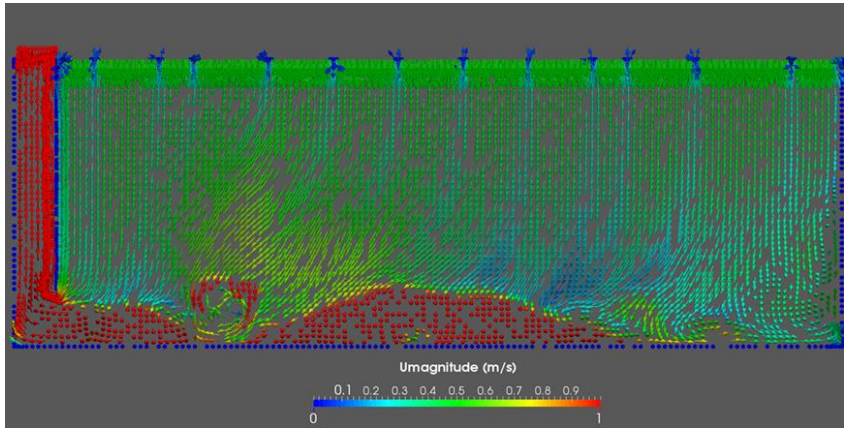
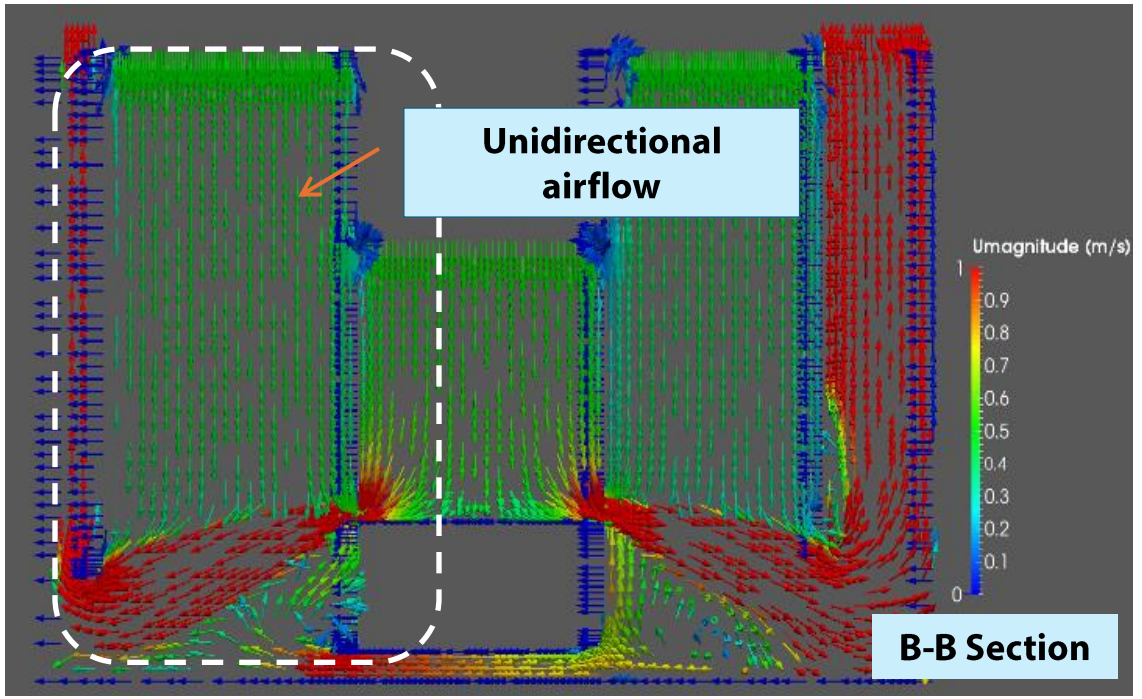




Computational Fluid Dynamics

CFD – Example #1 – ASEPTIC FILL-FINISH LINE INSIDE AN OPEN RABS - (3/4)

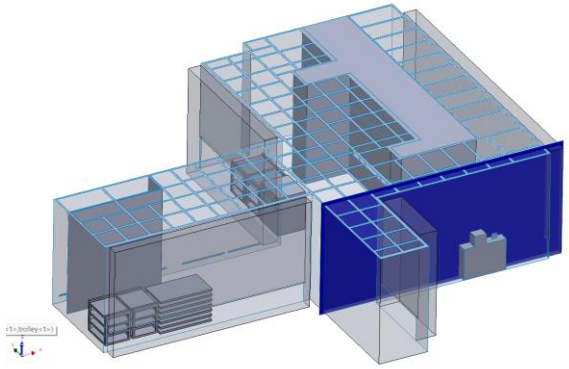
Smoke-test



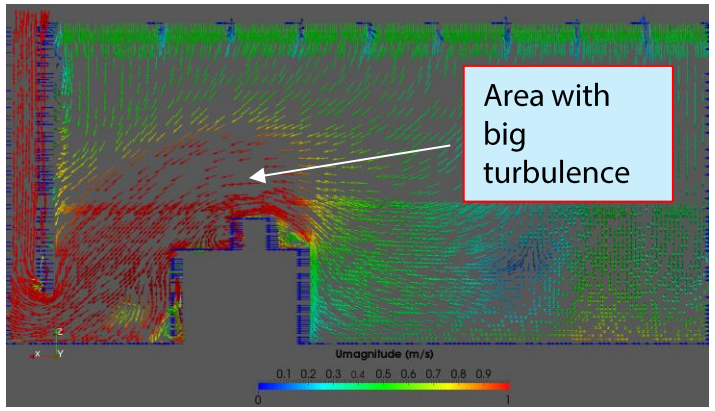
CFD output (after optimization)

Good agreement between CFD simulation and smoke studies later conducted in the field

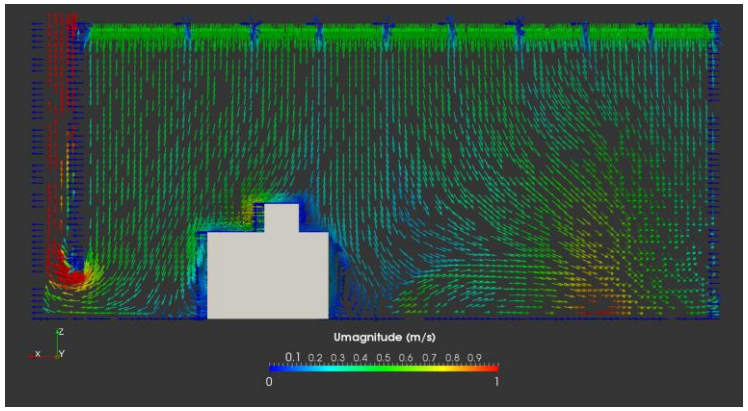
CFD – Example #1 – ASEPTIC FILL-FINISH LINE INSIDE AN OPEN RABS - (4/4)



Cross section 3



Before corrective actions



After corrective actions

- **In general:** airflow patterns after corrective actions are more even
- **Eddies** shown in the sections 1,2 &3 are eliminated and unidirectionalty of air flow is much more present in the room space → risk of back flow from floor level to critical areas (staging areas, open RABS outlets and mouse-hole) is reduced

CFD – Example #2 – FACILITY FOR BIOLOGICAL-BASED INJECTABLES - (1/3)

- **New pharmaceutical facility for the manufactucturing of biological-based injectable products**. Green field project with extensive use of simulation techniques (process simulation, dynamic energy simulation, computational fluid dynamics (CFD))
- **CCS strategy** → Adoption of a barrier-technology scheme for **critical process equipment** (**isolators** for filling line and F.D. ALUs, **open RABS** for capping machines and other critical equipment)
- **Reduction by design of supply airflow rates** in GMP grade-C areas in operation and further reduction at rest based on analytical calculations (according to: ISO 14644-4, ISO 14644-16) and with support of CFD to **locally** assess **ventilation efficiency** and **recovery time** values
- The adopted design strategy allows an **averaged reduction in the supply airflow rate ranging from 17% to 50%** (in-operation and at-rest conditions, respectively) when **compared with a typical reference value** obtained by applying the old (and incorrect) rules of thumb based on the average hourly air change rate (30 ACH)

CFD – Example #2 – FACILITY FOR BIOLOGICAL-BASED INJECTABLES - (2/3)

Optimization of air distribution in the Filling area

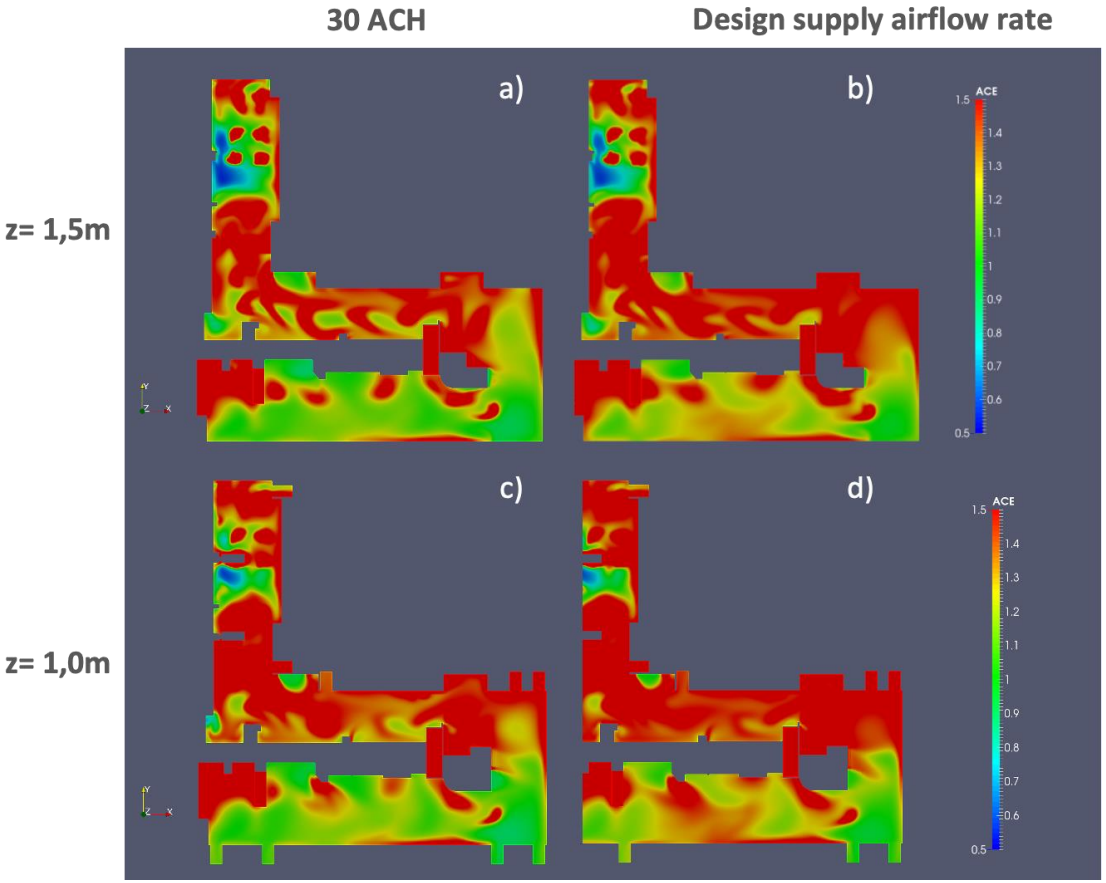
Local Ventilation Effectiveness (ε) contours at sections representative of working planes

- No substantial change in the ε value trend is observed in the design configuration (*)
- Lowest ε values due to geometrical reasons and technical constraints on diffusers' location
- **(*) Ventilation Effectiveness (ε) value expressed in terms of Air Change Effectiveness (ACE)**

Air Change Effectiveness

$$\varepsilon = ACE = \frac{ACH}{ACH_{tot}}$$

- ACE = Air Change Effectiveness [-]
- ACH = Air Change Rate at measuring location [s^{-1}]
- ACH_{tot} = overall average Air Change Rate of cleanroom [s^{-1}]

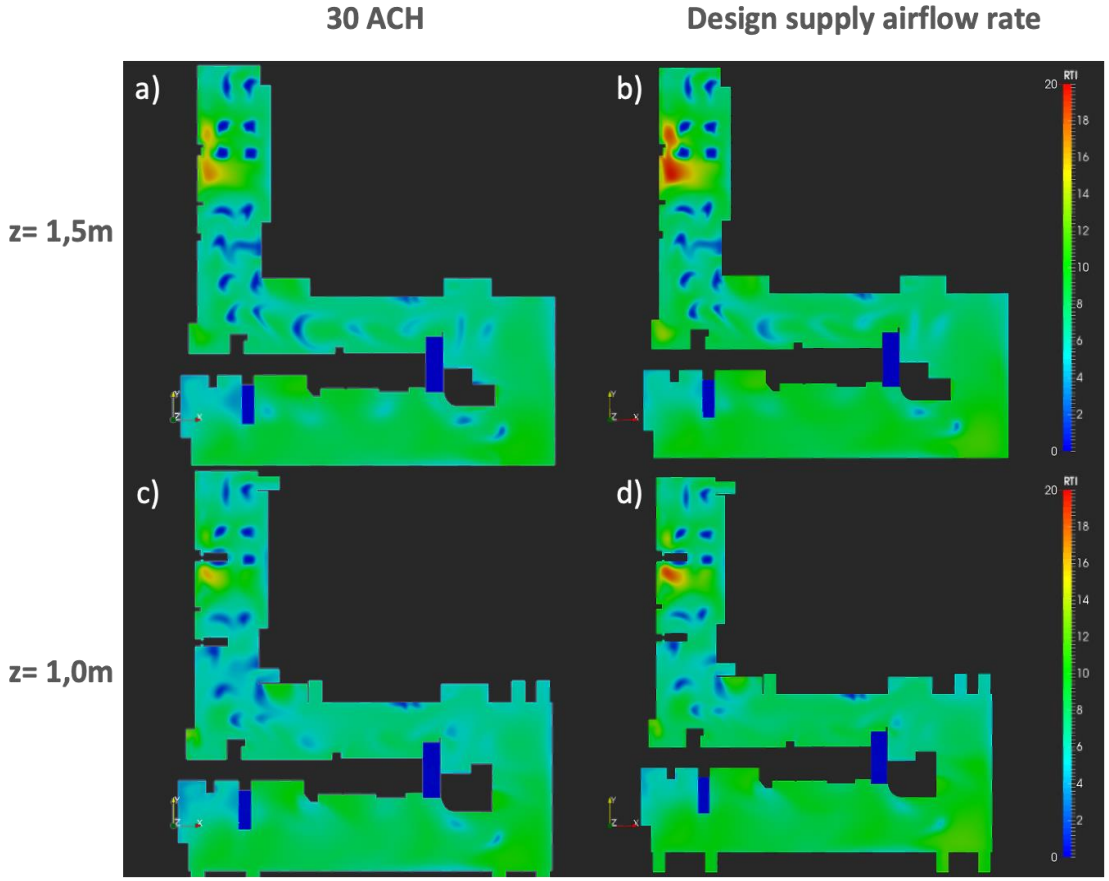


CFD – Example #2 – FACILITY FOR BIOLOGICAL-BASED INJECTABLES - (3/3)

Optimization of air distribution in the Filling area

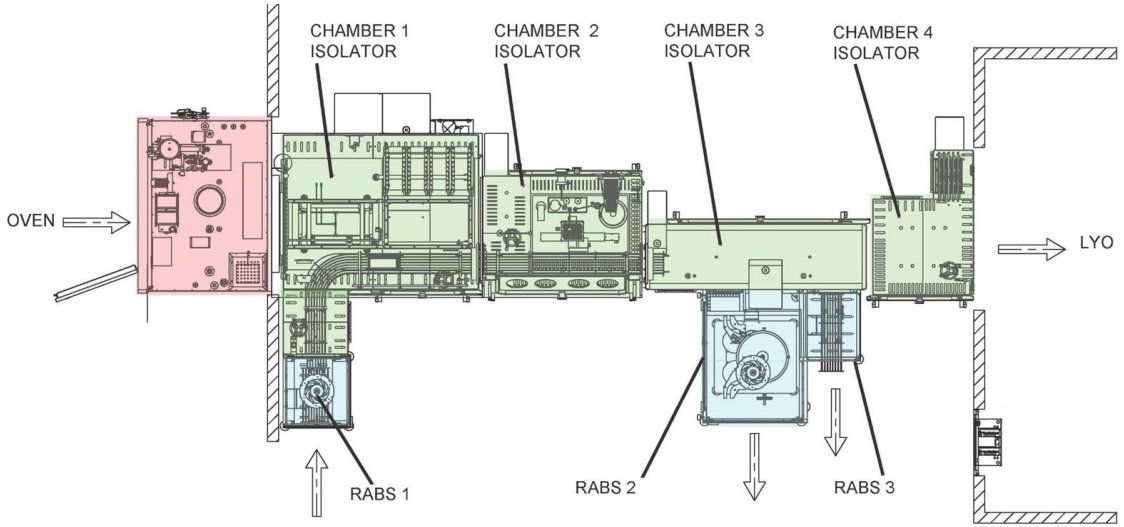
Local Recovery Time contours at sections representative of working planes

- **Low mean RTI values** for both the configurations
- Blue rectangles represent open RABS with full HEPA filter converage
- Highest RTI values due to geometrical reasons and technical constraints on diffusers' location
- The (expected) increase in RTI values @ the design configuration, is limited and **air distribution uniformity is not affected**



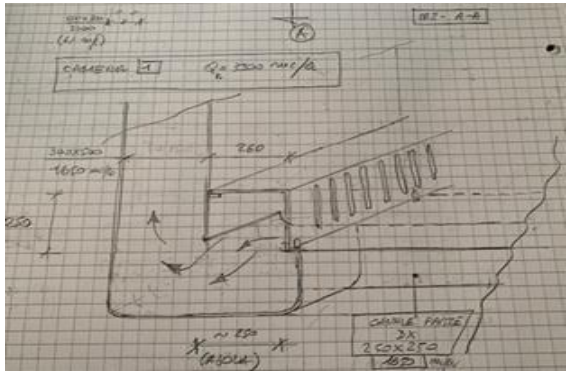
Recovery Time $\quad t_{0,01} = 4{,}6\,\frac{1}{\varepsilon\, ACH}$

CFD– Example #3 – ASEPTIC FLEXIBLE-FILLING LINE INSIDE AN ISOLATOR (1/4)

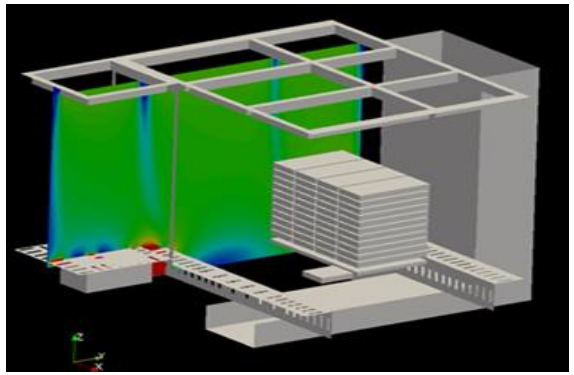


- **Aseptic flexible-filling line** inside a 4-chambers isolator, connected with a depyrogenation oven, a freeze-dryer, a vial capper (inside RABS N.2); RABS N.1 and N. 3 for loading/unloading of vials and syringes in TUBS
- **Flexibility:** manual handling of TUBS and bulk-vial frames on rails (through gloves), different product containers (ready to use vials, ready to be sterilized vials, ready to use syringes) – Liquid or lyophilized products
- **CFD has been used extensively** to support/improve the aerodynamic design of the isolator chambers (vials/syringes buffer, filling, discharge to capper/discharge of TUBS, buffer for freeze-dryer) and to verify the correctness of airflow @interfaces with the three RABS (**mouse holes**)

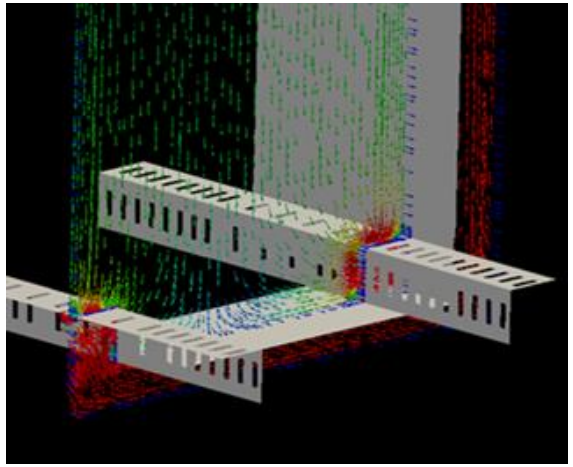
CFD– Example #3 – ASEPTIC FLEXIBLE-FILLING LINE INSIDE AN ISOLATOR (2/4)



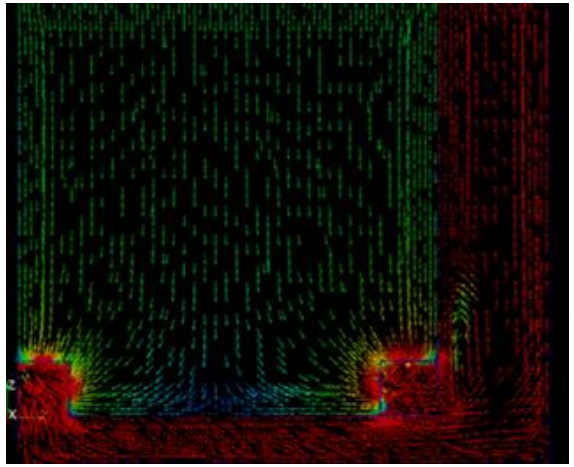
Preliminary sketch of return ducts



3-D model of the chamber N. 1

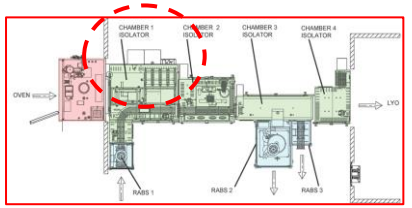


Detail of airflow around final return ducts

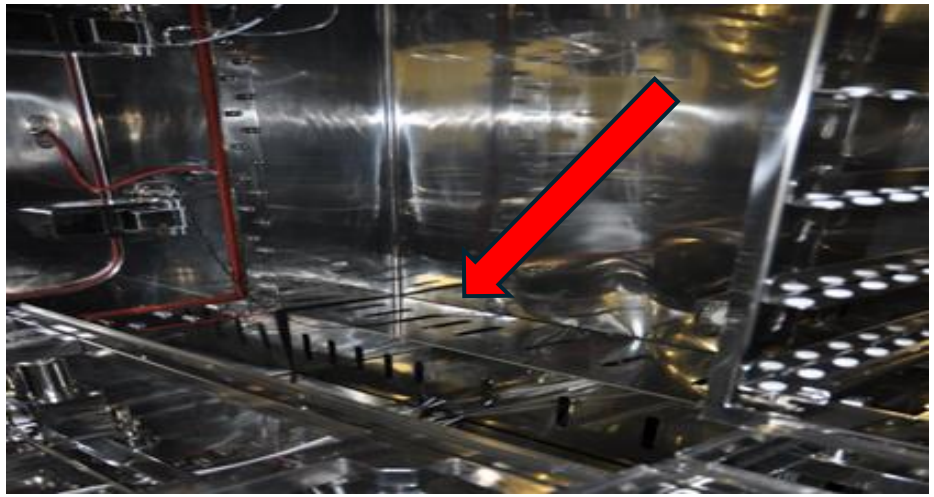


Airflow in chamber N. 1: cross section

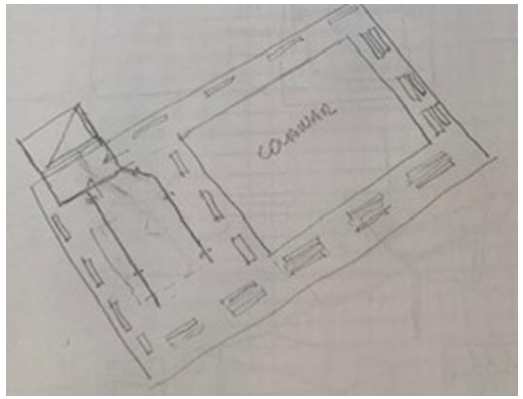
CHAMBER N.1 – BUFFER



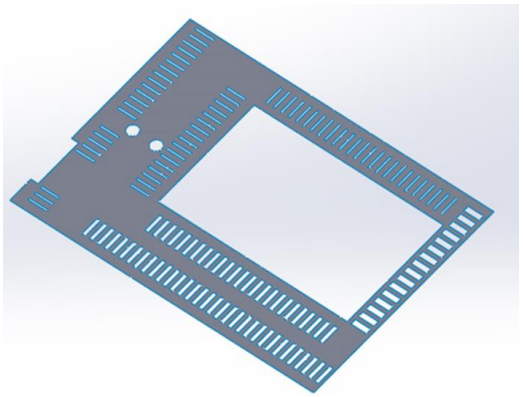
- CFD was used to optimize the suction slots on the removable return ducts
- Simulations were executed with and without load inside the chamber
- CFD outcomes showed a pretty unidirectional airlow distribution



CFD– Example #3 – ASEPTIC FLEXIBLE-FILLING LINE INSIDE AN ISOLATOR (3/4)

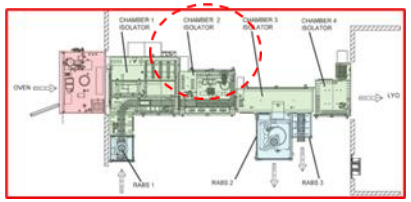


Preliminary sketch of suction slots on the filling section baseplate

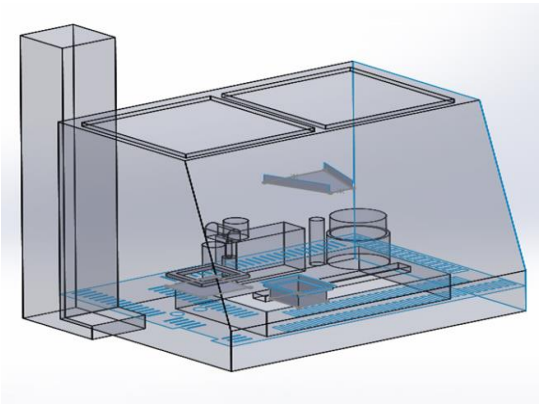


Final layout **of suction slots**

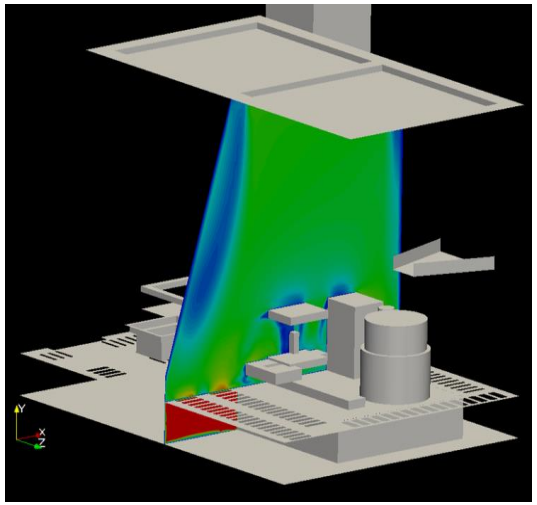
CHAMBER N.2 – FILLING



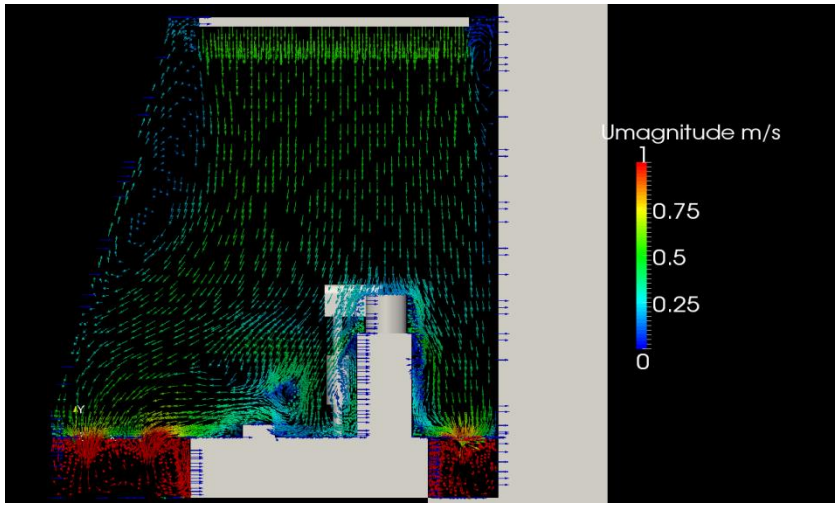
- CFD was used to optimize the suction slots of the filling section base-plate and to verify the influence of the sloped front screen on the airflow inside the chamber
- CFD outcomes showed a good protection of critical areas (filling head, stopper hopper&bowl, TUBS station, etc)



3-D model of the chamber N. 2

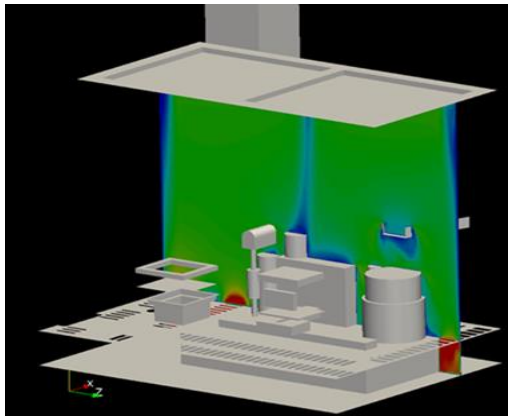


3-D model of the chamber N. 2

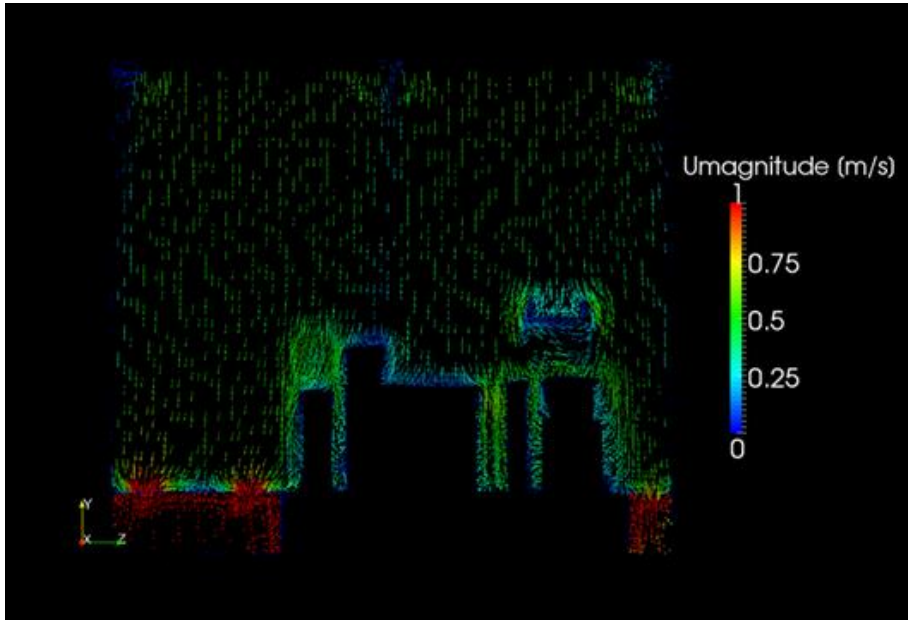


Airflow vectorial distribution in chamber N. 2: cross section

CFD– Example #3 – ASEPTIC FLEXIBLE-FILLING LINE INSIDE AN ISOLATOR (4/4)

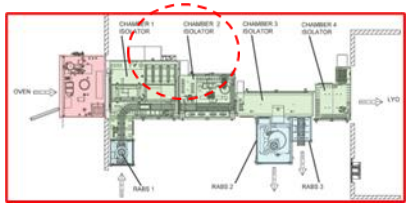


3-D model of the chamber N. 2



Airflow vectorial distribution in chamber N. 2: longitudinal section

CHAMBER N.2 – FILLING



Airflow vectorial distribution showed a unidirectional distribution also along a longitudianal section of the chamber ; we can expect a good protection of critical areas

VR Design Review – Stakeholder Engagement

- **History of Project Visualization**
  From 2D Layouts to a scale models, from 3D renderings to video walkthrough, the objective was to give more intuitive ways to visualize the end results of a project.

- **Stakeholders Engagement**
  An immersive experience relieves from the effort needed to transpose a 2D or 3D image to reality so the stakeholders can focus on what's important: evaluate if the project matches their vision.

- **Agile Project Development**
  Regular project updates, coupled with clear previews of the expected results, promote a collaborative environment with the client. This ensures that once the project is completed, the end result aligns with their requirements.

Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

Andrea Daviddi, Techniconsult Firenze

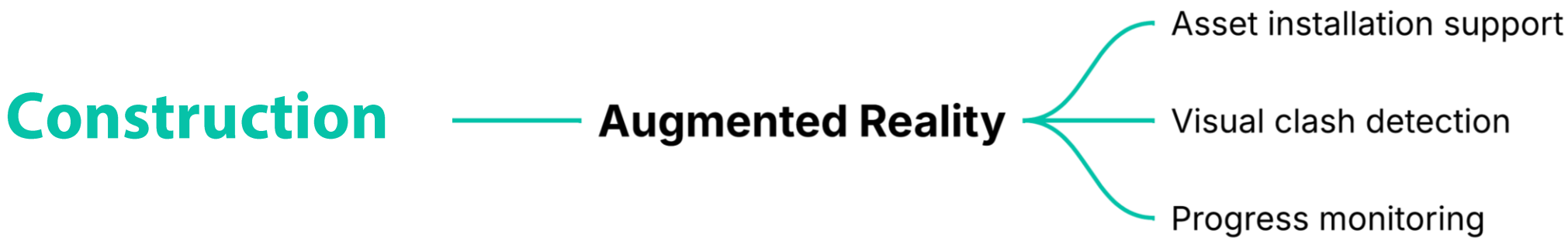
VR Design Reviews

VR Design Review – Ergonomics Optimization & Space Management

- **The Importance of Ergonomics Optimization**
  Ergonomics optimization is so vital that equipment suppliers often make a mockup 1:1 scale to simulate and optimize operations. This wouldn't be possible to achieve at building scale.
  A VR Design Review is inexpensive and people from all around the world can join without the need for travel.

- **Chinese Factory and American Office**
  In China, one of our clients failed to account for the average height of the Chinese population when building a laboratory. This forced them to construct steps in front of the laminar flow hoods to allow for proper operation. In the United States, they encountered the opposite problem with office desks due to the taller average American population.
  A single VR Design Review could have prevented both scenarios.

- **Facility-Scale Simulation**
  Personnel, material and process flows can be simulated to optimize layouts and processes for compliance checks and identifying potential bottlenecks, optimizing workflows to improve efficiency.



Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

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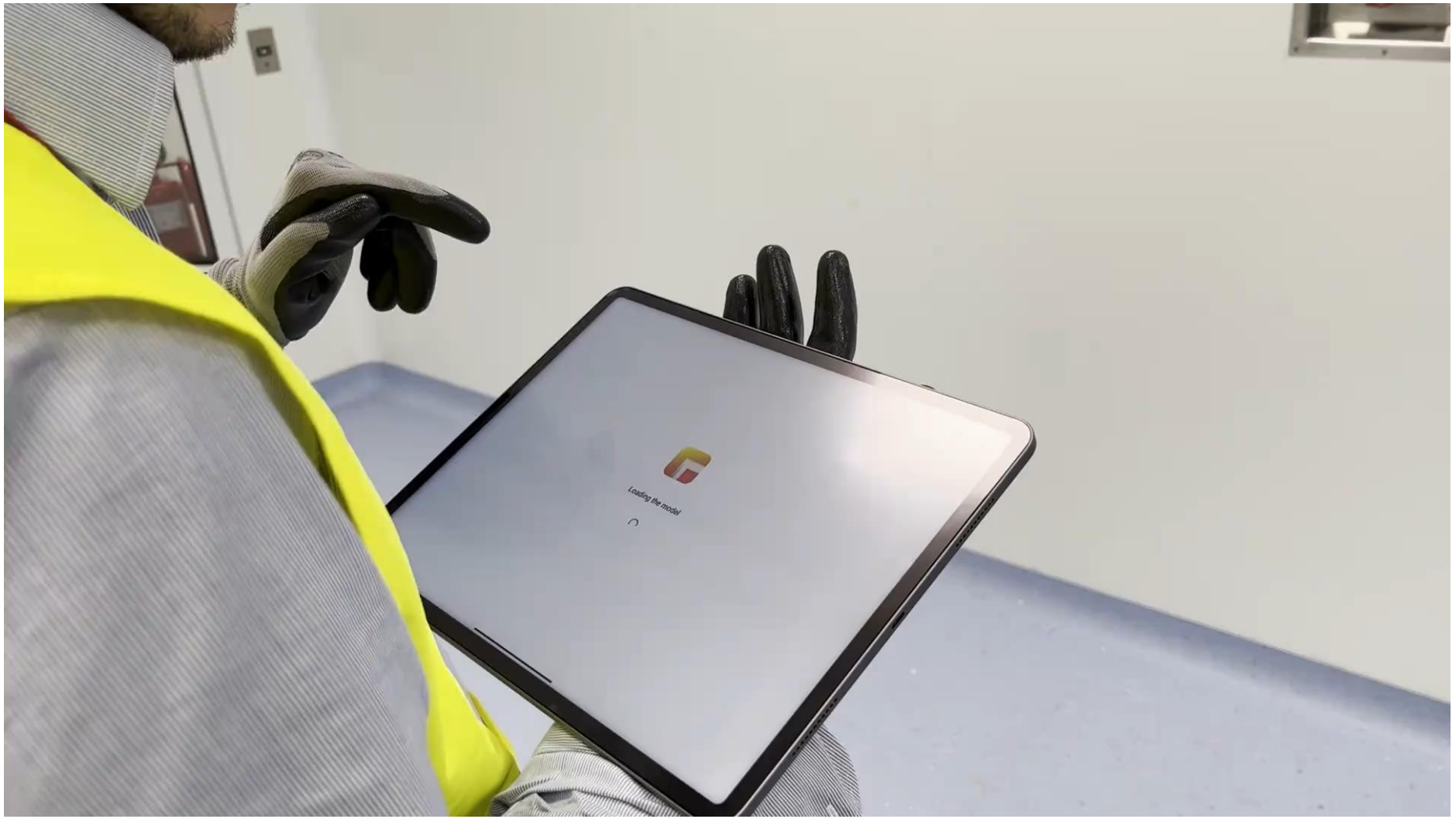

Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

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Augmented Reality

Augmented Reality

- **AR Visualization of BIM Models**

  AR devices enable teams to see digital BIM models superimposed onto reality for enhanced visualization of the construction site elements.

- **Contextual Design Understanding**

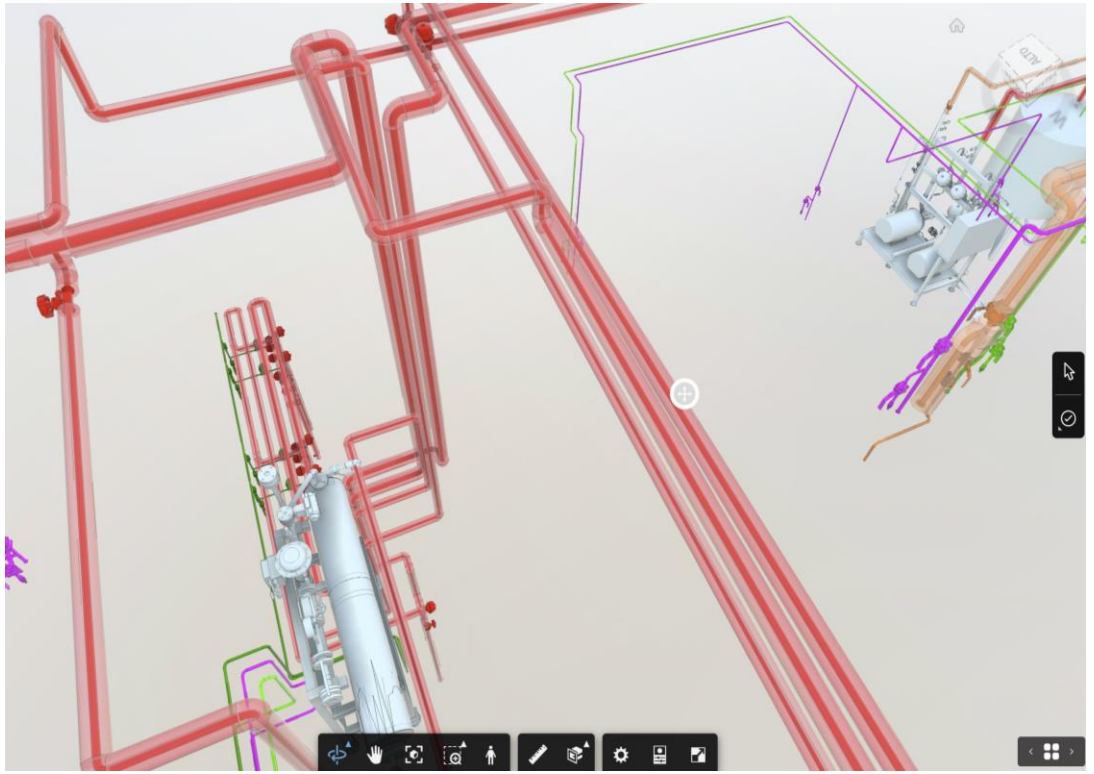
  Overlaying design elements in the physical environment helps teams understand spatial allowances and prevents unwanted collisions.

- **Early Discrepancy Identification**

  AR projections help identify discrepancies between design and construction at an early stage, reducing possible future rework.

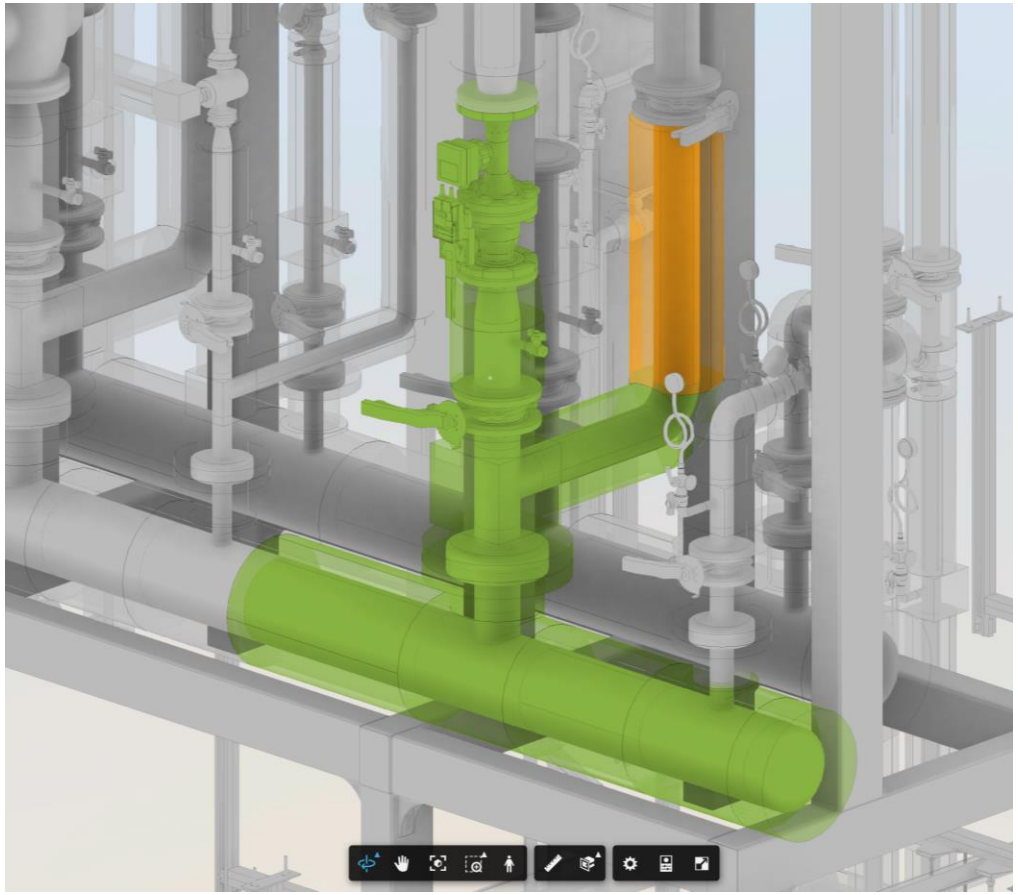
Augmented Reality – Asset Data Acquisition

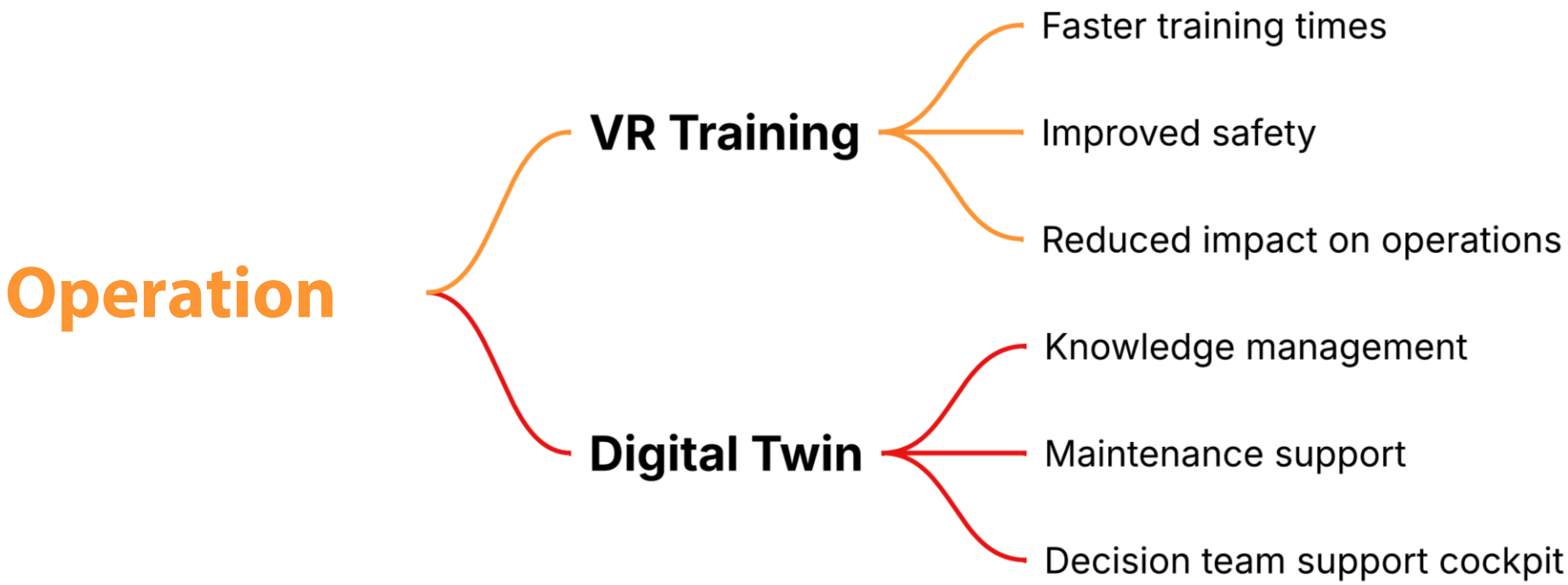
- **Progress Monitoring**
  AR devices are used during field inspections to select elements and update their construction status (built, not built, needing rework).
- **Creating Issues**
  Site supervisors can easily point out observed issues, append photos, assign tasks and add descriptions without leaving the AR application.
- **Always connected**
  Progress and issue data are automatically syncronized with the CDE so that every player has access to the latest information and follow-up can be managed off-site.



Augmented Reality – Asset Data Fruition

- **Asset Data Availability**
  Data collected through AR visualization software is readily available online through «color coded» lists and 3d Model.
- **Legacy Export**
  At the moment data is exported in csv format to be imported in excel sheets for progress monitoring.
- **Future Developments**
  We are currently integrating other dedicated tools, part of the CDE platform, linking Assets to Timeline, Submittals and Change management.





Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

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Anticipating the reality through modeling: VR, AR, CFD and Digital Twin technologies

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VR Training

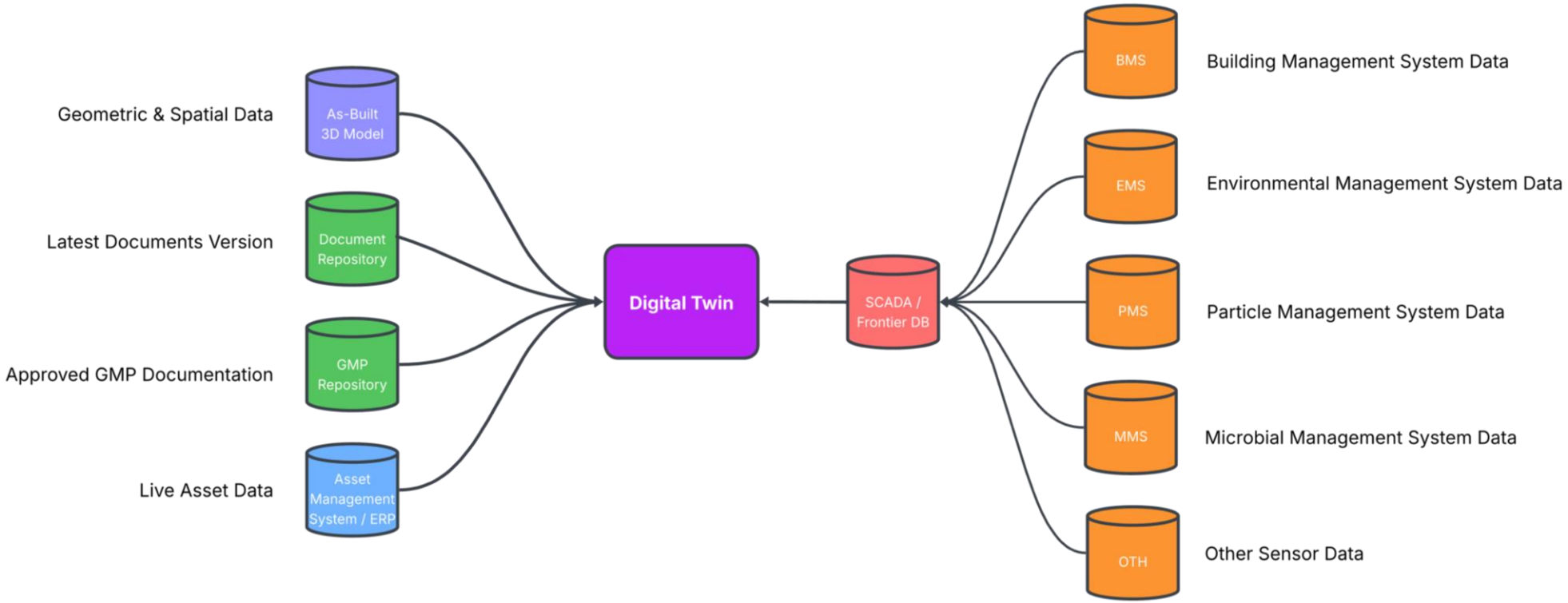
VR Training

- **Shorter Training Programs**
  VR training significantly accelerates onboarding and skill development for pharmaceutical production staff. Our clients have reported a **50% reduction** in training time compared to traditional methods, enabling employees to achieve proficiency more rapidly and improve overall production efficiency sooner.
- **Improved Safety**
  VR provides a risk-free environment for safety protocol training within the pharmaceutical facility. By simulating hazardous scenarios, personnel can practice emergency procedures and learn best practices remotely, effectively eliminating safety risks while building muscle memory for critical responses.
- **Reduced Impact on Operations**
  Personnel can receive necessary training remotely without hindering or interrupting critical manufacturing processes – substantially reducing the impact on daily operations.

VR Training

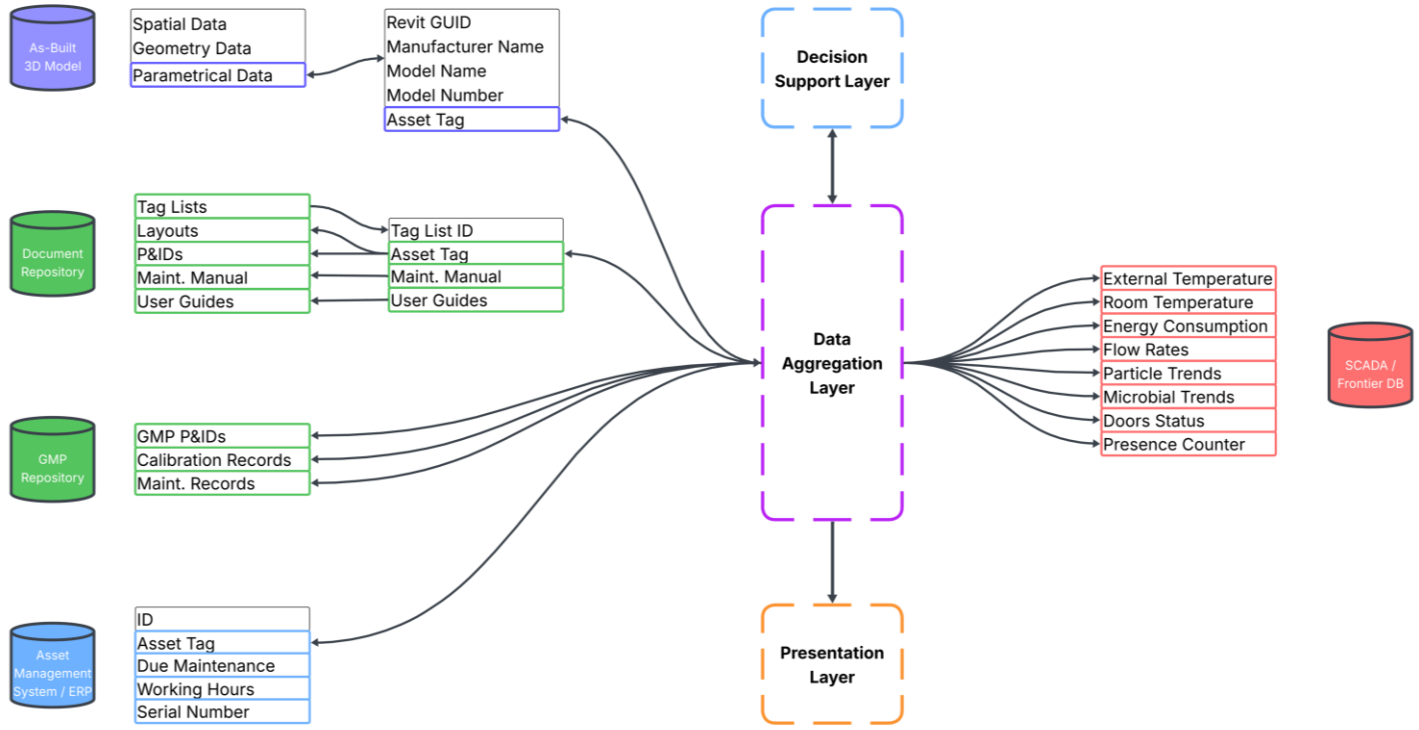
- **What happened after 2021?**
  Although Techniconsult's core business is EPC and EPCM, clients frequently request support for R&D activities ahead of the standard technological development at the time. The KPIs emerging from this experience have enabled clients to act early and establish partnerships with software development companies for subsequent implementations.

DIGITAL TWINS – Beyond the 3D Model (1/2)



- **As-Built 3D Model** is only the starting point.
- **Data Integration** is the key for a living Digital Twin.

DIGITAL TWINS – Beyond the 3D Model (2/2)



- An information graph is built connecting asset data coming different sources.
- Data must be coherent so the data linking process can be automated.

DIGITAL TWINS – Knowledge Management

- A digital twin helps knowledge management by capturing, structuring, and linking information about assets, processes, and their context into a single model.
- **Knowledge graph linking** represents entities and relationships explicitly so queries return contextually relevant items.
- **Preserves company knowledge** so expertise does not leave with people.
- **Speeds up problem resolution:** less time spent **looking for** data, more time spent **using** data.
- **Enables continuous learning** from past events through linked historical records.

DIGITAL TWINS – Maintenance & Decision Support

- **Maintenance Support**
  Augmented Reality can give maintenance personnel immediate, hands-free guidance by visually pinpointing components and overlaying step-by-step instructions. Contextual search tools present data coming from maintenance manuals, SOPs and past service records, relevant to the task and equipment state.
  Integrated access to P&IDs, safety checks, and part lists reduces diagnostic time and human error.
  This real-time, on-site knowledge delivery speeds up repairs, improves compliance and shortens training for new technicians.

- **AI and Decision Support Cockpit**
  Structured data within a Digital Twin lays the foundation for Artificial Intelligence applications. Future applications will integrate AI-driven control systems to manage dynamically adapt involved systems based on changing operative conditions.
  The most immediate scenarios are:
  1) The optimization of utilities production methods (gas fired boilers, heat pumps, etc.) based on load request, efficiency curves, climate conditions, energy source costs and other factors.
  2) Adaptive HVAC control with variable supply airflow rate, based on the current contamination source strength.

DIGITAL TWINS – Key Hurdles

- **High Implementation Costs & Unclear ROI**
  Digital twin platforms require cospicuous upfront investments in preparation, pre-project assessments and data engineering.
  Today companies can hardly justify significant CAPEX without proven returns before full implementation.
- **Data Quality & Integration Challenges**
  Pharmaceutical companies often lack 3D as-built models for their facilities and operate on legacy systems with inconsistent data standards, making normalization costly and time-consuming.
- **Regulatory Uncertainty**
  FDA and EMA lack comprehensive guidance on validating digital twin outputs against cGMP requirements.
  Regulators are still determining liability frameworks when AI-driven decisions might affect product quality, creating compliance risks that delay adoption.
- **Complexity & Skill Gaps**
  Operating functional digital twins requires multidisciplinary talents, combining pharmaceutical domain expertise with machine learning, and data architecture skills, hybrid roles that the traditional pharma workforce doesn't currently possess.

DIGITAL TWINS – Future Adoption Enablers

- **Generative AI & Automation**
  AI-powered data aggregation will reduce digital twin creation from months to days.
- **Data Quality Improvements**
  New facilities are frequently designed and built using BIM, ensuring the client receives an as-built 3D model and a comprehensive handover package once construction is complete.
- **Digital Twin Software Maturity**
  Today, each platform has distinct strengths and weaknesses, but they are all evolving to address their respective gaps.
- **Pressure Towards Sustainability**
  In the coming years we will probably assist to a race toward energy optimization, driven by both growing public awareness and the quest to reduce supply costs.

«Remote Reality» PoC - Honorable Mention

- **Point Cloud Acquisition**
  A laser scanner equipped robot can efficiently take a daily 3D snapshot of the construction site, this data can be shared and analyzed without the need of being in site.
  In the near future, the same point clouds will be used for automated progress tracking and tolerance checks.
  We are currently starting a PoC to test and develop this application.
- **Site Security and Surveillance**
  The robots can be used for site security and surveillance, alerting nearby appointed personnel able to intervene.
- **Remote Presence**
  The intervention of a SME in a production environment is hindered by the need to follow access procedures to access the premises.
  A remotely controlled robot can be used to quickly assess the issue from remote and evaluate the need of a physical intervention.

Thank you for your attention!

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https://scs.gzs.si

Slovenian Cleanroom Society

PTZ Opportunity Tradition Knowledge
CHAMBER OF SMALL BUSINESS AND TRADE

Gospodarska zbornica Slovenije
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International Conference

CLEANROOMS TODAY AND TOMORROW:

INNOVATION, SUSTAINABILITY, EXCELLENCE AND REGULATORY COMPLIANCE

30 – 31 MARCH 2026

BRDO PRI KRANJU, SLOVENIA

Good and Poor Practices in the Design and Execution of Cleanrooms

Primož Vrtačnik, Novartis d.o.o.

30 – 31 MARCH 2026
BRDO PRI KRANJU, SLOVENIA

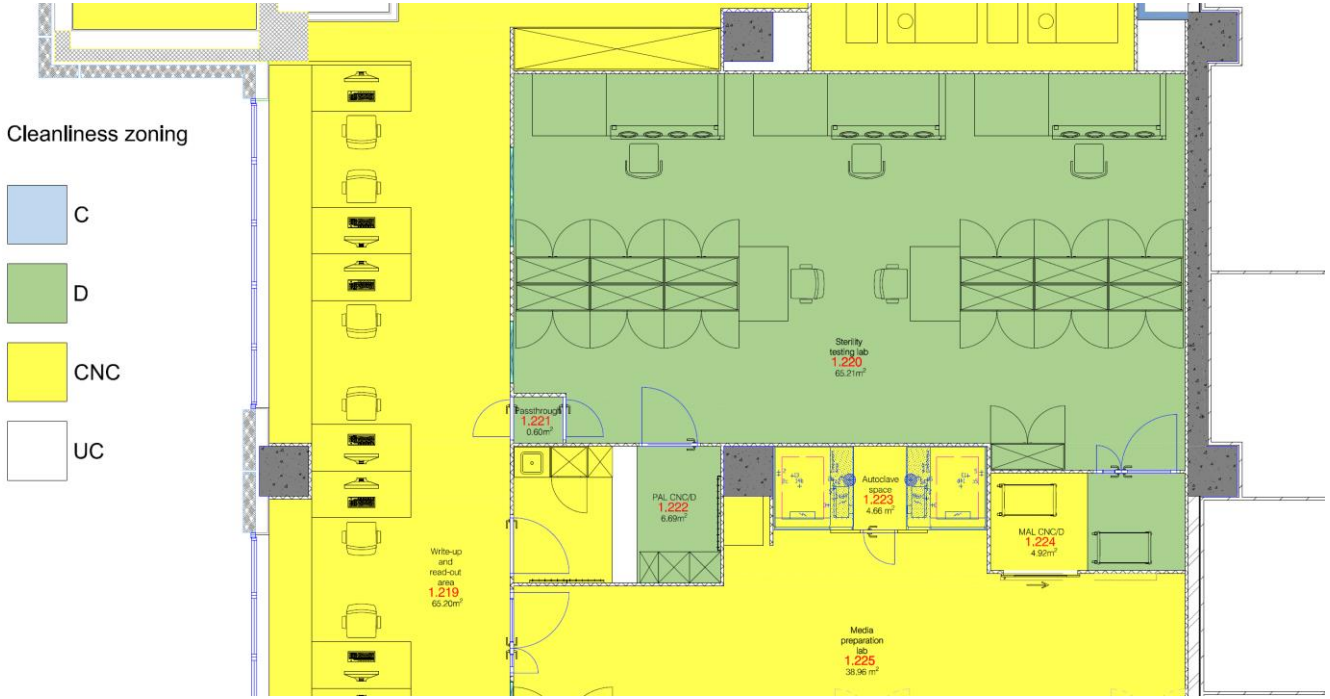
- I graduated from the Faculty of Mechanical Engineering in Ljubljana.
- Project Engineering Investment Manager at Novartis.
- Leading SME Engineering Group (NOCC).
- Driving technical standards & project documentation excellence.
- Coordinating capital investment projects in GMP environments.
- Collaborating with global teams & external partners.
- Focused on efficient execution & high-quality engineering solutions.
- Certified Engineer at the the Slovenian Chamber of Engineers.

Requirements for the construction of cleanrooms

- All surfaces shall be smooth, flat, and free of discontinuities, with rounded transitions (coved radii) at wall–floor and wall–ceiling interfaces to enable effective cleaning. All fixtures including lights, diffusers, exhaust grilles, and glazed elements shall be installed flush with the wall or ceiling surface.
- Fully sealed room envelope (no uncontrolled air leakage).
- All materials used within the room shall be non-shedding and shall not generate, release, or regenerate particles under normal operating or cleaning conditions.
- All materials and surface finishes shall be resistant to approved cleaning and disinfection agents, discoloration, or loss of integrity throughout the lifecycle of the facility.

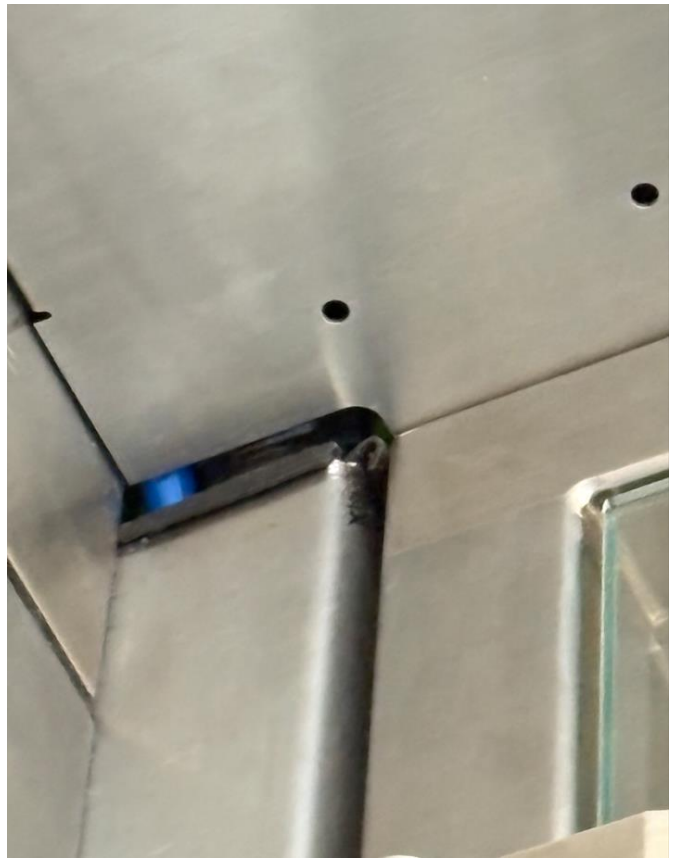
Cleanliness zoning

- All personnel airlocks, material airlocks, pass-boxes, and airlocks shall be of the same cleanliness classification as the adjoining process cleanroom.
- These rooms shall be subject to the same qualification activities as the process rooms.
- All airlocks shall maintain defined pressure differentials relative to both the process area and the adjacent entry areas.
- There must also be a clear separation between areas of different cleanliness classifications.

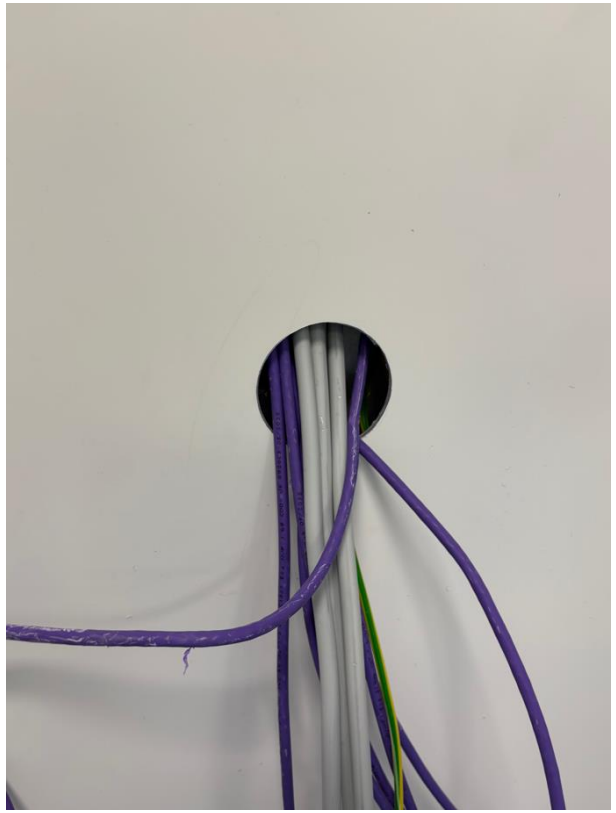


Tightness of room - all partitions have to be fully sealed and airtight.

Tightness of room - Process equipment



Tightness of room - Room instalations



Lecture Title

Primož Vrtačnik, Novartis d.o.o.

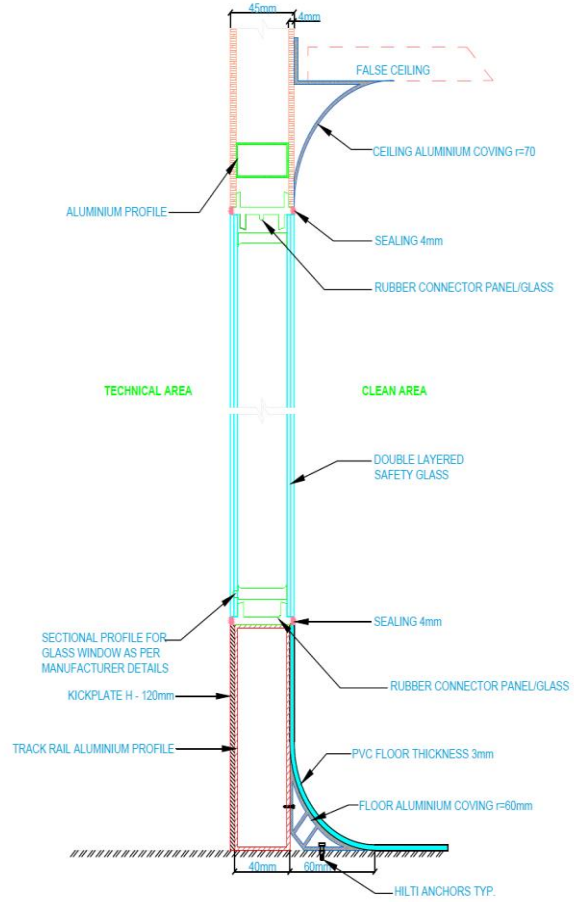
Tightness of room – Hydrants, fire extinguishers and doors

Lecture Title

Primož Vrtačnik, Novartis d.o.o.

