Air Flow Visualization

David Matsuhiro
Cleanroom Compliance Inc.
dmatsuhiro@cleanroomcompliance.com

Air Flow Visualization

- **Velocity Testing**
  - Rotometer
  - Hotwire
  - Velgrid

Air Flow Visualization

- **Velocity Testing**
  - Rotometer

3

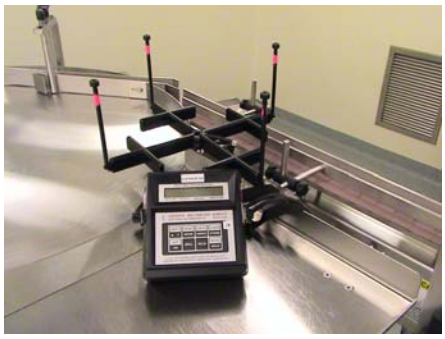
Air Flow Visualization

- **Velocity Testing**
  - Hotwire

4

Air Flow Visualization

- **Velocity Testing**
  - Velgrid



5

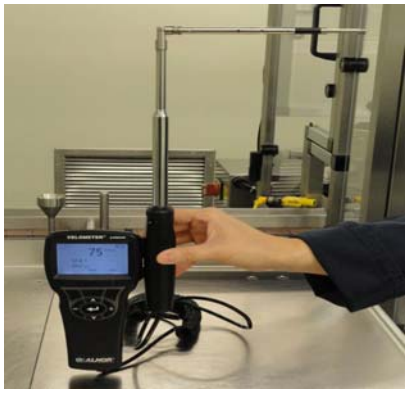
Air Flow Visualization

- **Velocity Testing**
  - Hotwire Filter Face

6

Air Flow Visualization

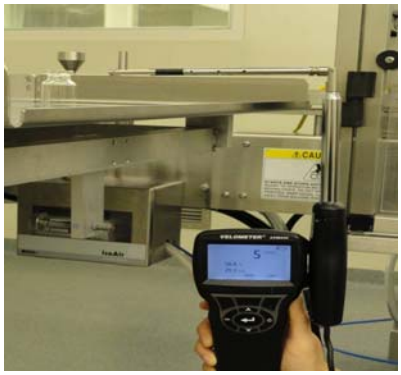
- **Velocity Testing**
  - Hotwire 18-Inches from work height



7

Air Flow Visualization

- **Velocity Testing**
  - Work Height, Vertical



8

Air Flow Visualization

- **Velocity Testing**
  - Work Height, Horizontal

9

Air Flow Visualization

- **Volume Testing**
  - Velocity
  - Area of HEPA Filter surface
  - Determine the volume of the room
  - Calculate the room air exchanges
    - The number of times the entire room volume exchanges within 1-hour

10

Air Flow Visualization

- **Volume Testing**

11

Air Flow Visualization

- **Generation Systems**
  - Titanium Tetrachloride
  - Dry Ice, Carbon Dioxide
  - Glycol
  - Ultra Sonic
  - Liquid nitrogen

12

Air Flow Visualization

Equipment: Titaniun Tetrachloride

Smoke Sticks by TEL TRU

13

Air Flow Visualization

Equipment: Titaniun Tetrachloride

T-T Puffer by TEL Tru

14

Air Flow Visualization

Equipment: Titaniun Tetrachloride

Smoke Sticks by Draeger

15

Air Flow Visualization

Equipment: Titaniun Tetrachloride

- **Advantages**
  - Small, portable and easy to use
  - Can produce smoke for a maximum or 45 minutes
  - Dreager tubes can be covered and re-used but not stored for a long time
  - Smoke is easily visible
- **Disadvantages**
  - Smoke irritating to eyes and mucous membranes
  - Provides only a single stream of smoke
  - May require multiple tubes to be used at one time
  - Leaves a residue on surfaces
  - Must be shipped by ground

