

# Risk Based Environmental Monitoring (EM) and EM Data Management and Trending

*An Industry Roundtable Discussion*

**Marsha Stabler Hardiman and Parsa Famili**

**March 11, 2015 PDA NE Chapter Meeting**





## Presenters



### ***Marsha Stabler Hardiman***

- Over 20 years experience in the Pharmaceutical and Medical Device industries
- Microbiologist and Senior Consultant, Concordia ValSource LLC



### ***Parsa Famili, MS.***

- Over 20 years experience in Pharmaceutical and Biotech industries
- President, Novatek International



# Presentation Outline

- Definition Environmental Monitoring (EM)
- Regulations
- Room Classifications
- Risk-based EM
- Risk Assessment Tool
- Data Trending
- EM Software
- Q & A



# What is Environmental Monitoring?

- Sampling of controlled environments for non-viable and viable air particulates as well as surface viables
- Allows for assessment of effectiveness of cleaning/disinfection
- Allows for identification of trends
- Facilitate early detection of potential problems



# Regulations

*The FDA believes:*

1. Manual systems have large inherent operational risks, therefore they are difficult to validate.
2. If it isn't documented, it wasn't done.
3. If it wasn't done using an appropriate process, it wasn't done properly.





# *The FDA believes:*

**From:** Friedman, Rick L [mailto:[rick.friedman@fda.hhs.gov](mailto:rick.friedman@fda.hhs.gov)]

**Sent:** Tuesday, January 13, 2009 10:18 PM

**To:** [ilona.endisch@ntint.com](mailto:ilona.endisch@ntint.com)

**Subject:** Re: FDA and a computerized environmental monitoring program

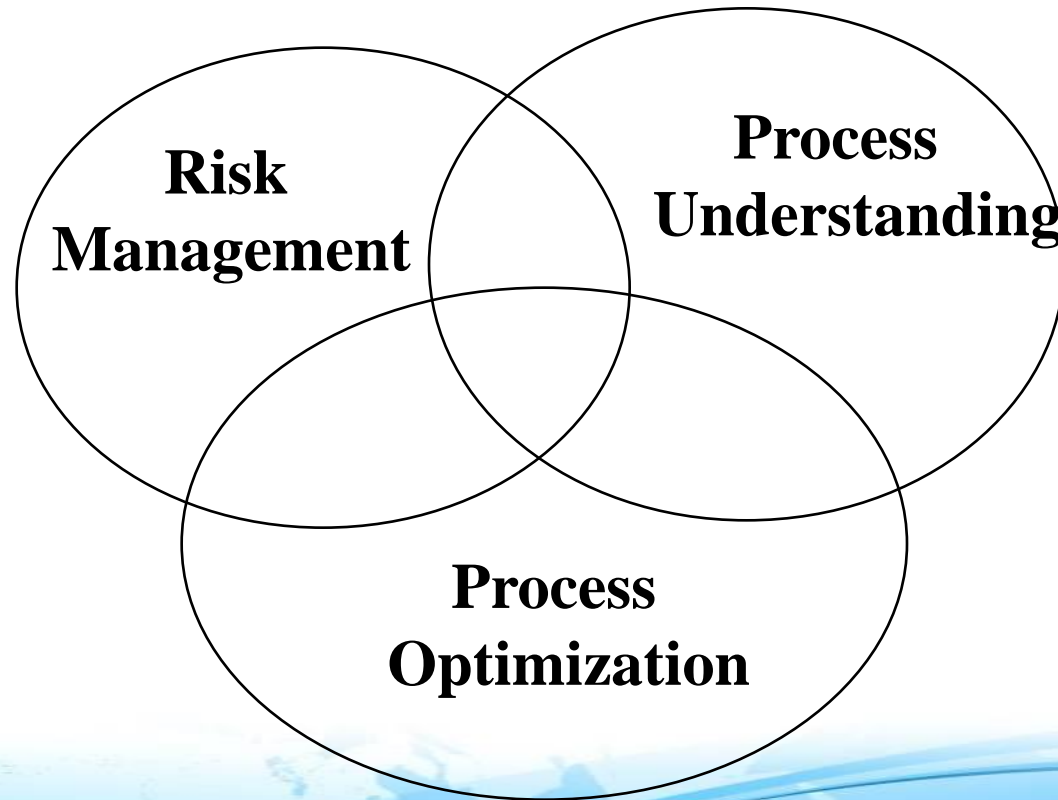
Computer trending for pattern recognition is the most efficient and effective way to handle such large quantities of data.

Rick Friedman



# The Roadmap to Compliance

## Harmonized Risk and PAT Solution



# Room Classification

- ISO 14644 assigns ISO classification levels to be used for the specification of air cleanliness in cleanrooms and associated controlled environments

## ***Classification – defined per ISO 14644-1***

- level (or the process of specifying or determining the level) of airborne particulate cleanliness applicable to a cleanroom or clean zone, expressed in terms of an ISO Class  $N$ , which represents maximum allowable concentrations (in particles per cubic meter of air) for considered sizes of particles



# Room Classification - Non-Viable Airborne Particulates

## **ISO 14644-1 *maximum allowable* particle concentrations**

*Airborne particulate cleanliness shall be designated by a classification number*

ISO 5 – Unidirectional airflow, aseptic processing, exposure of sterile products and packaging components

$\geq 0.5 \mu\text{m} - 3,520 \text{ particles/m}^3$

ISO 6 – Possible background to ISO 5 – not required

$\geq 0.5 \mu\text{m} - 35,200 \text{ particles/m}^3$

ISO 7 – Background to ISO 5

$\geq 0.5 \mu\text{m} - 352,000 \text{ particles/m}^3$

ISO 8 – Non-sterile areas, prep, terminally sterilized

$\geq 0.5 \mu\text{m} - 3,520,000 \text{ particles/m}^3$

# Airborne Particulate Cleanliness Classes

ISO Class	0.5 $\mu\text{m}$	5.0 $\mu\text{m}$
ISO 5	3 520	29
ISO 6	35 200	293
ISO 7	352 000	2 930
ISO 8	3 520 000	29 300

**Maximum concentration limits (particles/m<sup>3</sup> of air)**



# Room Classifications – Global Differences

ISO	USA/FDA	EU/JP
ISO 4.8	Class 100	Grade A in Operation
ISO 5	Class 100	Grade B in Operation, Grade A at rest
ISO 6	Class 1000	
ISO 7	Class 10,000	Grade B at Rest, Grade C in Operation
ISO 8	Class 100,000	Grade C at Rest, Grade D in Operation

*EU and Japan have limits for 5 micron particles*



# Common Misperception with ISO 14644

B 4.1.1 - Minimum number of sample point locations based on formula:

$$NL = \sqrt{A}$$

(NL = (square root) of A)