Good examples

Personnel airlock – Flat surface and rounded surfaces.

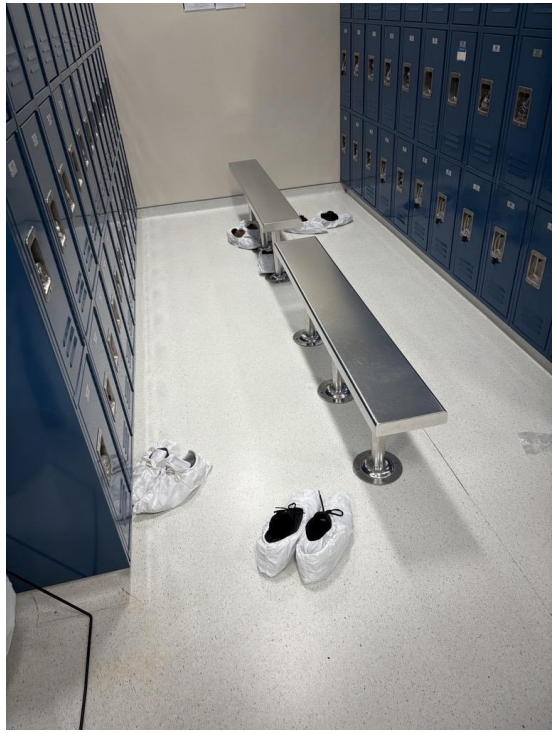


TYPICAL DETAIL FOR CLEANROOM GLASS WALLS

Poor examples

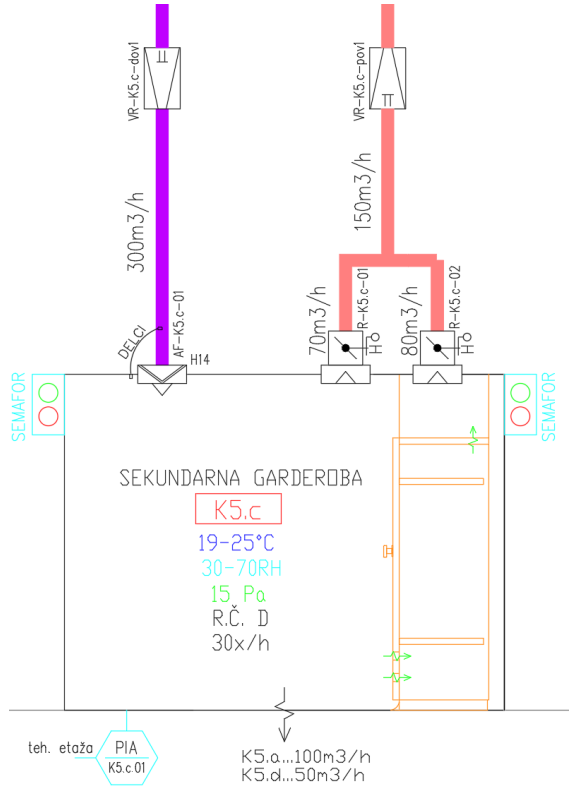
Passive pass box between a non-GMP area and a GMP area.

Civilian clothing and footwear are not stored in designated lockers. Civilian clothing is mixed together with work clothing in the same lockers, and civilian footwear is left freely in the room.



Actively ventilated gowning locker - Good examples

Actively ventilated gowning locker.



Lecture Title

Primož Vrtačnik, Novartis d.o.o.

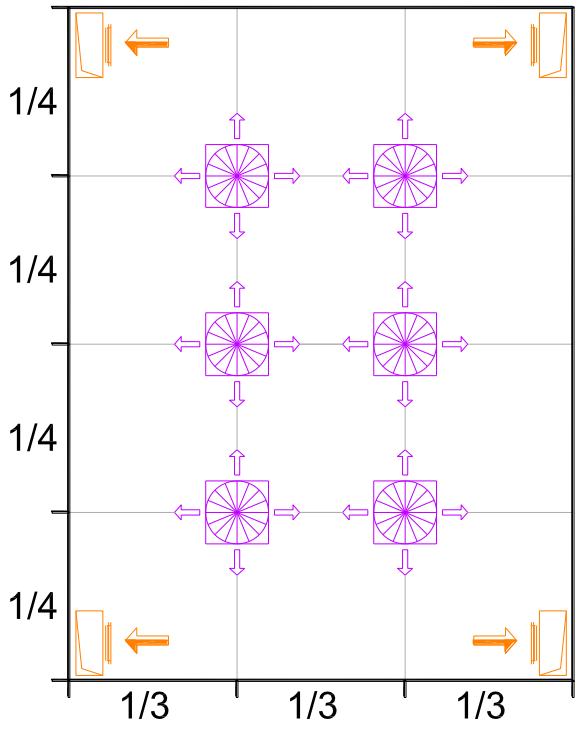
Poor examples

Equipment that is not suitable for cleanrooms and cannot be effectively cleaned.

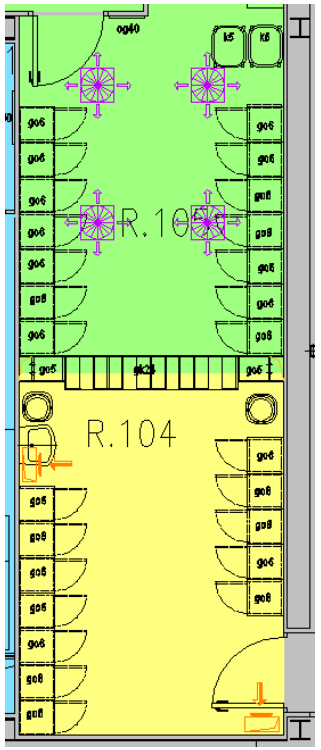
Air distribution

The HVAC system must ensure proper air distribution throughout the entire room.

Example: Production

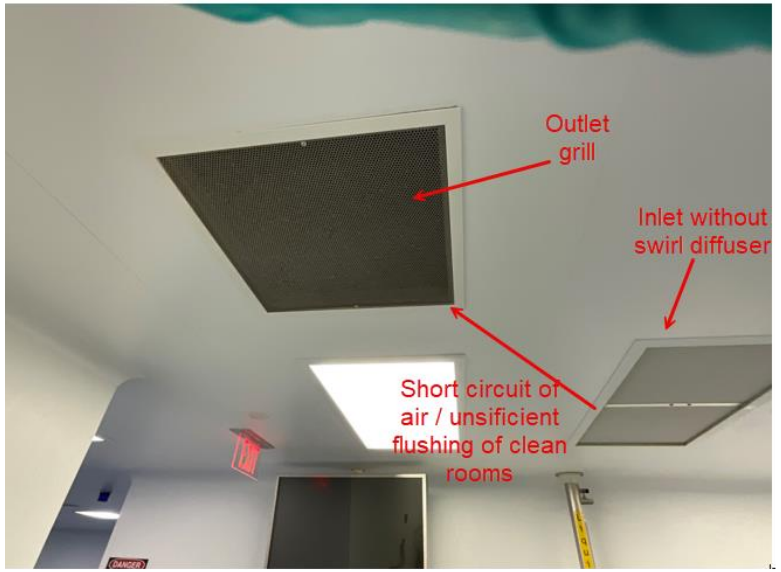


Changing room:



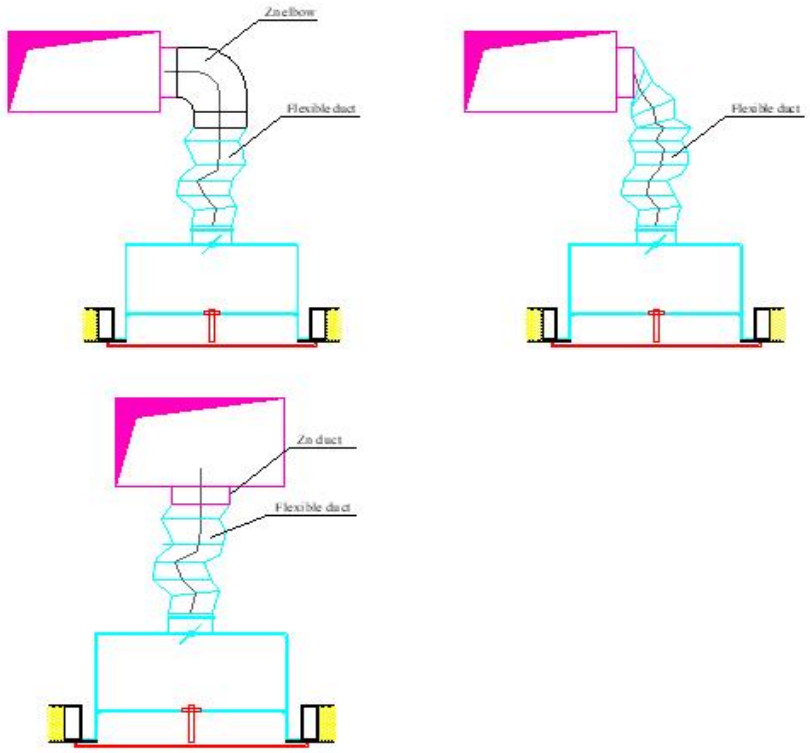
Air flow from cleaner area to less clean area

Not suitable



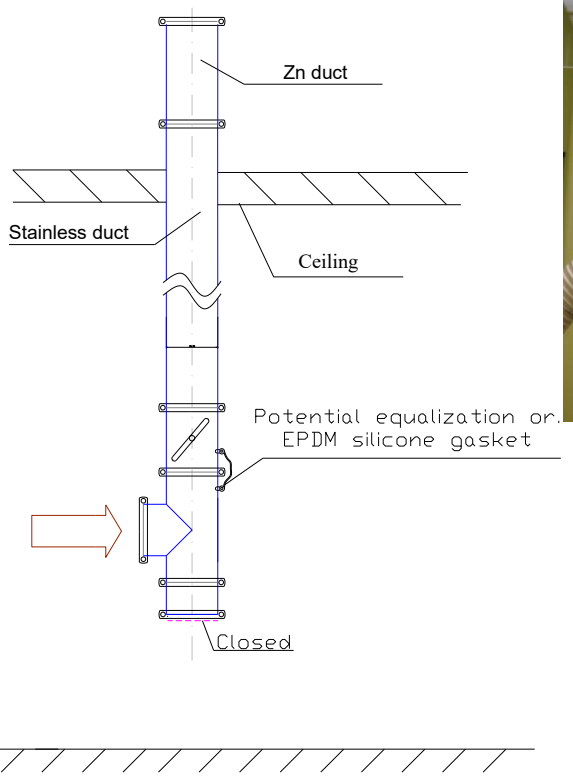
Air distribution

OK Not suitable

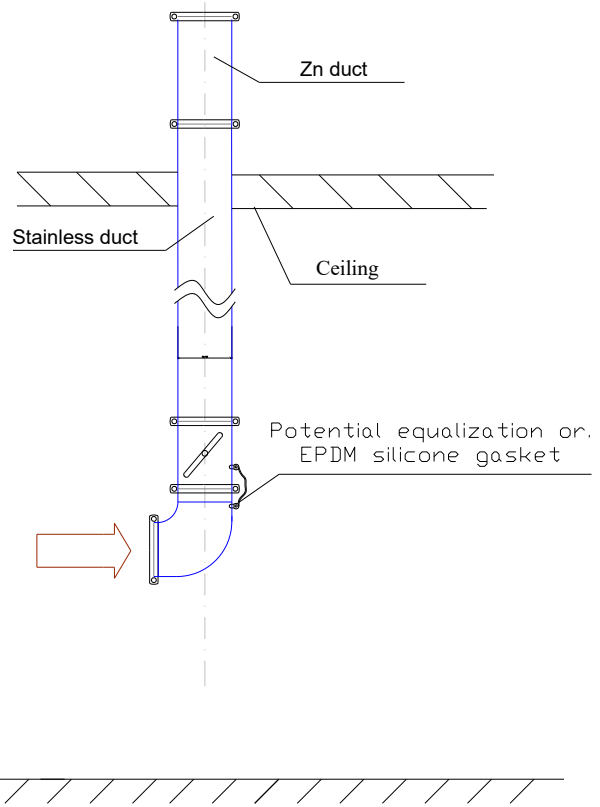


Air distribution

OK



Not suitable



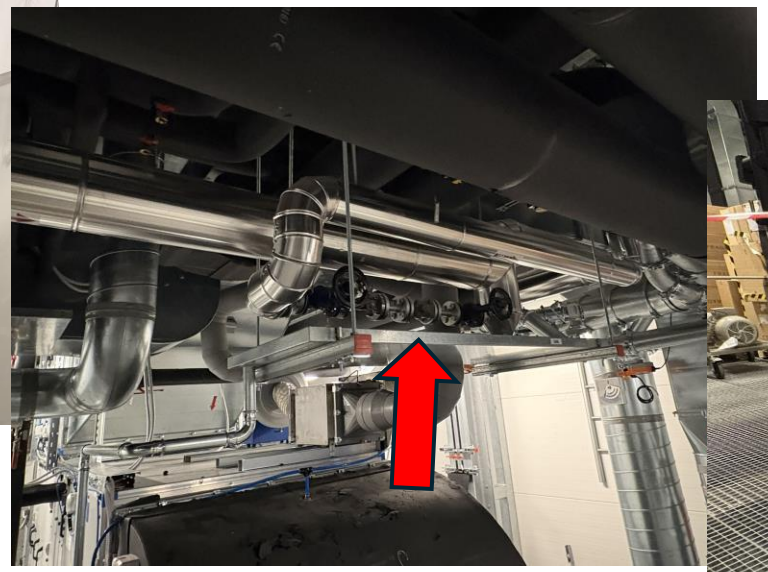
Air distribution

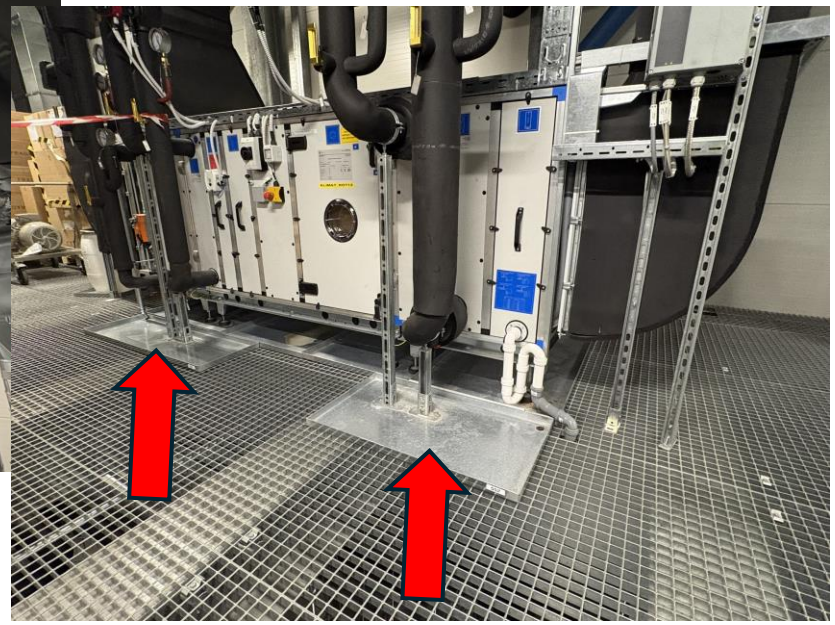
- Air ducts shall be delivered clean and installed to ensure airtight performance in accordance with the required leakage class.

- Manufacturer installation instructions shall be complied with when installing actuators within the HVAC system.

Air distribution

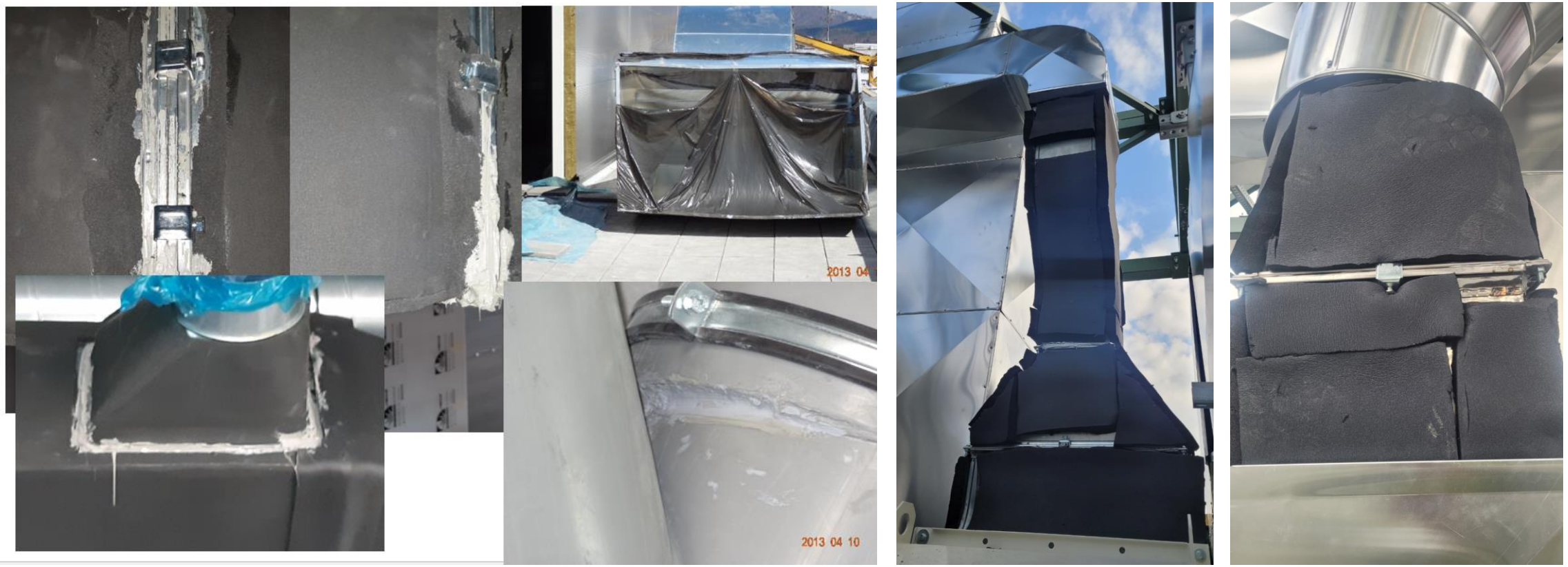
Uncontrolled water discharge from overflow edges in technical spaces or from collection/drip trays shall be prevented.





Air distribution

New ductwork and insulation identified as non-conforming and rejected during inspection.



Lecture Title

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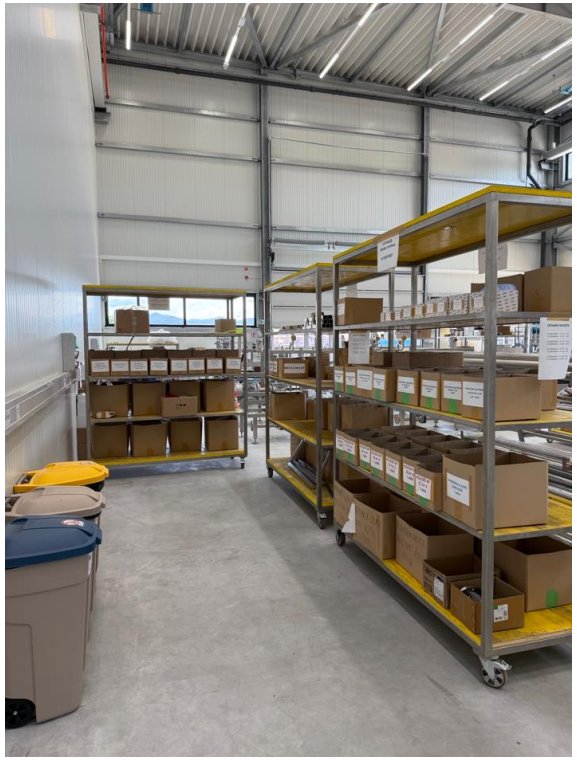
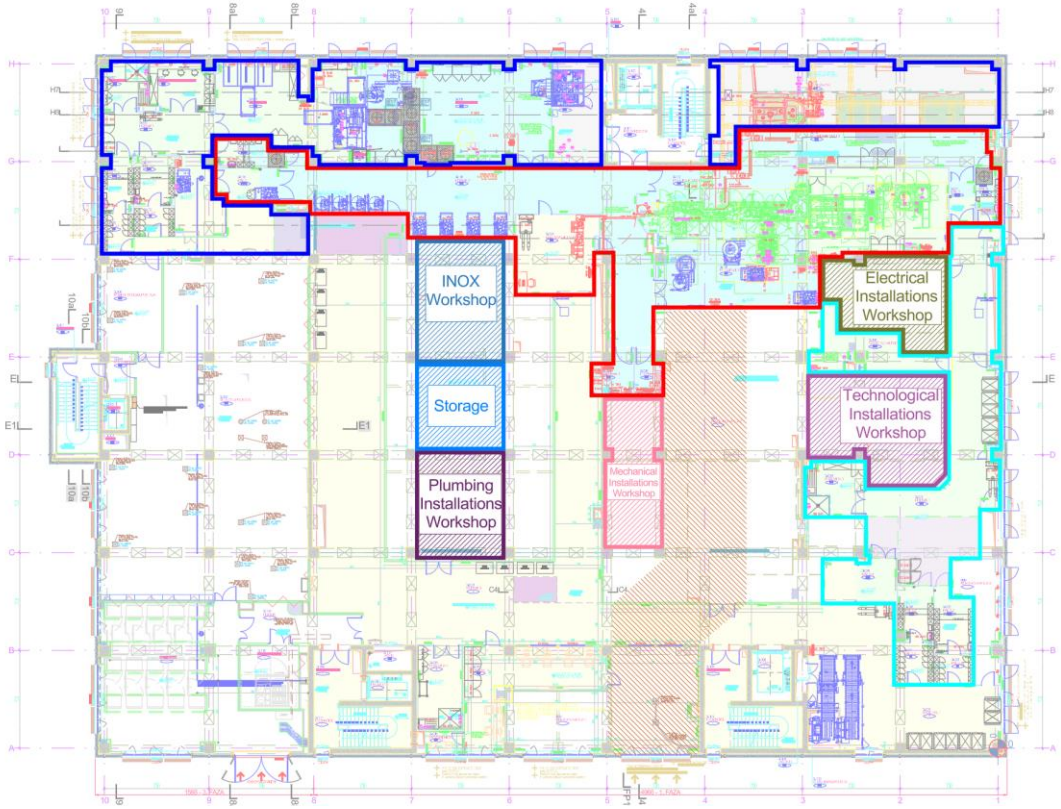
GMP media

- Cleanliness during construction and traceability of documentation, certificates... are very important.
- Pipes must be stacked in racks with closed ends and all openings must be closed even after welding.



GMP media

On the construction site, the work area for stainless-steel installations must be separated from the black steel.

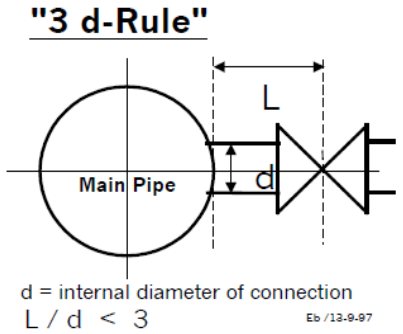


These pipes shall not be installed.

GMP media - Pharmaceutical waters

Dead legs:

- Requirement L< 3xD



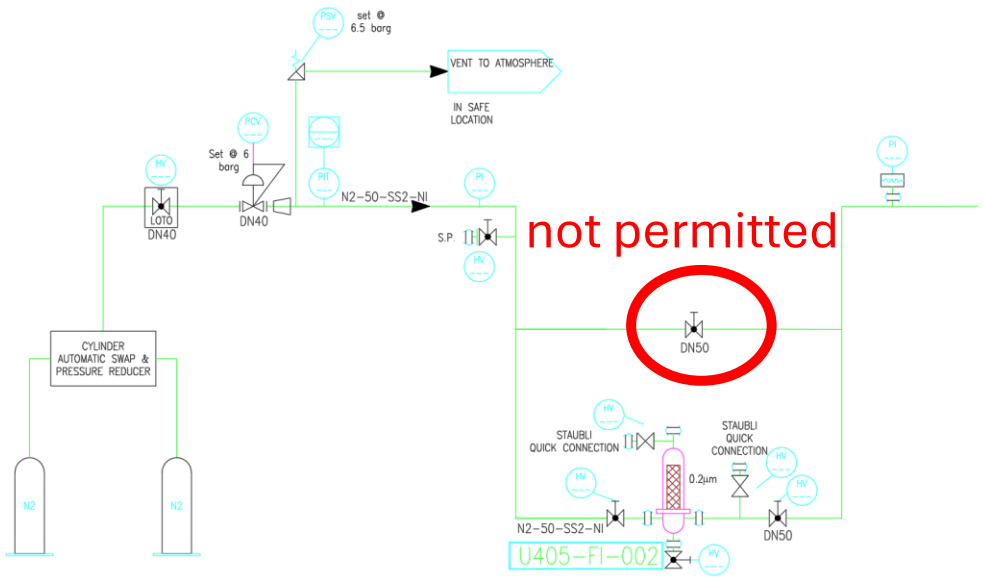
Appropriate solution - minimal oz zero dead leg:

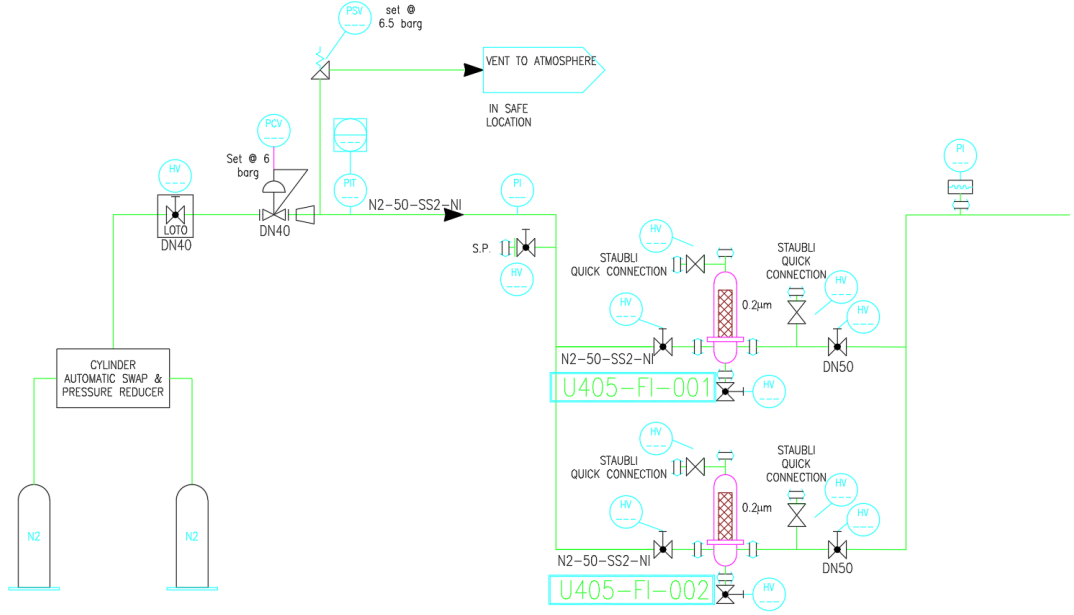
Inappropriate solution:

Drainability: whole system needs to be drainable (slope, discharge valves in lowest points)

GMP media - Clean gases (principal sample)

Where the medium is filtered, a bypass with a valve is not permitted.





Lecture Title

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Key takeaways

- Cleanroom construction is a multidisciplinary process requiring alignment of
  - architecture,
  - mechanical/GMP utilities,
  - HVAC,
  - electrical/IT-OT systems.
- Full compliance with GMP, URS, and Novartis internal standards is mandatory.
- Cleanrooms must allow:
  - validated cleaning and decontamination,
  - safe and accessible maintenance, stable,
  - controlled, and monitored environment,
  - complete qualification documentation (DQ, IQ, OQ, PQ).
- Infrastructure must support long-term reliable, safe, and compliant operation.
- Use of standardized and proven components is preferred wherever feasible.
- Innovation should focus on:
  - reducing energy use,
  - increasing system autonomy and robustness,
  - minimizing maintenance needs, selecting durable,
  - use of sustainable materials suitable for GMP environments.
  - continuous focus on system automation.
  - Novartis has set a clear commitment to lowering its carbon footprint.

Lecture Title

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Added consideration:

Where cleanrooms are heading in the future?

- Dark factory (minimal or no human presence).
- The business requires the elimination of annual shutdowns or at minimum and a significant reduction in qualification time.
- The challenge is to deliver qualifications of the same quality within a shorter timeframe. Annex 1 has introduced new requirements and extended the qualification periodicity.

NOVARTIS

Thank you for your attention!

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CLEANROOMS TODAY AND TOMORROW:

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Smart HVAC design – Opportunity for Demand Based Contamination Control using Venturi Valves

David Rausch, Phoenix Controls

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Critical Environments

ISO Class Spaces

Cleanrooms

Battery Production

Semi-Con

Isolation rooms

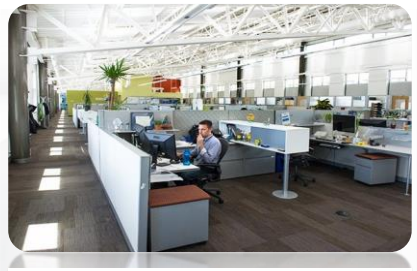
Life science/vivarium's

Operating rooms

BSL 3+/BSL4

Wet Chemistry

Non-Critical Environments



Office Space

Hotel Rooms

Classrooms

Slovenian Cleanroom Society

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Class ISO 146144-1 (Federal Standard 209E)	Average Airflow Velocity m/s (ft/min)	Air Changes Per Hour	Ceiling Coverage
ISO 8 (Class 100,000)	0.005 – 0.041 (1-8)	5 – 48	5 – 15%
ISO 7 (Class 10,000)	0.051 – 0.076 (10-15)	60 – 90	15 – 20%
ISO 6 (Class 1,000)	0.127 – 0.203 (25-40)	150 – 240	25 – 40%
ISO 5 (Class 100)	0.203 – 0.406 (40-80)	240 – 480	35 – 70%
ISO 4 (Class 10)	0.254 – 0.457 (50-90)	300 – 540	50 – 90%
ISO 3 (Class 1)	0.305 – 0.457 (60-90)	360 – 540	60 – 100%
ISO 1-2	0.305 – 0.508 (60-100)	360 – 600	80 – 100%

Class	Maximum Particles/m^3						FED STD 209E equivalent
	≥ 0.1 µm	≥ 0.2 µm	≥ 0.3 µm	≥ 0.5 µm	≥ 1 µm	≥ 5 µm	
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		Class 1
ISO 4	10,000	2,370	1,020	352	83		Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7				352,000	83,200	2,930	Class 10,000
ISO 8				3,520,000	832,000	29,300	Class 100,000
ISO 9				35,200,000	8,320,000	293,000	Room Air

Most stringent → Least stringent

As a result of new code guidance using **“Effective Air Exchange”.** That allows you to consider energy saving design strategies without compromising the quality and cleanliness of the space.

- To reduce energy and therefore reducing operational costs, we can lower the air exchange rate to meet the ISO Class maximum particle quantity and size for ISO3 to ISO 8 standards

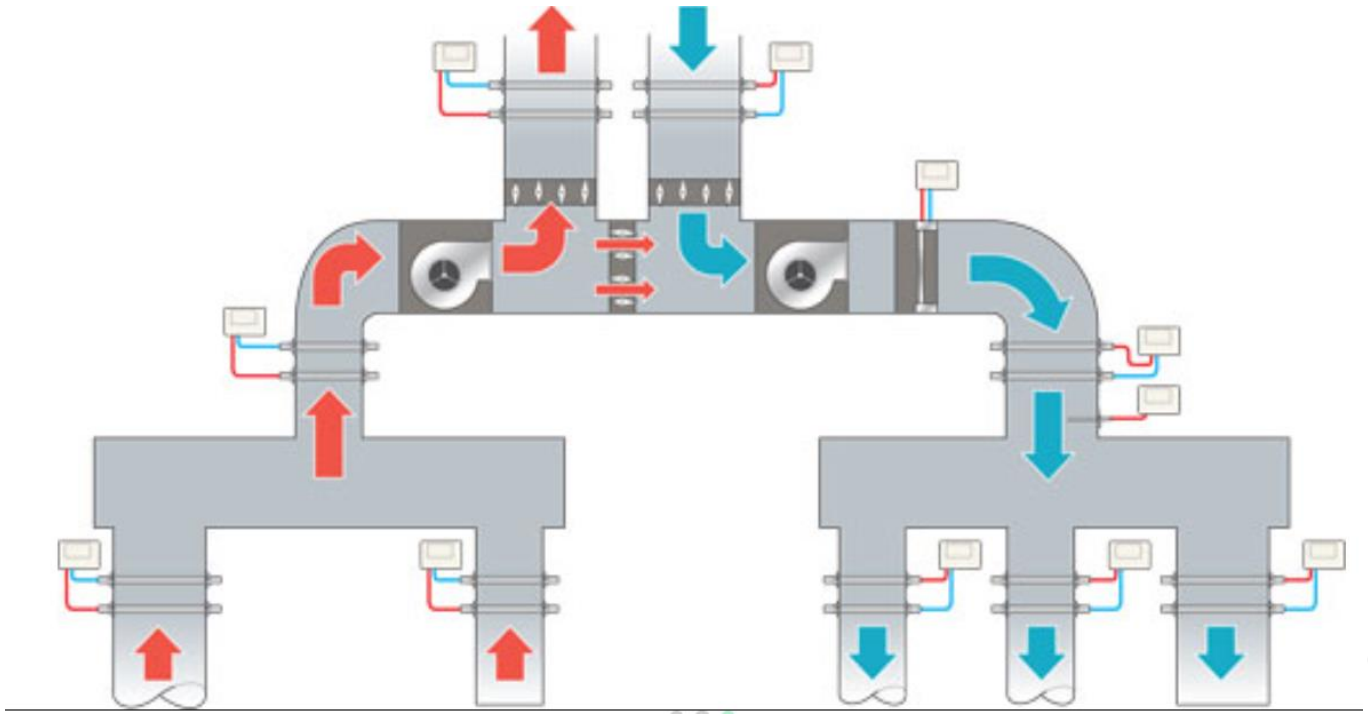
- To do this we need to provide a better airflow control device, that neutralizes the pressure fluctuations in the duct work.

