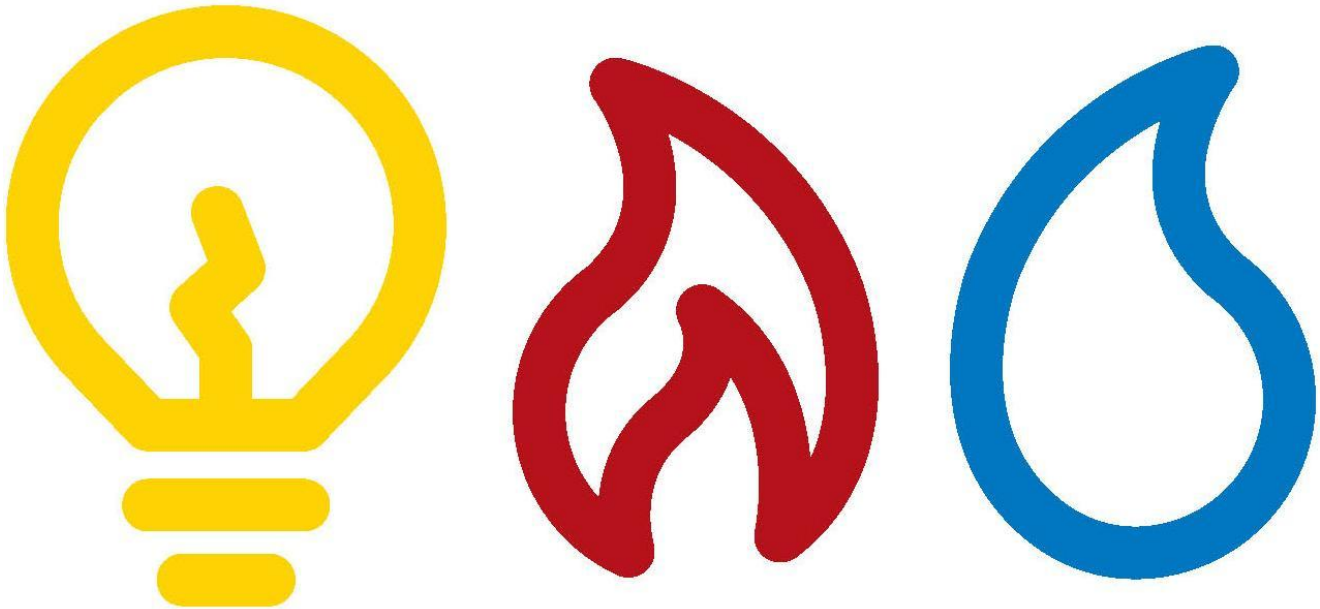
VHP as a Utility



john_klostermyer@steris.com

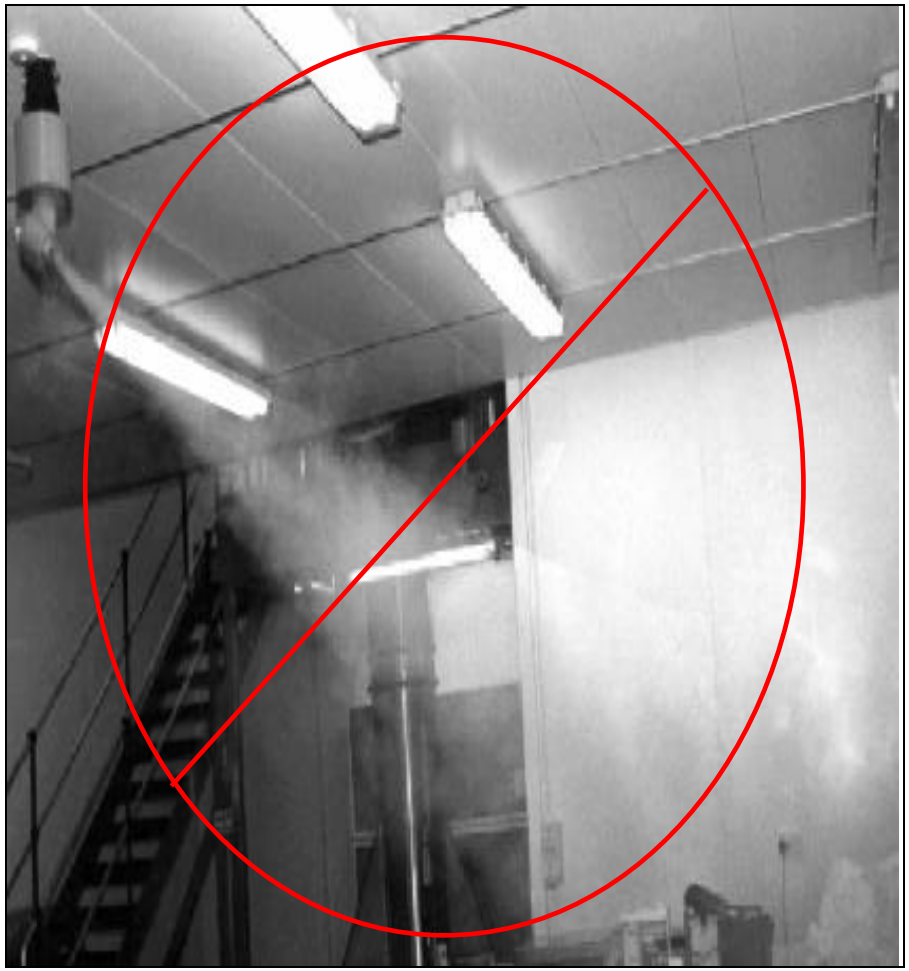
VHP as a Utility Outline

- VHP 101
  - Advantages
  - Process
  - Vapor vs. Mist
  - Kill Curve
  - Emissions
- Portable or Modular
  - Why Modular
- Installation
  - Modular Schematic
  - Options for Integration
  - Single Pass
  - Recirculating
- Examples
  - Large Room
  - Pass-Throughs
  - HEPAs
  - BSL Labs
  - Automated Sequences