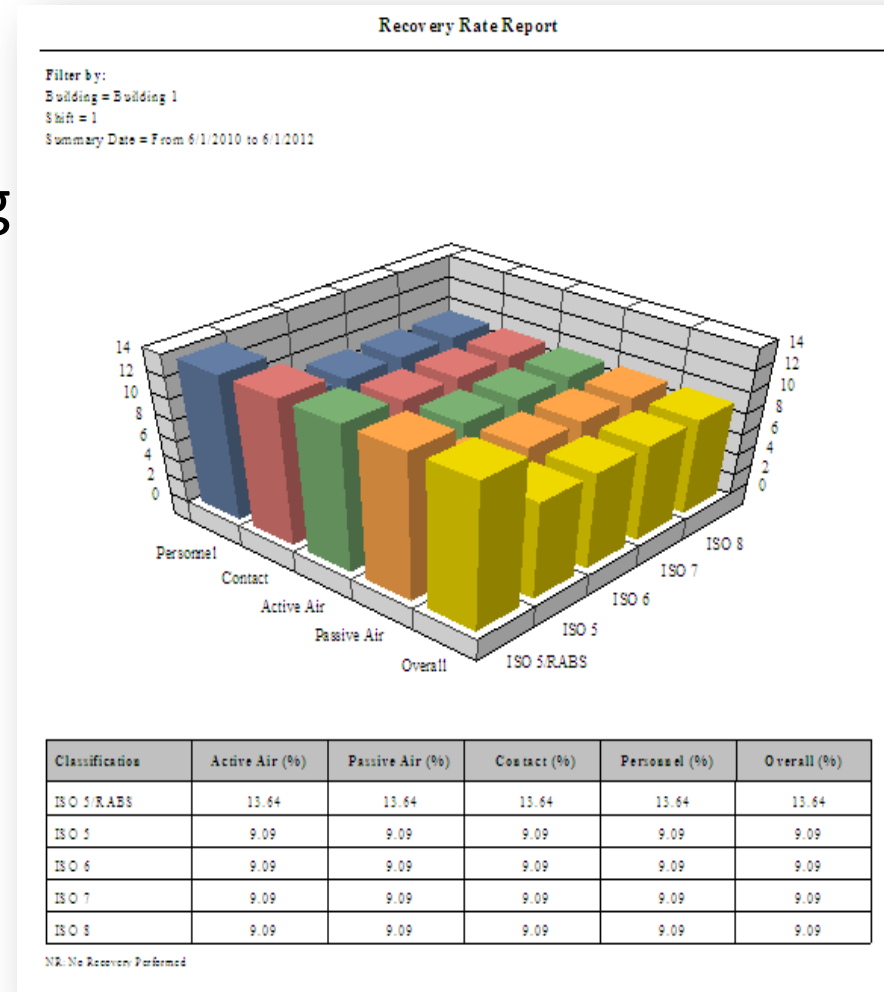
- NL is the minimum number of sampling locations (rounded up to a
- whole number)
- A is the area of the cleanroom or clean zone in square meters.

***Room grid based on room area***

**Specific to nonviable particulate sample locations for cleanroom classification – evaluates air quality against design – not routine EM**

# USP <1116>

- Significant changes made to USP <1116> in late 2012
- This Chapter is NOW specific to EM of aseptic processing environments
  - Sterile products, bulk “sterile” drug substances, sterile intermediates, excipients, medical devices (i.e., contact lens solutions)
- Risk based sample locations and frequencies with documented rationale
  - Table 2 suggests sampling frequency in relation to product risk
- Rate of occurrence of excursions in place of CFU levels
  - Contamination recovery rates – percentage of plates showing any microbial recovery regardless of the number of CFU
  - Alert and action levels are defined relative to these percentages

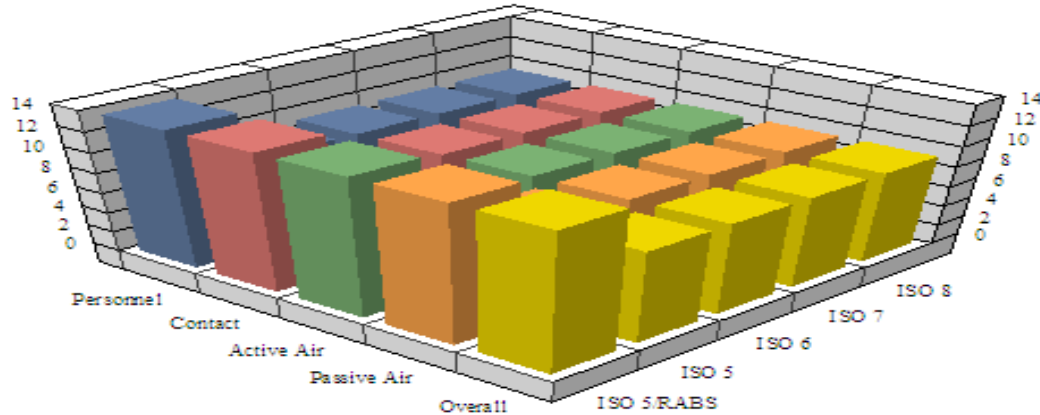


# USP CHAPTER <116>

## Snap Shot Report

### Recovery Rate Report

Filter by:  
Building = Building 1  
Shift = 1  
Summary Date = From 6/1/2010 to 6/1/2012



Classification	Active Air (%)	Passive Air (%)	Contact (%)	Personnel (%)	Overall (%)
ISO 5/RABS	13.64	13.64	13.64	13.64	13.64
ISO 5	9.09	9.09	9.09	9.09	9.09
ISO 6	9.09	9.09	9.09	9.09	9.09
ISO 7	9.09	9.09	9.09	9.09	9.09
ISO 8	9.09	9.09	9.09	9.09	9.09

NR: No Recovery Performed

- Gives a quick snapshot based on whatever you filter for.
- Includes overall rate for each test category for each ISO class.

**New Feature**



# USP <1115>

- Describes Microbial Assessment of Non-sterile Product Manufacturing Environments
  - Part of Risk-Based Microbiological Control Program
- Contamination Recovery Rates from <1116> are not intended for non-sterile environments
- Contamination likely depends on level of human activity and levels of gowning
- Sampling locations should be selected based on risk evaluation
- Frequency of monitoring should reflect the potential risk associated with the dosage form
  - Products that are resistant to microbial contamination require little to no monitoring

# AAMI TIR 52

- New AAMI TIR on Environmental Monitoring
  - **Complete**
  - **Published in April 2014**

**TIR 52 Environmental Monitoring for the Manufacture of Terminally Sterilized Healthcare Products**



# EM Program's of the Past

- Maybe this is your current EM Program
  - If so, you are not alone and this is the time to start to change your program to a risk based one
- Viable and Non-Viable
  - Center of the Room
- Surface Viable
  - Center of Each Wall
  - Floor - corner of each room, center of room

**IS THIS WRONG?**

**IS THIS RISK BASED?**



# EM Program Risk-based Approach

Two way approach – similar but different based on prior knowledge:



1 – New EM Program

2 – Reassessment of Current/Existing EM Program

# New EM Program

- New Facility?
- New Controlled Environment additions to existing facility?
- Any Prior Knowledge contamination types and levels?

Prior knowledge is an input

Assess Microbial Risk of New Area

- Product Type
- Process



# Step 1 - Planning

- Risk Management Planning
  - Determine Team/Members – cross functional (Micro, QA, MFGing, Facilities, Engineering)
  - Select Facilitator – not bias to activity
  - Define Scope of Risk Activities for EM Program assessment
  - Determine the Risk Management Tools to be used
  - Determine Scoring to be used – company procedure may already exist
  - Determine Communication of Risk Plan
    - Who needs to be communicated to, when, how often, how much detail
  - *Impact to Regulatory Filings – unlikely for new*
  - *Costs – EQ, automation*