16

Air Flow Visualization

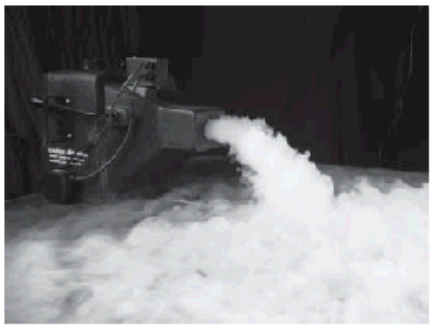
Equipment: Carbon Dioxide

Applied Physics Inc Model 5 CO2

17

Air Flow Visualization

Equipment: Carbon Dioxide



Pea Souper Machine Model 1800

18

Air Flow Visualization

Equipment: Glycol Based

Portable Generator by Flow-Marker

19

Air Flow Visualization

Equipment: Glycol Based

Theatrical Stage Fogger & Glycol

20

Air Flow Visualization

Equipment: Glycol Based

Theatrical Fogger by Battle

21

Air Flow Visualization

Equipment: Ultra-Sonic

Utility Fogger by Applied Physics Inc

22

Air Flow Visualization

Equipment: Ultra-Sonic

Clean-Air Trakker by Clean Air Solutions

23

Air Flow Visualization

Equipment: Liquid Nitrogen

MSP Model 2001

24

Air Flow Visualization

- **Frequency of Testing**
  - During validation of new facility
  - After significant modifications to an existing facility
  - If HEPA velocities are not within 90 ft/min ± 20% (72 – 108 ft/min)
  - Not required on a routine basis*

25

Air Flow Visualization

- **Testing Requirements**
  - HEPA certification signed off
  - Air balancing between rooms must be approved with all documentation completed
  - Balance the airflow within the fill room Evaluate the velocities at the returns
  - Differential pressures defined and set
  - Room exchanges defined

26

Air Flow Visualization

- **Testing Requirements**
  - Confirm air returns are not blocked
  - No alarms with BMS system associated with differential pressure system
  - Door interlocks must be defined
  - Justification for duration the door can be open
  - Facility ready for operational use

27

Air Flow Visualization

- **Phase I Testing**
  - Performed under static conditions
  - Gowning not required but recommended
  - Sterilized are not required at this time
  - Video tape the airflow study
  - Performed at 6 – 18 inches from filter face if possible
  - Evaluate turbulent areas based on blank ceiling tiles, lights, and HEPA grid system

28

Air Flow Visualization

- **Phase II Testing**
  - Performed 18 - 24 inches above critical areas
  - Evaluate airflow towards the air returns
  - Assess when the doors to the room are opened and closed
  - Lexan doors to access the critical areas opened and closed
  - Evaluate when the pass through is open and closed

29

Air Flow Visualization

- **Phase II Testing**
  - Evaluate the results to determine if there are any significant airflow issues
  - If any of the following are observed, re-evaluate air balancing within the room
    - Turbulent air over critical areas
    - First Air concepts are not in place
    - Airflows from dirty to clean

30

Air Flow Visualization

- **Phase II Testing**
  - Interior of filling cabinet does not allow proper air flow within the cabinet
    - Increase the open area of the filling cabinet
    - Cut holes or slats into the cabinet
  - Curtains too long/short and interfere with the airflow

31

Air Flow Visualization

- **Phase II Testing**
  - Ensure environmental monitoring locations do not impact the critical areas of filling operations
  - Lexan covers/shields do not allow access to critical locations
  - Doors open to a lower classified area
  - HEPA filter not over entire critical areas

32

Air Flow Visualization

- **Phase III Testing**
  - Confirm all issues from Phase I and II have been addressed
  - Set up the filler or aseptic processing area
  - Evaluate how each piece of equipment is set into place
  - Evaluate how bio-shield/covers on sterile items are removed

33

Air Flow Visualization

- **Phase III Testing**
  - Assess how each of the commodities are placed into the bowls or hoppers
  - Assure the airflow goes from clean to dirty
  - Determine the areas that need to be sanitized after set up

34

Air Flow Visualization

- **Phase III Testing**
  - Evaluate critical operations for First Air
  - Run the filling machine or aseptic process
  - Determine where personnel can/can not stand in proximity to the critical areas
  - Include fill volume/weight check
  - Assess the locations where hands are sanitized with alcohol

35

Air Flow Visualization

- **Phase III Testing**
  - Ensure environmental monitoring personnel are involved at this phase
    - Assess the set up of viable air and particulate counting systems
    - Evaluate changing plates
    - Review how equipment is sanitized in the clean room
    - Confirm EM does not impact the aseptic process

36

Air Flow Visualization

- **Phase IV Testing**
  - Perform both routine and non-routine interventions
    - Assess for First Air concepts
    - Optimize placement of personnel while performing an operation
    - Enhance the process if the potential for contamination is significant