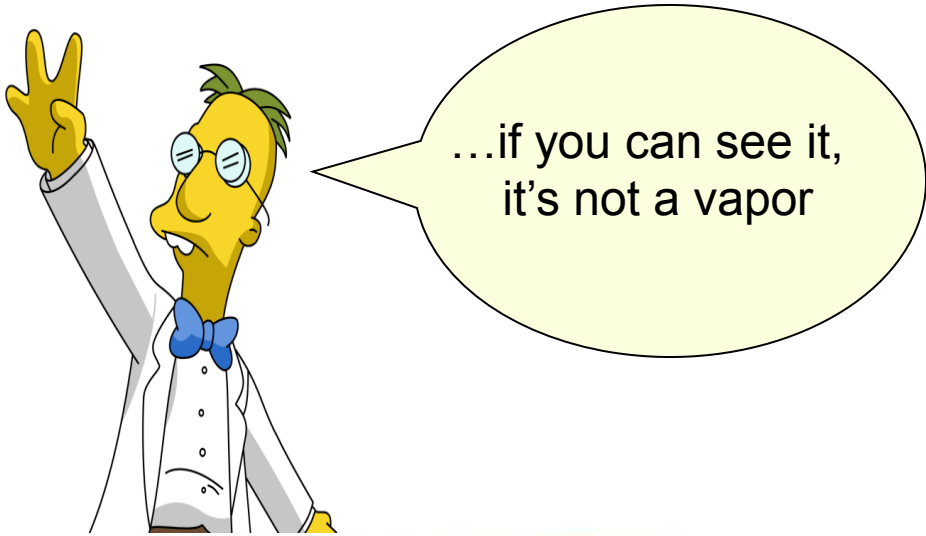
Why Use VHP?

- ✓ Consistency & Distribution
  - ➢ Wet surfaces / minimal contact times -not an issue
  - ➢ Passes through HEPA filters
  - ➢ Decontaminates biosafety cabinets and HEPAs during room decon
  - ➢ Kills airborne and surface microbes
- ✓ Labor
  - ➢ Minimal labor required
  - ➢ Easy to validate
- ✓ Environmental
  - ➢ Excellent material compatibility
  - ➢ Low toxicity
  - ➢ No residues
  - ➢ EPA approved