# Step 2 - Assess Activity Affecting Microbial State of Control

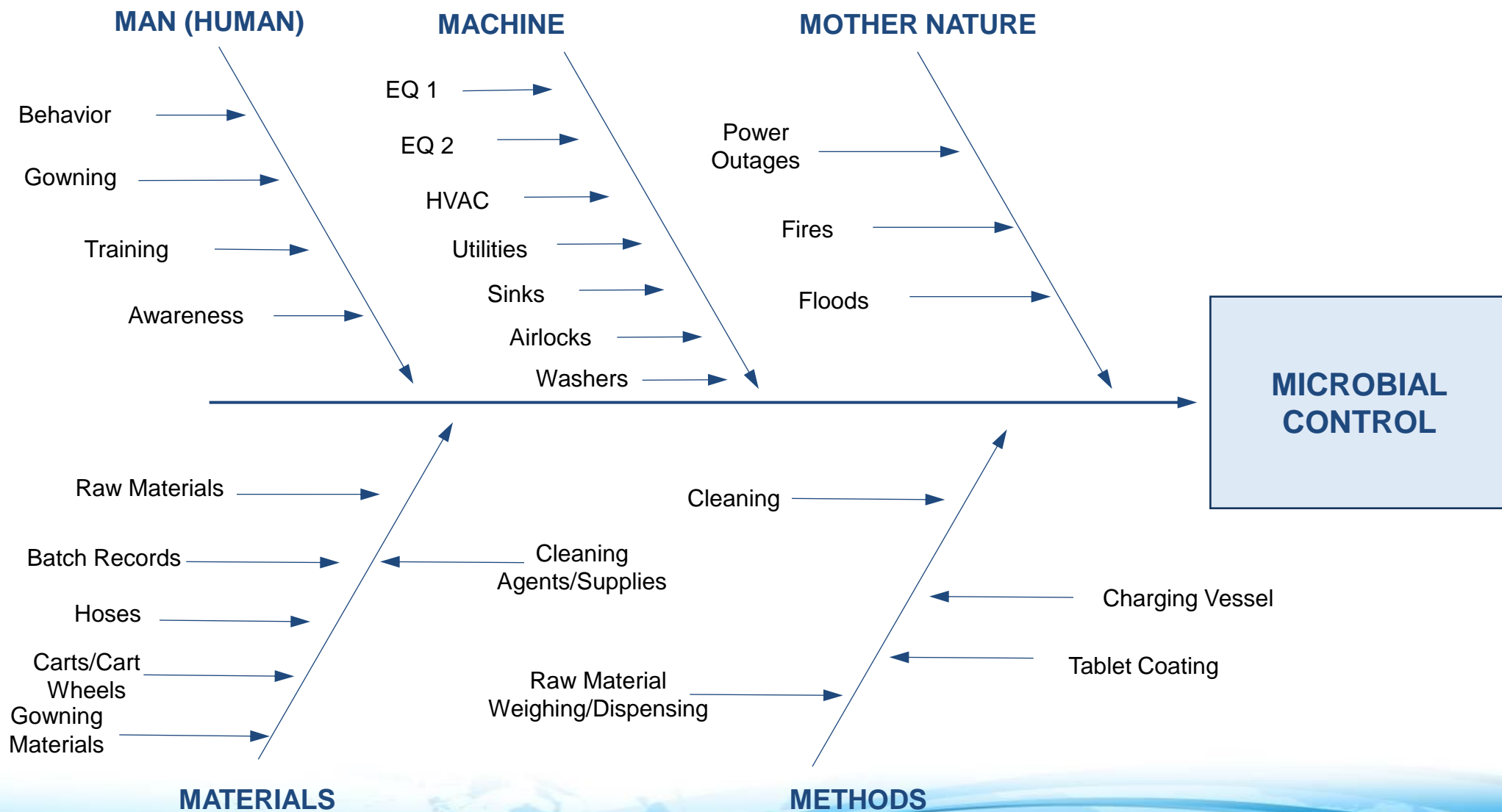
- Brainstorm
- Fishbone
- Cross functional team – Microbiologists, Manufacturing, Engineers, Quality, Facilities
  - May want to break down by sub-teams for different rooms if large facility

**No need to discuss current controls in place at this point**

Simply identifying all areas of microbial risk



# CAUSES OF MICROBIAL CONTAMINATION



# Step 3 - Assess Activity and Flow

- Gemba each room/area if possible
  - If construction phase, do via paper until you can get in the area
  - Best case - Work with engineers prior to design and construction start to identify microbial risk points and plan them OUT
- Assess planned personnel flow
- Assess planned material flow
- Sample site locations should be based on risk of activity
- Likelihood of contamination from process
  - Open or Closed Process
  - People likely largest contributors of room contamination if closed process
- Maybe you have a wet process – Gram negatives
- Contamination from other products



# Step 4 – Perform Risk Assessment

- Next use the information obtained in the brainstorming activity and floor assessment as a foundation to perform a risk assessment
- Include known controls and risk mitigations
- Cross functional team – Microbiologists, Manufacturing, Engineers, Quality, Facilities
- Preliminary Hazard Analysis (PHA) or Failure Modes and Effects Analysis (FMEA)



# FMEA Process Example

- **Identify Hazards**
    - Example: Not meeting Air Quality Viable EM Levels
  - **Identify Harms**
    - Example: Airborne contamination in controlled environment
  - **Identify Hazardous Conditions**
    - Contamination of Room EQ
      - Contamination of product contact surfaces
    - Contamination of People
    - Contamination of work surfaces
  - **Determine Severity, Occurrence and Detection Scores**
  - **Determine Risk Priority Number (RPN)**
  - **Determine Control Measures in Place**
    - Example: Cleaning/Disinfection
    - Example: HVAC System
  - **Determine if Additional Controls are Needed**
    - Example: More Gowning
- 

# Risk Ranking

- Determine HIGH, MEDIUM and LOW risk areas from RPN results
- Could be used to determine frequency or site locations

HIGH – daily


MEDIUM – weekly

LOW – monthly





# Step 5 - Selection of Sample Locations and Sampling Frequencies

- Use all prior tools to now select your sample sites
  - Document your rationale based on the risk of contamination
  - Same sized (area) and same class rooms may have different numbers of required sample sites based on risk of contamination in each room
  - Make it about the activity, flow and VALUE ADDED
  - UNDERSTAND THE PROCESS IN EACH ROOM and the MICROBIAL RISK POINTS
  - Ability to assess effectiveness of sanitization – for that reason floor and wall locations may still be needed in your program – reduced number and justification/thought process
- 

# Reassessment of Current EM Program

- Remember that slide on EM Programs of the Past?
  - *Maybe you are saying - YES THAT IS ME!!!!*
- Time to make some changes
- Years of DATA which is KNOWLEDGE which you will use to make changes to your existing EM Program
  - Sample site locations
  - Frequency
  - Type of media
  - Incubation

# Step 1 - Planning

- Risk Management Planning
  - Determine Team/Members – cross functional (Micro, QA, MFGing, Facilities, Engineering)
  - Select Facilitator – not bias to activity
  - Define Scope of Risk Activities for EM Program assessment
  - Determine the Risk Management Tools to be used
  - Determine Scoring to be used – company procedure may already exist
  - Determine Communication of Risk Plan
    - Who needs to be communicated to, when, how often, how much detail
  - **Impact to Regulatory Filings**
  - **Cost Impact**



# Step 2 – Previous Risk Assessment Review

- Do you have a Product and/or Process Risk Assessment which already identifies the microbial contamination risk points in your processes?
  - HOPEFULLY – YES
  - ***If No – This is your step 2***, Q8/Q9/Q10 or ISO 14197
  - Cross-functional activity
  - Fishbone from New EM Program Slides
- Assume Yes
  - Perform a review of this document to identify your microbial risk points as a starting place



# Step 3 – Data Review Current EM

- Assess current EM locations and results
- What are your trouble spots – frequent alerts/actions or recovery of objectionable organisms
  - Flag these – likely keeper for your new EM Program



# Step 4 – Floor Walk/Gemba

- Assess EQ, material and people flow ON THE FLOOR
- Talk to current Production Operators
  - Ask them what they see as microbial risk points
  - They have VAST knowledge from being on the floor everyday
- Cross functional – smaller group than risk assessment
  - Microbiology Lead
  - MFGing support
  - Most process knowledge
- Where have you had bioburden or water or compressed air contamination concerns?