37

Air Flow Visualization

- **Phase V Final Report**
  - Complete Airflow Report
    - Ensure all issues defined in each Phase has been addressed
    - Optimize all operations and procedures based on the air flow

38

Air Flow Visualization

- **Phase V Final Report**
  - Airflow patterns must not present a contamination risk. Air patterns must ensure that airflows do not distribute particles from a person, operation or machine to a zone of higher product risk

39

Air Flow Visualization

- **Phase V Final**
  - **Evaluation Criteria**
    - **(+++)** Excellent airflow, unidirectional airflow with no turbulence, no breach in First-Air
    - **(++)** Good airflow, slight disruption of unidirectional airflow and/or First-Air, no significant impact on aseptic operations
    - **(+)** Adequate airflow, with disruption of unidirectional airflow and/or breach of First-Air. Acceptable conditions for aseptic processing if procedurally controlled. Sanitization post operation and/or end of fill Environmental Monitoring may be required
    - **(-)** Turbulent airflow with significant swirling and/or tumbling that could compromise the procedure and/or product

40

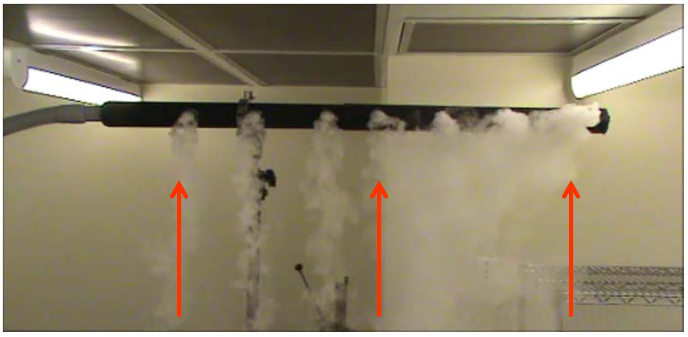
Air Flow Visualization

- **Phase VI Training**
  - Use airflow evaluation for aseptic process training
    - Operators should review once per year as part of routine training
    - New employees should review airflow testing as a part of training

41

Air Flow Visualization

- **Airflow Examples**



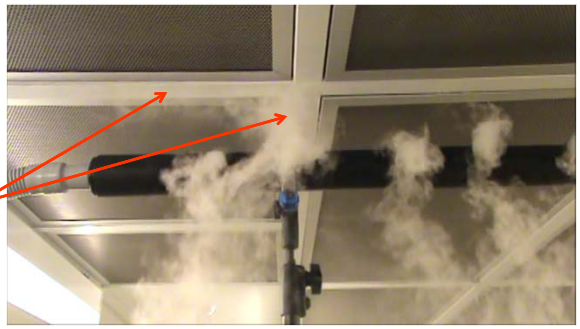
Unidirectional Mixed Turbulent

42

Air Flow Visualization

- **Airflow Examples**
  - Turbulent air at the HEPA grids

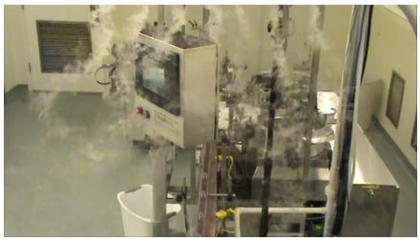
Turbulent

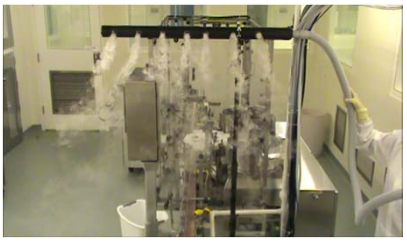


43

Air Flow Visualization

- **Airflow Examples**
  - Location of HMI screen





44

Air Flow Visualization

- **Airflow Examples**
  - Optimal position for the HMI screen

45

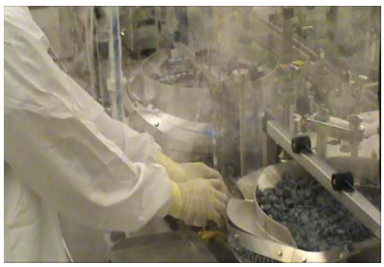
Air Flow Visualization

- **Airflow Examples**
  - Unidirectional air inside/outside cabinet

46

Air Flow Visualization

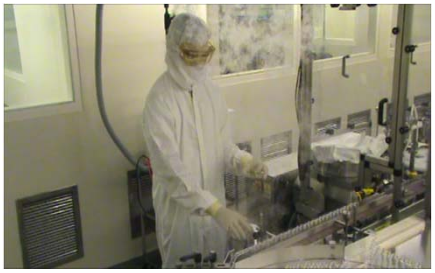
- **Airflow Examples**
  - Loading viable air heads. Sample and stopper bowl remains in First-Air

