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

An Industry Roundtable Discussion

Marsha Stabler Hardiman and Cheryl Zaman Zadeh November, 2015 PDA Metro Chapter Meeting



#### Presenters



#### Marsha Stabler Hardiman

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



#### Cheryl Zaman Zadeh, MS.

- Over 15 years experience defining EM User Requirements for Pharmaceutical and Biotech
- Director, 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]
Sent: Tuesday, January 13, 2009 10:18 PM
To: 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

Process Analytical Technology



### **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

<u>>0.5 μm - 3,520 particles/m<sup>3</sup></u>

*ISO 6* – Possible background to ISO 5 – not required

<u>>0.5 μm - 35, 200 particles/m<sup>3</sup></u>

ISO 7 – Background to ISO 5

<u>>0.5 μm - 352,000 particles/m<sup>3</sup></u>

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

<u>>0.5 μm - 3,520,000 particles/m<sup>3</sup></u>

### Airborne Particulate Cleanliness Classes

ISO Class	0.5 μm	5.0 μm
ISO 5	3 520	N/A
ISO 6	35 200	293
ISO 7	352 000	2 930
ISO 8	3 520 000	29 300

Maximum concentration limits (particles/m3 of air)



### Common Misperception with ISO 14644

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

NL = √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





Recovery Rate Report

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

NR: No Recovery Performed

#### USP CHAPTER <1116>

#### **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 (%) Co		Contact (%)	Personnel (%b)	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	
IS O S	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.

### 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 nonsterile 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





### **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 <u>modified risk assessment</u> 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



by: Date Done: 27/05/2011 - 29/05/2011



Test Type	Location	Total Samples	Zero Count	Alerts	%Alert	Actions	%Action	% Total
May, 2011								
Air Sample	A1	3	2	0	0.00	0	0.00	0.00
Settle Plate	F1	3	0	2	66.67	0	0.00	66.67
Swabbing	S1	3	D	D	0.00	2	66.67	66.67
	Total for May, 2011:	9	2	2	22.22	2	22.22	44.44
	Grand Total:	9	2	2	22.22	2	22.22	44.44

### **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

<sup>\*</sup>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)

- 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)

#### **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

#### **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)

- 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

#### **Duration – Number of People Risk Class Determination**

Duration (Time)



#### **Proximity - Risk Class Comparison Table**

	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	

Proximity

Risk Class (From Table above)

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

#### **Duration – Number of People Risk Class Determination**

Duration (Time)



#### **Proximity - Risk Class Comparison Table**

	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

Proximity

Risk Class (From Table above)

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								
tial Sources Micro amination	Sample Location	Sample ID	# of People	Duration / Time	Risk Class	Proximity	Risk Priority of Sample	Comments
Materials, tivity Area	Inside Door to Room	V1, NV1, F1	М	L	3	н	2	High Traffic Flow - all ppl enter room through this area, #P: 5 ppl working in this room
Materials, tivity	Area between BSC and Chromatography Table	V2, NV2, F2	м	н	1	н	1	High activity area – 2 ppl working all day
Materials, tivity	Area Near EQ X and Stainless Steel Table	V3, NV3, F3	м	Н	1	Н	1	High activity area – 2 ppl working all day
Traffic Flow	Area in front of door to exit/return corridor	V4, NV4, F4	м	L	3	н	2	Traffic Flow to Exit Room
High Area	Stainless steel table center of room – top shelf	S1	м	Н	1	н	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	М	Н	1	Н	1	Low shelf on table will be used – risk from near floor
ent, People	Stainless steel table with EQ XX	S3	М	Н	1	Н	1	High activity area in room with equipment XXX, people, batch records on table.
ient, S	Shelf on the shelving unit between airlock in and out of room	S4	М	L	3	М	3	Supply Work In Progress (WIP) storage area.
	Wall Between EQ 1 and EQ 2 Table Area	W1	М	L	3	М	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 <u>RISKS</u>