360° solutions



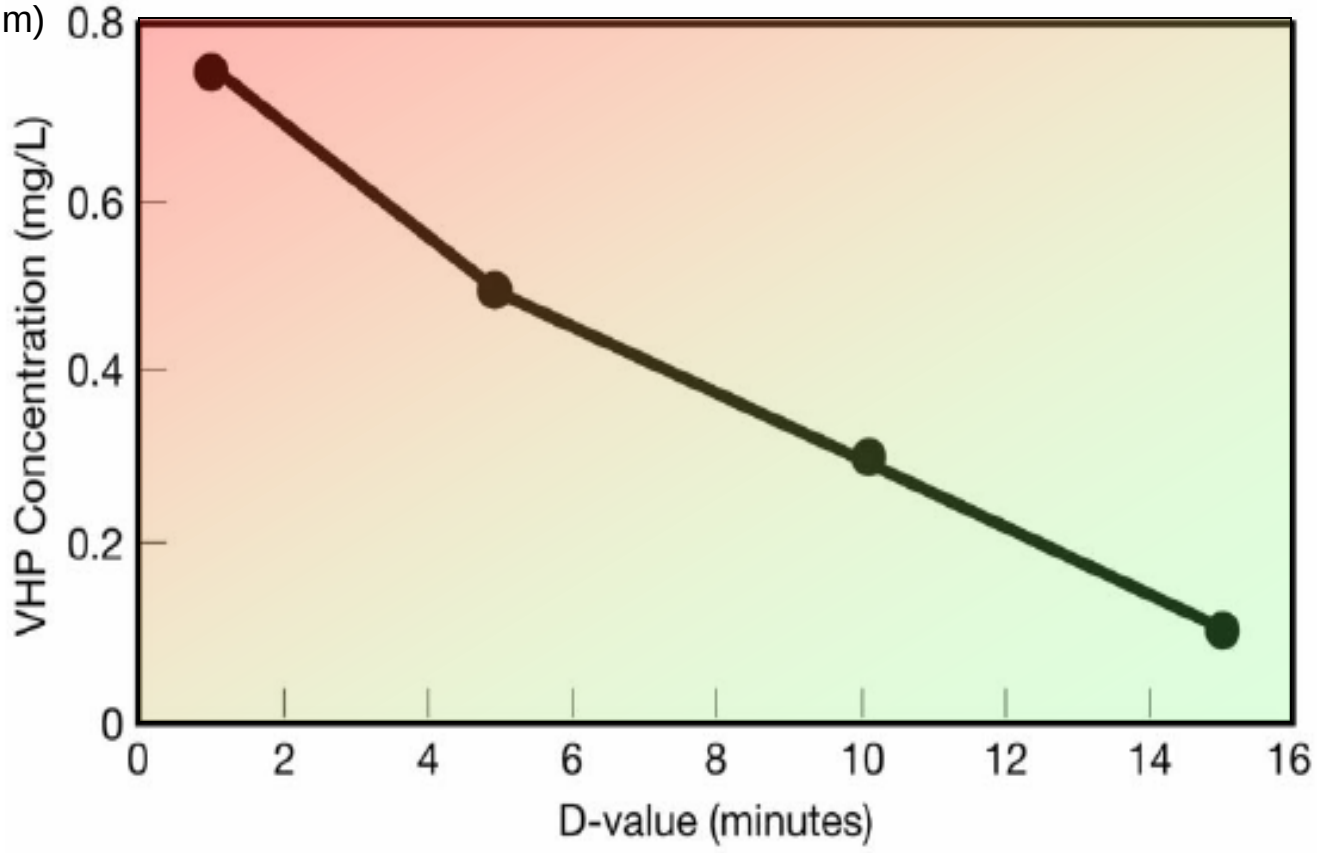
Boiling Points:
H2O 100 C
H2O2 150°C



VHP® Kill Matrix

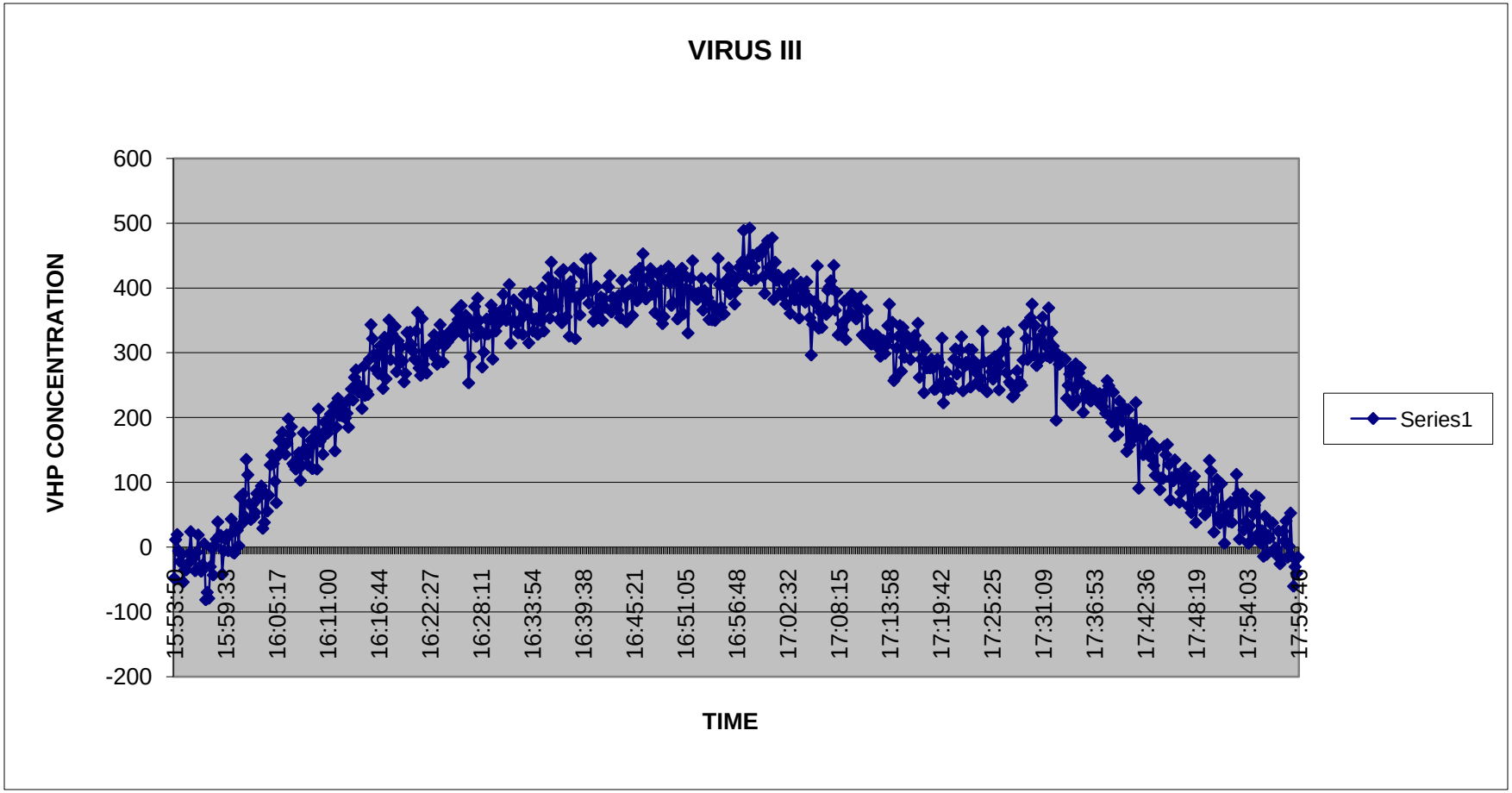
1 mgH_2O_2/liter air = 720ppm

(~576 ppm)



(~70 ppm)

G. stearothermophilus spores inoculated on Stainless Steel Coupons at 30^0C



300m3 (10600ft3)
Application Example

Which VHP System?

portable

- ✓ Spaces not yet defined
- ✓ Uses in different buildings
- ✓ Typically less than 10,000ft3
- ✓ Cycle time not a constraint
- ✓ Use of fans not an issue
- ✓ Less frequent use

modular

- ✓ Large and small spaces up to ~80,000 ft3
- ✓ Same enclosures repeatedly
- ✓ Frequent use (chamber)
- ✓ Short cycle times
- ✓ Automated sequenced decontamination of multiple rooms

Why Modular?

Keep Equipment Outside Space

- Save space within room / Pass Through
- Avoid cross contamination
- Keep maintenance activities outside

No Set Up

- Decon at the Press of a Button
- Run Sequential Decons via BMS*
- Reduced Handling of Peroxide
- Excellent Distribution

Cost

- Less expensive than multiple portables
- Save on labor
- The easier to use – the more frequent the use – the cleaner the space