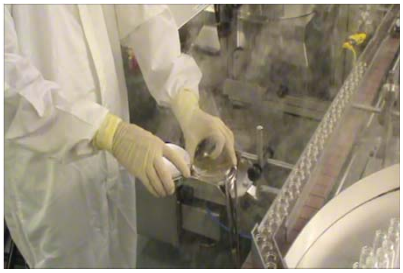


47

Air Flow Visualization

- **Airflow Examples**
  - Loading viable air heads. Sample and exposed vials remains in First-Air





48

Air Flow Visualization

- **Airflow Examples**
  - Aseptic connection points remain in First-Air

49

Air Flow Visualization

- **Airflow Examples**
  - Aseptic connection points in First-Air

50

Air Flow Visualization

- **Airflow Examples**
  - Installing the filling needle using sterile forceps. Note, needle stays in First-Air at all times

51

Air Flow Visualization

- **Airflow Examples**
  - Removing the sterile wrap and setting filling needle

52

Air Flow Visualization

- **Airflow Examples**
  - Lowering needle into position

53

Air Flow Visualization

- **Airflow Examples**
  - Note the different body positions

First-Air to the bags

Air flows over operator onto the bags

54

Air Flow Visualization

- **Airflow Examples**
  - Airflow towards the operator keeping the tray of vials in First-Air

55

Air Flow Visualization

- **Airflow Examples**
  - Forceps tips up or down? Think First-Air

56

Air Flow Visualization

- **Airflow Examples**
  - Blocking airflow coming out of the stopper bowl creating turbulent air under the bag

57

Air Flow Visualization

- **Airflow Examples**
  - Loading stoppers from left side is high risk. Note the stoppers are facing up

Product contacting side facing up and exposed

Air Flow Visualization

- **Airflow Examples**
  - Loading stoppers from right side is lower risk. Note the stoppers are facing down

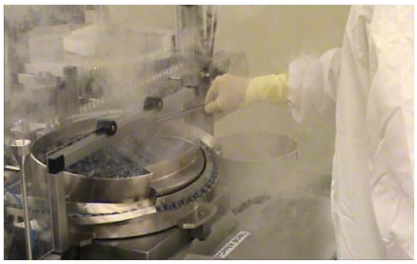
Product contacting side facing down and covered

59

Air Flow Visualization

- **Airflow Examples**
  - Removing stopper jam

Hand over bowl

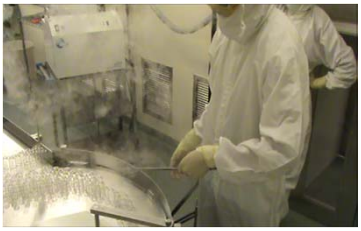


Hand on the side of the bowl

60

Air Flow Visualization

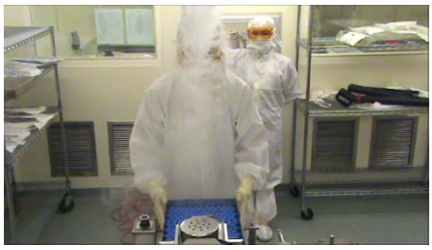
- **Airflow Examples**
  - Removing fallen vial. Note hand position not over the turn table. Vials in First-Air



61

Air Flow Visualization

- **Airflow Examples**
  - Turbulent air at the HEPA grids



Sub-optimal
filming position

62

Air Flow Visualization

- **Airflow Examples**
  - Optimal film position from the left and right sides. Air flows towards operator

63

Air Flow Visualization

- **Manual Stoppering**
  - Air flows over operator onto the open vials

64

Air Flow Visualization

- **Manual Stoppering**
  - Air flows towards the operator keeping the vials in First-Air

65

Air Flow Visualization

- **Take Away Message**
  - Evaluate airflow video to evaluate their aseptic process
  - Airflow must represent the entire process, setup, interventions environmental monitoring and adding commodities
  - Determine if airflow is a part of aseptic training
  - Assess the risk based on airflow

66