The Current HVAC System in Cleanroom Designs:

- **Current approach** to air exchange in cleanrooms is…
- **Inefficient,**
- **Unintelligent** and completely **inflexible**…..

- In essence it is` **"Counterproductive"** to meeting Operational efficiency, airflow effectiveness and GMP.

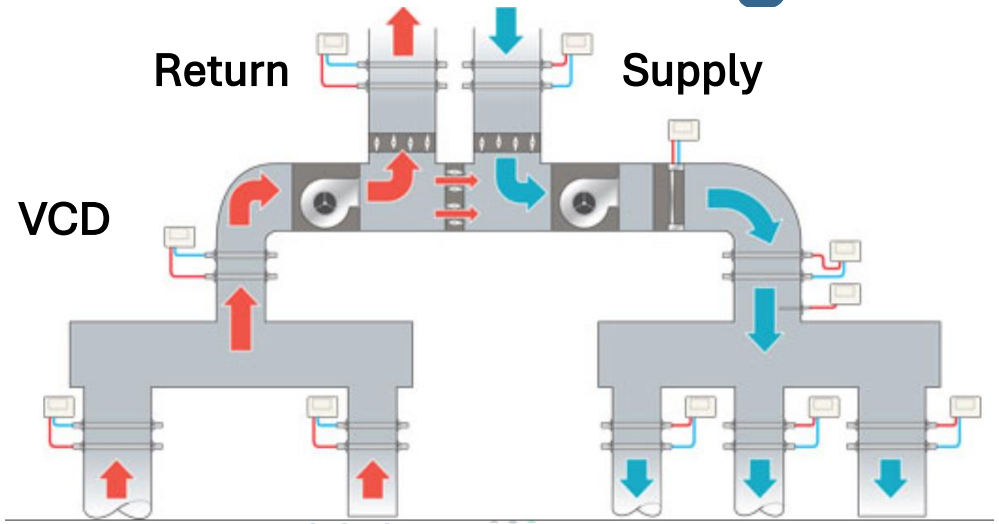
Large, constant amounts of air in and large constant amounts of air out..



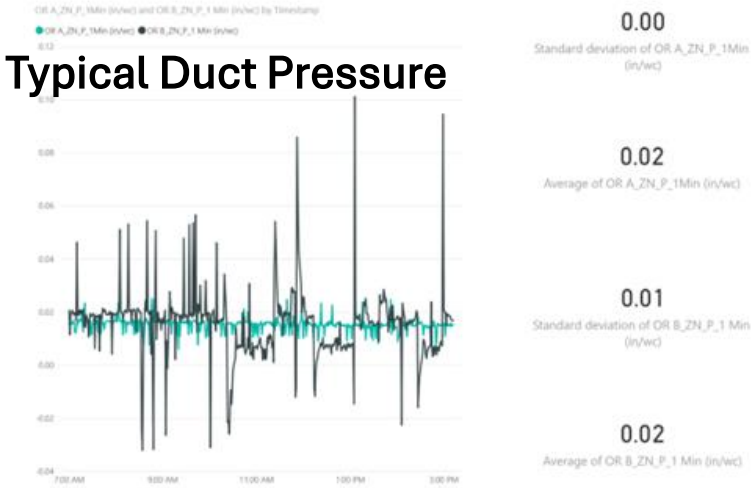
The Current HVAC System in Cleanroom Designs:

- **Current approach** to Environmental control and Pressure Control in cleanrooms use…
- **Variable Control Dampers (VCD)**
- **Focus Control on Device vs The Space**.
  - Pressure in duct work changes all the time.. So how can you accurately control based on something that is dynamically changing?

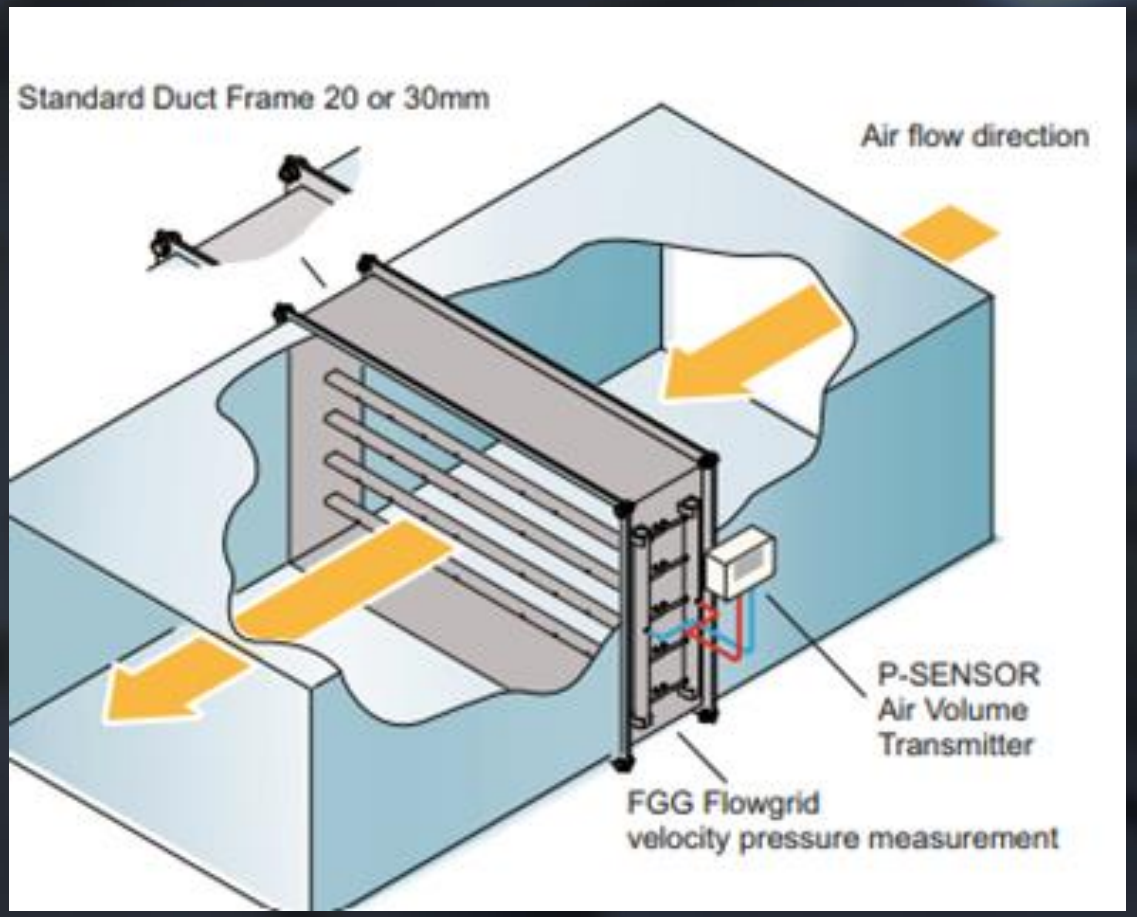
- Consider a different Airflow Control Device that allows you to control more accurately with less air providing significant energy savings



ISO Class Cleanroom



VCD - Flow Measuring



- Flow sensors direct systems flow control - Independently
- Requires long, straight duct runs; Otherwise, flow measurement can prove to be imprecise
- Actuators are constantly moving, requiring frequent replacement
- Time delays and control lags often implemented to control device

VCD - Flow Measuring

- Drift over time causing need for increased flow by 40%
- Limit flexibility of implementing setback or other control strategies due to effects of dynamic duct pressure changes. Don’t want to touch.
- Does not have the ability to track other VCD’s to balance zone or maintain set offset

VCD - Flow Measuring

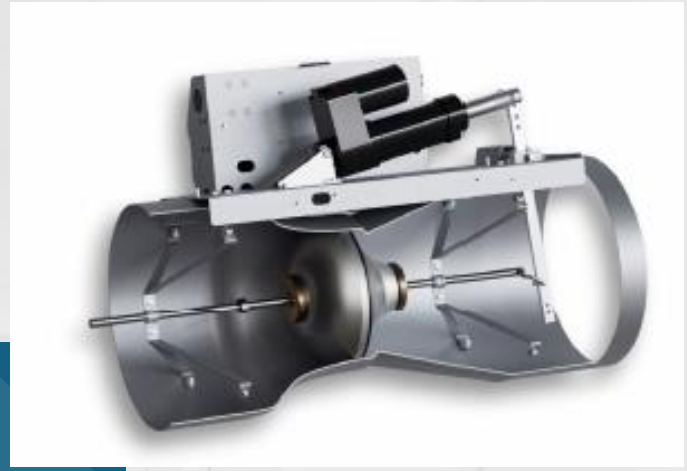
- Accuracy gets worse with less pressure and less Air. When you drop your air volume flow rates and you have lots of dynamic changes during operations, e.g. rooms off a corridor, the Room DP changes can be significant and frequent. If you deaden the BMS then the actual fluctuations can be significant and even reversed

VCD Measurements need high velocity pressure!

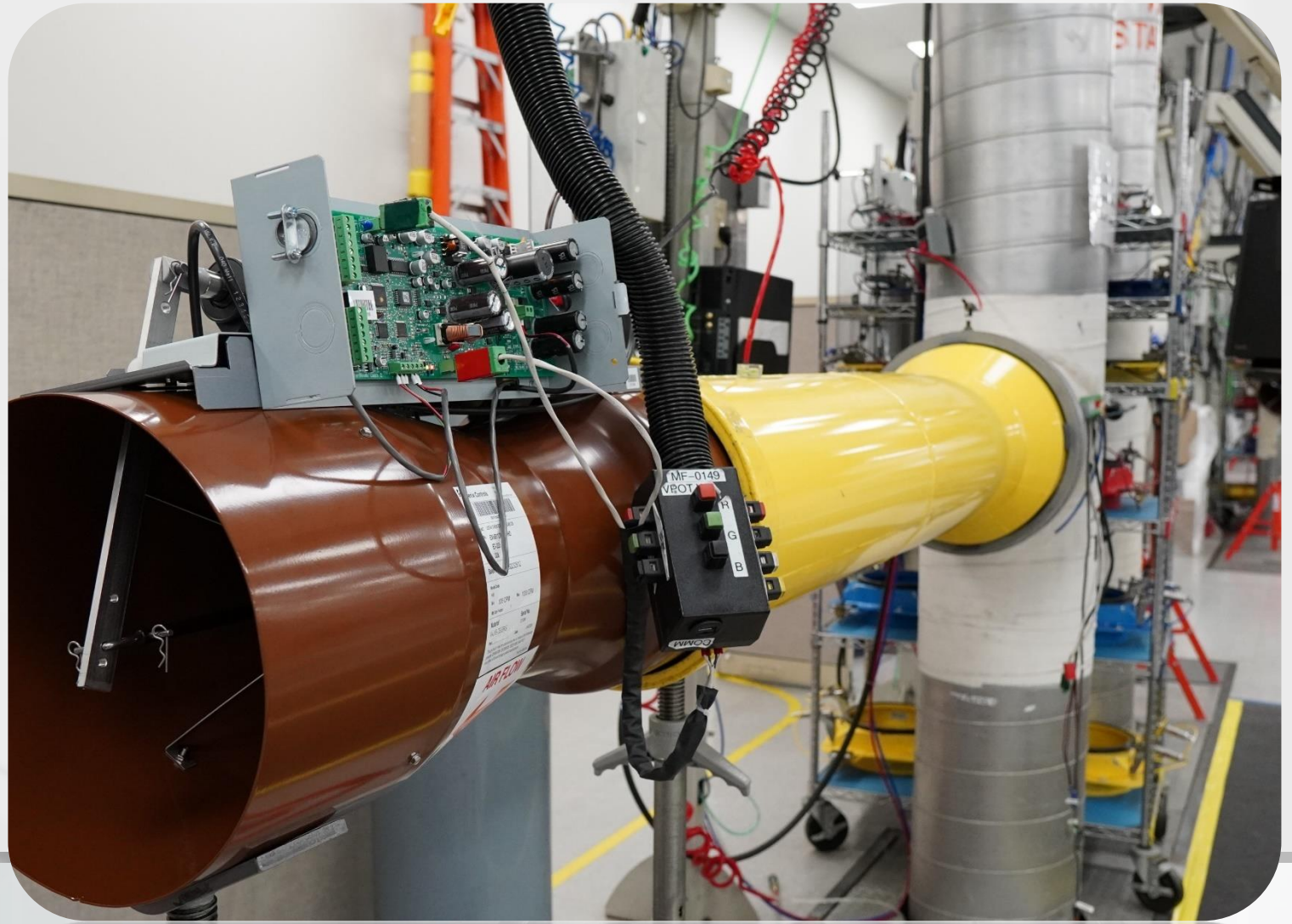
They become inaccurate at lower pressures and lower flows..

0.25" w.c. transducer, 1% F.S. accuracy					
Turn down	Velocity	P_v	Error (-)	Error (+)	% of signal
1:1	1000	0.062344	20	-20	2%
2:1	500	0.015586	42	-39	8%
3:1	333	0.006927	67	-56	20%
4:1	250	0.003897	100	-70	40%
5:1	200	0.0025	200	-83	100%

Variable Control Dampers introduce too much risk in attempting to change state of controls or reducing air exchange



Introducing the **Venturi Valve**



Every Venturi Valve is Factory Characterised (accredited) on air stations for accuracy and conformance. Venturi valves are widely used in Labs, Clean Spaces and are the "standard" in handling variable flow rates arising from Fume Hoods and space management without compromising pressure.

The Value of Venturi Valves over VCD's

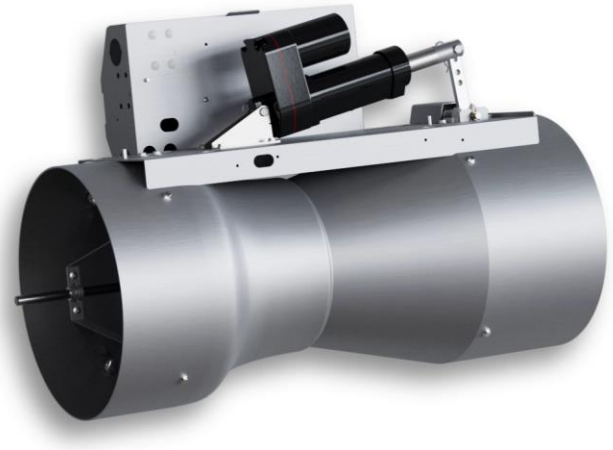
P Pressure independent (Mechanically using Spring))

A Accuracy of +/- 5% of command

I Inlet/exit insensitivity

N No Sensors, No scheduled maintenance

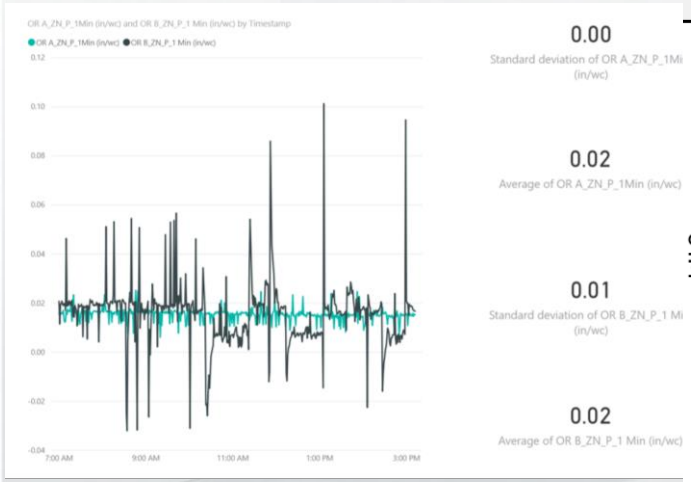
T Turndown up to 20:1 (Large Flow Range)

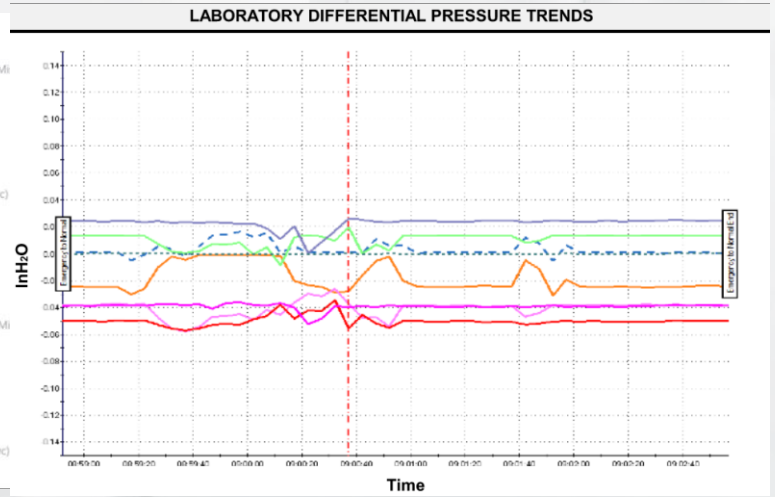


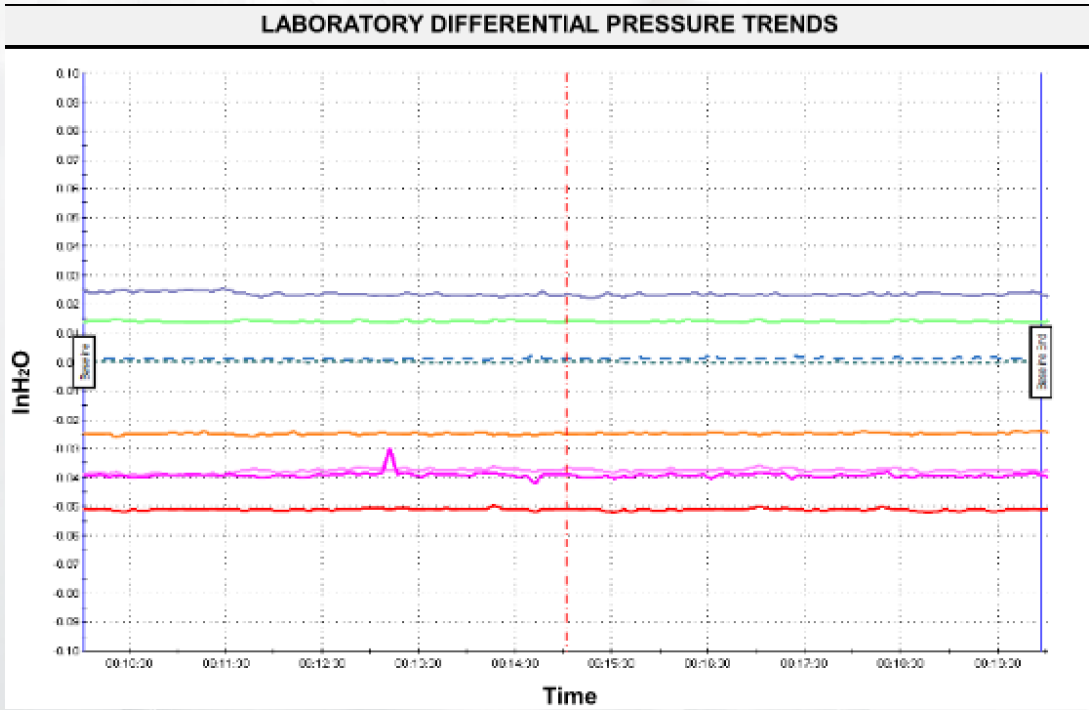
S System stability and high-speed response time (<1 second)

These devices do not measure pressure or airflow, they "Meter Air" within +/- 5% accuracy at anywhere on the flow curve.

Constant Volume vs. Constant Pressure

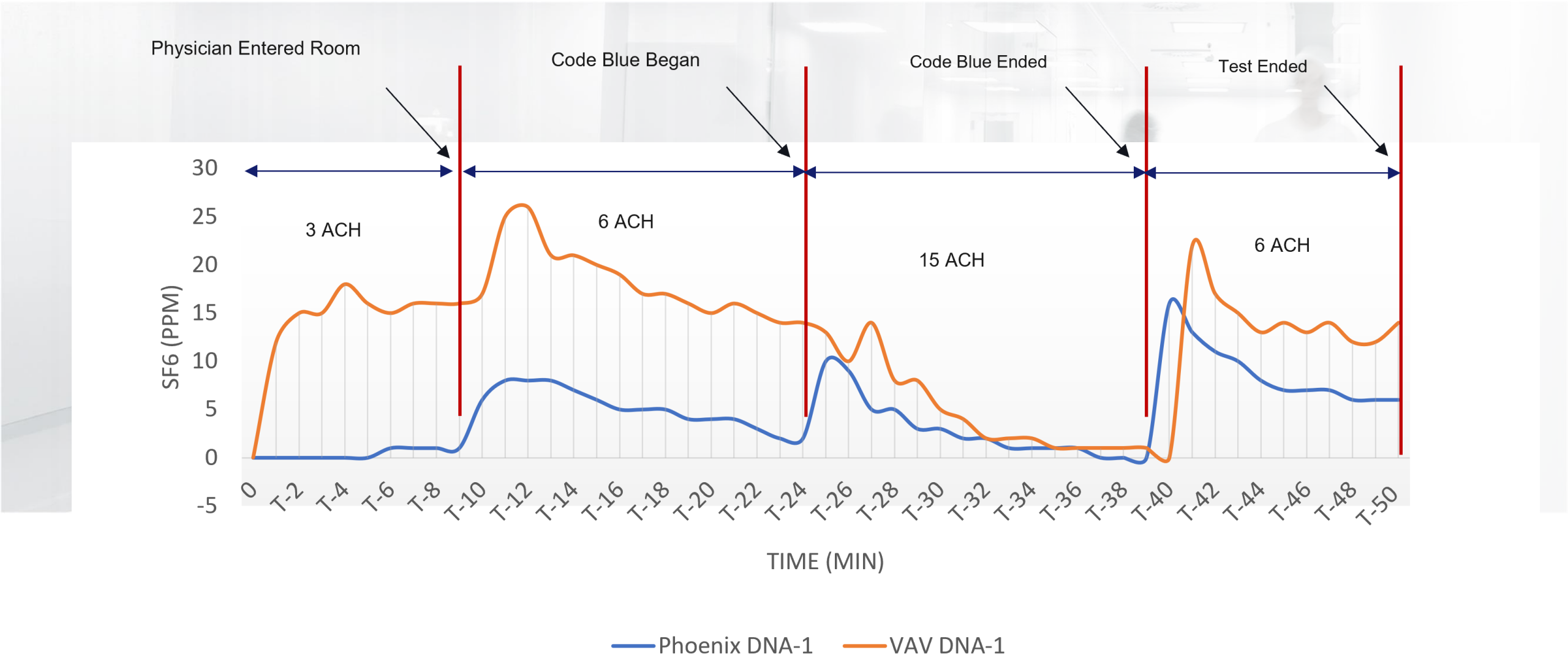






Is the Constant Volume approach really Constant Flow?

Constant Pressure with Venturi (MPI)


Physician Entered Room
Code Blue Began
Code Blue Ended
Test Ended
3 ACH
6 ACH
15 ACH
6 ACH
SF6 (PPM)
30
25
20
15
10
5
0
-5
0
T-2
T-4
T-6
T-8
T-10
T-12
T-14
T-16
T-18
T-20
T-22
T-24
T-26
T-28
T-30
T-32
T-34
T-36
T-38
T-40
T-42
T-44
T-46
T-48
T-50
TIME (MIN)
Phoenix DNA-1
VAV DNA-1

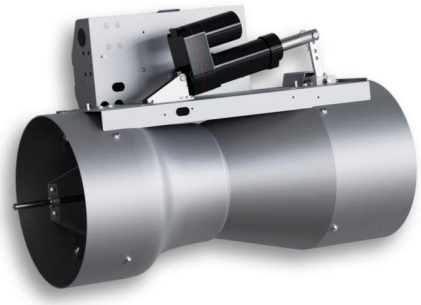

Phoenix Controls
PRÄZISE
RAUMDRUCKREGELUNG
MIT VENTURI-
VOLUMENSTROMREGLERN
FLEXIBLE
CLEANROOM
CONTROL

Venturi Valves provide energy savings because..

1. *They offer more effective pressure control at lower duct pressures, lowering break horsepower demand.*

2. *They Provide a More Effective air Exchange at lower Air Change rates. Keeping desired ISO class environmental quality with less conditioned air "More with Less…"*

3. *They Provide "Space Control" and Track each other for a total zone pressure balance using "Volumetric Offset". Space by Space or Zone by Zone.*



4. *With No Sensors, Position equals flow, quick to command and setpoint, immediate response and stability to repurpose or re-allocate spaces easily while maintaining pressure control .. quickly adjust offset to compensate for leakage over time for the life of the clean space.*

5. *Venturi's are a performance-based ventilation device that enable different levels of intelligent airflow Control strategies throughout the life of the cleanroom fab managing your conditioned air more effectively*

- *Occupied, Unoccupied, POC Purge Mode, Demand Based Ventilation*
- *Schedule or Automate Modes*

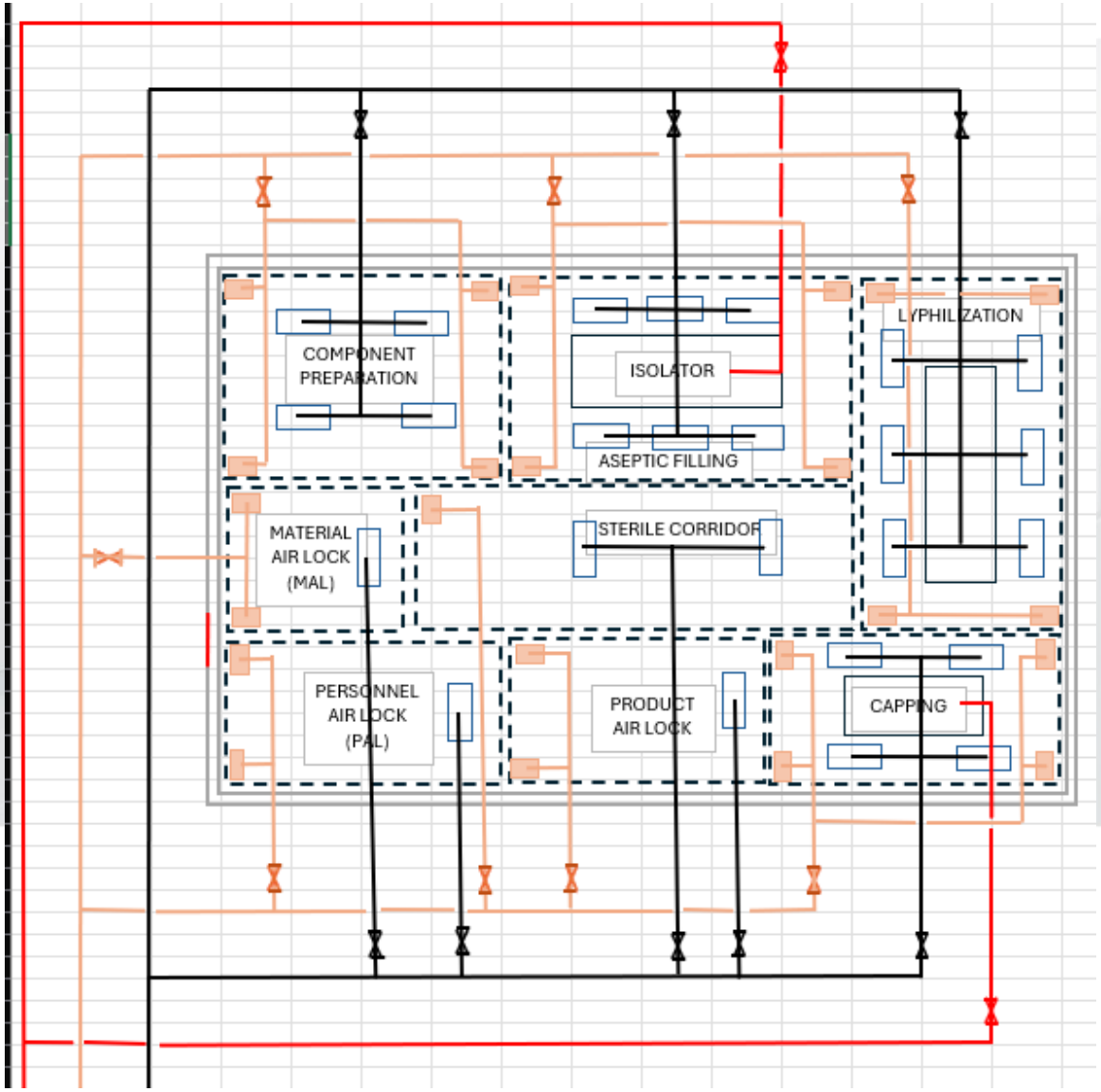
Venturi Valves offer a number of opportunities to reduce energy costs associated with conditioned air and environmental quality needed for clean spaces.

Why Demand Based Ventilation (DBV) ?

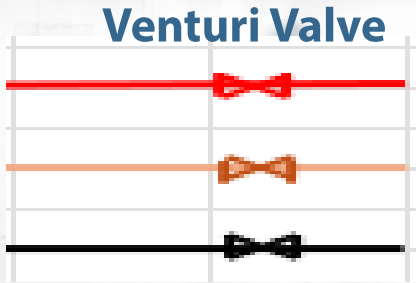
Cleanrooms are designed for highest particulate generation. High particulate generation time frames are typically only several hours a day resulting in opportunities to save energy by variable airflow to maintain cleanliness class.

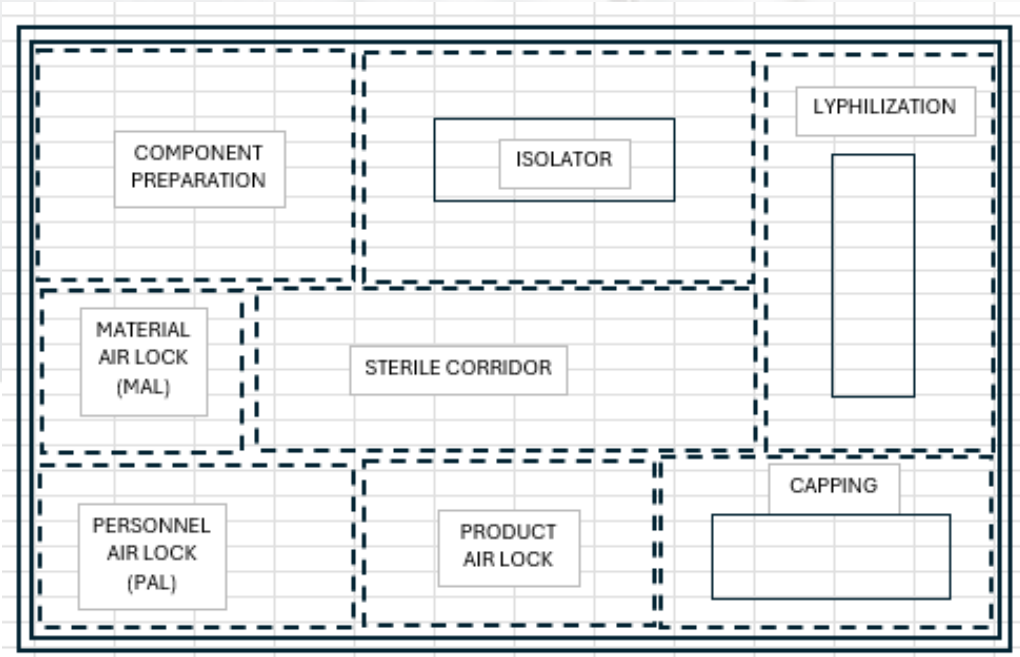
- Reducing airflow saves substantial fan energy!!!!
  - Fan Affinity Law for Power
    - $P_2/P_1 = (CFM_1/CFM_2)^3$
    - $P_2 = P_1 (CFM_1/CFM_2)^3$ Energy savings is cube of CFM reduction

  - Example: normal operation is 1,000 CFM airflow can be reduced to 750 CFM.
    - $P_2 = P_1 (750/1{,}000)^3$
    - $P_2 = 0.42\ P_1$
    - A 25% reduction in airflow saves 58% in energy.

