Sustainable Facilities, HVAC and Controlled Environments – An ISPE Community of Practice

Jim Quinn

ISPE Communities of Practice (CoPs)

CoPs are groups of ISPE Members with a common interest and similar job functions who voluntarily collaborate on topic-specific discussions using the ISPE networking forum, ISPE Engage.

- Learn proven practices from others, including your competitors
- Don’t reinvent the wheel
- Tap into a knowledge base of experts in the field (SMEs)
- Obtain guidance on understanding regulatory requirements
- Share for the common good of the industry

Current List of CoPs

- Active Pharmaceutical Ingredients
- Advanced Therapy Medicinal Products (ATMPs)
- **New** Artificial Intelligence
- Biotechnology
- Commissioning & Qualification
- Combination Products
- Containment
- Critical Utilities
- Disposables/Single-Use Technologies
- GAMP®
  - GAMP® Blockchain Special Interest Group
  - GAMP® Computer Software Assurance Special Interest Group
  - GAMP® Data Integrity Special Interest Group
  - GAMP® MES Special Interest Group
- Investigational Products
- Oral Solid Dosage
- Pharma 4.0
- Pharmaceutical Compounding
- Process Analytical Technology & Lifecycle Control Strategy
- Process/Product Development
- Project Management
- Quality Control/Analytical
- Sterile Products Processing
- Supply Chain, Operations and Packaging (SCOPE)
- **New** Sustainability
- Sustainable Facilities, HVAC & Controlled Environments

Sustainable Facilities, HVAC and Controlled Environments CoP

- Leadership
  - Chair - Allen Koester
  - Co-Chair - Chris Anderson
  - Secretary - Nick Haycocks

- Major Activities
  - Bimonthly meeting for Committee members
  - Develop library of useful documents
  - Prepare articles for ISPE Magazine
  - Maintain discussion forum for topics of interest
  - Update of ISPE Good Practice Guide for HVAC – Rev. 2
  - Contribute to updates of other ISPE Good Practice Guides
  - Develop training webinars

Revision 2 of ISPE HVAC Good Practice Guide

- A lot has changed since First Revision of HVAC GPG issued 2009
  - Decarbonization
  - More emphasis on energy reduction and “sustainability”
  - Net Zero
  - Contamination Control Strategies
  - Regulatory Requirements

Revision 2 of ISPE HVAC Good Practice Guide

- Example 1: Air Change Rates for Clean Rooms
  - Old approach: Use standard “recipe”:
    - Grade D = 20 ACH
    - Grade C = 30 ACH
    - Grade B = 60 ACH
  - Results in “overkill” and excess energy consumption
  - New Approach: Calculate required ACH per ISO 14644-16 Dilution Modeling
    - For example, assume 8 people, Grade C clean room, 1 log recovery clean-up time of 15 minutes
    - Calculation results in 13.2 ACH, less than half of “recipe”

Revision 2 of ISPE HVAC Good Practice Guide

- Example 2: Airside Economizers
  - Airside economizers introduce outside air for “free cooling” when outdoor temperatures permit and this is required by International Energy Conservation Code
  - Old approach: Most pharma avoid airside economizing because of concerns about losing room pressure control when outside air is suddenly introduced.
  - New approach: Take advantage of modern, precise airside flow control and include airside economizing for significant cooling energy savings.

Discussion Forum

- Recent Discussion Threads

Sustainable Facilities, HVAC and Controlled Environments

Settings

Search Discussions

Term / Keyword / Phrase

Community Home | Discussion 2.3K | Library 87 | Members 3.5K

1 to 50 of 426 threads (2.3K total posts)