# Step 5 – Select New Sample Locations and Sampling Frequencies

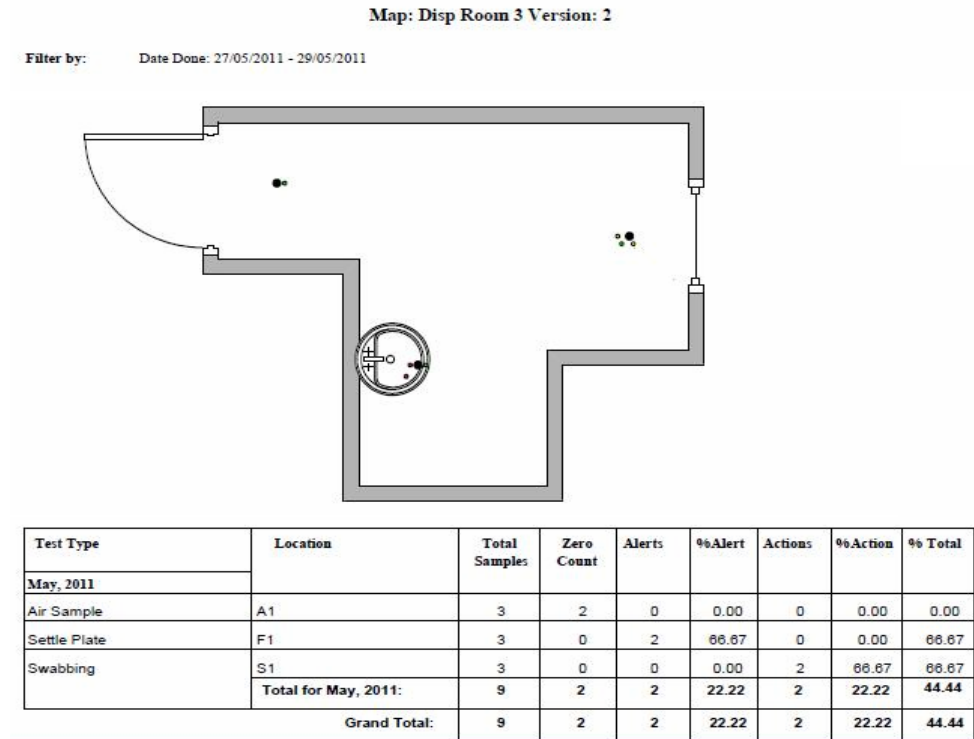
- Document all findings and risk points
- You can perform a [modified risk assessment](#) – using knowledge gained in product and process risk assessments
- Talk about activity, people and flow in each room
- Rationalize new chosen sample locations based on microbial contamination risks in these areas
- Documentation needs to be a living document, signed off Site Head, QA Head, Microbiology Management at a minimum.





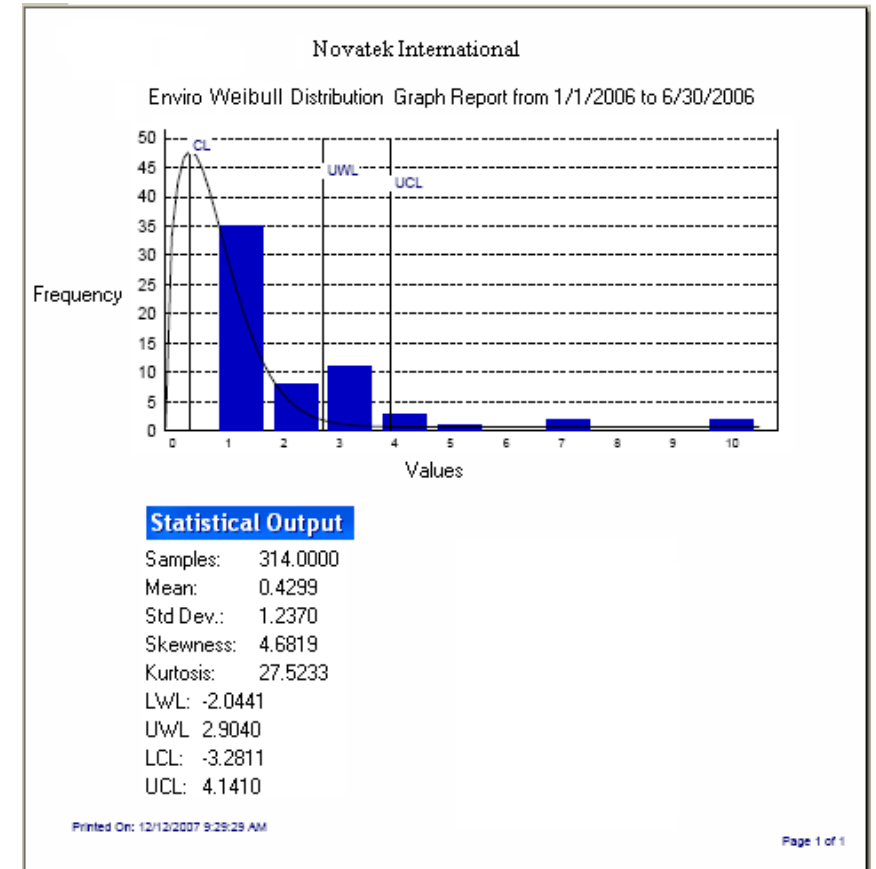
# Example of Modified Risk Assessment

- Room Number
- Room Description
- Classification
- Current Number V/NV/S locations
- Microbial Risks in Rooms
- People Movements/Flow
- Number Proposed New V/NV/S locations
- Comments discussing rationale based on risk



# Execute Protocol

- If new sample locations and frequency are very different than your prior EM Program, suggest execution of protocol to collect baseline data
  - Aid in setting alert/action levels



# New EM Risk Model

EM-REM

Environmental Monitoring Risk Evaluation Model

Evaluate if current samples are risk based or not – rationalize risk based sample site selections

# Risk Based EM – EM-REM\*

- *Risk – combination of the impact of the hazard or unwanted event and its likelihood of occurring and harming the patient*
- Focus on proximity of sample location to potential contamination
- Severity of product contamination is always HIGH risk
  - Consider this a constant
  - Remove from assessment
- Focus on product and process knowledge, material flow, people flow, duration of time that people in working in the area

\*Contamination Control in Healthcare Product Manufacturing, Volume 3, Jeanne Moldenhauer and Russell Madsen, PDA DHI Technical Books, Chapter 11 Hal Baseman and Mike Long- Intervention Risk Assessment Model (IREM)

# EM-REM

- Use Key Word\* risk assessment approach instead of using general, subjective terms for the level of risk (often, frequently, rarely)
- Example: Duration of activity:
- Long, Medium, Short – **subjective**
- > 10 minutes, greater than 1 minute but less than 10 minutes, less than 1 minute – **objective, measurable**

# EM-REM

## Proximity

How close the EM sample is to area of potential contamination

Risk Level	Proximity
High	EM sample is in immediate proximity to a potential contamination source, open product/processing – microbial contamination source (0 - 2 feet away)
Medium	EM sample is near the potential microbial contamination source but not immediately proximal (3 feet to 5 feet away)
Low	EM sample is not near a potential microbial contamination source or open product/processing (5 or more feet away)

# EM-REM

## Number of PPL Routinely Present in Area

- The more people in the area of the sample location, the higher the risk of contamination
  - The longer the activity, the more risk for contamination
  - Traffic Flow – high, medium, low
  - Number of People ---- more ppl, more risk
  - Utilize batch record data, talk to operators, time the actual events to determine and set up a scale for your own EM risk assessment

Risk Levels	Number of People Working Near Sample Site
HIGH	8 or more people
MEDIUM	2-7 people
LOW	0 or 1 person



# EM-REM

## Duration – Time

The longer the activity, the more risk for contamination

Risk Levels	Time People are in Location
HIGH	>6 – 8/10+ hours (Entire Shift)
MEDIUM	>1 – 6 hours
LOW	Less than 1 hour

# Risk Based EM

- Two Level Risk Block Assessment Method:
- Used to consider relationship of all three-risk elements
- Two three block risk tables:
- 1- Duration/Time and Number of People – to provide a risk level
- 2 – Risk Class and Proximity

**Determine if sample location is high, medium or low risk**

Goal – select and rationalize risk based sample locations as part of your EM Program (ensure high risk locations have sample sites)

# EM-REM

- EXAMPLE 1:
- Cell Culture Room, Viable Air Sample V1, Center of Room, Location Not Near Processing Activity

Factor	Result	Risk Level
# PPL	5	MEDIUM
Duration/Time	>1 hour	LOW
Proximity	Not near any processing, ppl or contamination sources	LOW

# EM-REM

## Duration – Number of People Risk Class Determination

*Duration (Time)*

*Number of People*

	Low	Medium	High
High	Risk Class 2	Risk Class 1	Risk Class 1
Medium	Risk Class 3	Risk Class 2	Risk Class 1
Low	Risk Class 3	Risk Class 3	Risk Class 2

# EM-REM

## Proximity – Risk Class Comparison Table

*Risk Class  
(From Table above)*

	<i>Proximity</i>		
	Low	Medium	High
High	Risk Priority 2	Risk Priority 1	Risk Priority 1
Medium	Risk Priority 3	Risk Priority 2	Risk Priority 1
Low	Risk Priority 3	Risk Priority 3	Risk Priority 2