*BMS = Building Management System

Pharmacy Compounding

Syringe Decon

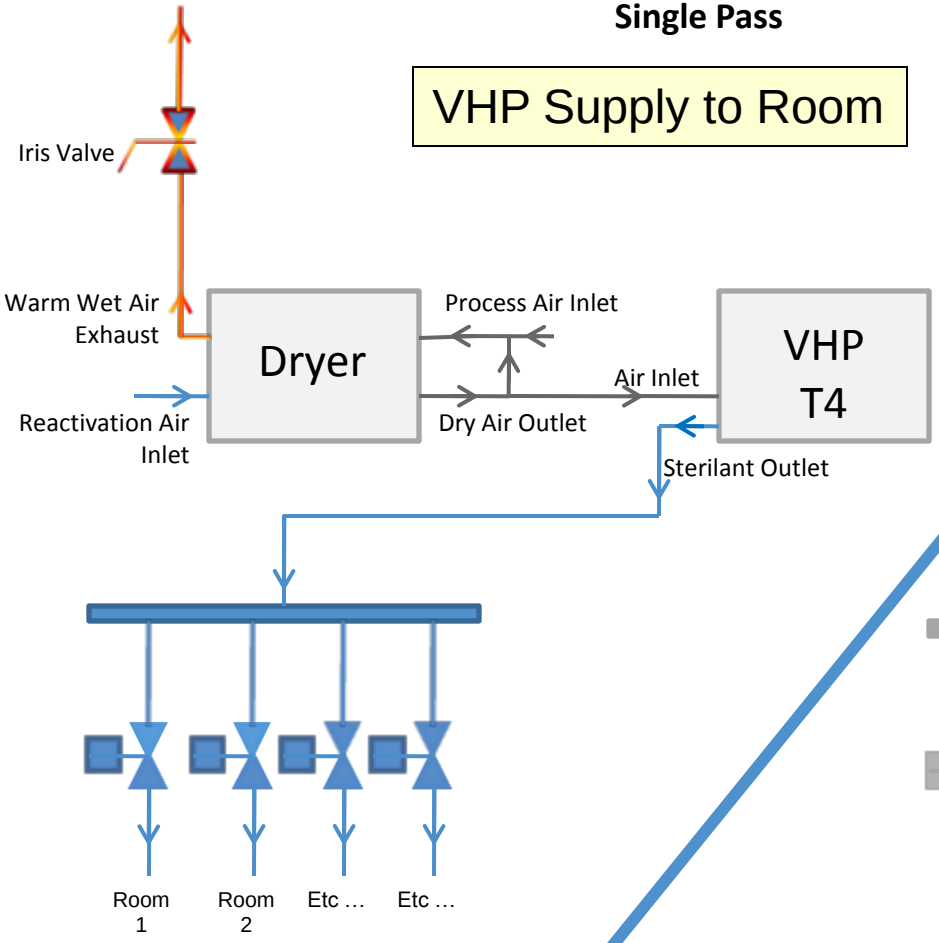
360° solutions

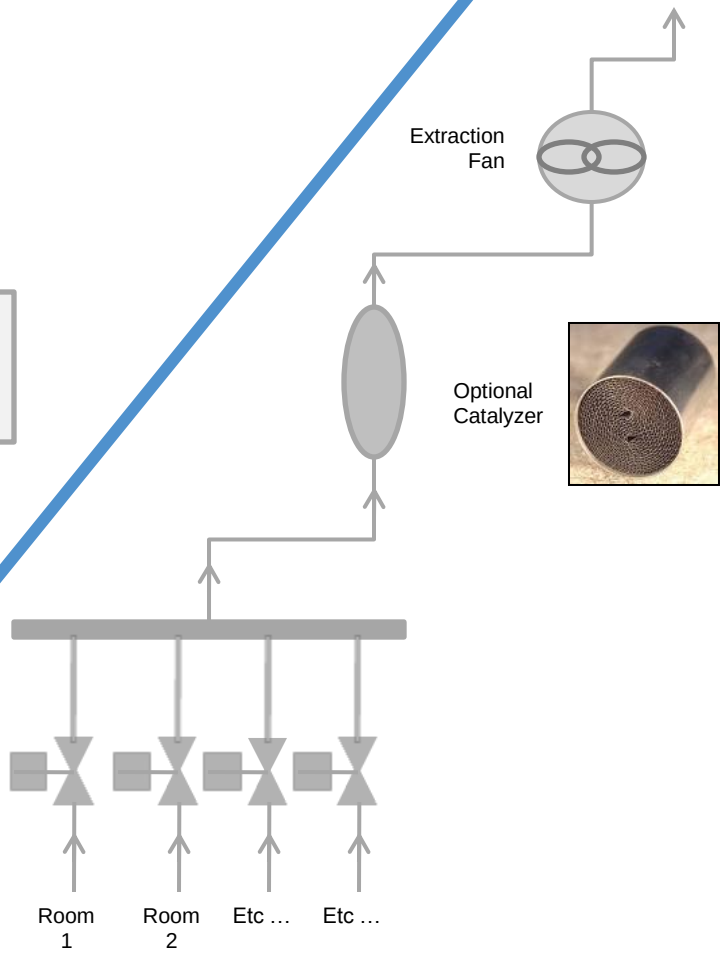
Chambers

VHP Modular Integration Schematic

Single Pass

VHP Supply to Room





VHP Exhaust from Room

Remote OP
+
Printer

1ph/220V/50Hz/5A

MPI cable

Printer cable

MPI communications cable to BMS or dry contacts

VHP out

Dry
Hot
Air

Vaprox

Pump box

Remote
Control

Regen Air

Process Air

1ph/220V/50Hz/10A

1ph/220V/50Hz/15A

Utilities & Communications

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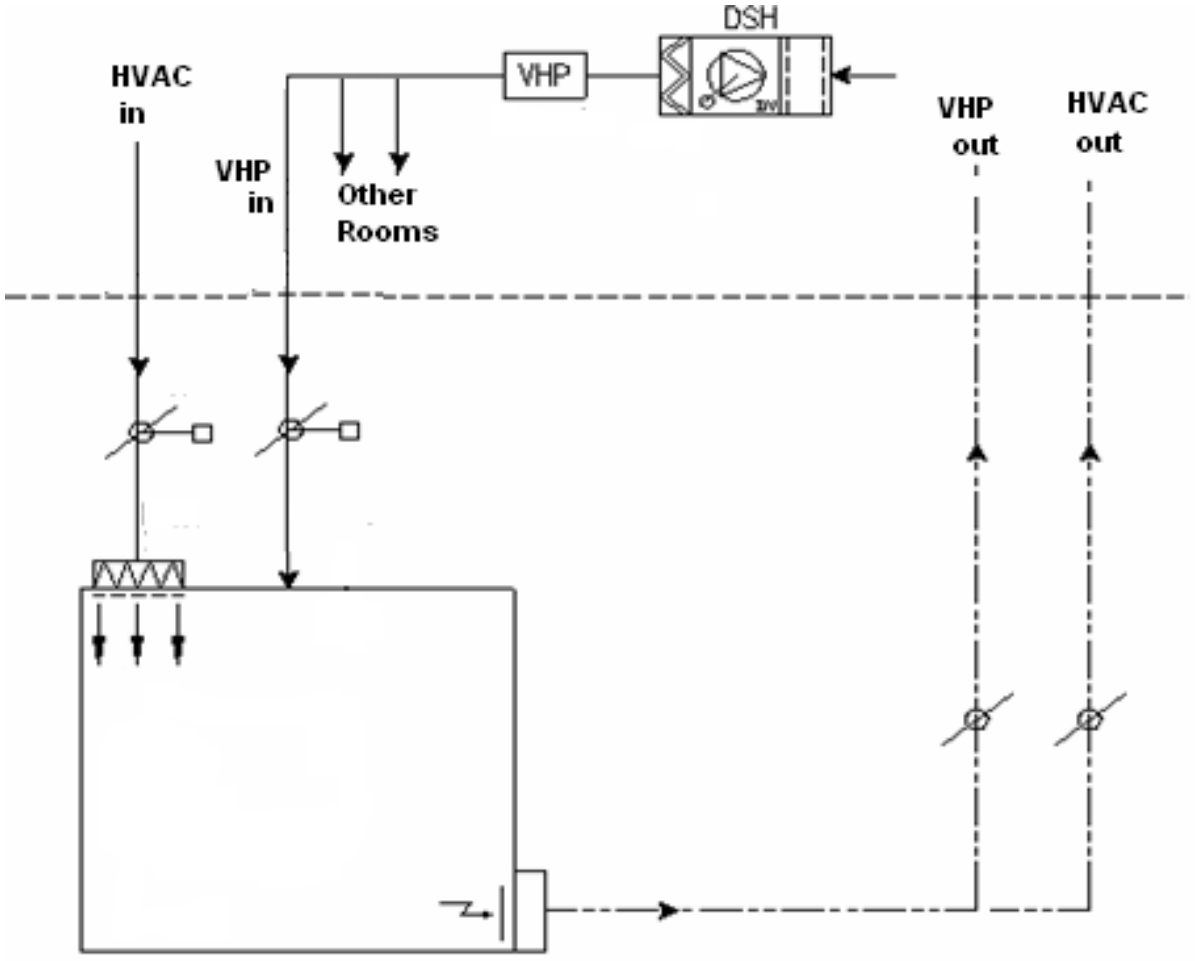
Single Pass System