Most Recently Updated | Posts in my forums | 50 per page | Post New Message

Thread Subject	Replies	Last Post	Status
LATAM Symposium Advanced Manufacturing, Manufacturing Operations, PAT, Pharma 4.0, Quality, Sustainability	0	an hour ago by Nissan Cohen	
HEPA filter replacement	6	12 days ago by Nissan Cohen Original post by Mohammad Forhad	
Annex 1 section 4.25	6	12 days ago by Oleksandr Belinskyi Original post by Nissan Cohen	
Monitoring directed air flow in CNC	5	20 days ago by Siegfried Adam Original post by Rudolf Fink	
Differential Pressure Article	3	21 days ago by Harald Flechl Original post by Norman Goldschmidt	
Drain port chemical disinfection	3	22 days ago by Norman Goldschmidt Original post by Mohammad Forhad	
Water cooler in a CNC space	3	22 days ago by Norman Goldschmidt Original post by Vasilios Vasiliadis	
Classification of Collection room of filled & sealed Vials	4	2 months ago by Muhammad Atiq Ur Rahman Original post by Kishor Datar	

Discussion Forum

How often should HEPA filters be replaced?

HEPA filter replacement

Nissan Cohen 12 days ago

Norm, I worked with Dan Milholland over 35 years ago in the semiconductor industry where we were astute ...

KK

Koji Kawasaki 19 days ago

Dear Norm, Regarding the content "The idea that a HEPA filter replacement frequency of 10± years might ...

Norman Goldschmidt 20 days ago

Hi Koji, I respect your experience, and you make a great point about filters that show discoloration ...

KK

Koji Kawasaki 20 days ago

Dear all, I have been involved with LF, RABS, and isolators for nearly half a century. For instance, ...

Norman Goldschmidt 22 days ago

All, As Ugo suggests, not all filters are the same any you should consult with your vendor. The topic ...

Ugo Morelli 06-27-2024 03:57:00

Good Morning / Afternoon / Evening Mohammad, As a reference please have a read to ISO 16444, which ...

MF

Mohammad Forhad 06-27-2024 03:20:00

Dear COP experts After replacement of HEPA filter (either terminal or in AHU plenum), we do a filter ...

Discussion Forum

How Much Time Should Elapse before an Airlock dP Alarm?

Differential Pressure Article

Harald Flechl 21 days ago

Norman, Thanks for clarifying in point 2. This is a more meaningful interpretation of the intent of ...

Norman Goldschmidt 21 days ago

All, Harald makes several good points, so let me be clear with my language: I agree, the pressure ...