This is a **LOW** risk sample location

# Risk Based EM

- EXAMPLE 2:
- Floor RODAC F2 - Next to Floor Drain in Wash Room

Factor	Result	Risk Level
Duration/# PPL	8	HIGH
Time	3 hours	MEDIUM
Proximity	Next to drain	HIGH

# EM-REM

## Duration – Number of People Risk Class Determination

*Duration (Time)*

*Number of People*

	Low	Medium	High
High	Risk Class 2	Risk Class 1	Risk Class 1
Medium	Risk Class 3	Risk Class 2	Risk Class 1
Low	Risk Class 3	Risk Class 3	Risk Class 2



# EM-REM

## Proximity – Risk Class Comparison Table

*Risk Class  
(From Table above)*

	<i>Proximity</i>		
	Low	Medium	High
High	Risk Priority 2	Risk Priority 1	Risk Priority 1
Medium	Risk Priority 3	Risk Priority 2	Risk Priority 1
Low	Risk Priority 3	Risk Priority 3	Risk Priority 2

This is a **HIGH** risk sample location

# Risk Based EM

- Opportunity to evaluate the risk and consider risk reduction for high risk locations that score HIGH or maybe even MEDIUM risk
  - Evaluate changes to process to reduce the risk of the location and rescore
- Risk assessment allows for training of operators on high risk areas in the room
- Use risk assessment to evaluate overall process and determine priorities in implementing changes to the process
- Allows for identification of high risk locations to rationalize EM locations
- Now need to tie in controls to select sample locations

### Purification Room 1234

Material Sources Microamination	Sample Location	Sample ID	# of People	Duration / Time	Risk Class	Proximity	Risk Priority of Sample	Comments
Materials, Activity Area	Inside Door to Room	V1, NV1, F1	M	L	3	H	2	High Traffic Flow - all ppl enter room through this area, #P: 5 ppl working in this room
Materials, Activity	Area between BSC and Chromatography Table	V2, NV2, F2	M	H	1	H	1	High activity area – 2 ppl working all day
Materials, Activity	Area Near EQ X and Stainless Steel Table	V3, NV3, F3	M	H	1	H	1	High activity area – 2 ppl working all day
Traffic Flow	Area in front of door to exit/return corridor	V4, NV4, F4	M	L	3	H	2	Traffic Flow to Exit Room
High Area	Stainless steel table center of room – top shelf	S1	M	H	1	H	1	Center work area for operators in the room, high activity area, batch records and equipment will touch table top shelf.
	Stainless steel table center of room – bottom shelf	S2	M	H	1	H	1	Low shelf on table will be used – risk from near floor
ent, People	Stainless steel table with EQ XX	S3	M	H	1	H	1	High activity area in room with equipment XXX, people, batch records on table.
ent, s	Shelf on the shelving unit between airlock in and out of room	S4	M	L	3	M	3	Supply Work In Progress (WIP) storage area.
	Wall Between EQ 1 and EQ 2 Table Area	W1	M	L	3	M	3	Assess cleaning of walls

# Risk Based EM


## Conclusion

- Risk assessment in EM is a tool to gain understanding of the high risk locations in each room
- Objective is:
  - to gain knowledge so you can make informed decisions about process and select risk based EM sample locations
  - Determine where to improve the process and reduce risk
- Control of risk = good process design
- Good process design begins with a firm understanding of the process

# Simplified EM Process



# Environmental Monitoring Common RISKS

- ...Irregular monitoring intervals
  - ...Inadequate detailing of test locations (sample points)
  - ...High volume of data difficult to track/manage
  - ...Lack of effective pattern recognition
  - ...Lack of effective lot traceability
  - ...Missed samples
  - ...Notifications on any deviation found are communicated manually
  - ...Manual reconciliation of actual vs. planned samples taken
  - ...Regulatory Compliancy
  - ...Costly Validation
  - ...Low operational efficiency
- 

# Environmental Monitoring HIGHEST RISK

**By the time a trend of activity is developed and recognized, the condition causing the trend is likely to have changed, making it difficult to support corrective action activities and nearly impossible to perform meaningful preventive actions.**





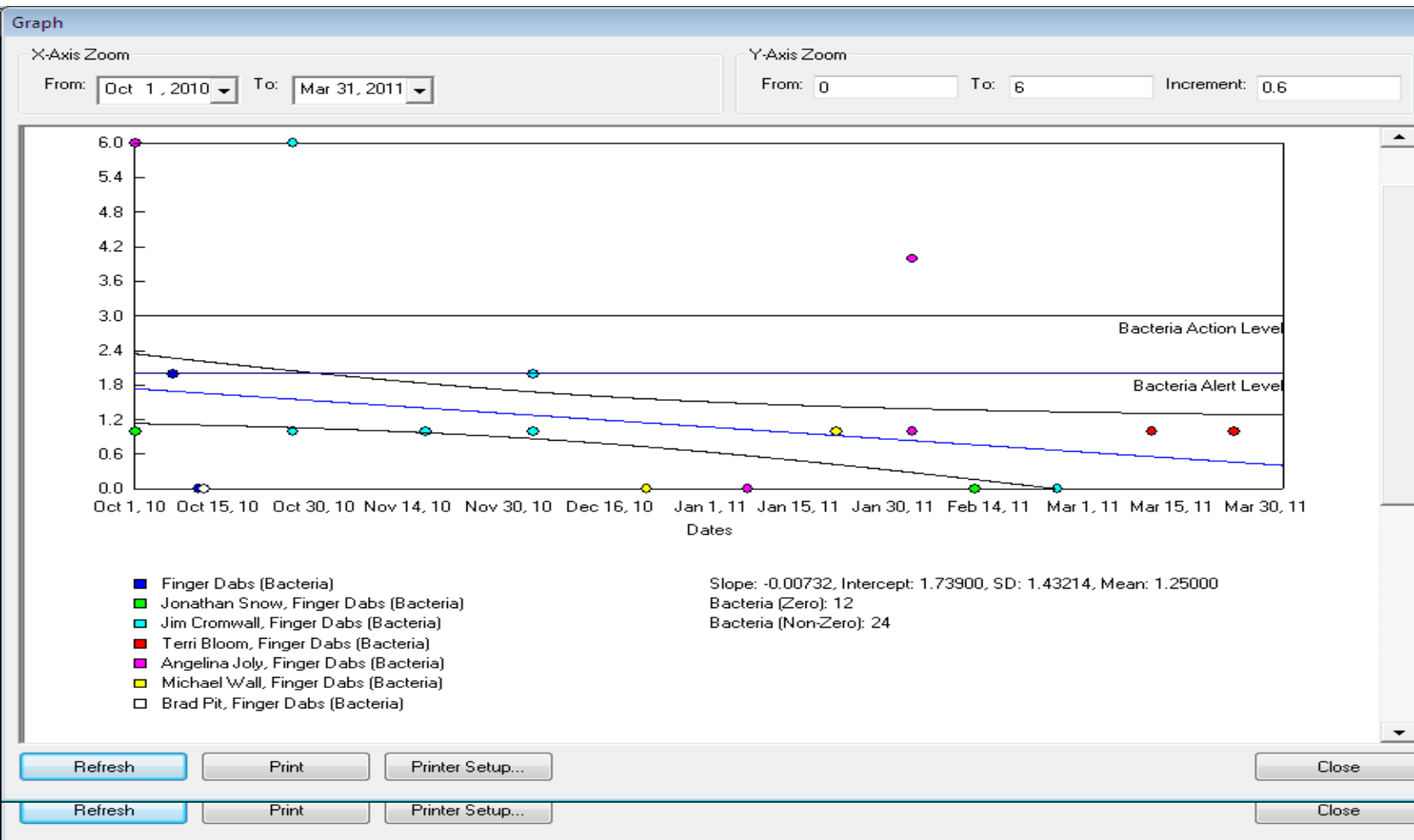
# Risk Mitigation

## Using Risk-Based Approach

Remediation of Risk via Quality Automation = Control



# Risk 1: Lack of Pattern Recognition due to Poor Trending Methods



- **Remediation: Real-time trending and correlation of criteria**

- Present monthly, quarterly, yearly or any period reports

- Trend one site in one room, multiple sites in one room or multiple rooms/departments etc.