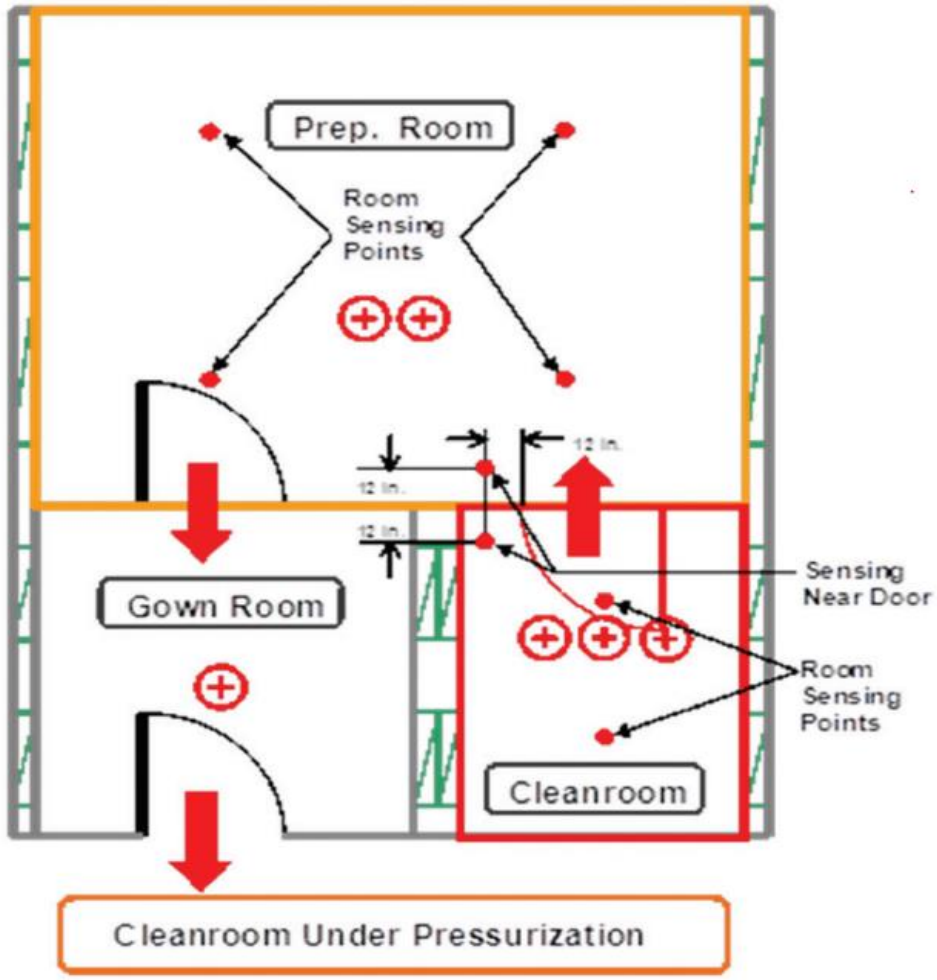


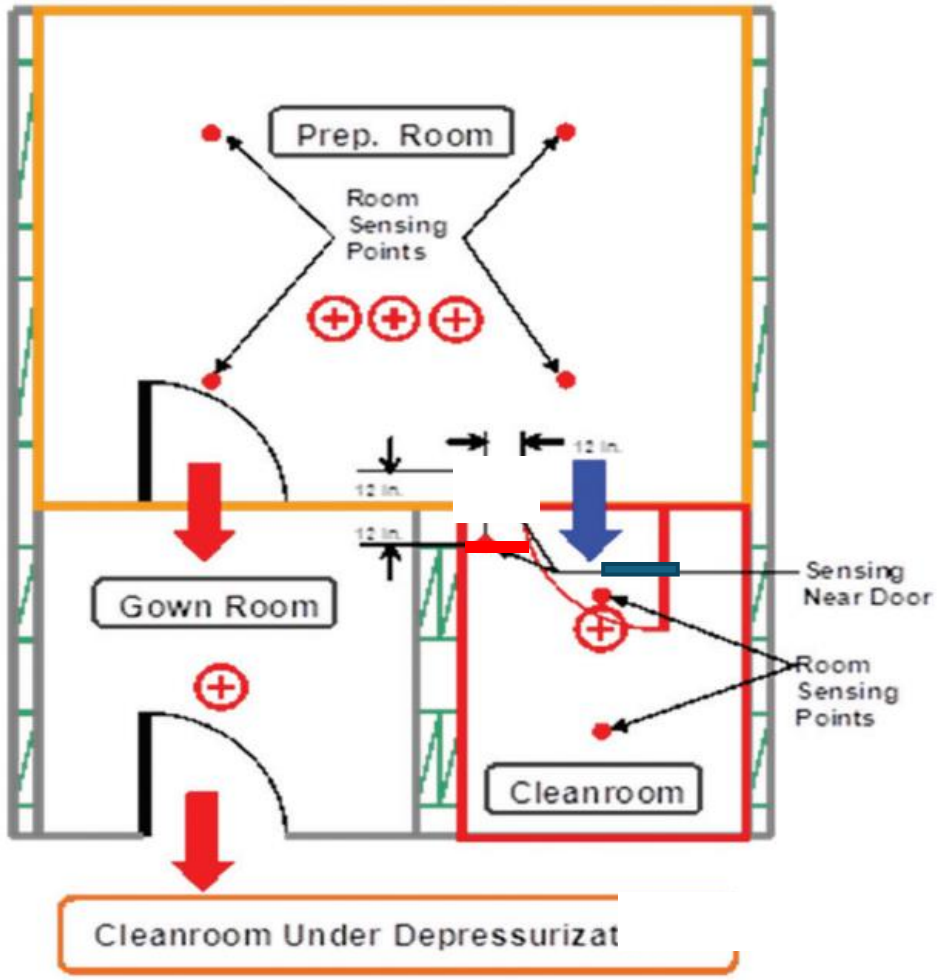
Pharmaceutical Sterile Fill





Volumetric Offset: Air Changes + Pressurization





Cconsistent - pressurization
Level 1

HVAC now part of QSM and CCS initiatives
Level 1

Production space flexibility
Level 2

Sustainable practices = Energy Savings
Level 3

The Different Levels of Control Strategies Enabled.

Accurate/Stable

- Tight pressurization controls
- Precise, consistent, and repeatable
- Volumetric Offset Approach and tracking Pair capabilities
- Easily adjust Exhaust flows due to leakage over time.

Smart, Flexible and Evolves with facility

- Environmental quality to control static, particulate matter, outgassing, and other sources of contamination
- Relative humidity / dewpoint
- Particulate control – volatile or non-volatile

- "Push Button" ISO Class switching with Vision CE
- Set Back Mode
- Reliable, repeatable cascading pressurization from space to space
  - No test and balance required

Efficient/Effective

- Performance Based Ventilation – "Purge Mode"
- Demand Based Ventilation
- Lower air change rates based on ISO Class PM requirements

Level 1 (MVO) – CxV with Venturi Valves

Space Pressurization Control Philosophy (DBV)

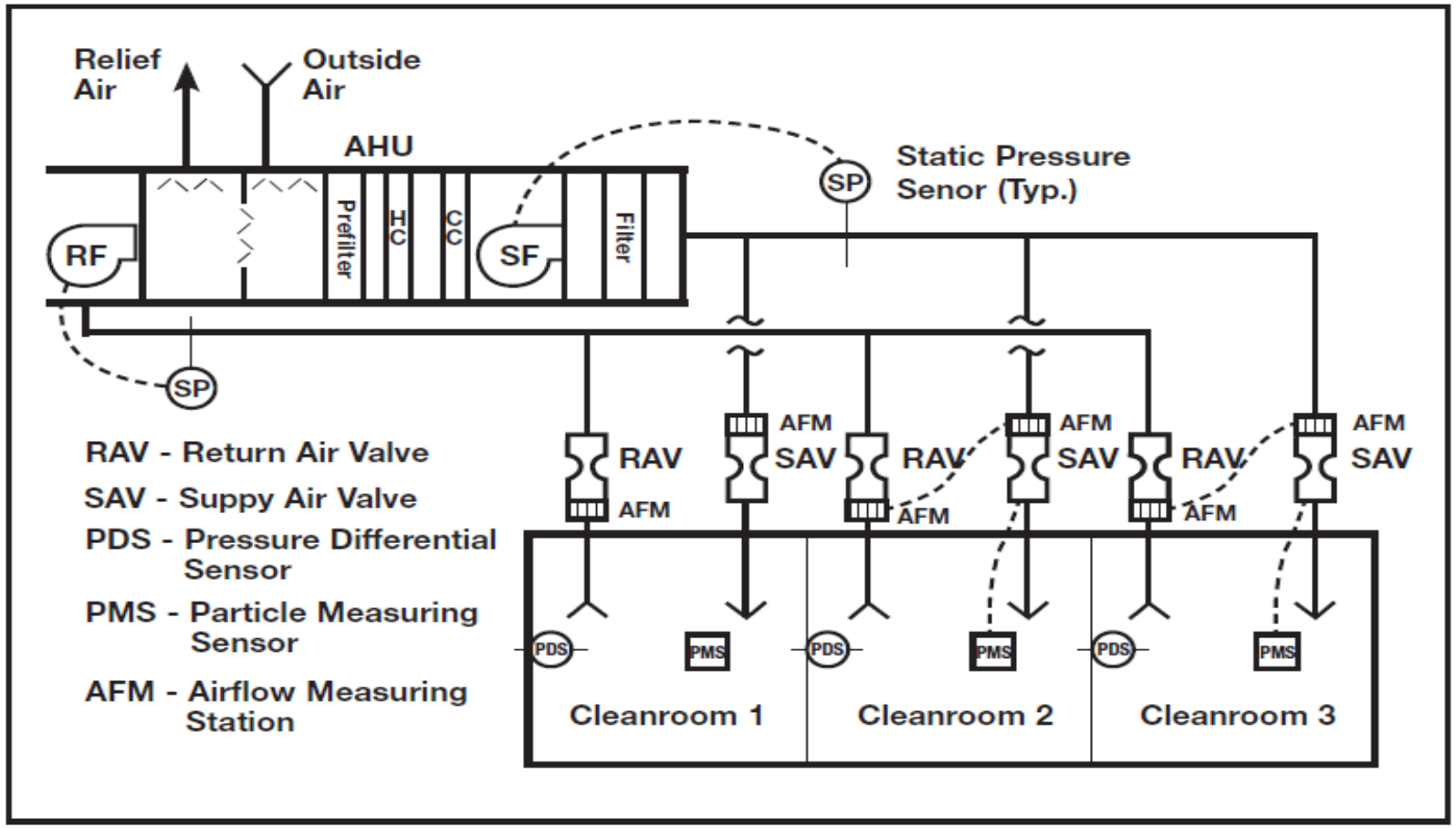


FIGURE 3. Volumetric offset control.

Demand Based Control for Cleanroom

The amount of time that the room is challenged with particle emissions is typically very small.

Demand-control concept in a cleanroom for significant reduction in the average airflow rate and thus a large reduction in energy use.

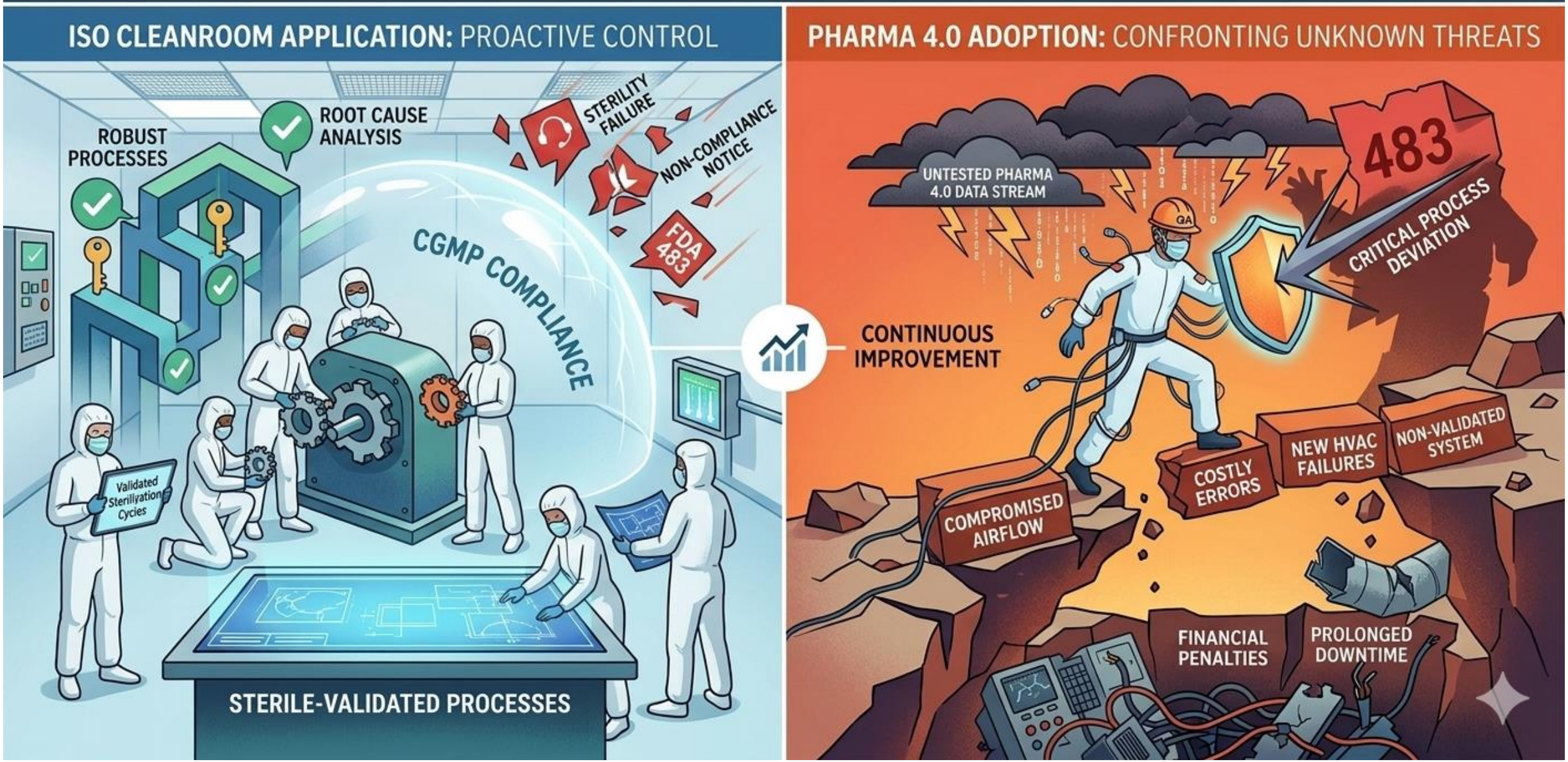
The best approach regarding setting cleanroom air change rates is to determine or vary the rate as needed based on the real-time quality of the air in the cleanroom.

There are two different space pressurization control philosophies used in controlling cleanroom space pressurization, they are:

- Volumetric Offset

* ASHRAE “Cleanroom Variable Airflow Design” 6/5/24, Vincent Sakraida, PE, LEED, AP

QUALITY: PREVENTION VS. RISK IN A REGULATED CLEANROOM



Demand Based Contamination Control (DBV) for Constant Compliance

New GMP HVAC control technology in regulatory alignment, without compromising quality compliance!

1. **Prove Compliance:** GMP Optimisation at a lower Constant Volume
2. **Prove Continued Compliance:** Set Back for unoccupied periods
3. **Prove Constant Compliance:** Demand Based CCS

Baseline Fingerprint

Air Volume Flow Rate
Equivalent ACH
Room DPs

Guardrail Boundaries

Minimum Airflow rate
DP Cascade
(15 Pa +/- 5Pa
10 – 20 Pa Alert band)

Demand based on

- Occupancy +
- Airborne Particles +
- Production/Process Schedule

What Quality is protecting?

Quality Concern

If new HVAC DBV control strategy fails or drifts, we could:

- Lose pressure cascade
- See contamination risk increase
- Trigger Deviations
- Impact batch (QP not happy!)
- Create regulatory exposure

Commitment

QA not asked to "trust" new control strategy

New HVAC control strategy introduced in a structured GMP roadmap:

- FOK with Change control + CCS-linked risk assessment
- Evidence before reliance (shadow mode)
- Qualified Boundaries + Alarms
- Fail-safe reversion to previous state

Fear is FDA 483 Observation/Warning "Red Letter" & risk to Drug license!

Constant Compliance → ONLY airflow becomes variable (within qualified limits)

If anything is uncertain, the system reverts to previous qualified settings.

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CLEANROOMS TODAY AND TOMORROW:

INNOVATION, SUSTAINABILITY, EXCELLENCE AND REGULATORY COMPLIANCE

PTZ Opportunity Tradition Knowledge
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- ISO Class Cleanrooms in SemiCon, Electronics, Battery and Pharmaceutical (Spaces from ISO 3 to !SO 8)
- Pipeline is growing over 58% YOY, Project wins from multiple regions (North America, Europe and China)
- Experience in Cleanroom Applications date back to Use in Labs since 1996 with Intel, Qualcomm and Hemlock Semiconductor in the USA.

Some Key ISO Class Clean Room Customers Currently Using Venturi Valves

arm
Colorcon
xfab
hp
GlobalFoundries™
intel
Texas Instruments
CCP 長春集團 Chang Chun Group
Lilly
acc AUTOMOTIVE CELLS Co
TESLA
ASML
NXP
TOYOTA
ENGIE

The Scale of Applications using Venturi Valves for Cleanrooms has grown 4 times in the last 3 years

WHAT'S NEXT?

CONSTANT COMPLIANCE

Maintain cleanroom compliance to the regulating guidelines that govern product quality and safety thru GMP and ISO Annex 1, CCS (Contamination Control Strategy) under all operational conditions. Including demand-based ventilation.

OPERATIONAL EFFICIENCY

Integrate multiple systems to streamline operations, create efficiencies, optimize resources and gain better insight into asset performance

RESILIENCY

Enable day-to-day system availability by implementing remote monitoring, predictive maintenance and diagnosis capability

PHARMA 4.0

Pharma 4.0 brings real-time monitoring of temperature, humidity, and other critical parameters through interconnected sensors and smart manufacturing systems.

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Scan QR Code to receive PDH credit...

Thank you for your attention!

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Airflow Visualization in Critical Environments: Advancements in Standards and Applications

Bill Shade, Microrite, Inc.

30 – 31 MARCH 2026
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- Outline
  - ASTM E3379-25, Standard Guide For Critical Airflow Visualization
  - Neutral Buoyancy
    - How do we design for it?
    - How do we test for it?
  - In Situ Air Pattern Analysis
    - What does the term mean
    - How do we accomplish this in Isolators
  - Questions?

ASTM E3379-25 Significance and Use

- Personnel with appropriate expertise in microbiology, sterility assurance, and manufacturing processes should oversee airflow visualization activities. This oversight includes reviewing study outcomes, evaluating airflow deficiencies, and determining whether procedural or equipment changes are required, supported by documented rationale. Demonstrating appropriate airflow over critical processing areas is an essential element of aseptic manufacturing qualification, and visualization techniques are commonly used to support this verification.

ASTM E3379-25 Significance and Use

- Airflow visualization relies on visual interpretation and inherently involves some subjectivity, particularly in operational environments where turbulence cannot be completely eliminated. The objective is to demonstrate that airflow remains controlled and that disturbances are minimized. These studies support confirmation that critical areas are protected and can inform environmental monitoring locations and evaluation of planned operational interventions.

ASTM E3379-25 Significance and Use

- Unidirectional, HEPA-filtered airflow is intended to reduce contamination risk by ensuring that clean air reaches critical surfaces first. Proper positioning of air returns, equipment, materials, and deliberate operator movements helps maintain airflow integrity. Observations made during operational airflow studies can be used to evaluate contamination control performance and may identify opportunities to improve equipment layout, operator positioning, or room configuration when airflow weaknesses are observed.

ASTM E3379-25 Significance and Use

- Qualification of aseptic processing areas should include visual confirmation that airflow moves uniformly across exposed product zones. Airflow return locations must function effectively to prevent localized turbulence or recirculation that could compromise contamination control.

ASTM E3379-25 Significance and Use

- The methods used to visualize airflow may differ depending on the stage of facility or process development. CFD modeling techniques may be useful during initial design, while direct visualization techniques are typically applied to evaluate airflow behavior in existing facilities under static or operational conditions.

ASTM E3379-25 Significance and Use

- Airflow behavior observed during visualization activities is commonly documented using digital recording equipment to allow for review, assessment, and long-term retention of study results.

ASTM E3379-25 Scope

- This guidance describes recommended practices for visualizing airflow in critical processing environments and is intended to be used alongside applicable regulatory and international cleanroom requirements related to contamination control.

ASTM E3379-25 Scope

- Airflow visualization techniques, including the use of tracer particles, are applied to observe and document airflow patterns in critical areas. These evaluations focus on understanding how HEPA-filtered air contributes to contamination control within critical zones.

ASTM E3379-25 Scope

- The focus of airflow visualization described here is limited to contamination control for product protection. Evaluation of airflow for personnel safety or containment of hazardous or highly potent materials is not addressed.

ASTM E3379-25 Scope

- Any area that relies on controlled airflow to protect exposed product or critical surfaces should be visually evaluated as part of the overall qualification process.

ASTM E3379-25 Scope

- Critical airflow evaluations are intended to confirm that clean air supplied from filtration systems moves in a consistent, unidirectional manner and effectively reduces contamination risk. Visualization methods use visible tracer particles to make airflow patterns observable. Tracer materials should be non-toxic, consistent in output, and capable of closely following air movement without significant influence from gravity or temperature.

ASTM E3379-25 Scope

- Results from airflow visualization activities can be used to compare actual airflow behavior with design expectations, improve contamination control performance, assess the impact of personnel and equipment movement, support risk assessments, establish environmental monitoring locations, and enhance operator training. Activities performed solely for experimental or optimization purposes may require different evaluation criteria.

ASTM E3379-25 Scope

- Measurements and observations associated with airflow visualization are expressed using internationally recognized metric units.

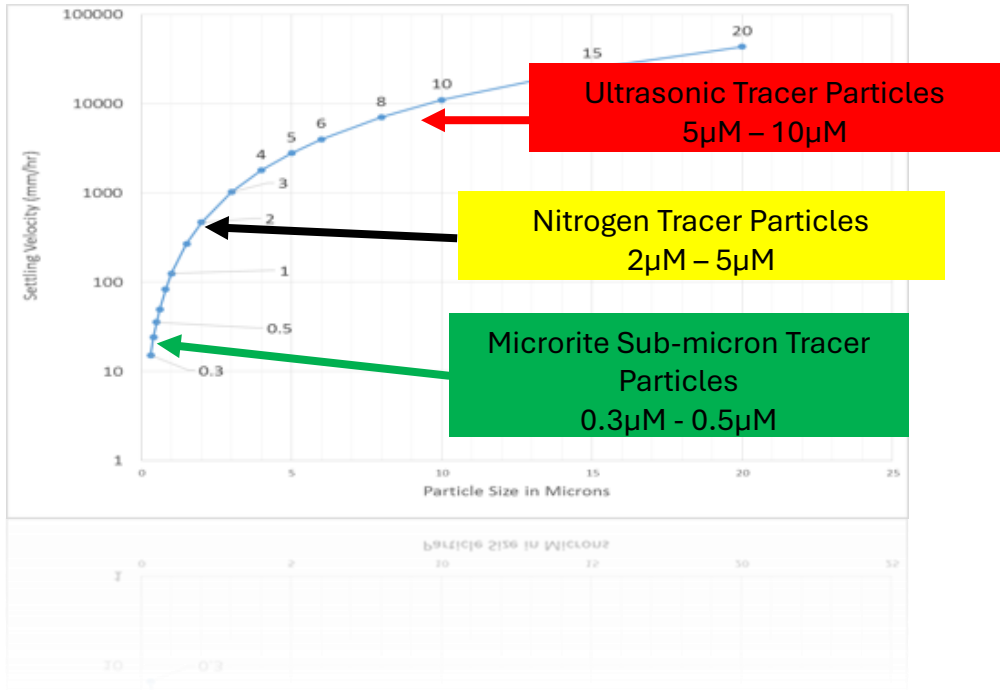
ASTM E3379-25 Scope

- Users of airflow visualization practices are responsible for establishing appropriate safety, health, and environmental controls and for determining the applicability of regulatory requirements prior to conducting studies.

ASTM E3379-25 Scope

- This Standard aligns with internationally recognized principles for the development and application of technical standards intended to facilitate consistent and reliable evaluation practices.

Chart 1: *Particle Settling Velocity



What is Neutral Buoyancy?

Answer: For Cleanroom Applications Particles with neutral buoyancy behavior are influenced only by air currents within the cleanroom or area being tested. Gravity and the particles temperature do not influence the particles behavior during the testing.

Microrite's Tracer Particles have a Very Low Settling Velocity comported with Water CO2 or Nitrogen Based "Cleanroom Foggers"

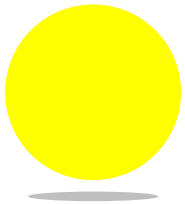
What is Neutral Buoyancy?

For Cleanroom Applications Particles with neutral buoyancy behavior are influenced only by air currents within the cleanroom or area being tested. Gravity and the particles temperature do not influence the particles behavior during the testing.

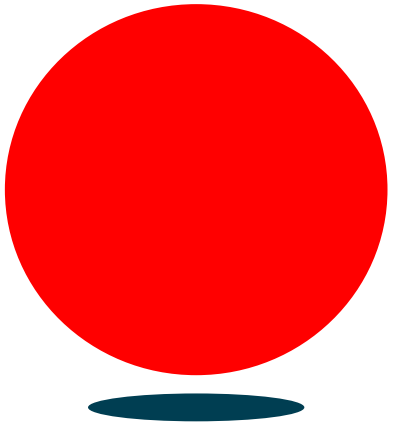
Microrite's Tracer Particles have a Very Low Settling Velocity compared with Water CO2 or Nitrogen Based "Cleanroom Foggers"

Microrite's Sub-Micron Tracer Particle
0.3µM – 0.5µM

Nitrogen Fog Tracer Particle
2µM – 5µM



Ultrasonic Water Fog Tracer Particle
5µM – 10µM



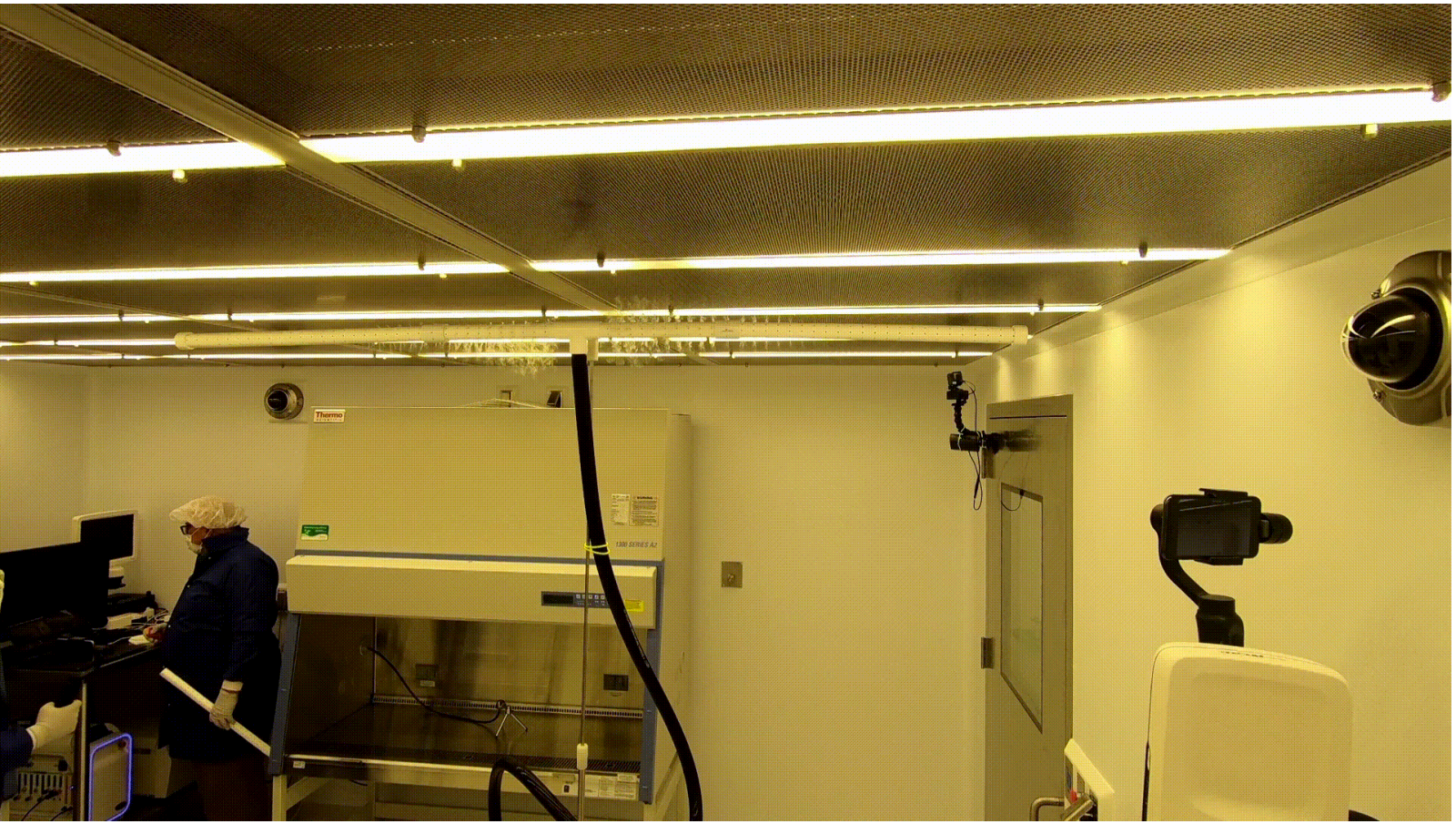
Video: WFI (water fogger in Conference Room)

Video: Comparison Between Nitrogen & Glycol

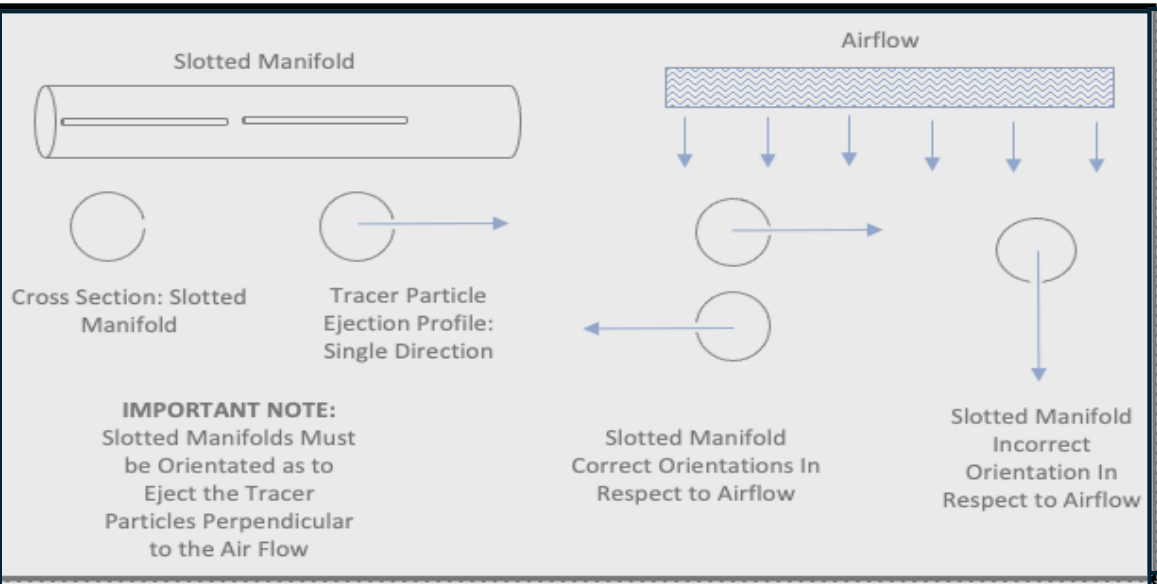
Testing an Air Return with Microrite TPG

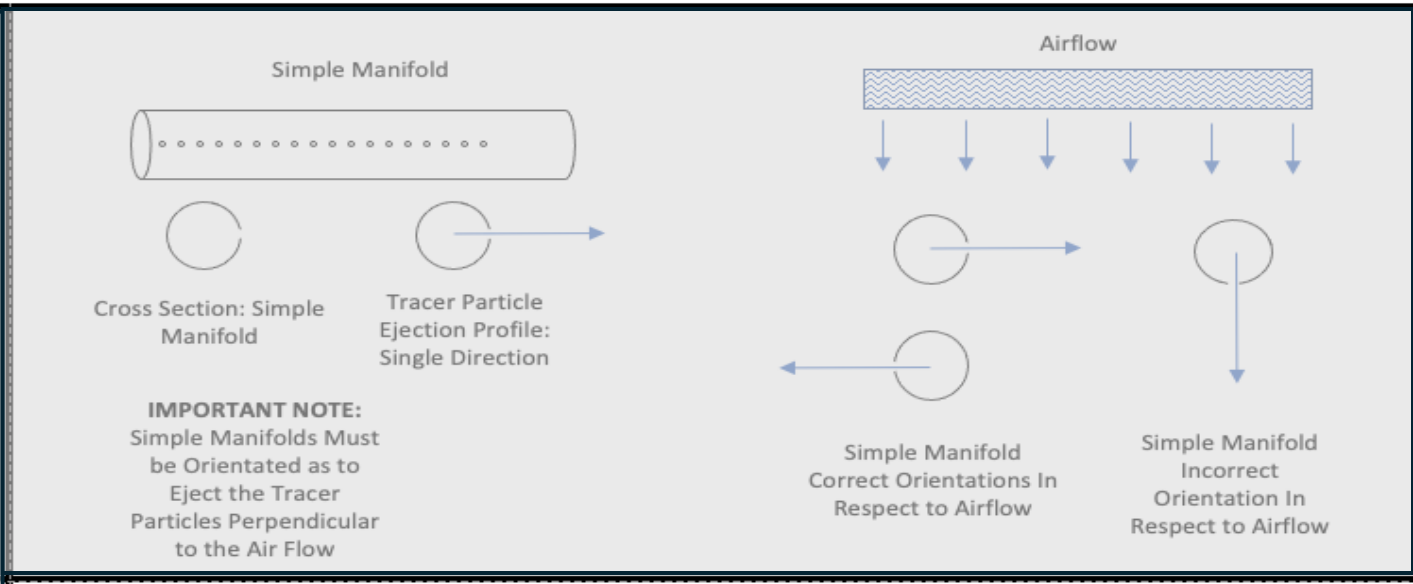
Video: Testing Air Return: Air Return is off.

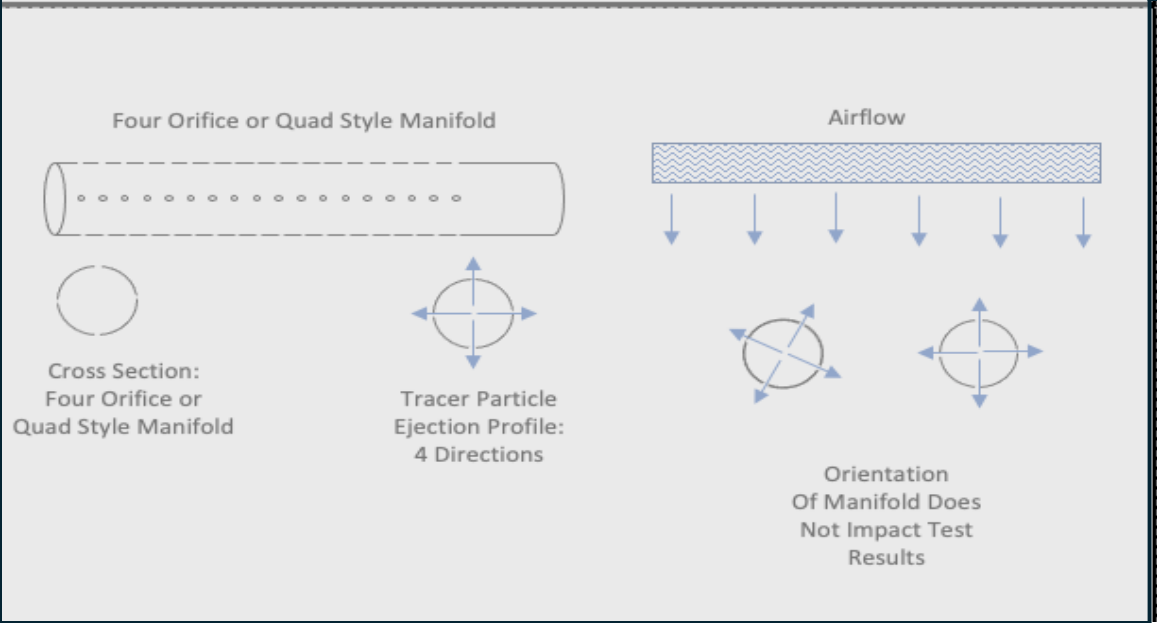
Microrite TPG Discovered Something Missed By the Certifiers & FMS



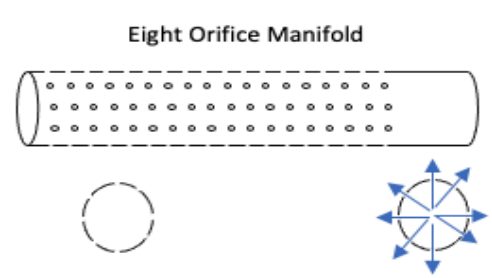
Video: Microrite TPG Discovered Something Missed By the Cleanroom Certifiers and not identified by the FMS system

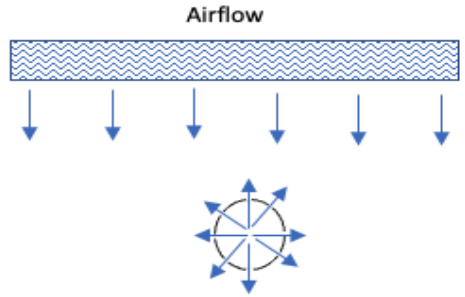






Microrite TPG Diffuser





Manifold Designs

microrite

- The 2004 FDA guidance mandates that **“in situ air pattern analysis should be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions”**
- Smoke studies (using smoke or fog to visualize air currents) must be done not only at rest but also during operations (with equipment running and personnel simulating interventions).