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Large Room Biopharmaceutical Fermentation Suite

Volume: 32,000ft^3 (900m^3)

Ceiling height: 28ft (8,5m)

Single pass, No fans

6-log reduction

Cycle time 6 hours

New construction

Cycle Phase	Time min.	Airflow	Injection g/min
Dehumidification	30	6 A.E./ hour	-
Condition	30	120 cfm	96
Decontamination	90	120 cfm	60
Aeration	210	40 A.E./ hour	-

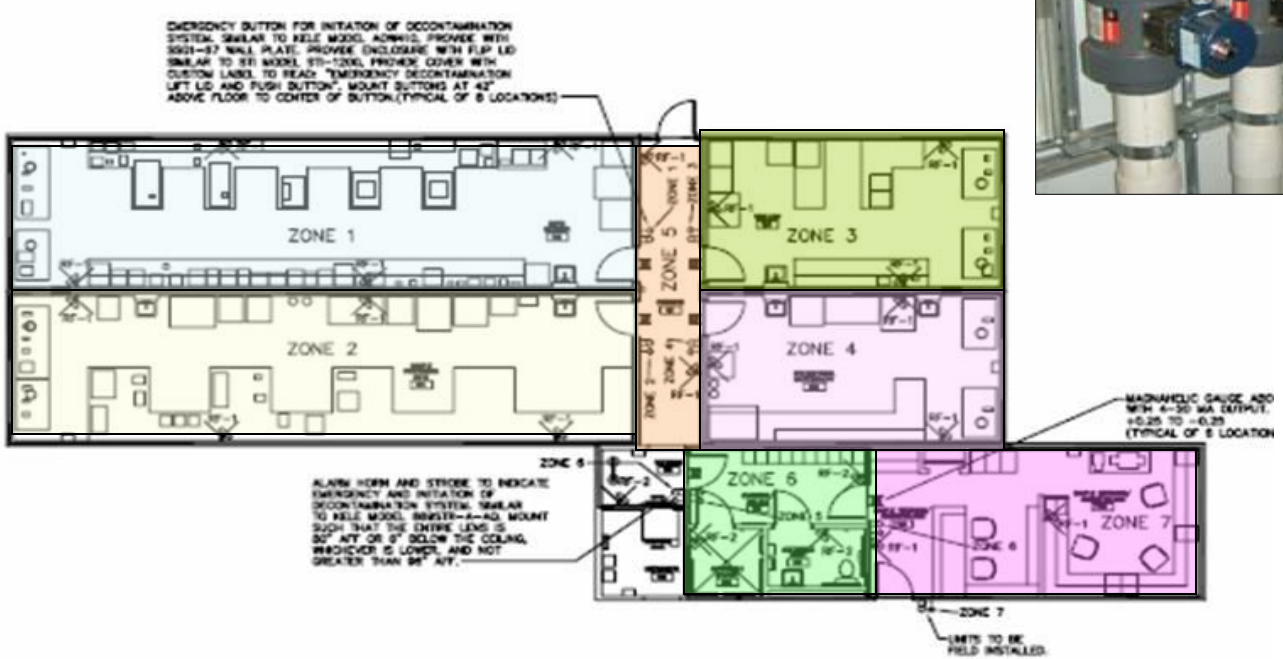
A.E. = Air Exchange

Pass-Through Chambers

Shown above

Enclosure v Volume ft3	Enclosure surface material	Injection rate Condition g/min.	Injection rate Decon g/min.	Decon time Min 6 log	Decon airflow ft3/min	PPM	Aeration airflow ft3/min	Total Cycle Time min.
460 (6x8x9.5'L)	Stainless	32	23	12	**120**	1000	**765**	45
175 (4x6x7'L)	Epoxy paint	12	9	8	**40**	950	**1750**	30