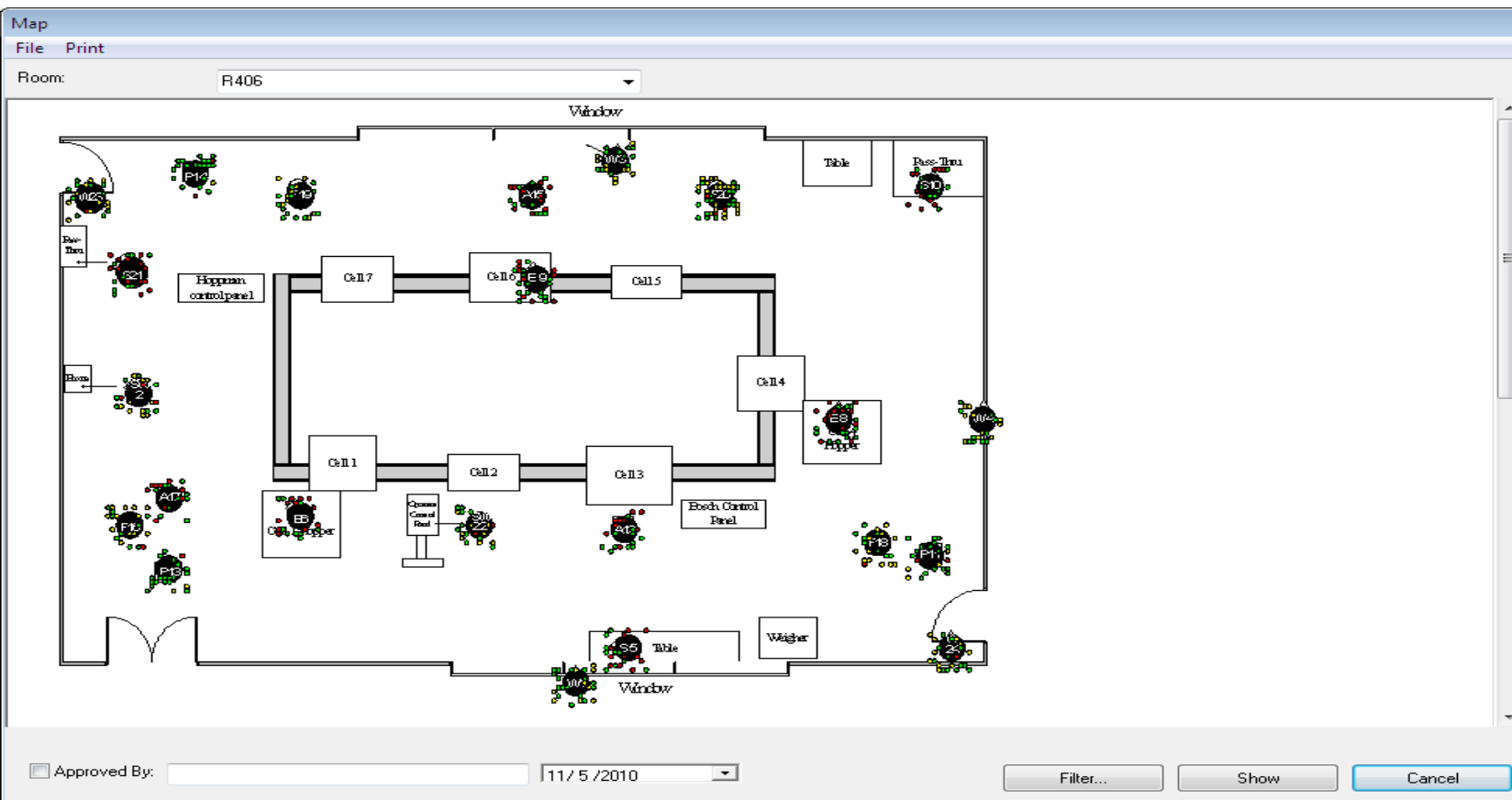
- Trend micro-organisms and their locations

- Track personnel monitoring

- Trend by lot, equipment

- **Goals: Visibility, Root Cause Analysis, Pattern Recognition, State of Control**

# Risk 2: Ineffective Sampling Due to Poor Sample Site Setup



- **Remediation: Tracking and mapping of sample sites coupled with trending methods**

- Setup effective sample sites based on room status (active/at rest).

- System scheduling and tracking

- Mapping of sites. Create your own map or import from Visio, Autocad or other.

- Sample status identified and tracked – chain of custody

- Use trending and dispersion mapping tools to analyze your site setup

# Risk 3: Repetitive Excursions Due to Incomplete EM Process

12:00:00 AM, Air Sample, R406, A17, Viable Air, Front of double doors

Sample Taken by: Jim Cromwall  
Handled by: Jim Cromwall  
Read by: Madonna Doe

Media Used

Name	Lot Number
TSA w/Lecithin & Polysorbate80	332

Test Status: Dynamic Exposure time: 100 L Date test done: Oct 1, 2010  
Alert: 1 cfu/m<sup>3</sup> Date test entered: Oct 1, 2010  
Action: 1 cfu/m<sup>3</sup>  CFU Formula: Date comment entered: Oct 1, 2010

Free format:  Multiplier: 1

Equipment Used

Name	ID	Calibration Date	Exposure Time	Exposure Unit
MAS-100		543 Nov 3, 2011	100	Litres

Incubator 1 Name: INC ID: A Temp: 25 °C Time: 72 hours Calibration Date:  Nov 18, 2011  
Incubator 2 Name: INC ID: B Temp: 35 °C Time: 46 hours Calibration Date:  Nov 18, 2011

Start Date: Nov 3, 2010 03:37:53  Transfer Date: Nov 4, 2010 03:37:55  End Date: Nov 5, 2010 03:38:00

Lot Number: LT 201 Occupant Number:   
Lot Number2:

OK Cancel

12:00:00 AM, Air Sample, R406, A17, Viable Air, Front of

Same data << < > >>

Barcode: 1

Bacteria Yeast/Mold Total

Comments

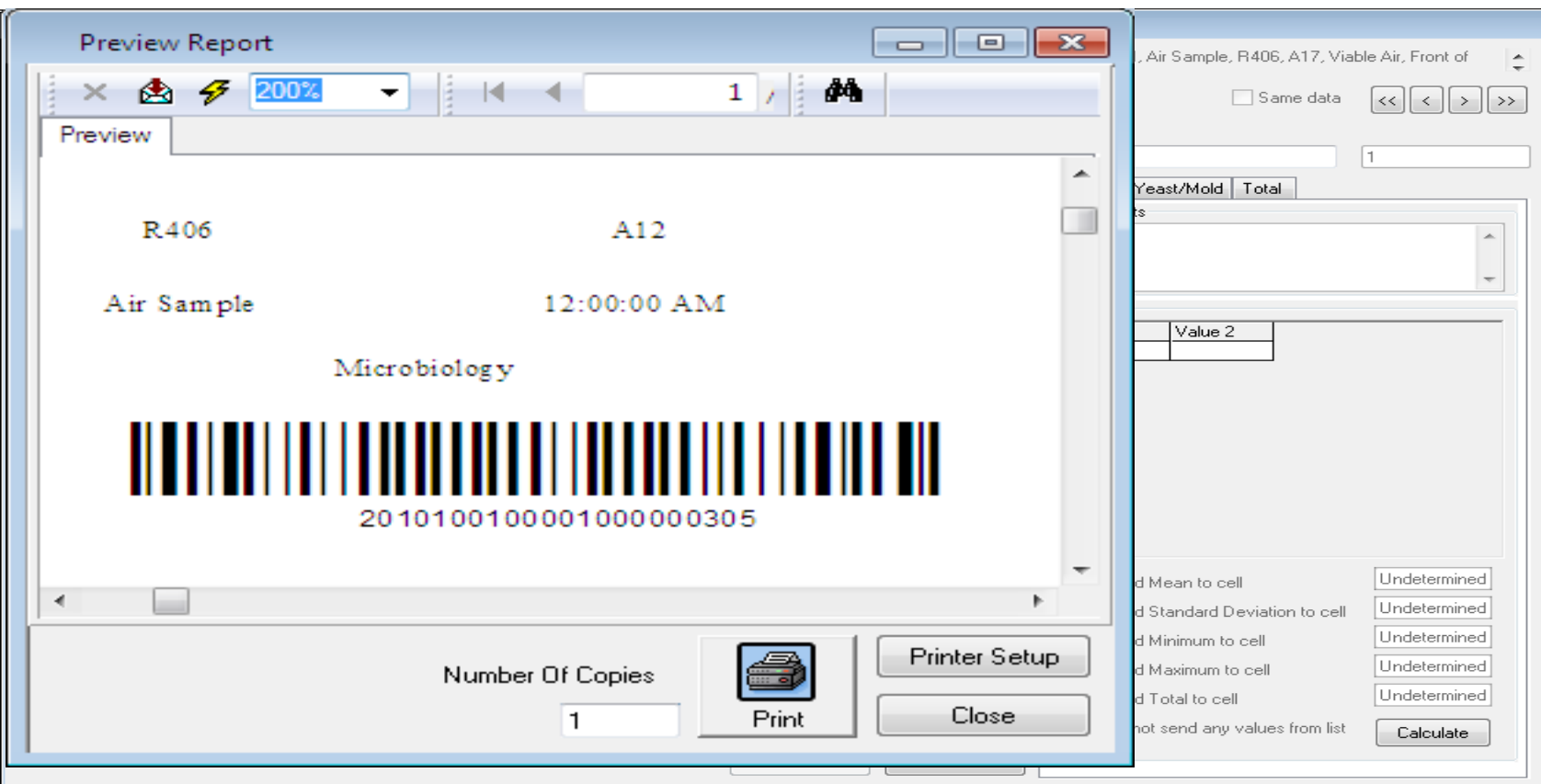
Values

Value 1	Value 2

Send Mean to cell Undetermined  
 Send Standard Deviation to cell Undetermined  
 Send Minimum to cell Undetermined  
 Send Maximum to cell Undetermined  
 Send Total to cell Undetermined  
 Do not send any values from list Calculate

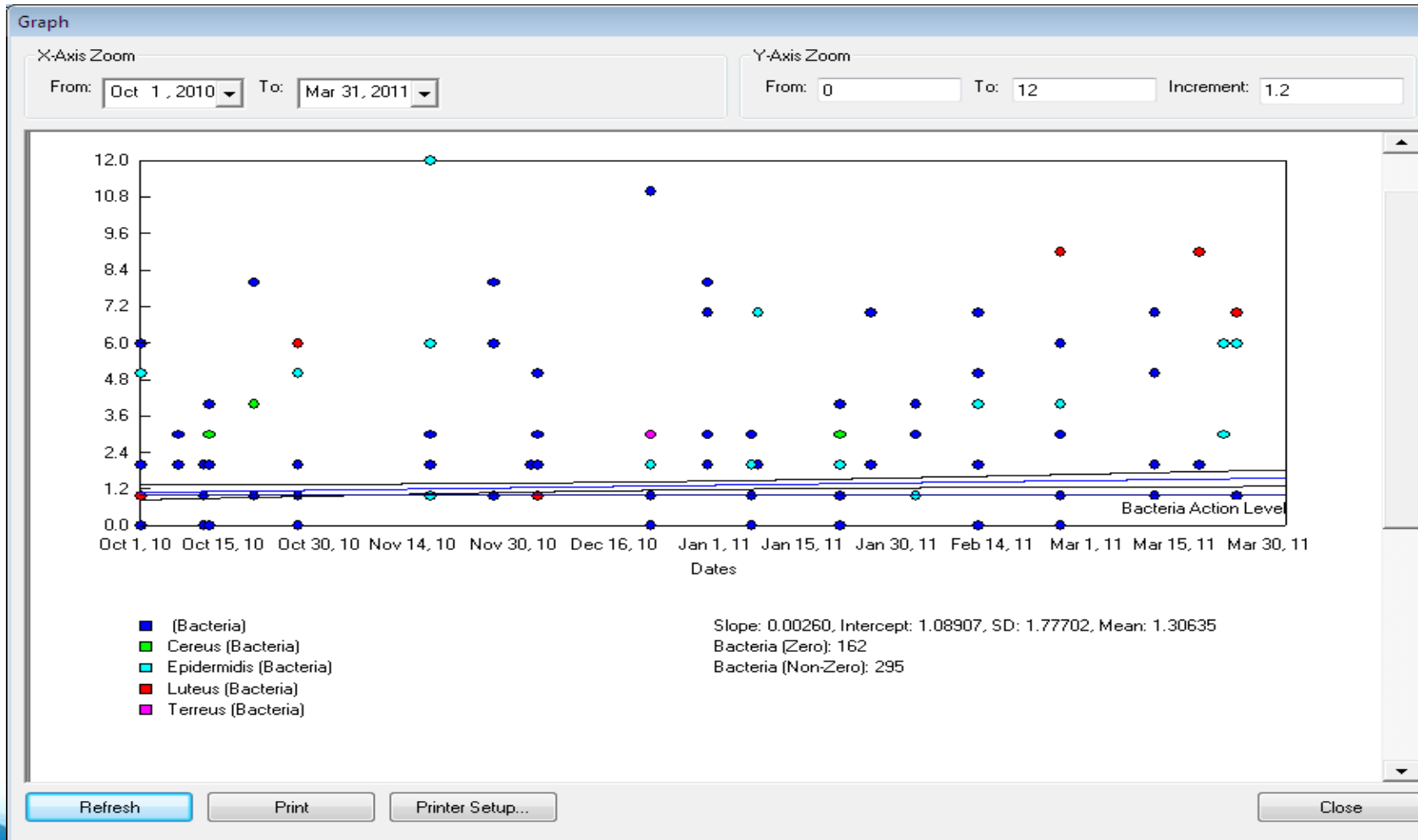
- **Remediation: Maintain control of your process by trending all the necessary EM data**
- Manage all viable/non-viable tests
- Include media fills and pre-filtration bioburden
- Monitor all utilities: water, clean steam, compressed gas, etc
- Monitor personnel
- Record alert/action specifications, media, incubation, lot, equipment, etc
- Trend to analyze all aspects of the complete EM process to improve state of control.