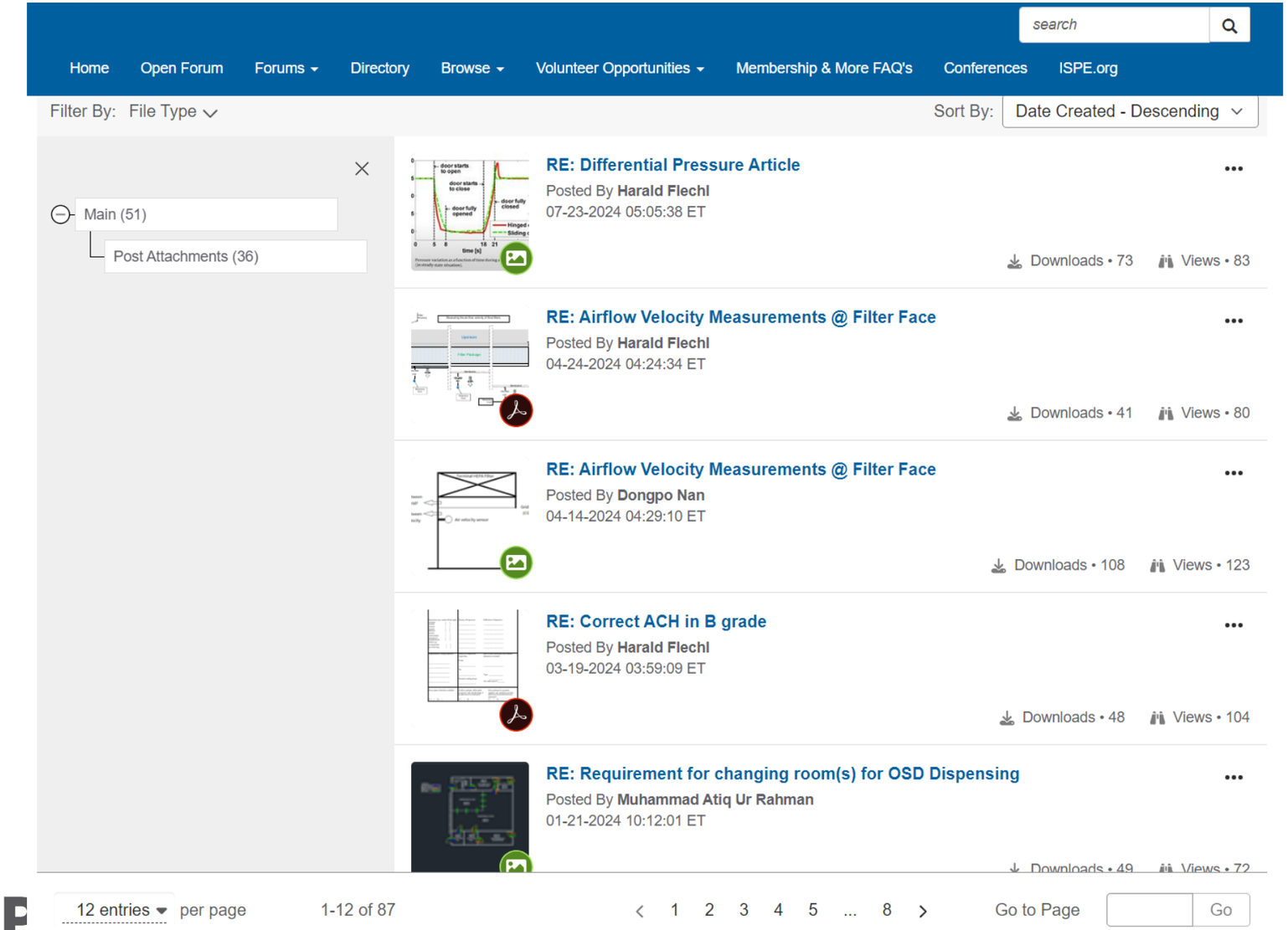
Harald Flechl 21 days ago

Dear All, room-pressure recovery in air-locks after door opening for pressure alarm delay is a matter ...

Norman Goldschmidt 22 days ago

All, Nick and I received these questions. I'm sharing in case they are of use to others... 1. Recovery ...

Library from Discussion Forums



ISPE Articles from CoP Members

PHARMACEUTICAL ENGINEERING | ISSUES | SECTIONS | TOPICS | WHITE PAPERS | ISPE

PHARMACEUTICAL ENGINEERING / JULY / AUGUST 2024 / ROOM DIFFERENTIAL PRESSURES IN FACILITY DESIGN: FUNDAMENTALS

Technical | July / August 2024

Room Differential Pressures in Facility Design: Fundamentals

By Norman Goldschmidt, Nicholas Haycocks, Ulla Thomsen

The expectations for room differential pressures to maintain air quality in pharmaceutical facility design are consistent and well defined from a regulatory perspective. However, there is no common approach to the design, monitoring, or alarming of area differential pressures. This article explores differential pressure concerns in aseptic manufacturing, or cleanroom classes B, C, and D.

TECHNICAL | FACILITIES AND EQUIPMENT

TEMPERATURE AND HUMIDITY REQUIREMENTS in Pharmaceutical Facilities

By Nicholas R. Haycocks, Norman A. Goldschmidt, and Ulla Thomsen

Defining room temperature and humidity limits is a frequent topic of debate when designing and operating pharmaceutical and biotechnology facilities. What are appropriate alarm limits and acceptable durations for an alarm condition? Understanding the source of temperature and humidity requirements, and strategies for setting limits, can ensure both compliance and optimum use of energy. This article provides guidance on these topics, with supporting rationales.

Table 1: EU regulations related to temperature and humidity controls [1, 2].

Source	Regulatory Guidance
EudraLex Volume 4, Part 1, Chapter 3	3.3. Lighting, temperature, humidity and ventilation should be appropriate and such that they do not adversely affect, directly or indirectly, either the medicinal products during their manufacture and storage, or the accurate functioning of equipment. 3.19. Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored.
EudraLex Volume 4, Annex 1	16. Other characteristics such as temperature and relative humidity depend on the product and nature of the operations carried out. These