Automated Sequential Zone BSL3 Lab Decontamination Single Pass



Zone
- 1
- 2
- 3
- 4
- 5
- 6
- 7

360° solutions

BSL Lab & BSC Decon
Single Pass

Simultaneous Decon. of Primary Containment

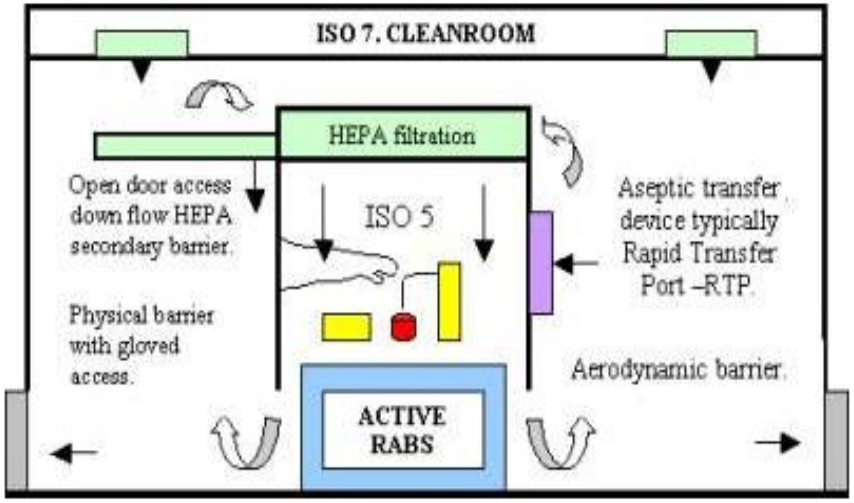
A2 type biosafety cabinets can be decontaminated together with the room

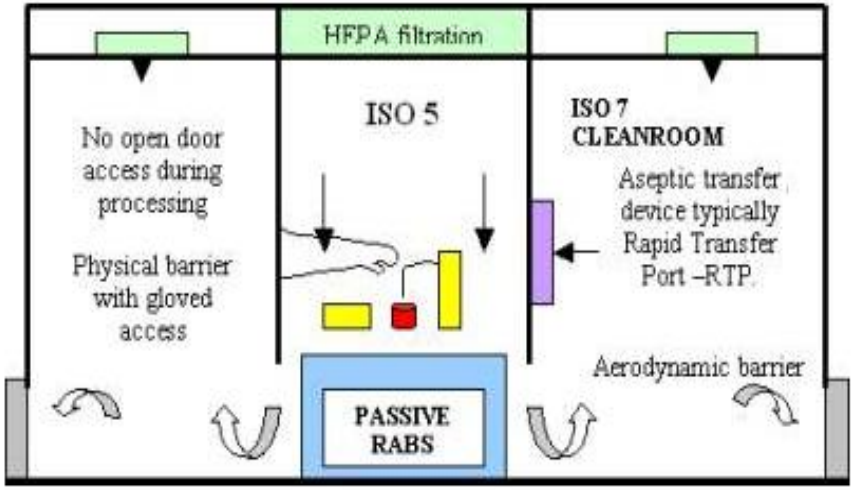
- exhaust dampers above cabinets are closed
- cabinet blowers left on

HEPA Filter Decontamination

RABS – (Restricted Access Barrier Systems)

Modular VHP systems can rapidly decontaminate both Active & Passive RABS and the rooms they are housed in





Source: Pharmaceutical International

U.R.S.

- VHP is treated as a building utility
- Decon can be performed after each
  - product change
  - product batch
  - during an incident
  - after maintenance
- No sealing of perimeter required, surrounding areas can continue to operate
- Zone 1 (AHUs 2-4, 2-5,and 2-6) will be decontaminated together
- Zone 2 (AHUs 2-9, 2-10 and 2-11) will be decontaminated together
- Multiple zones will be decontaminated sequentially
- Decontamination time per zone – about 2 hours *
- Aeration time per zone about 2 hours * (at 10 AE/hour)

* Typical timing only, actual timing depends on room load and configuration

Scope of work

- Conceptual design and specifications
  - Material, size, maximum lengths of VHP cPVC piping, connection to AHU ducting, etc
  - Type and sizing of dampers and valves
  - Recommended air exchanges
  - Utility requirements
- Equipment skid (1 x T4, 1 x Munters, handshake dry contacts, etc)
- SS braided tubing from T4 to bulk Vaprox (up to 10m)
- Sensors for H_2O_2 safety monitoring – 1 per zone
- Installation supervision