# Risk 4: Errors Due to Improper Tracking and Scheduling



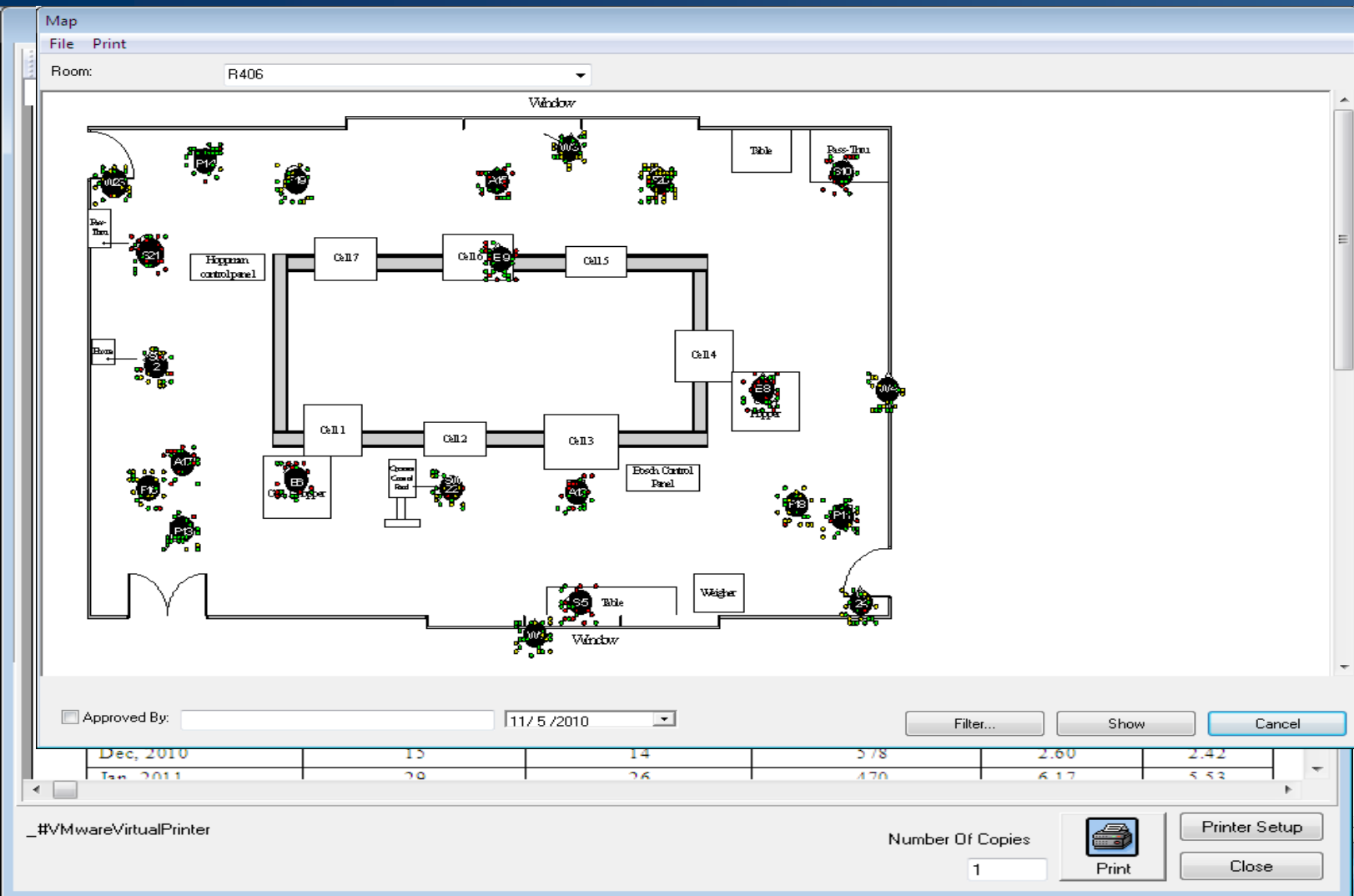
- **Remediation: Regular monitoring, tracking and scheduling of samples**
- Monitor any frequency of test
- Perform Routine, Non-routine, Batch, Process, At Rest, Dynamic monitoring as needed
- Track schedule and filter by due date, status, department, disposition, etc
- Lot and sample traceability

# Risk 5: Excursions Due to Poor Analysis of Detected Micro-Organisms



- Remediation: Automated system that allows for micro-organism identification and analysis
- Identify your micro-organisms and store pictures with your identification.
- View the distribution of your genus, species, strain etc
- View the distribution by room, department, etc.
- Trend micro-organisms detected in a specific area or correlate with other environmental information

# Risk 6: Inaction Due to Improper Identification and Follow-ups of Excursions



- **Remediation: System allows effective setup of limits, provides tools to monitor excursions, allows for effective CAPA**
- Use frequency analysis to help setup limits
- Rolling specifications
- System automatically provides visual and email notifications when an OOS or excursion occurs.
- Investigations can be initiated and tracked within the system
- Excursion reports
- Dispersion mapping associates excursions to sites on the map



# Risk 7: Ineffective Analysis Due to High Volume of Data

Stored Test Results

Filter: <none>

From: Oct 22, 2010 To: Nov 19, 2010 Refresh Grid Print Displayed Results

Date Stored	Instrument S	Test Type	Location	Test Time	Test Volume	Count	Entered By	Reason
Nov 3, 2010 04:08:26 PM	42666	Particle Count 0.5µ	RoomA_Loc1	Nov 3, 2010 04:05:28 AM	0.9996393 C	21827	sysadmin	room /location doesn't r
Nov 3, 2010 04:08:26 PM	42666	Particle Count 5.0µ	RoomA_Loc1	Nov 3, 2010 04:05:28 AM	0.9996393 C	876	sysadmin	room /location doesn't r
Nov 4, 2010 06:36:35 PM	42666	Particle Count 0.5µ	R25_A1	Nov 4, 2010 01:33:18 PM	0.999473 CF	21178	ajoly	room /location doesn't r
Nov 4, 2010 06:36:35 PM	42666	Particle Count 0.5µ	R25_A1	Nov 4, 2010 01:39:04 PM	0.9996465 C	19746	ajoly	room /location doesn't r
Nov 4, 2010 06:36:35 PM	42666	Particle Count 0.5µ	R25_A1	Nov 4, 2010 01:39:34 PM	0.2405608 C	25283	ajoly	room /location doesn't r
Nov 4, 2010 06:36:35 PM	42666	Particle Count 5.0µ	R25_A1	Nov 4, 2010 01:33:18 PM	0.999473 CF	393	ajoly	room /location doesn't r
Nov 4, 2010 06:36:35 PM	42666	Particle Count 5.0µ	R25_A1	Nov 4, 2010 01:39:04 PM	0.9996465 C	255	ajoly	room /location doesn't r
Nov 4, 2010 06:36:35 PM	42666	Particle Count 5.0µ	R25_A1	Nov 4, 2010 01:39:34 PM	0.2405608 C	2548	ajoly	room /location doesn't r
Nov 4, 2010 06:42:30 PM	42666	Particle Count 0.5µ	R25_A1	Nov 4, 2010 06:41:39 PM	0.9997687 C	23265	ajoly	room /location doesn't r
Nov 4, 2010 06:42:30 PM	42666	Particle Count 5.0µ	R25_A1	Nov 4, 2010 06:41:39 PM	0.9997687 C	239	ajoly	room /location doesn't r
Nov 5, 2010 12:10:45 PM	42666	Particle Count 0.5µ	R25_A1	Nov 5, 2010 12:12:37 PM	0.9997364 C	35097	sysadmin	error in sampling
Nov 5, 2010 12:10:45 PM	42666	Particle Count 5.0µ	R25_A1	Nov 5, 2010 12:12:37 PM	0.9997364 C	325	sysadmin	error in sampling
Nov 5, 2010 02:01:09 PM	42666	Particle Count 0.5µ	R25_A1	Nov 5, 2010 02:05:53 PM	6.612873E-0	30955	sysadmin	error in suction
Nov 5, 2010 02:01:09 PM	42666	Particle Count 5.0µ	R25_A1	Nov 5, 2010 02:05:53 PM	6.612873E-0	363	sysadmin	error in suction

Number of records: 14 CAPS NUM INS 11/5/2010 5:19 PM

OK Close

Row Height Filter...

- **Remediation: A truly paperless and rapid data entry system**
- Rapid data entry screen is the most flexible way to enter data in batches or copy it across different criteria
- Barcoding/RFID technology can provide additional automation
- Connectivity to instruments
- Notebook PC and push screens



# Take Away

*Meaningful process = meaningful data*

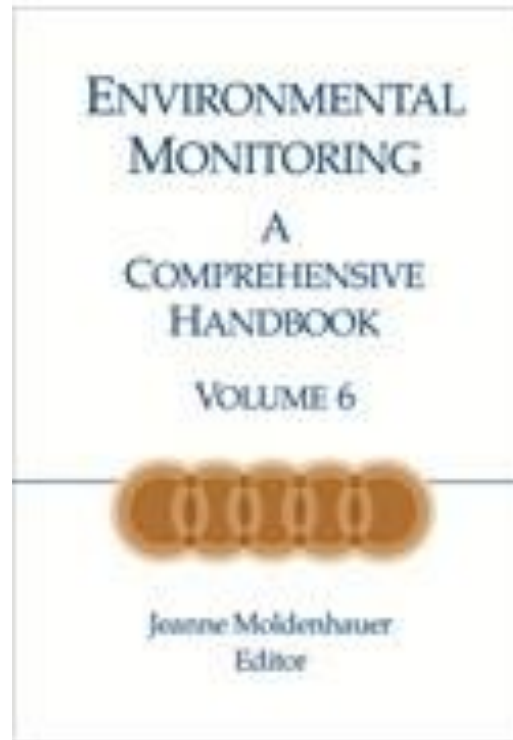
*Use knowledge to apply findings back to your process for continuous improvement*



# References

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- USP <1115> and <1116>

# Extra Reading Materials



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# Thank You

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