In Situ Air Pattern Analysis Equipment

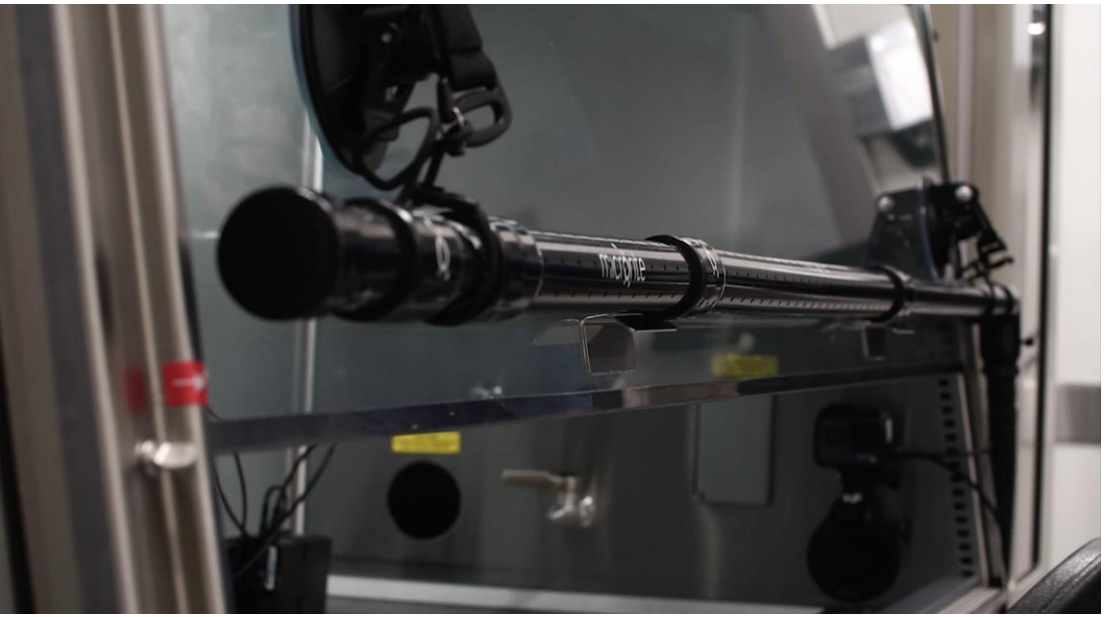
- Diffuser Manifold:
  - Design Creates the Vapor to Particle Conversion
    - Submicron Neutrally Buoyant Tracer Particles
    - Custom assembled for the required test
  - Addresses the requirement for "In situ air pattern analyses" by allowing HANDS FREE testing of isolators, RABS & benches

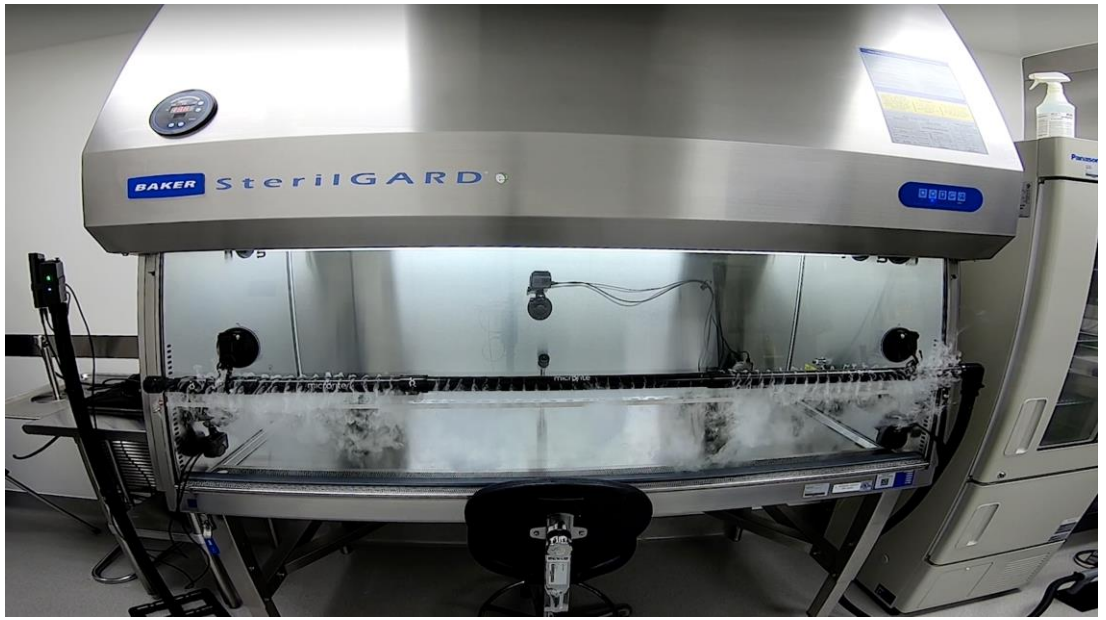
In Situ Air Pattern Analysis (BSC Example)

- Generator Placed Remotely From The Scene.
- Manifold For Tracer Particles Held in Place by Gear Ties and Suction Cups (not a person)
- Remote On/Off Control

BSC with Diffuser Along the outside of BSC Sash

- Attach Diffuser Manifold to Outside of BSC on the Sash. (just above the handles (~ 1 inch from bottom of sash) Using Suction cups and Gear Ties.





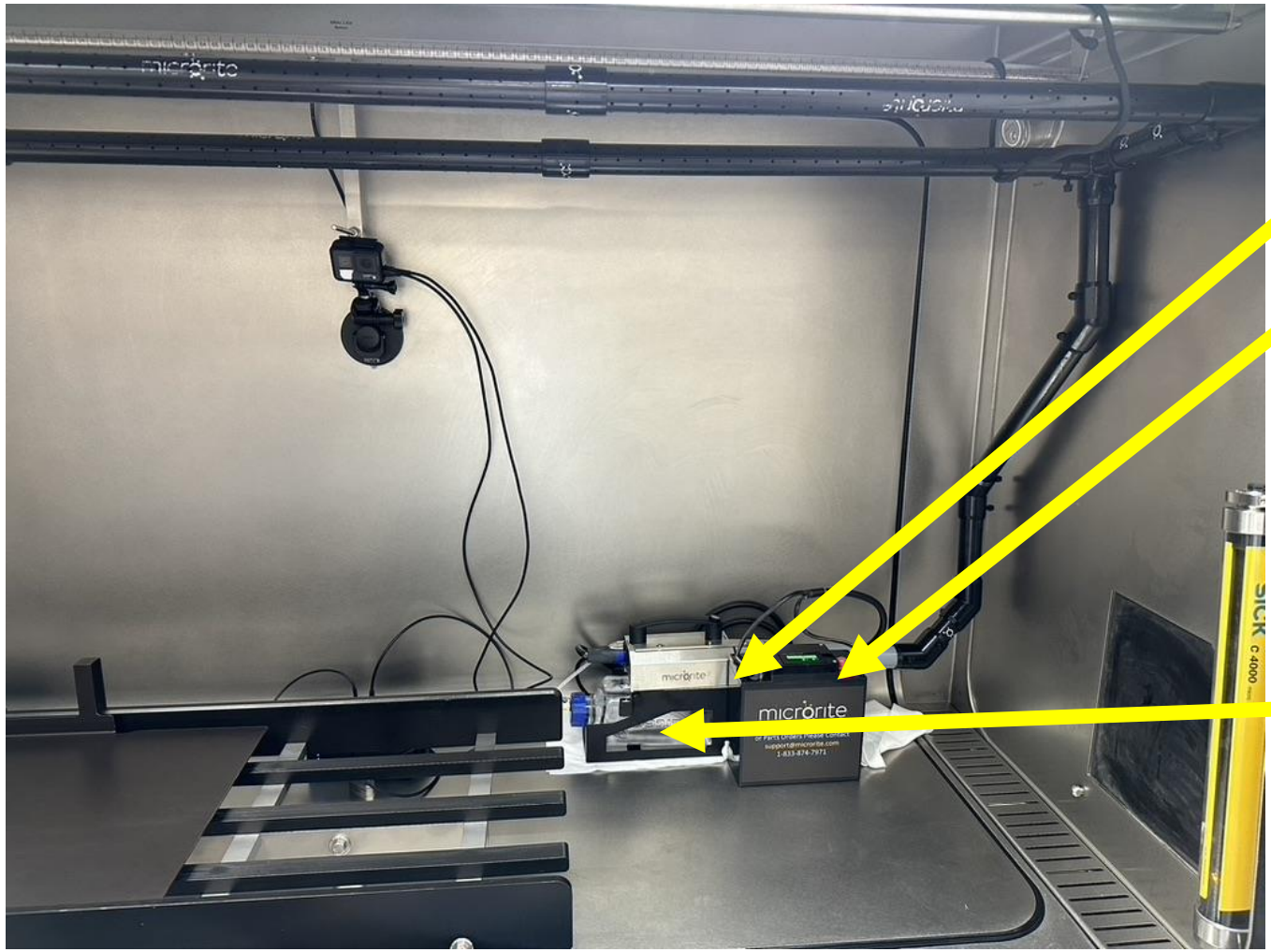
Sash Testing to Demonstrate:

- Outside Air does not enter the BSC by generating Tracer Particles along the length of the BSC on the outside just above the sash.

- This test is good for loading of the BSC to demonstrate that loading does not cause outside air to enter the interior of the BSC

- In Situ Air Pattern Analysis in Isolators
- Manifold Attached to the inside of isolator
- Using Supplied Gear Ties and/or Suction Cups

- Manifold Attached to the inside of isolator
- Using Supplied Gear Ties and/or Suction Cups



- Generator
- Optional Li-Po Battery Pack allows for the isolator to be completely sealed and the TPG can operate via remote control.
- Optional 1 Liter Reservoir allows up to 100 minutes of operation before the fluid has to be replaced.

- Generator below deck connected to manifold via flexible hose

Airflow Visualization in Critical Environments: Advancements in Standards and Applications

Bill Shade, Microrite, Inc.

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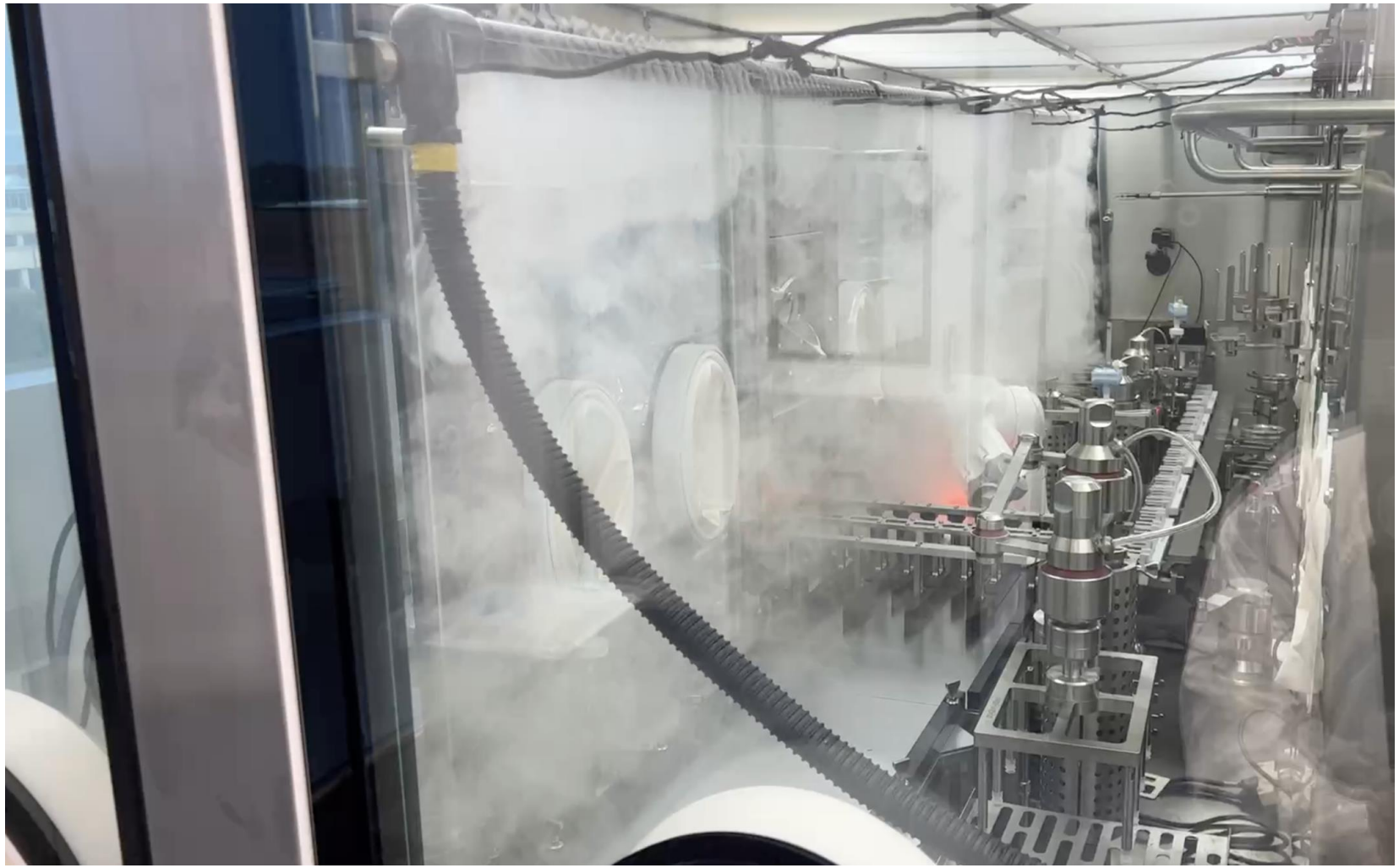
Fully Loaded Example



Spanning Multiple Glove Ports

Airflow Visualization in Critical Environments: Advancements in Standards and Applications

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- Mouse Hole Testing: GMP Requirement.
- Test on both Sides of the Mousehole.
- Testing Should include opening and closing of the enclosure door as well as the entrance to the surrounding cleanroom.
- This tests if there is a reversal in flow when doors are opened.

Airflow Visualization in Critical Environments: Advancements in Standards and Applications

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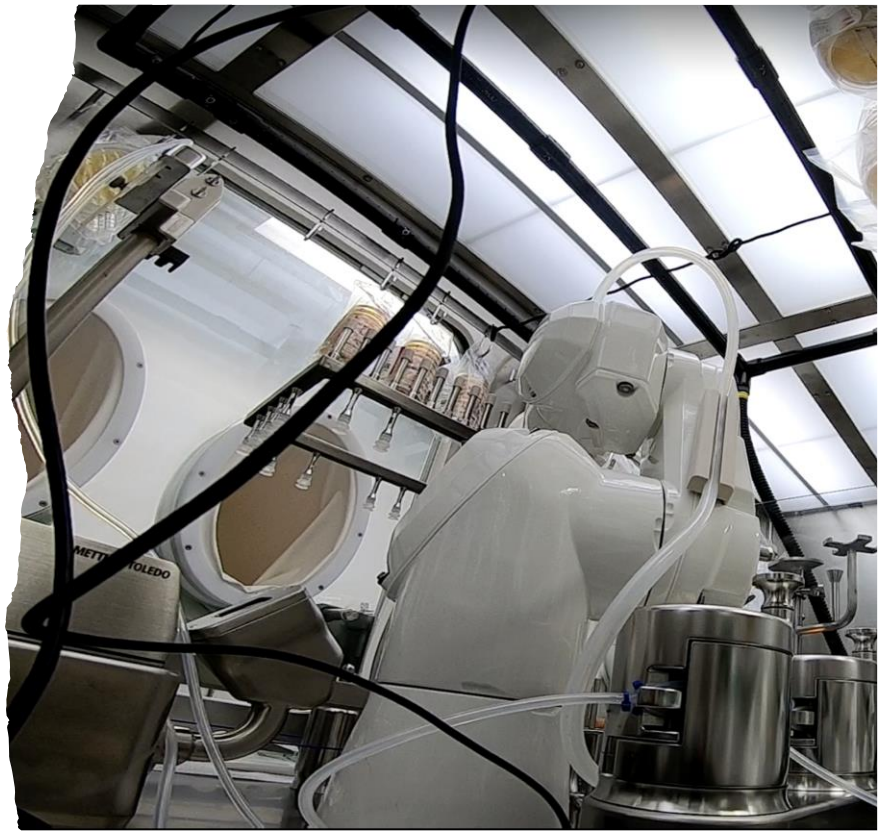
Test only the areas of interest to minimize impact on equipment

Flexibility in manifold design allows the construction of small or large manifolds.



Smoke Studies during Isolator operation

Isolator Intervention

WiFi battery operated cameras provide real time multi angle premium quality video

Thank you for your attention!

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Designing Cleanroom Robotics Right

Qualification, Testing and Contamination Risk Management under IEST-RP-CC053.1

Hasim Solmaz, Lighthouse Worldwide Solutions

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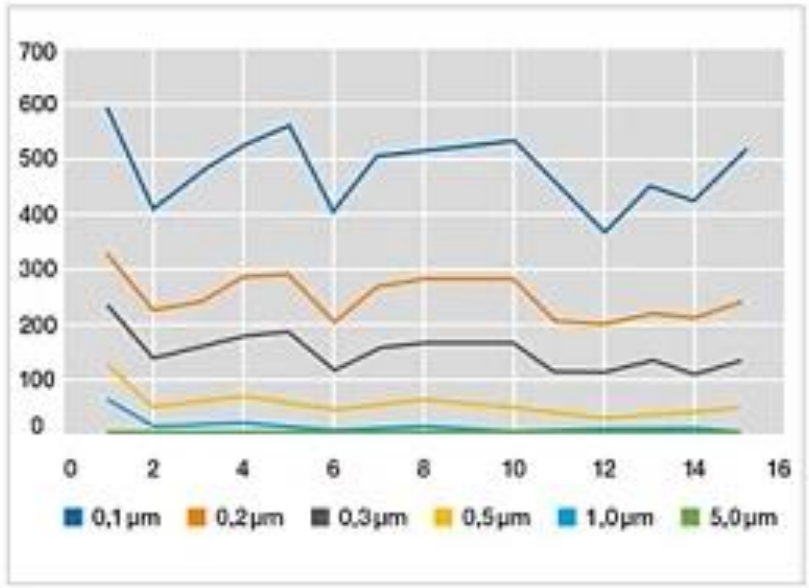
THE PROBLEM

"Why Robotics Projects Fail in Cleanrooms?"



The graph shows the totalised concentration of particles at 2kg load, 80% speed and 10s pause.

Designing Cleanroom Robotics Right
Qualification, Testing and Contamination Risk Management under IEST-RP-CC053.1

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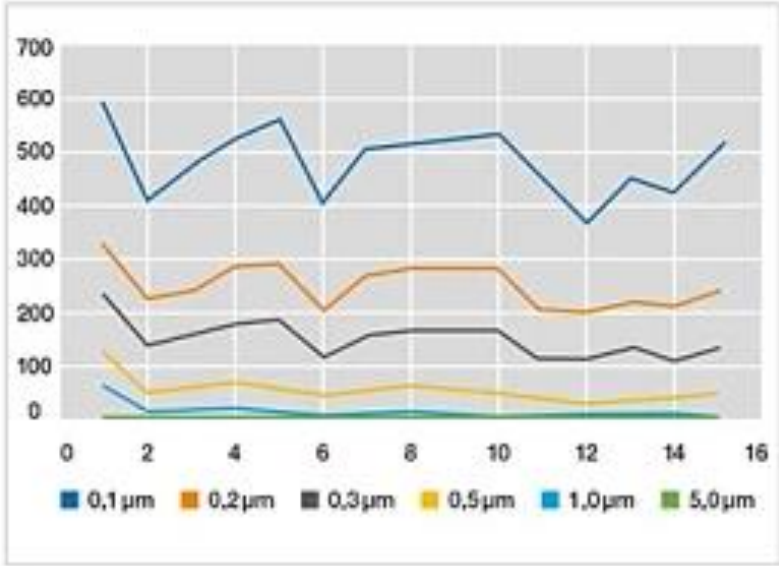
THE PROBLEM

"Why Robotics Projects Fail in Cleanrooms?"

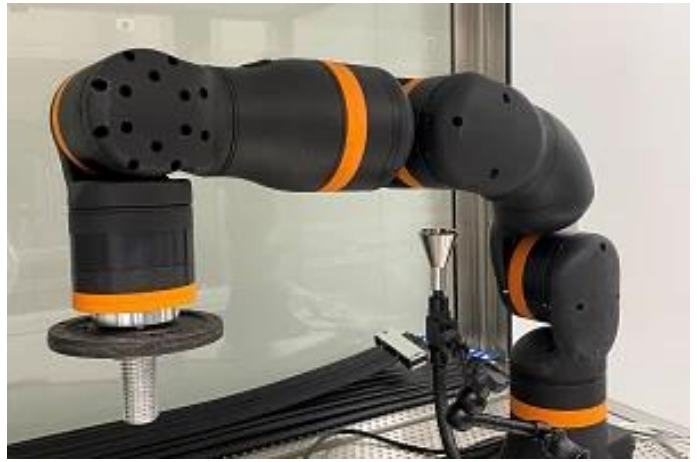
- Unexpected particle increase
- Airflow disruption
- Microbial hotspots
- Integration conflicts

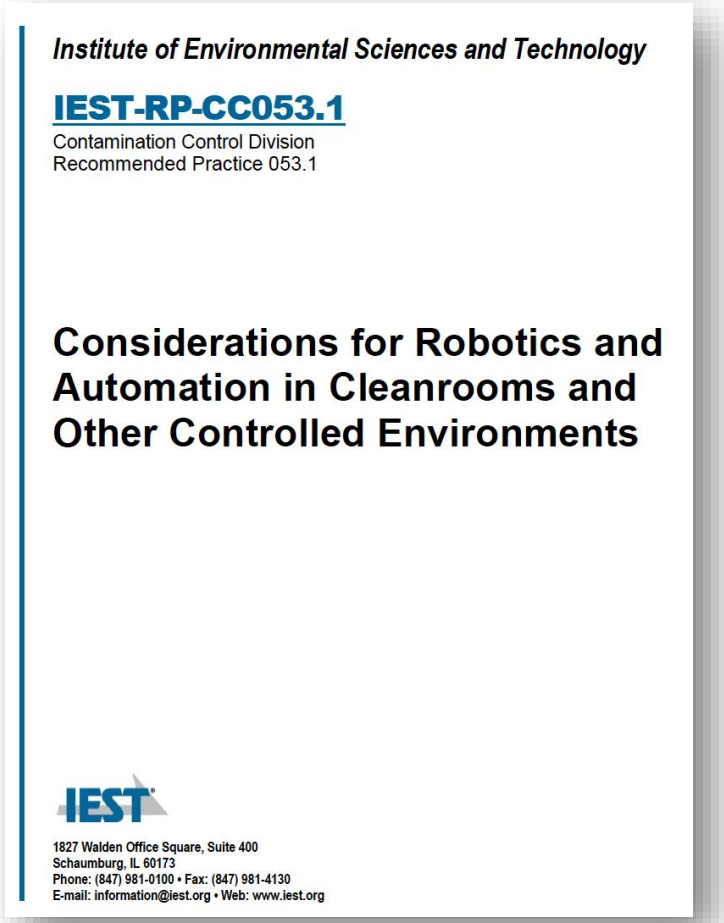


THE MISCONCEPTION

"Automation ≠ Clean"

- Robots generate particles
- Robots disturb airflow
- Robots introduce new surfaces





Designing Cleanroom Robotics Right

Qualification, Testing and Contamination Risk Management under IEST-RP-CC053.1

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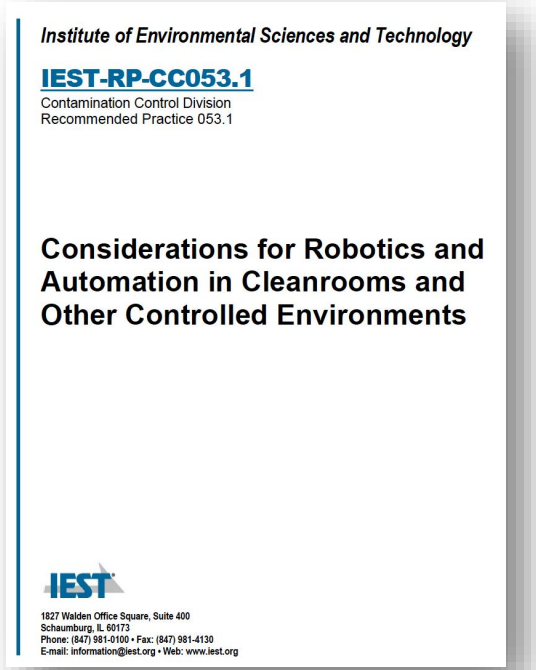
WHAT IEST RP-CC053 REALLY IS

"not a robotics standard. It is a contamination control framework"

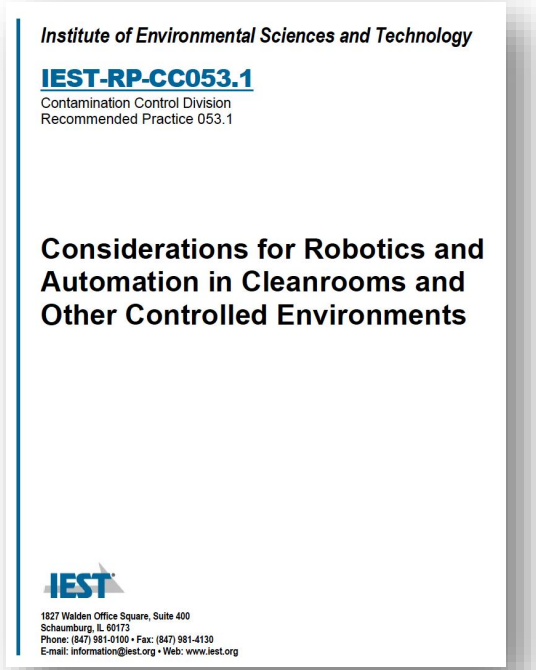
- Design considerations
- Contamination control principles
- Testing & qualification
- Commissioning lifecycle



WHAT IT DOES NOT COVER

Important Boundaries

- Not a safety standard
- Not software validation
- Not process equipment robotics



SHOULD YOU USE A ROBOT?

"Automation without justification is just expensive contamination."

Risk-Based Justification
Contamination risk
Process benefit
Business impact
Regulatory needs

Horizontal Risk Scale for Cleanroom Robotics

Risk Level	Example	Critical Concern
Low	ISO 8 AMR	Airflow disturbance
Medium	Grade C robot	Particle shedding
High	Aseptic fill robot	Sterility risk

"This is how we should think—not robot vs no robot, but risk positioning."

DESIGN: SURFACES & MATERIALS

"If you cannot clean it, you should not install it."

Smooth & cleanable

Chemical resistant

Minimal joints & gaps

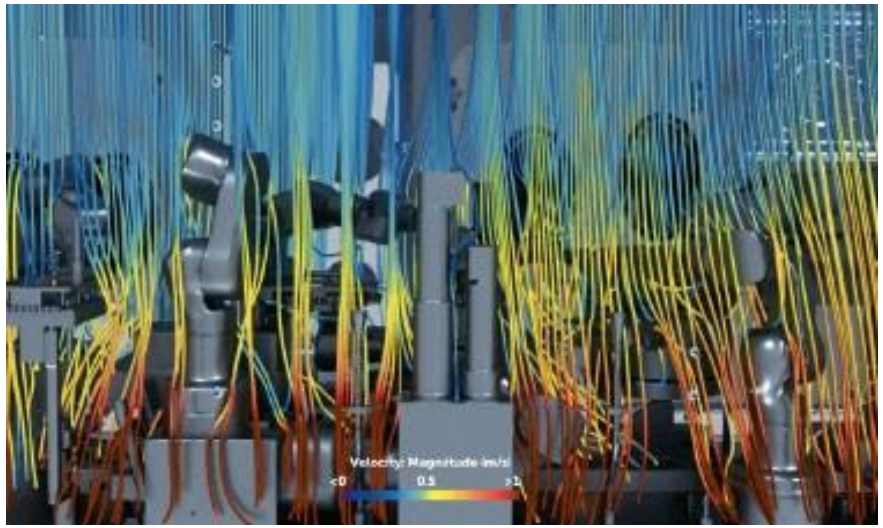
DESIGN: AIRFLOW

"Your robot is now part of your HVAC system"

Turbulence generation

Blocking supply/return

Impact on critical zones



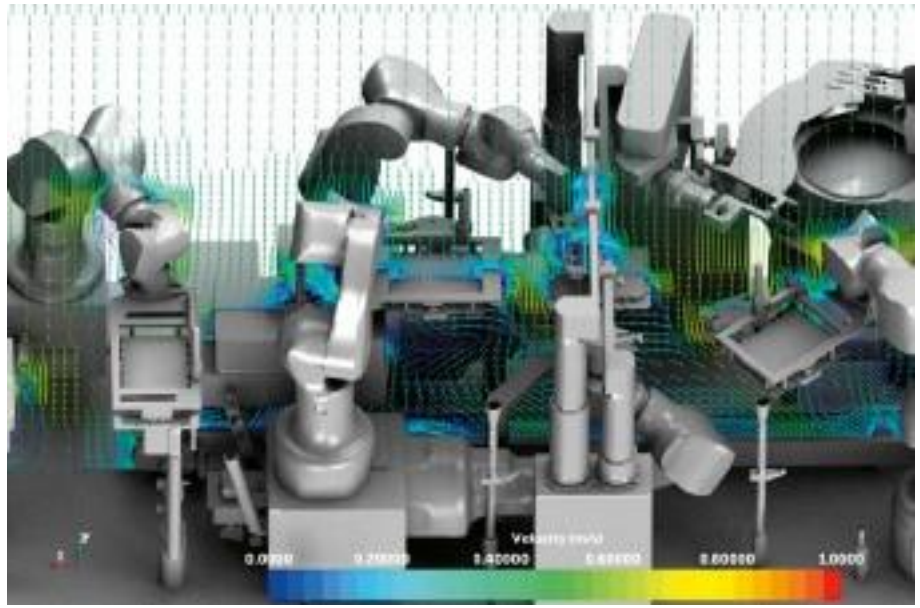
DESIGN: PARTICLE & CONTAMINATION CONTROL

"Every robot is a contamination source. The question is: ***controlled or not?***"

Internal particle generation

Filtration of exhaust

Lubricant control



TESTING & SUITABILITY

"If you don't test it dynamically, you don't understand it."

Validate in Operation;

- Particle (In Operation ISO 14644-1 & Monitoring ISO 14644-2)
- Microbial (IEST RP CC023, EN17141)
- Surface Contamination
- CFD modeling

Understanding Robotics' Contamination Impact

Particle generation from moving parts

Airflow disruption due to presence

Additional surfaces for contamination

Integration challenges with systems

3 Takeaways

1. Robotics introduces new contamination risks
2. Design must consider airflow + emissions
3. Qualification must be risk-based

“Don’t integrate robots into cleanrooms.

Integrate cleanroom thinking into robotics.”

Thank you for your attention!

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Panel Discussion

Moderator: Klemen Škrlec, Vice President SCS, Associate Director/Business Manager for ITOT Solutions, Novartis d.o.o., Slovenia

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Advanced HVAC Optimization for Pharmaceutical Cleanrooms

Driving energy savings with Predictive control

Rok Prešeren, PhD, Metronik d.o.o.

METRONIK

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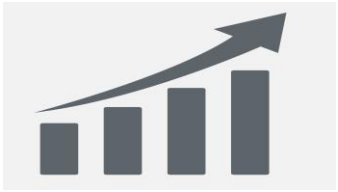
Metronik – a leading regional company for automation, process management and digitalization in industry

Added value partners



- Over 30 years of business growth

Expert for automation and industry digitalization

- Broad solution portfolio for automation, process management, digitialization and production informatization
- Solutions for various branches from pharma, food&bevarege to metal working, utilities …

International presence

- Over 200 employees with strong sales and support network through SKAN AG group

Rok Prešeren, PhD, Metronik d.o.o.

METRONIK

Why air matters?

- Air as raw material
- Deviations degrade batches

Clear-room air is not optional; it is mission critical

Heating, Ventilation and Air Conditioning is large energy consumer

HVAC energy consumption of mid-sized facility

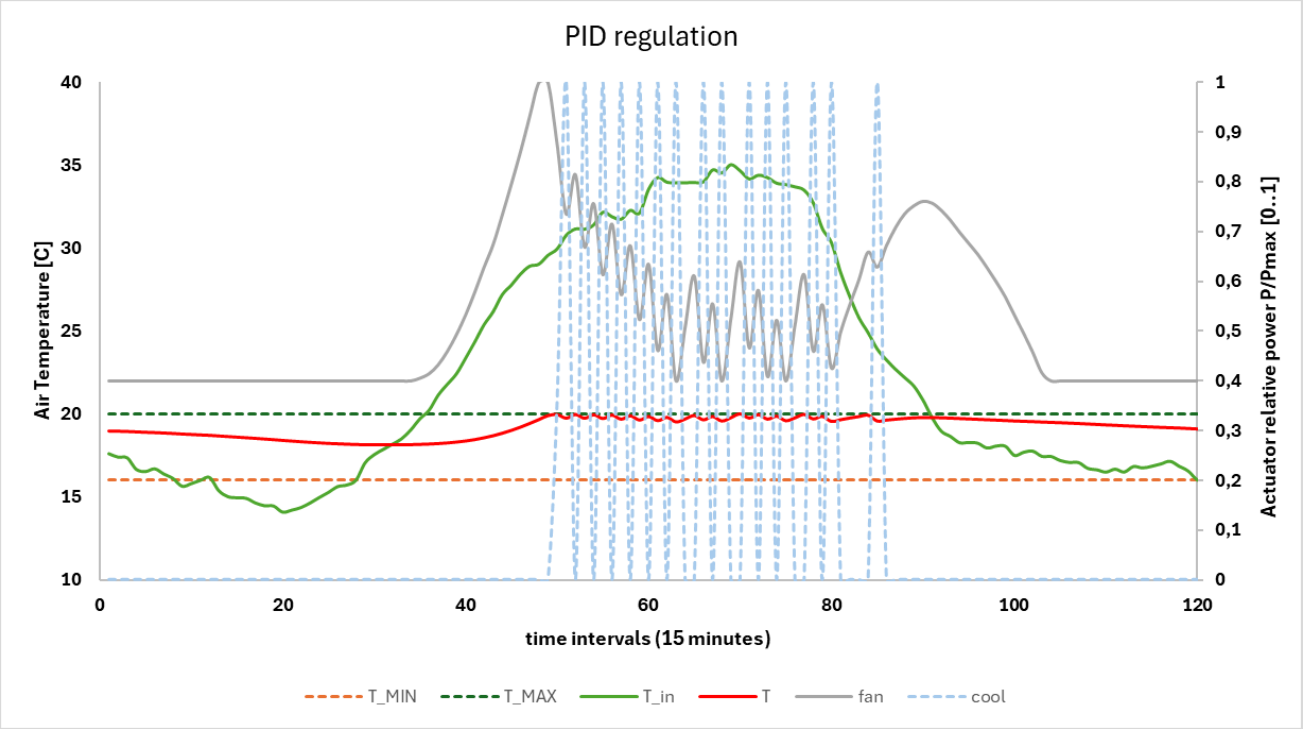
30%

of production hall electricity

Among largest controllable energy expenses … yet regulation is reactive.