Process Concept
Distribution

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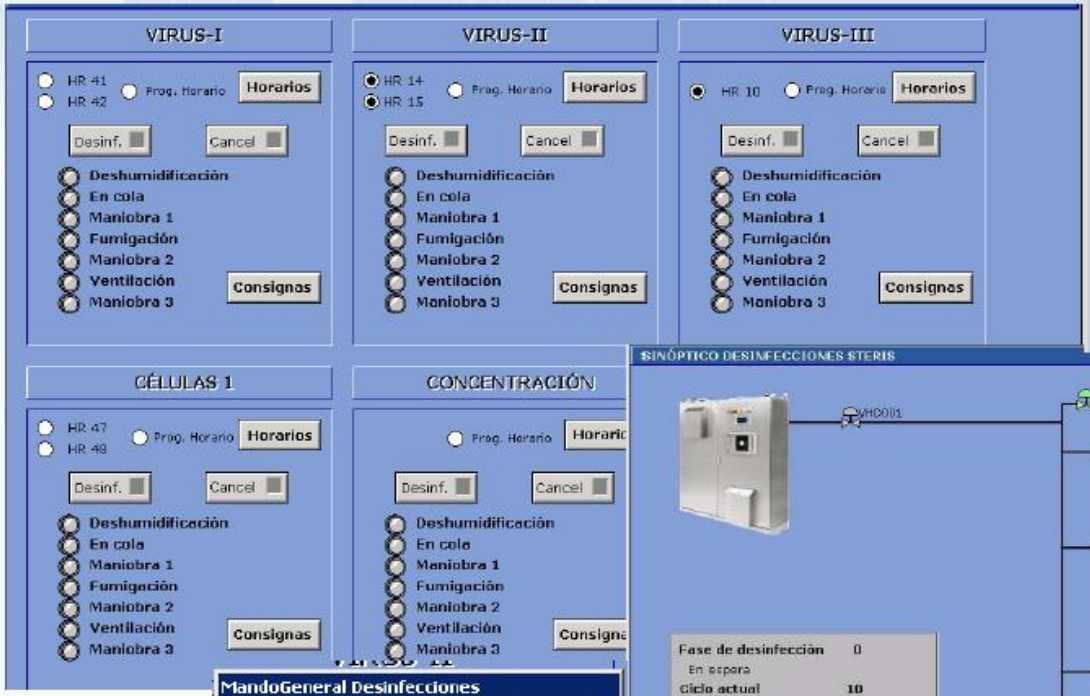
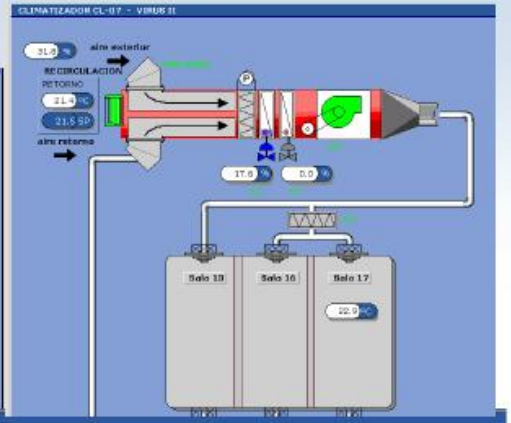
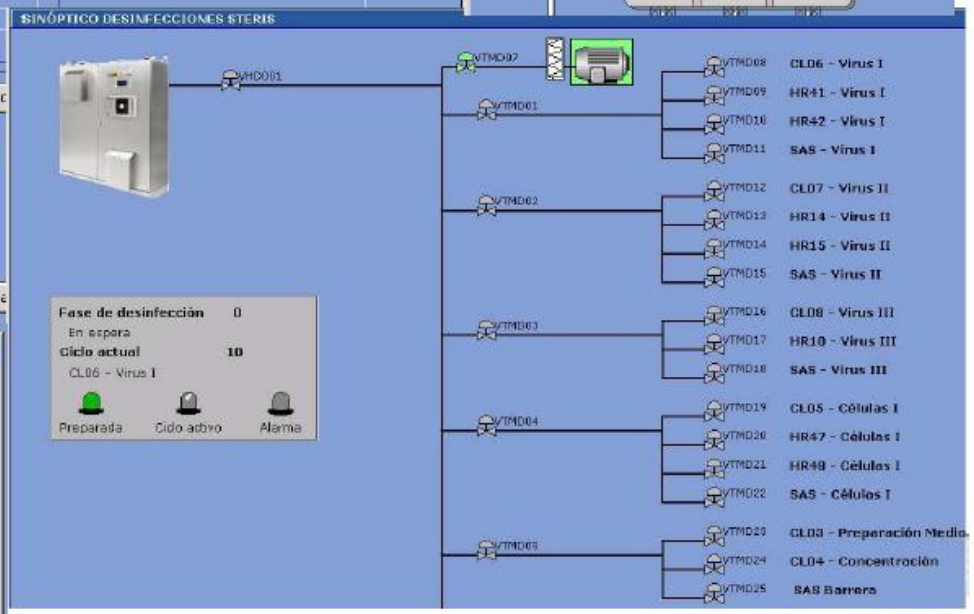
Automatización







ISPE Spain Affiliate ENGINEERING

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Direct injection setup

Technical Area

VHP M1000-T4

Proposed area of installation on AHU mechanical floor

Zone 1

Zone 2

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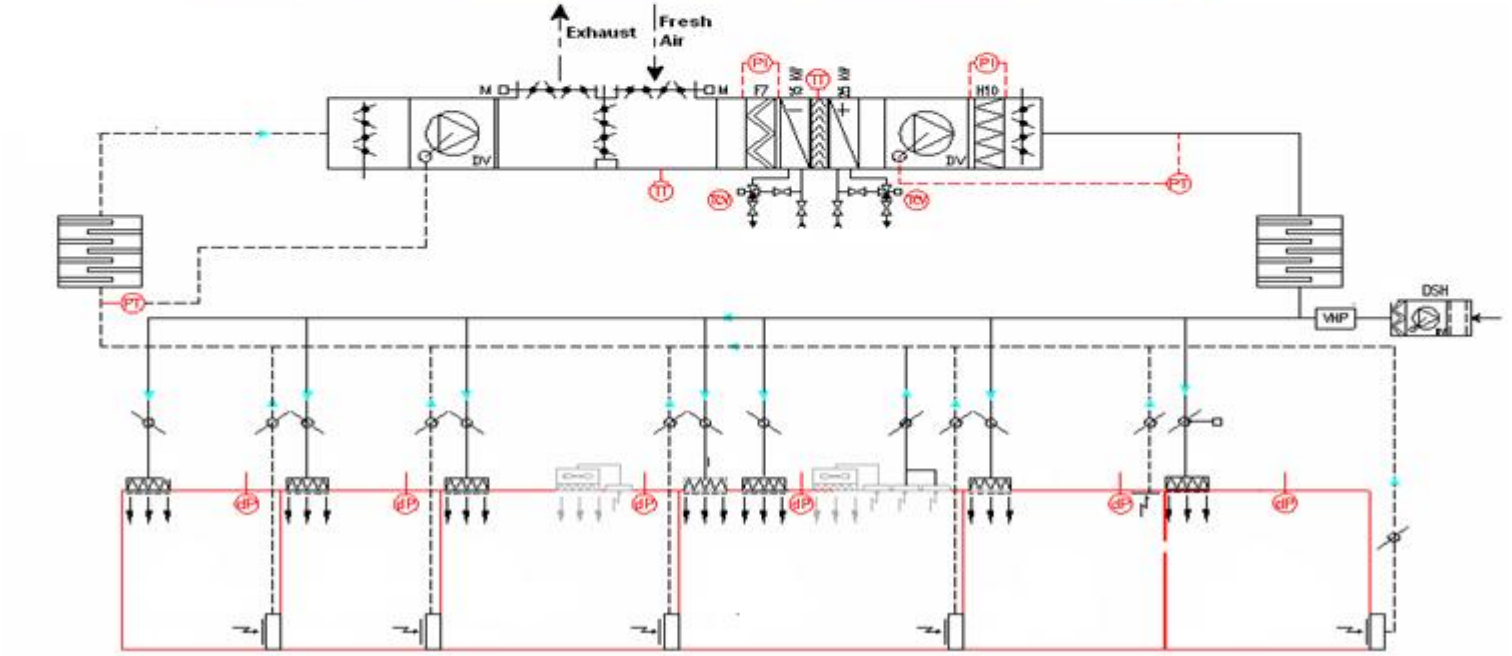