Proven classical HVAC regulation is PID technology

- **Fast** regulation response
- **Reacting** to changes in environment
- **Stable** in driving the system to desired state
- **Cannot anticipate next environmental shift**
  "Chasing" external fluctuations



Higher energy consumption, mechanical wear & shorter lifetime.

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What if your HVAC system knew the future?

Advanced HVAC Optimization for Pharmaceutical Cleanrooms

Rok Prešeren, PhD, Metronik d.o.o.

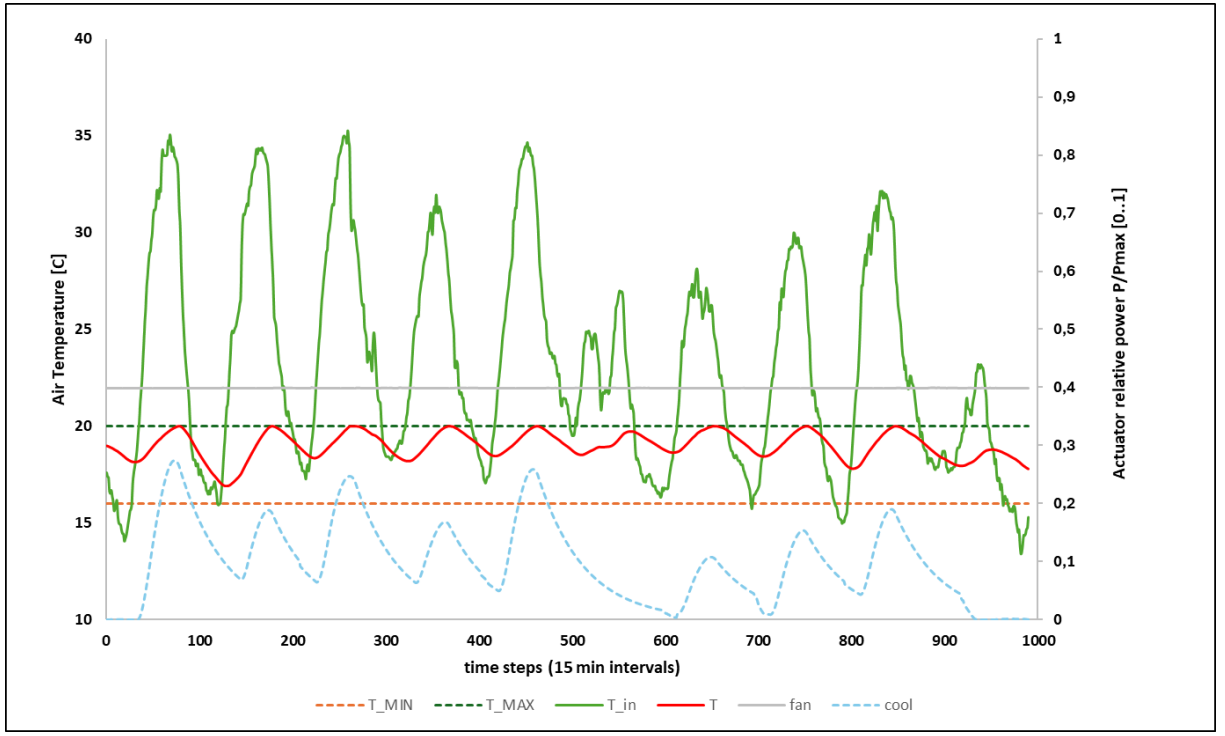
METRONIK

Model Predictive Control enters the stage

Uses:

- **Current HVAC state** (temperature, humidity)
- Predicted **future outdoor air conditions**
- Clean-room setpoints and constraints

Orders of magnitude **slower than PID**



…to optimize ahead of time, not after the fact, either operating regimes schedules or even control trajectory. It acts like autopilot for HVAC.

Future outdoor conditions; why weather prediction matters?

Public meteorological forecasts are good…

…but not good enough to drive predictions for clean-room.

Typical a-day-ahead errors of a forecast:

- Temperature: ±1.5°C
- Humidity: ±10% relative

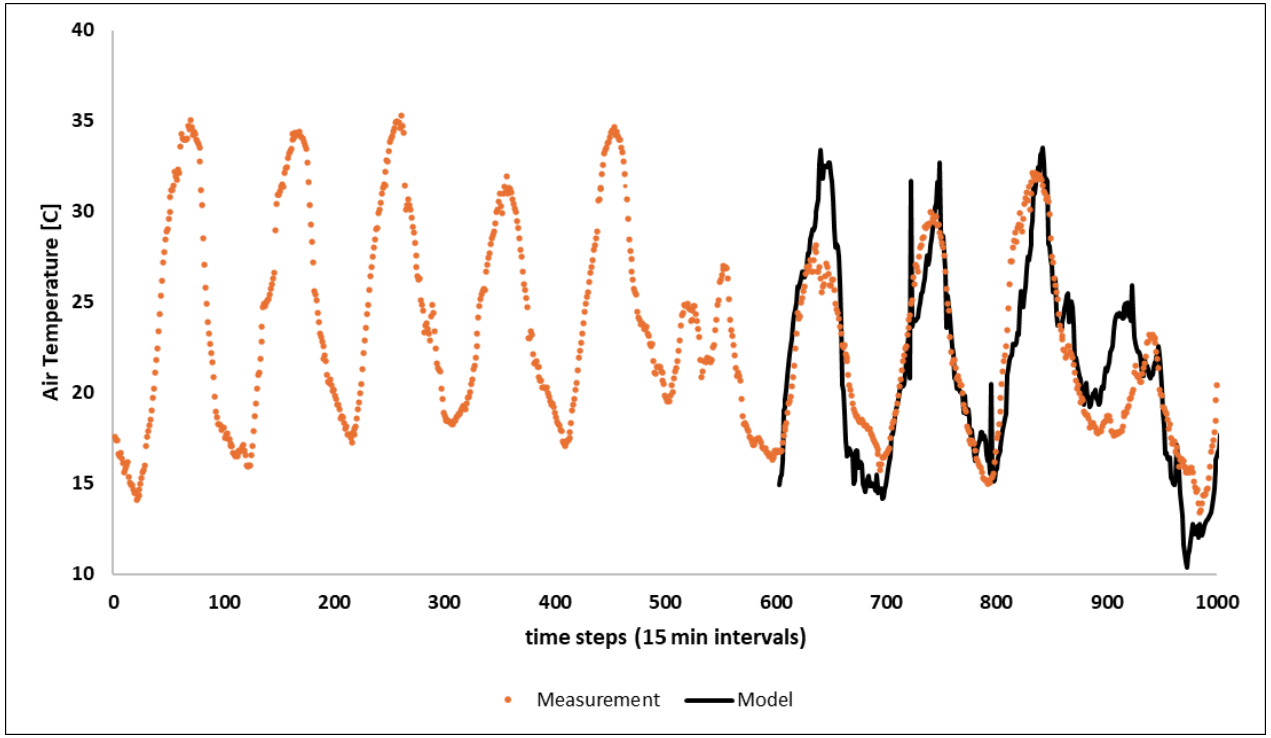
On microlocation the errors can double.

… these are regional, while we need microlocation forecasts.

Building a good Microlocal Model

Combine:

- Regional weather forecasts
- Local temperature and humidity measurements



… and create Machine Learning trained forecast model

From Prediction to Control - recipe

- Create HVAC model (fans, valves … and their interaction)
- Use microlocation air forecasts **and production plan** inputs to compute:
  - HVAC dynamics
  - output HVAC temperature and humidity
  - optimized HVAC regimes plan driven by production plan
- **Use computed values to adjust HVAC regimes schedules**, i.e. adjust PID regulation set-points or drive the HVAC parameters

… to find optimal future path by varying HVAC parameters

Results: Energy impact

7%

Reduction in electrical energy consumption

for 10GWh yearly consumption of mid-sized production line … a substantial 80.000 EUR saving.

Extended HVAC Lifetime? Possible bot not proven yet.

Reduced parameter changes may also lead to:

- Lower mechanical stress
- Less thermal cycling
- Reduced wear on actuators and fans
- Longer maintenance intervals
- Extended HVAC system lifetime

Stability = longevity

What this could mean for Operations?

- Energy savings
- Reduced operational and delayed investment costs
- Increased operational robustness

Let's explore what Metronik can do for your operation!

Thank you for your attention!

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Innovative solutions for transfer, filling and packaging of API substances in a closed sterile environment

Tilen Ovnicek, Iskra Pio d.o.o.

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ISKRA PIO:

Clean visions.

- 30+ years of experience,
- own R&D,
- global footprint in Pharma and Biotech,
- specialized in:
  - Turn-key cleanroom solutions

Innovative solutions for transfer, filling and packaging of API substances in closed sterile environment

Tilen Ovnicek, Iskra Pio d.o.o.

Clean room solutions

- Various types for different applications:
  - Modular clean rooms
  - Regular clean rooms
  - SmartCon GMP Clean rooms
- Controls:
  - operation and safety functions
  - regulation of temperature and humidity
  - working/standby mode
- Directives:
  - euGMP, ISO 14644-1: 2015

ISKRA PIO:

Clean visions.

- 30+ years of experience,
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- Specialized in:
  - Turn-key cleanroom solutions,
  - equipment for clean and cleaning technology,

Innovative solutions for transfer, filling and packaging of API substances in closed sterile environment

Tilen Ovnicek, Iskra Pio d.o.o.

Iskra PIO equipment:

- Personal airlocks:
  - Mist Shower
  - Air shower
- Material airlocks:
  - Passive pass-box chambers
  - Active pass-box chambers
  - De-dusting cabin
  - H2O2 pass-box

Iskra PIO equipment:

- Safety cabinets:
  - product protection
  - operator protection
  - radiation protection

Iskra PIO equipment:

- Uni-directional airflow cabins:
  - UDF units
  - Sampling booths
  - Weighing booths
- RABS systems
  - Assure class 5 – ISO1466

ISOLATORS:

- radiopharmaceutical hot cell
- containment
- aseptic

ISKRA PIO:

Clean visions.

- 30+ years of experience,
- own R&D,
- global footprint in Pharma and Biotech
- Specialized in:
  - Turn-key cleanroom solutions,
  - equipment for clean and cleaning technology,
  - GMP & ISO qualification
- Compliances: ISO 9001 | ISO 14001 | EN 1127-1 (Atex)

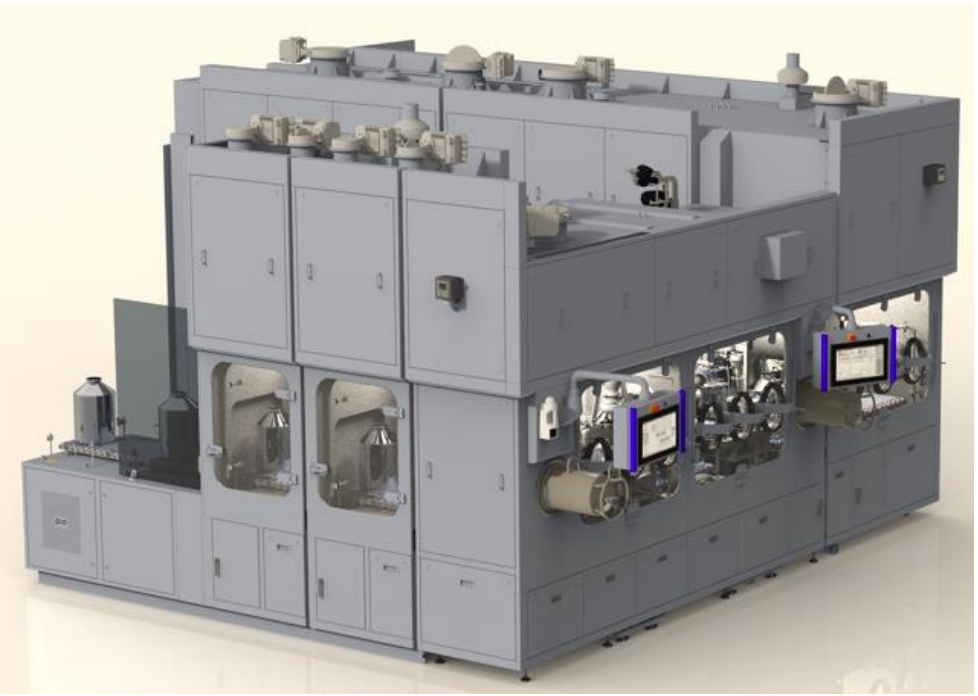
Innovative solutions for transfer, filling and packaging of API substances in closed sterile environment

Tilen Ovnicek, Iskra Pio d.o.o.

Advanced aseptic solutions

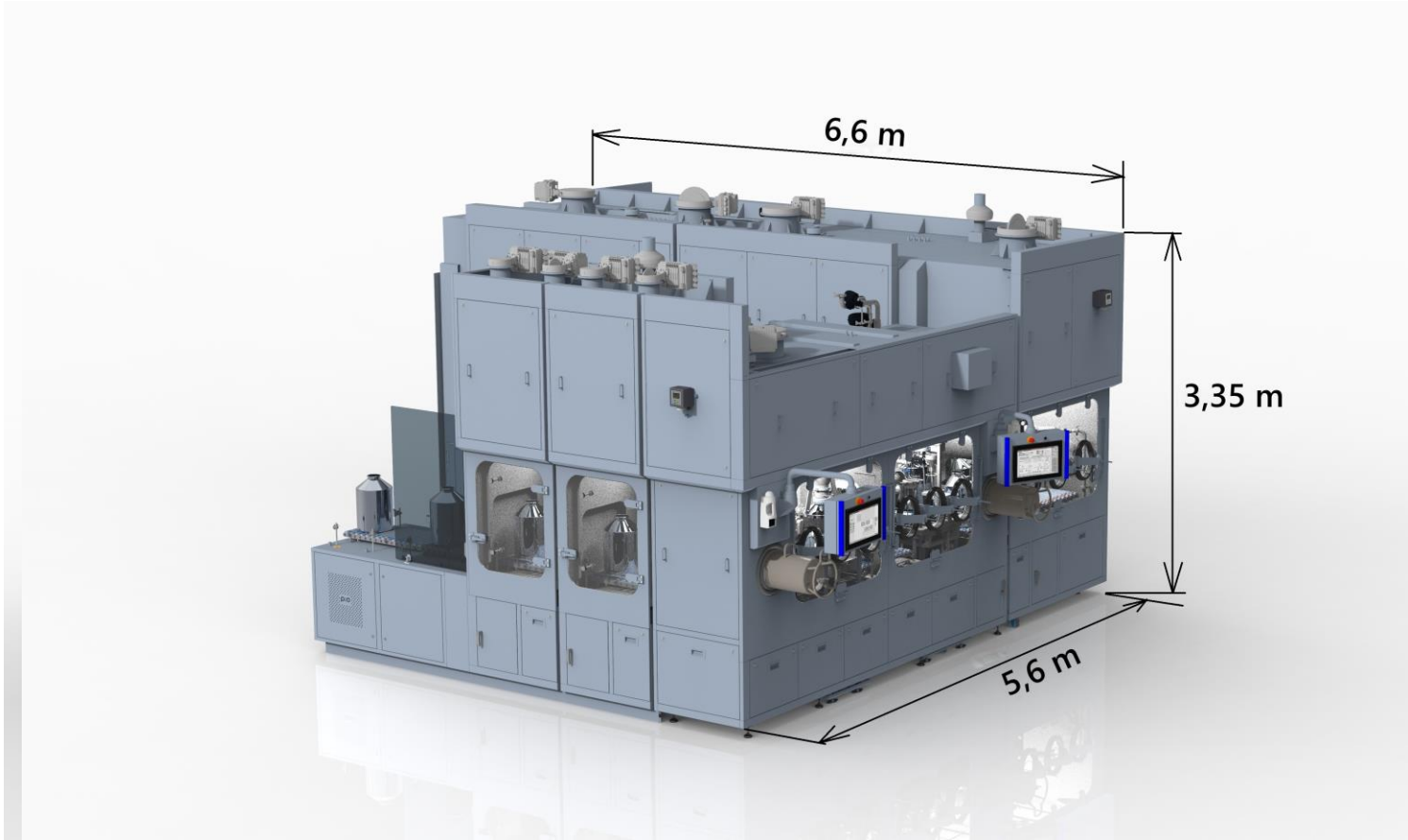
- Recipient of the National Gold Award for Innovation in 2024

CCIS's Award for Best Innovation 2024



Introduction

- 5,6m (width) x 6,6m (lenght) x 3,35m (height)
- Complexity:
  - >130 sensor, >3000 drawings
  - >1300 el. components
  - >5000 pg. of documentation
- Process divided to 5 stages
  - off-loading
  - buffer
  - filling
  - packing
  - exit



Course of the project

- Project phases:
  - concept design
  - Mock up
  - detail engineerin
  - design specifica
  - manufacturing
  - testing
  - FAT
  - delivery - installation - SAT
  - qualification

Diving into details of our filling line

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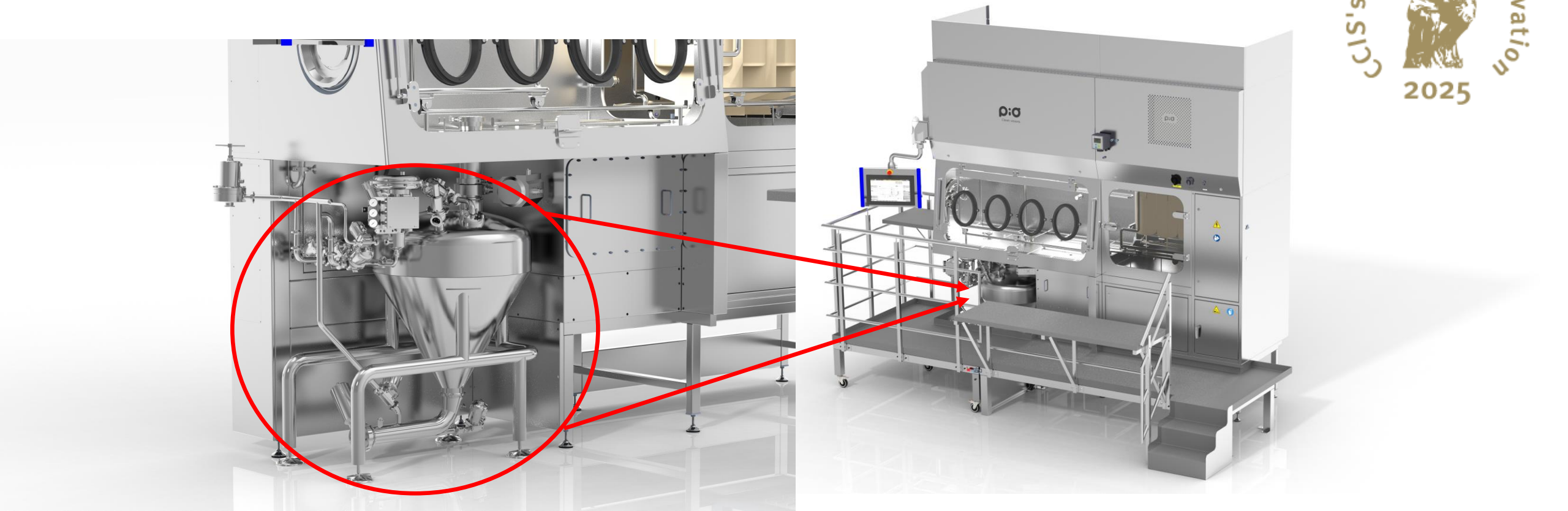
Advanced aseptic solutions – JetLoad steri isolator

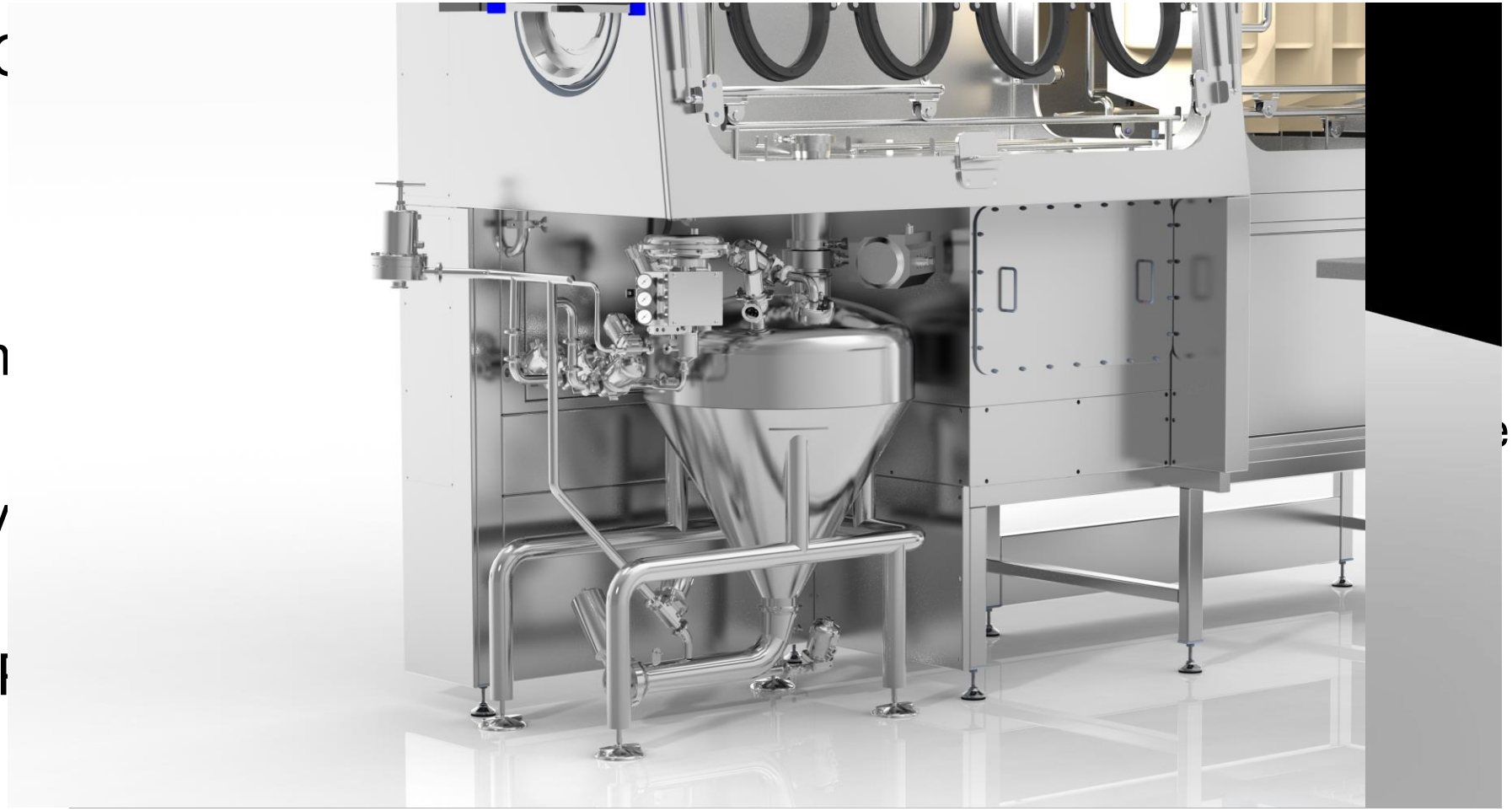
- Recipient of the National Gold Award for Innovation in 2025

CIS's Award for Best Innovation 2025



Isolator overview

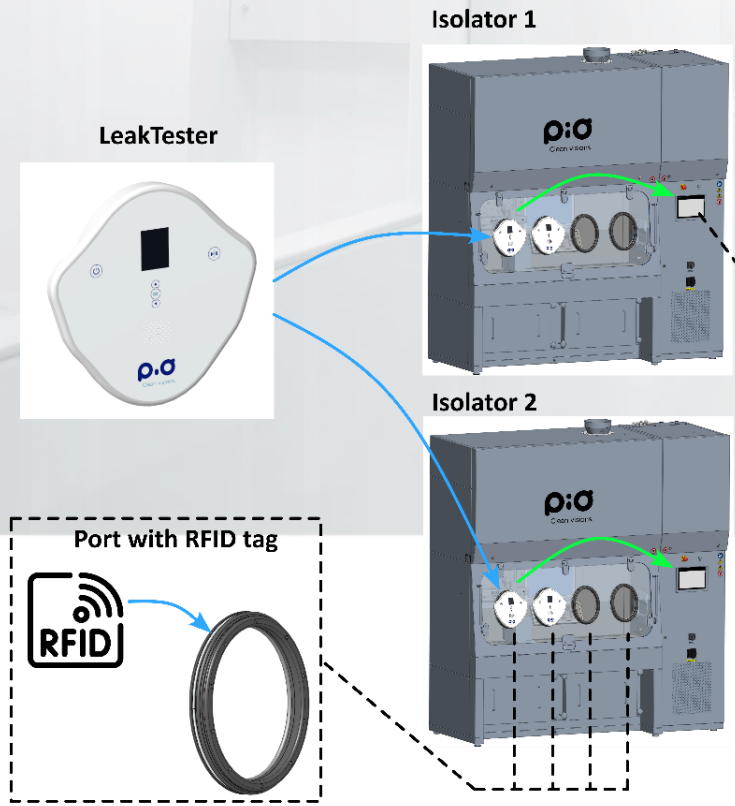
- PIC
  -
  -
  -
- Un
  -
- Ov
  -
- CI
  -

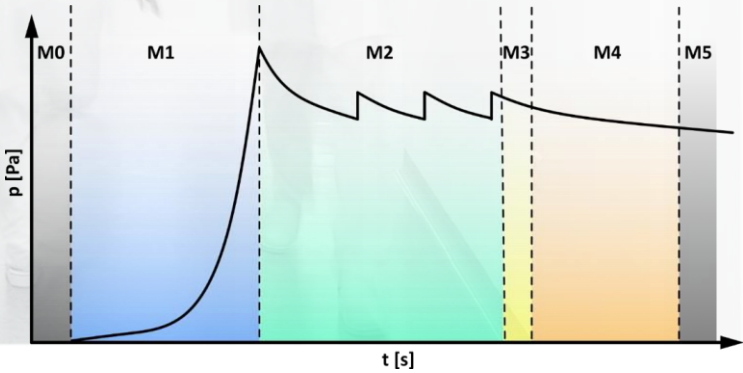


eration

Iskra PIO is shaping the future of pharma industry through:

Innovation | Precision | Knowledge | Experience





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Mednarodna konferenca

ČISTI PROSTORI DANES IN JUTRI:

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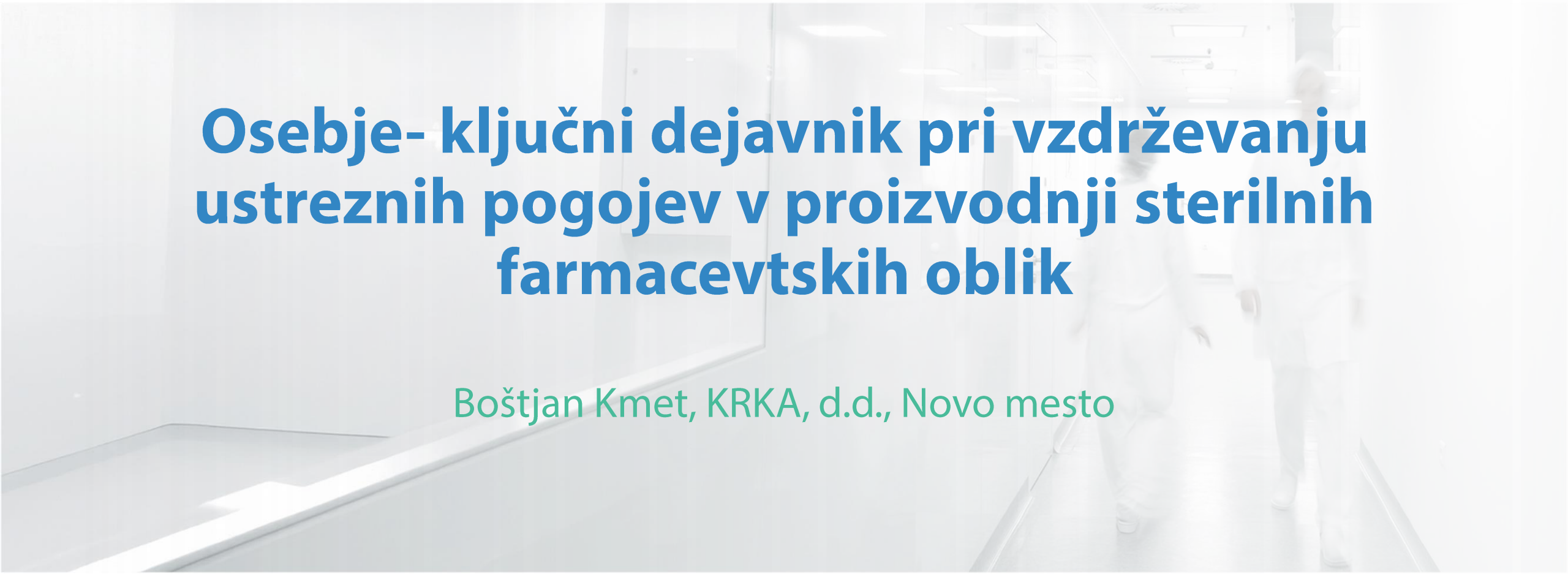

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

Boštjan Kmet, KRKA, d.d., Novo mesto

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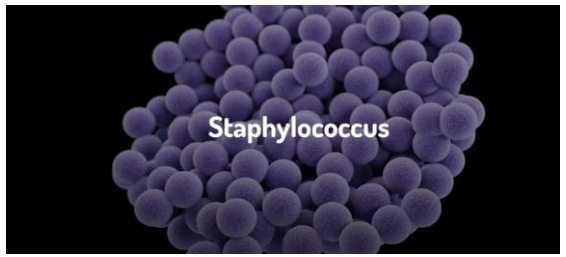
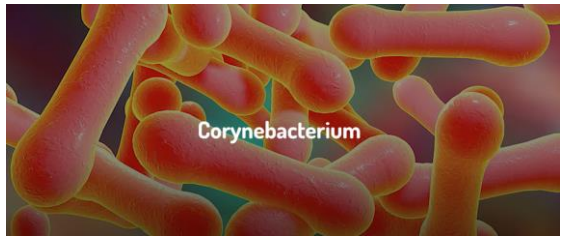
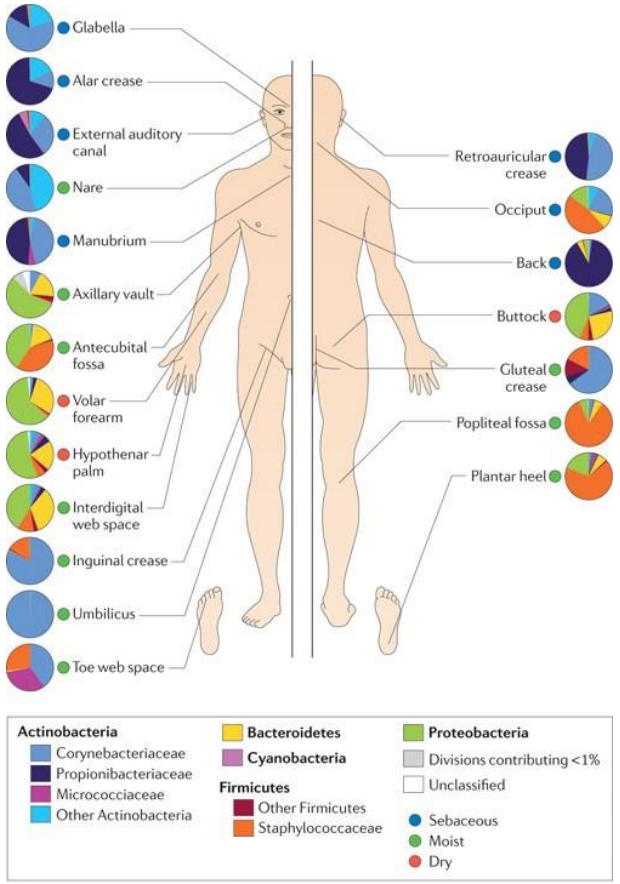
- ~ 38 x 10^{12} bakterijskih celic v človeškem telesu
- prebavila (debelem črevo), koži, ustih, dihalih,...
- 0,2-0,3 % telesne mase človeka
- KOŽA: 1.5 x 10^{12} mikroorganizmov (bakterije, glive, virusi)
- Obraz, roke, dlani, prsti: do 10 milijonov bakterij na cm^2







Vir: Sender R, Fuchs S, Milo R (2016) Revised Estimates for the Number of Human and Bacteria Cells in the Body
Sandle T (2024) Do we pose the biggest risk? Our skin and cleanroom contamination

Vir: Grice and Segre, 2011

Nature Reviews | Microbiology

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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- Sedeča oseba: 8 milijonov kožnih delcev / uro (1-10 µm)
- ~ 4-7 g delcev / dan (koža, lasje, delci s sebuma in znoja)
- ~ 10-20 % odpadlih kožnih celic nosi mikroorganizme
- Govor: do 300 delcev / sekundo (večinoma delci < 10 µm)
  Kašelj: ~ 10^3 delcev / 1 kašelj (velik razpon: < 5 µm in > 100 µm)
  Kihanje: ~ 10^4 - 10^5 delcev / 1 kihanje

Vir:
Licina, Tian & Nazaroff (2017) – *Emission rates and the personal cloud effect associated with particle release from the perihuman environment* (Indoor Air)
Sandle T (2024) Do we pose the biggest risk? Our skin and cleanroom contamination
Rajiv Dhand & Jie Li (2020) Coughs and Sneezes: Their role in transmission of respiratory viral infections, including SARS-CoV-2