Recirculation concept

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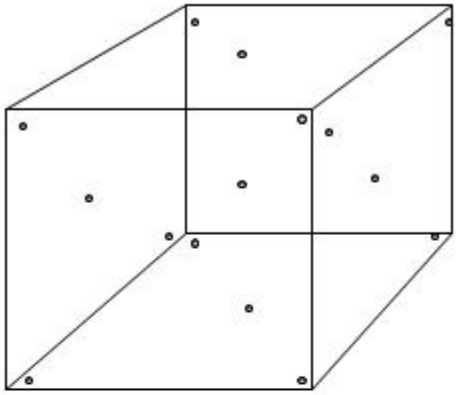
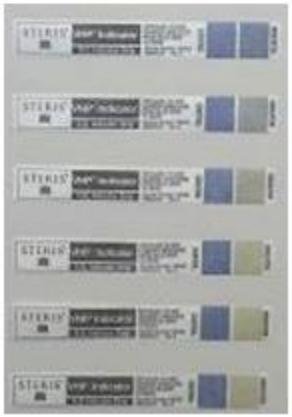


BI's incubated at
55° C for 7 days



Application
Cycle Developpement

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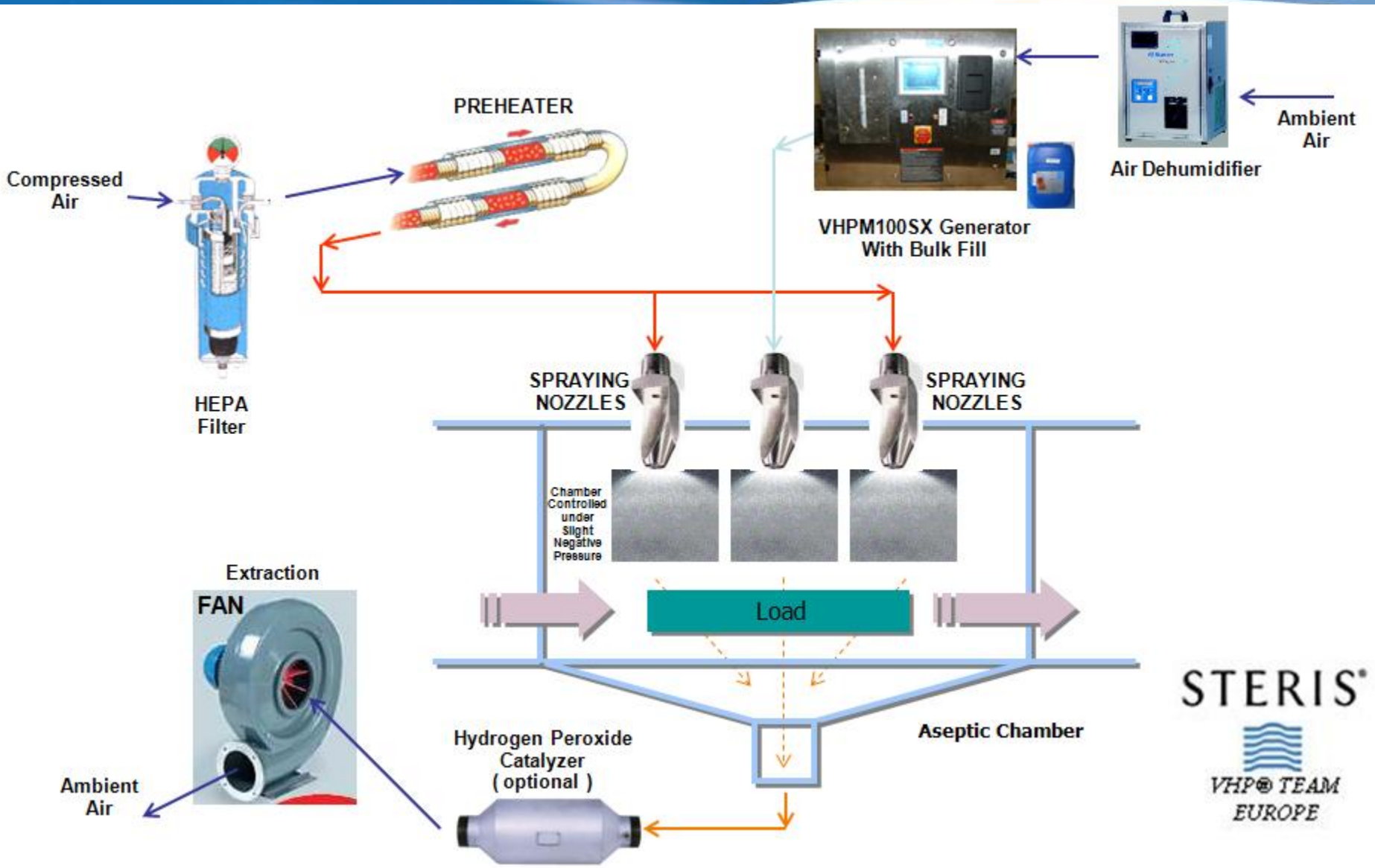
360° solutions



F & B
Horizontal Filling Lines
Flash Decon Theory

360° solutions

F&B application

Selected Installations

Pharma / Animal Health

- GSK
- Intervet
- Fresenius
- Sanofi
- Merial
- Alcon
- Pfizer
- Boehringer
- Hisun

Public Health Labs

- Indiana
- New Jersey
- West Virginia

Others

- Tripler- US Army
- Univ. Nebraska
- Lawrence Livermore National Labs
- INRS
- NCI
- WP-AFB

B & V TESTING and STERIS Advanced Biodecontamination Solutions (ABS)

Advanced Biodecontamination Solutions

- **ABS: a Flexible service offering matching the field service expertise of B & V TESTING with STERIS VHP technology and EPA-registered consumables**

Contract* VHP*biodecontamination services

- National leader in biodecontamination and contamination control technologies testing, certification and maintenance services:
  - 30 years experience performing gaseous Biodecontamination Services (formaldehyde, VHP, CD)
  - Testing, Certification and Maintenance of Cleanrooms, Biological Safety Cabinets, and HEPA-filtered systems

- STERIS is a global leader in infection prevention, contamination control, surgical and critical care technologies, and more. Manufacturers of EPA registered Vaprox® 35% and 59% hydrogen peroxide (EPA reg. no. 58779-4), Spor-Klenz (EPA reg. no. 52252-4-1043 and VHP® technology