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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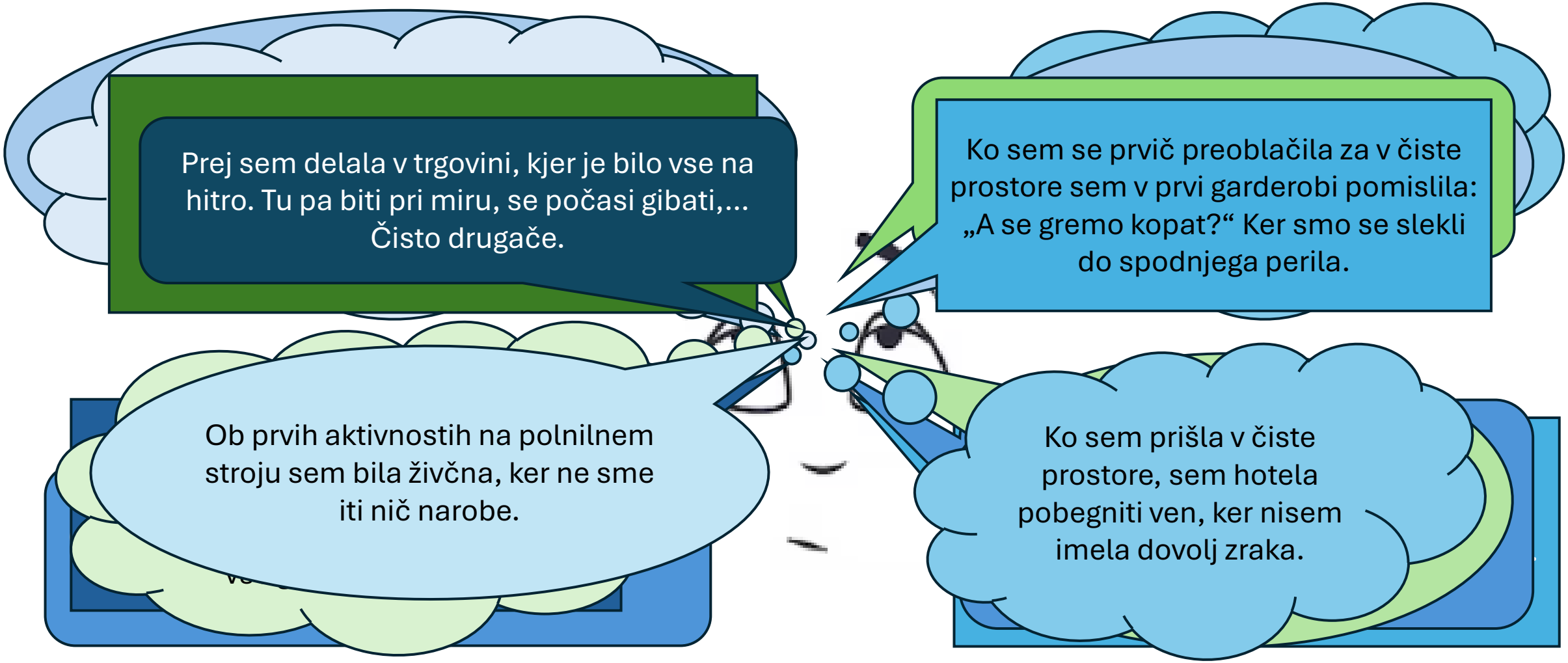

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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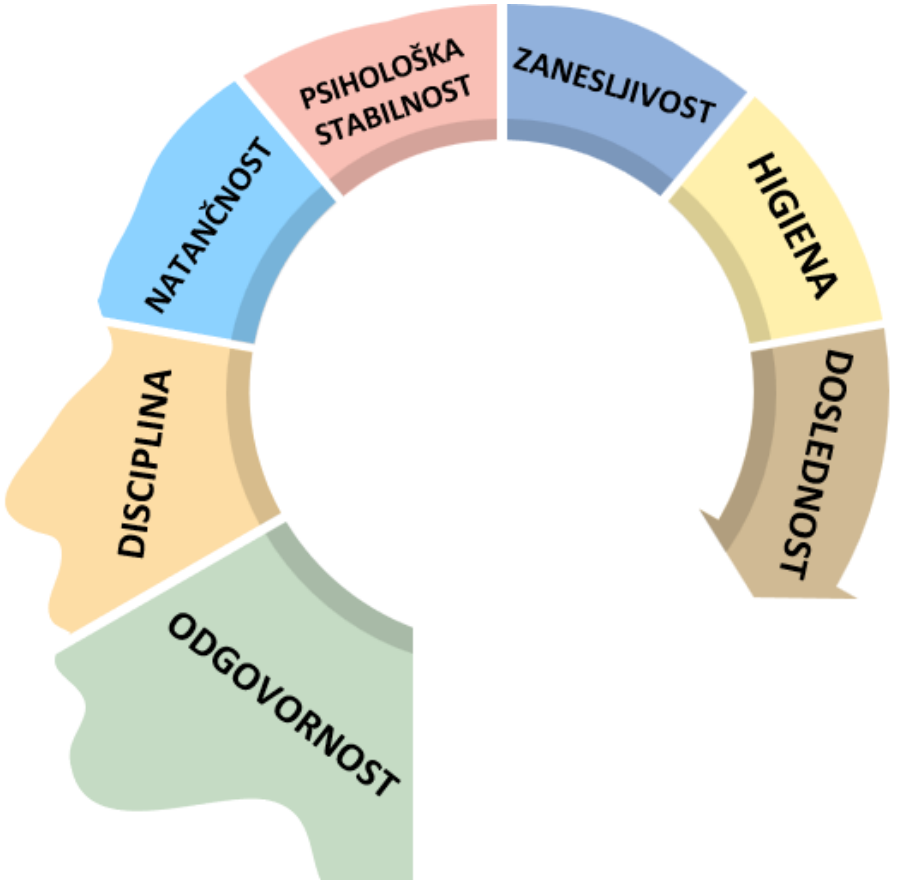

Lastnosti so rezultat sistema in načina vodenja.

KAKO? ⟩⟩ **ZAKAJ?**

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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PROCES USPOSABLJANJA

modularen sistem za vstop in delo v A/B za zmanjšanje tveganja kontaminacije okolja

A	B	C	D	E
				

Vir: slike generirane s pomočjo Microsoft 365 Copilot

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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Modul 1

USPOSABLJANJE SODELAVCEV Z OSNOVNIMI ZNANJI ZA VSTOP IN DELO V ČISTIH PROSTORIH

vsi sodelavci iz programa usposabljanja.

Običajno traja do 14 dni in vključuje izobraževanje:

- osnove mikrobiologije
- čiste prostore
- HVAC
- čiščenje in razkuževanje
- mikrobiološko vzorčenje
- vstopanje v čiste prostore razreda C in D

Modul 2

USPOSABLJANJE SODELAVCEV ZA KVALIFIKACIJO PREOBLAČENJA

vsi sodelavci, vključeni v program usposabljanja, ki vstopajo v razred čistosti A/B

Običajno traja do 14 dni in vključuje:

- praktični prikaz in trening preoblačenja za vstop v razred čistosti A/B
- 3 uspešne kvalifikacije oblačenja z razširjenim mikrobiološkim vzorčenjem.

Modul 3

USPOSABLJANJE SODELAVCEV ZA DELO V ČISTIH PROSTORIH

sodelavci OPSI in TS, ki sodelujejo pri aseptičnem delu, čiščenju, MKB vzorčenju in nadzoru

Običajno traja do 120 dni in vključuje:

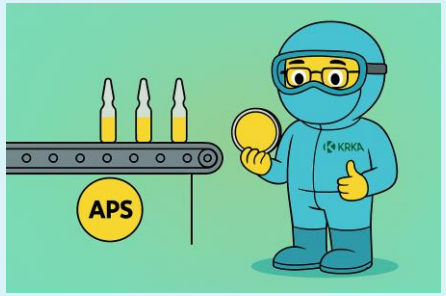
- praktični prikaz procesa izdelave sterilnega izdelka v Učnem Centru
- predstavitev validacije aseptičnega polnjenja
- predstavitev aseptičnega dela/posegov s pomočjo posnetkov
- sestavo polnilne linije v razredu čistosti A/B (trening z mentorjem)
- praktično izvajanje posegov na polnilni liniji
- usposabljanje in spremljanje izvajanja MKB vzorčenja po vseh MKB tehnikah
- usposabljanje in spremljanje izvajanja čiščenja in dezinfekcije

Modul 4

POTRDITEV USPOSOBLJENOSTI (ASEPTIČNO DELO) SODELAVCEV Z VALIDACIJO ASEPTIČNEGA POLNJENJA

vključimo sodelavce OPSI in TS, ki sodelujejo pri aseptičnem delu

Udeležba pri uspešni validaciji aseptičnega polnjenja.



Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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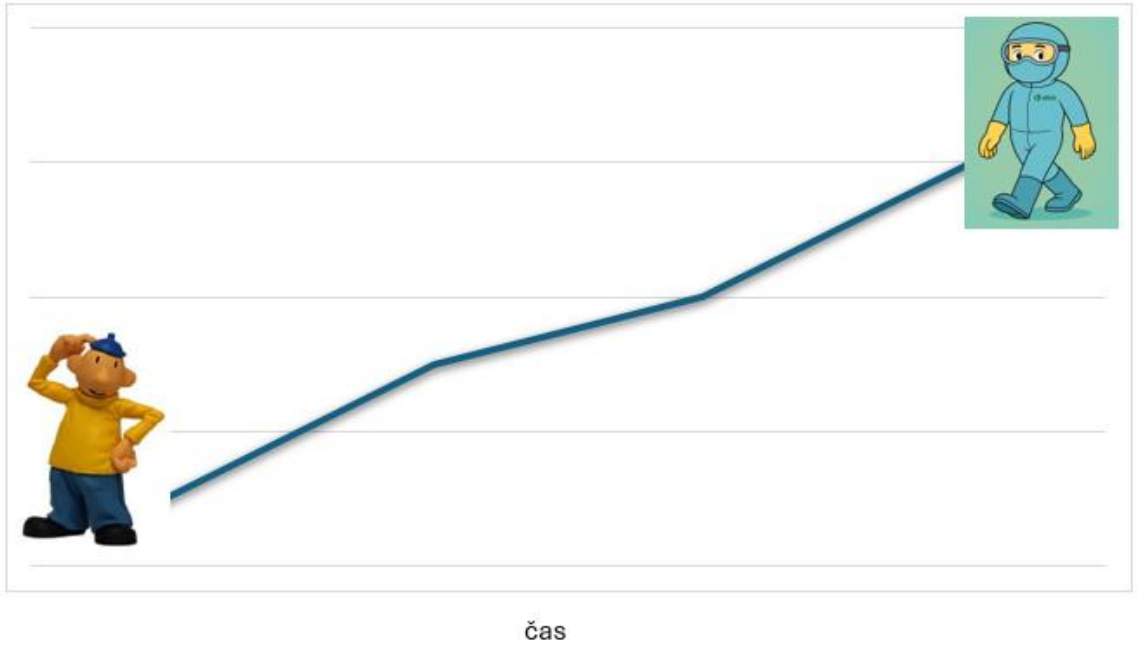
MODUL 3 – USPOSABLJANJE SODELAVCEV ZA DELO V ČISTIH PROSTORIH



VRSTA USPOSABLJANJA	VELJA ZA VRSTO DELA					DOKAZILA	ODGOVORNOST
Praktični prikaz procesa izdelave sterilnega polizdelka v učnem centru.	A	B	C	D	E	/	Odgovorna oseba
Seznanitev s prilogami OT-000090/XX in SOP za polnjenje, skladno s polnilno linijo oz. mestom na katerem bo delal/nadziral mentoriranec.	A		C		E	Lista prisotnosti izpopolnjevanja znanja in izobraževalni list	Odgovorna oseba
Predstavitev validacije aseptičnega polnjenja.	A		C		E	Lista prisotnosti izpopolnjevanja znanja	Odgovorna oseba
Predstavitev aseptičnega dela/posegov s pomočjo posnetkov.	A		C		E	Lista prisotnosti izpopolnjevanja znanja	Odgovorna oseba
Začetek treninga izvajanja dela (skladno z obsegom nalog na delovnem mestu).	A					/	Mentor ali odgovorna oseba
Sestavljanje polnilne linije ali filtracijske linije (mobilna in fiksna) v prostorih razreda čistosti A/B (trening z mentorjem). Po sestavi izvedemo MKB vzorčenje mentoriranca skladno z MKB shemami.	A					MKB rezultati v SAP EM USPEŠNO/NEUSPEŠNO	Mentor
Praktično izvajanje posegov na polnilni liniji ali pri pripravi izdelka v prostorih razreda čistosti A/B. Po posegih izvedemo MKB vzorčenje skladno z MKB shemami.	A					MKB rezultati v SAP EM USPEŠNO/NEUSPEŠNO	Mentor
Spremljanje usposobljene osebe pri izvajanju neaseptičnega dela. Po osvojitvi neaseptičnega dela izvede delo samostojno (3-krat).		B				Vizualna kontrola USPEŠNO/NEUSPEŠNO	Mentor
Usposabljanje MKB vzorčenja po vseh MKB tehnikah.	A	B	C		E	Vizualna kontrola USPEŠNO/NEUSPEŠNO	Odgovorna oseba MKB laboratorija
Spremljanje usposobljene osebe pri izvajanju MKB vzorčenja. A se usposobi samo za vzorčenje v polnilnih linijah po vseh relevantnih MKB tehnikah. Po osvojitvi tehnike MKB vzorčenja mentoriranec izvede MKB vzorčenje samostojno (3-krat).	A	B	C		E	Vizualna kontrola USPEŠNO/NEUSPEŠNO	Mentor
Spremljanje usposobljene osebe pri izvajanju čiščenja. Po osvojitvi tehnike čiščenja mentoriranec izvede čiščenje samostojno (3-krat).	A			D		Vizualna kontrola USPEŠNO/NEUSPEŠNO	Mentor
Tehnik/tehnolog - mentoriranec spremlja usposobljeno osebo in spoznava vrste dela A, B, C in D.					E	USPEŠNO/NEUSPEŠNO	Mentor
Izvedba rednega MKB vzorčenja pri izhodu iz prostorov razreda čistosti A/B (AM ne sme biti dosežena) po predpisanem minimalnem času zadrževanja (najmanj 4 ure) (3-krat).	A					MKB rezultati v SAP EM USPEŠNO/NEUSPEŠNO	Mentor in odgovorna oseba

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

Boštjan Kmet, KRKA, d.d., Novo mesto

VSTOP V RAZRED ČISTOSTI B/A

1. garderoba

KRKA
KRKA, d. d., Novo mesto

Dnevnik vstopa in izstopa iz čistih prostorov polnjenja injekcij
Oznaka dnevnika: LogbookID

Datum	Priimek in ime	Čas vstopa	Čas izstopa	Podpis

Istočasno so lahko v posameznem prostoru garderobe tri osebe. V prostoru ob polnilni liniji/aseptični pripravi se lahko istočasno nahaja največ 7 oseb oziroma 15 oseb v celotnem razredu čistosti A/B.

Pregledal/Datum:

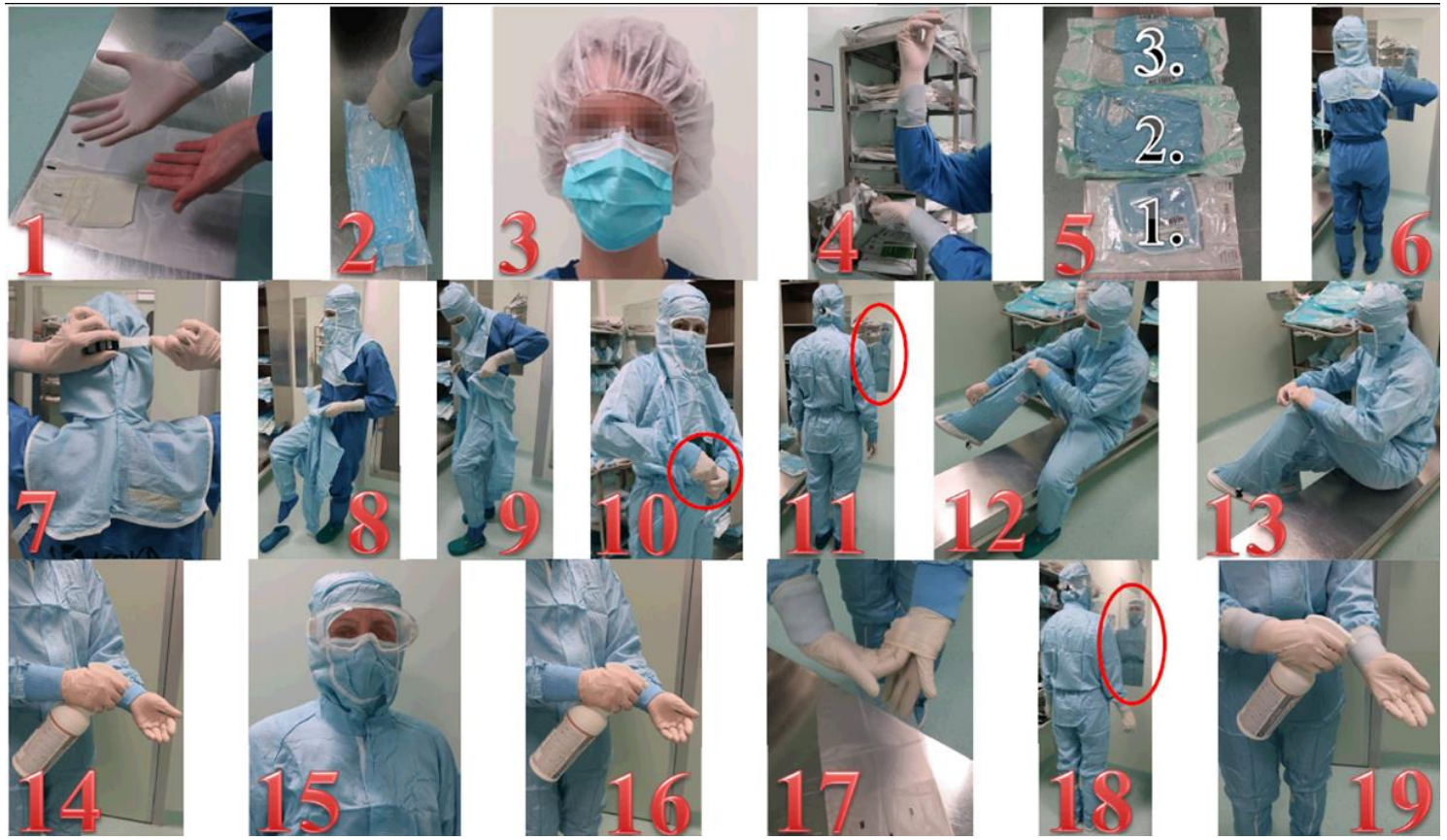
2. garderoba

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

Boštjan Kmet, KRKA, d.d., Novo mesto

VSTOP V RAZRED ČISTOSTI B/A

3. garderoba



Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

Boštjan Kmet, KRKA, d.d., Novo mesto

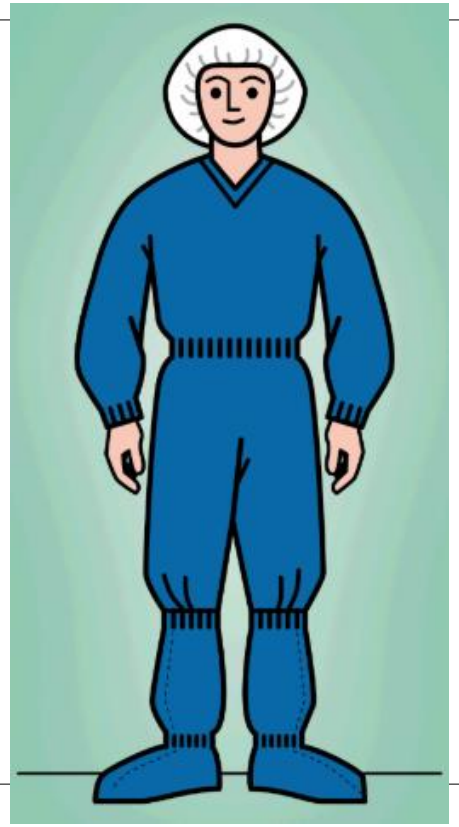
PODOBLEKE: INTERNI STANDARD, SOP

PAKIRANJE

- ZLOŽENE HLAČE, MAJICO IN PAR NADNOGAVIC VLOŽIMO V PE VREČKE TER ZAVARIMO
- VELIKOSTNA ŠTEVILKA KOMPLETA

GMP ZAHTEVE

- MATERIALI DEKLARIRANI ZA RAZRED ČISTOSTI C
- NE SMEJO ODPUŠČATI DELCEV



PRANJE, SUŠENJE, VIZUALNA KONTROLA

- NAMENSKI STROJ
- DEFINIRANA POLNITEV STROJA
- DEFINIRAN PROGRAM
- PREVERJANJE CELOVITOSTI MANŠETE
- ODSOTNOST NITK
- ODSOTNOST NEOČISTLJIVIH MADEŽEV
- IZLOČITEV NEUSTREZNIH

SESTAVA

MATERIAL

- UMETNA VLAKNA (POLIESTER)

- HLAČE
- MAJICA
- NADNOGAVICA

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

Boštjan Kmet, KRKA, d.d., Novo mesto

DELOVNE OBLEKE ZA RAZRED ČISTOSTI A/B

- GMP ZAHTEVE
- SESTAVA KOMPLETA OBLEKE
- MATERIAL
- ŠIVI
- NAČIN OBLAČENJA
- VELIKOSTI
- PRANJE IN STERILIZACIJA
- TESTIRANJE PREPUSTNOSTI
- PREPUSTNOST MATERIALA ZA DELCE
- PAKIRANJE IN DOBAVA
- SLEDLJIVOST

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

Boštjan Kmet, KRKA, d.d., Novo mesto

DELOVNE OBLEKE ZA RAZRED ČISTOSTI A/B

- Pri vsakem vstopu v čist prostor- sterilen komplet oblačil za čiste prostore.

- Pokrivalo, kombinezon in prevleke za obutev (t.i. boots-i).

DELOVNE OBLEKE ZA RAZRED ČISTOSTI A/B- obdelava materiala

SLEDLJIVOST

- sistem sledljivosti
- preverjena nepoškodovanost oblačil

STERILIZACIJA

- sterilizacija mora potekati po validiranih postopkih

PRANJE

- namenski pralni stroji
- validirani programi pranja z nadzorom parametrov: polnitev, doziranje pralnih sredstev, čas cikla
- ločitev nečiste in čiste strani

SUŠENJE

- sušenje v namenskih sušilnikih s filtriranim zrakom.
- po končanem sušenju zlaganje po predpisanih postopkih v čistih prostorih ISO14644 s kontrolo delcev

Slovensko združenje za tehnologijo čistih prostorov

ČISTI PROSTORI DANES IN JUTRI:

INOVACIJE, TRAJNOST, ODLIČNOST TER SKLADNOST Z REGULATIVO

PTZ Priložnost Tradicija Znanje – PODJETNIŠKO TRGOVSKA ZBORNICA | Gospodarska zbornica Slovenije

PAKIRANJE

- **STERILIZACIJSKI ROKAVI**

PRANJE IN SUŠENJE

- RAZTOPINA DETERGENTA, KRPICA
- BRISANJE
- VIZUALNA KOTROLA

VIZUALNA KONTROLA

- PRIMERJALNO GLEDE NA NOVA NEUPORABLJENA REFERENČNA OČALA
- OHIŠJE OČAL: UKRIVLJENOST
- STEKLO: NE SME BITI MOTNO ALI POŠKODOVANO
- TRAKOVI ZA NALEGANJE: GIBKOST KOT PRI REFERENCI, NEPOŠKODOVANOST

ŠTEVILO CIKLOV STERILIZACIJE

- ŠTEVILO CIKLOV GLEDE NA PRIPOROČILO DOBAVITELJA
- 20 MIN, 121°C/ 20 CIKLOV
- OZNAČITEV Z NEIZBRISNIM PISALOM NA ROB OČAL

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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Uporaba

- redna uporaba v B za vsa vstopanja in vse vrste neaseptičnih del
- 3. rokavice pri sestavi in izvajanju aseptičnih posegov v polnilni liniji.
- 3. rokavice pri sterilni filtraciji in aseptični pripravi.

Zahteve

- Obstojnost po dezinfekciji z alkoholi
- Izjava EU o skladnosti po Prilogi IX uredbe (EU) 2016/425
- Certifikat o obsevanju (sterilizacije)
- Certifikat o skladnosti
- Standard SIST EN 374 -5
- Standard SIST EN 455 – 1,2,4

Dolžina / Debelina (dlan) / Velikost

- 300 mm / 0,15 mm
- 400 mm / 0,20 mm
- 600 mm / 0,21 mm

- 6.5, 7, 7.5, 8, 8.5, 9

Material

- Neopren
- Naravni lateks (3.rokavice)

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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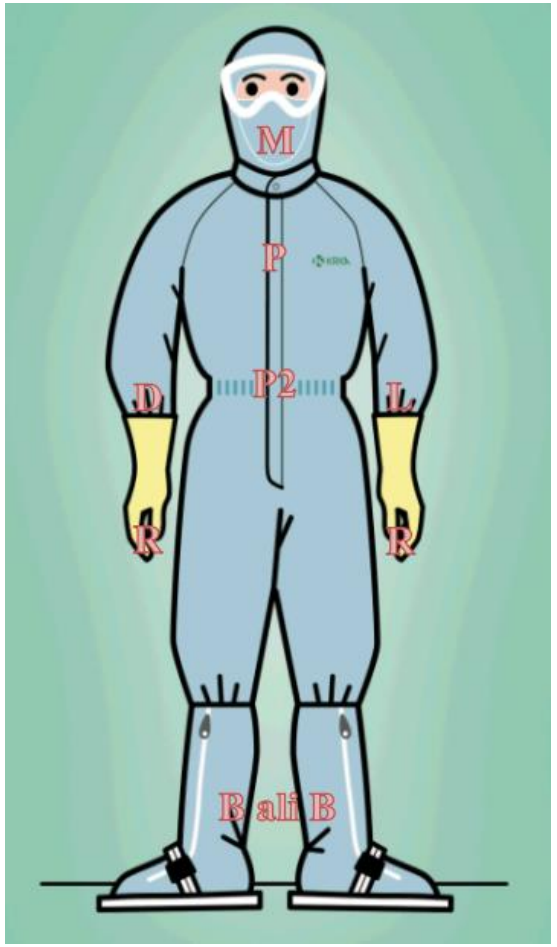
PODJETNIŠKO TRGOVSKA ZBORNICA

Gospodarska zbornica Slovenije



Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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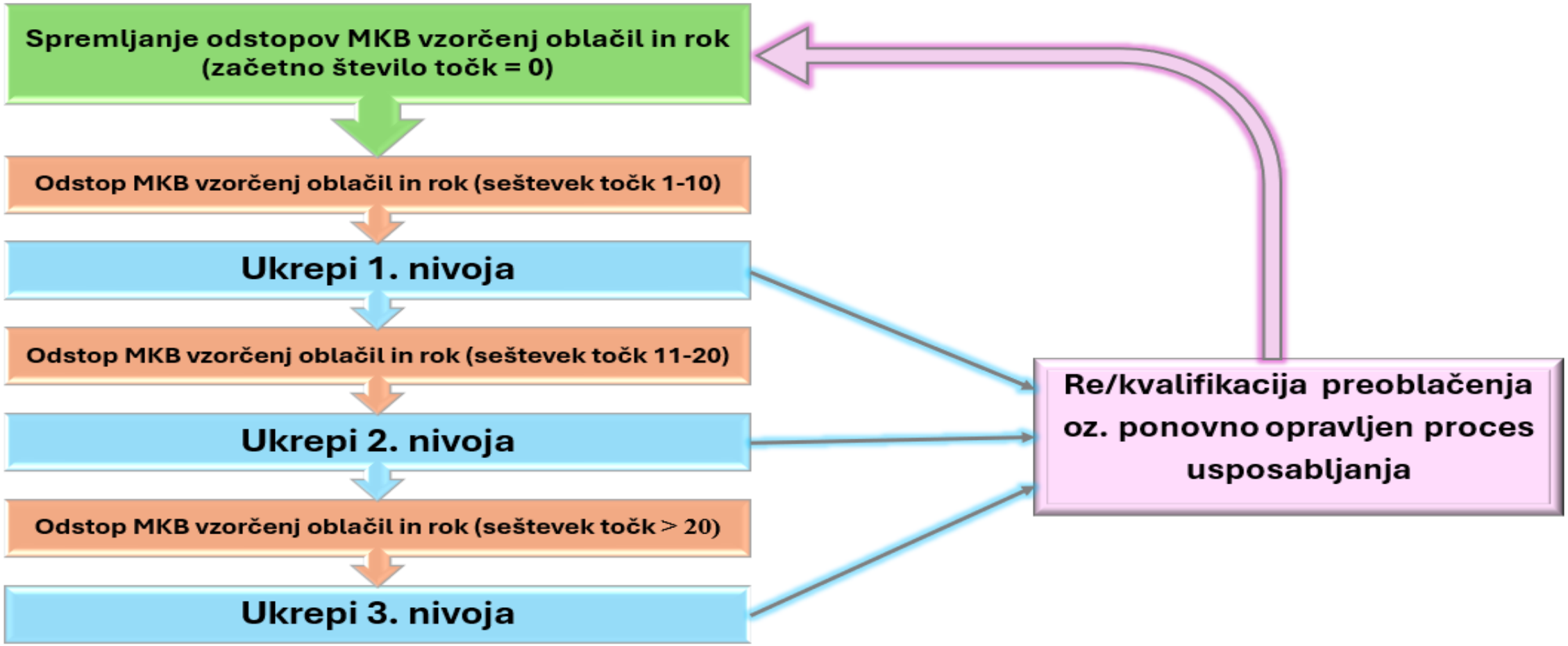

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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do vključno 10 točk

- seznanitev in razgovor
- raziskava vzrokov
- dodaten ukrep glede na oceno odgovorne osebe.

11-20 točk

DODATNO K UKREPU 1:

- praktična preveritev vstopanja in obnašanja ter delo v prostorih razreda čistosti A/B,
- izobraževanje na mestu.
- dodaten ukrep glede na oceno odgovorne osebe.

več kot 20 točk

DODATNO K UKREPU 1:

- **KOMISIJSKA OBRAVNAVA:**
  - trendi
  - tveganje,
  - zdravstveno stanje,
  - ostali dejavniki, ki bi lahko vplivali na odstop.
- **UKREPI:**
  - opozorilo,
  - zdravniški pregled,
  - rekvalifikacija preoblačenja (ponovna vključitev v APS)
  - preklic dovoljenja za samostojno vstopanje in delo v prostorih razreda čistosti A/B.
- dodaten ukrep glede na oceno komisije.

Osebje- ključni dejavnik pri vzdrževanju ustreznih pogojev v proizvodnji sterilnih farmacevtskih oblik

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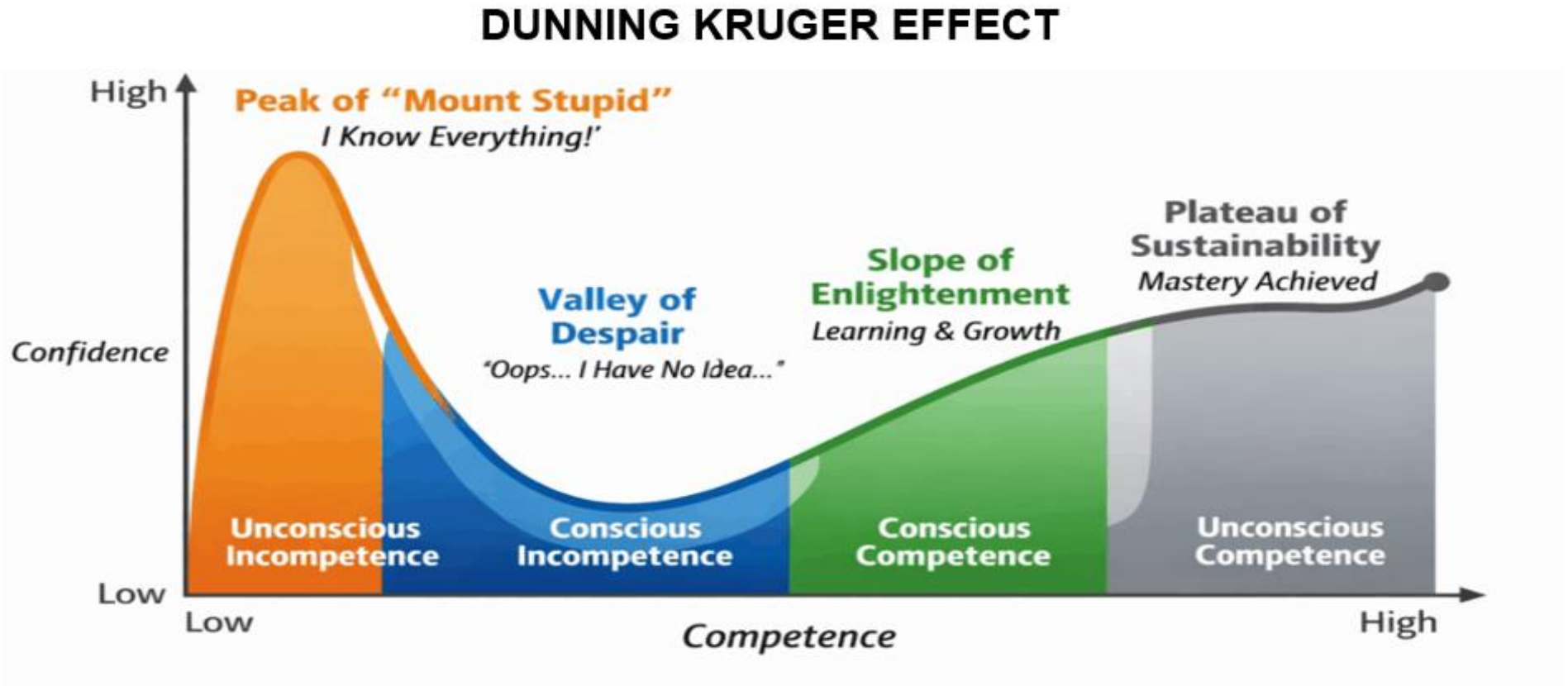
TAKE AWAY MESSAGE:



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Hvala za pozornost!

Slovensko združenje za tehnologijo čistih prostorov
Dimičeva ulica 13 I 1504 Ljubljana
T: 01 5898 312 I F: 01 58 98 317 I E: ptz@gzs.si
https://scs.gzs.si

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International Conference

CLEANROOMS TODAY AND TOMORROW:

INNOVATION, SUSTAINABILITY, EXCELLENCE AND REGULATORY COMPLIANCE

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