... 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



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



#### Risk 3: Repetitive Excursions Due to Incomplete EM Process

<u> </u>										
12:00:00 AM, /	Air Sample, R406, A17, V	iable Air, Front	t of double doo	ors						
Sample			Media Used					10,00,00,444,41,0,1,1,10,400,447,47		
Taken by:	Jim Cromwall	Cromwall - Name			Lot Number			12:00:00 AM, Air Sample, R406, A17, Viable Air, Front or		
			TSA w/Lecithi	n & Polysorbate80	)	332				
Handled by:	Jim Cromwall				, 			Same data	<<   <   >   >>	
								Bassa das		
Read by:	Madonna Doe							Barcode:		
			1						1	
Test								Bacteria Yeast/Mold Total		
Status:	Dynamic Exposure ti		ne:	Date test done	× Oct	Oct 1,2010		Commonto		
Alort		100	L 🚽		1			Comments		
Alon	I cru/m²			Date test enter	red: Oct	1,2010	-		<u>^</u>	
Action:	1 cfu/m <sup>3</sup>	CFU Forn	mula:		1					
				Date comment	entered: Oct	1,2010	-		-	
					J			Values		
Free			*					Value 1 Value 2		
rormat:			-	Multip	lier 1					
Equipment U	Jsed	1	1			1				
Name			Calibrat	ion Date Exp	osure Lime	Exposure Unit	<u> </u>			
MAS-100			543 Nov 3,	2011	100	) Litres				
							_			
- Incubator 1 -			Incub	ator 2						
Name:	INC		- Nam	e: INC			-			
ID:	A		- ID:	В			-			
Temp		_	Tem	D: 05		~			[ Lin deberrie ed]	
remp.	25	-		P. 35		-		Send Mean to cell	Undetermined	
Time:	72 h	ours	- Time	* 46	h	ours		Send Standard Deviation to cell	Undetermined	
Calibration	Date:	lov 18, 2011	Calib	ration Date:		lov 18, 2011	-		Undetermined	
				adon biato.				Send Minimum to cell	Ondecentined	
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Lot Number2:										
						Car	nce			

Remediation: Maintain control of your process by trending all the necessary EM data

- Manage all viable/non-viable tests
- Include media fills and prefiltration 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

Preview Report			, Air Sample, R406, A17, Viat	ble Air, Front of
× 🖄 🛷 200%	▼             1 /	#	Same data	<< < > >>
		<u>^</u>	Yeast/Mold Total	1
R406	A12			^ ~
Air Sample	12:00:00 AM		Value 2	
Mi	crobiology			
2	2010100100001000000305			
•			d Mean to cell d Standard Deviation to cell	Undetermined Undetermined
	Number Of Copies	Printer Setup	d Minimum to cell d Maximum to cell	Undetermined Undetermined
	1 Prir	nt Close	d I otal to cell not send any values from list	Calculate

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 microorganism 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



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

Stored Test Results								
Filter:	<none></none>	•		-				
From	Oct 22, 2010	▼ To	Nov 19, 2010 👻	Refresh Grid				Print Displayed Results
Date Store	ed	Instrument Si	Test Type	Location	Test Time	Test Volume   C	Count Entered	1By Reason
Nov 3, 20	10 04:08:26 PM	42666	Particle Count 0.5µ	RoomA_Loc1	Nov 3, 2010 04:05:28 AM	0.9996393 C 2	1827 sysadm	in room /location doesn't rr
Nov 3, 20	10 04:08:26 PM	42666	Particle Count 5.0µ	RoomA_Loc1	Nov 3, 2010 04:05:28 AM	0.9996393 C 8	76 sysadm	in room /location doesn't m
Nov 4, 20	10 06:36:35 PM	42666	Particle Count 0.5µ	R25_A1	Nov 4, 2010 01:33:18 PM	0.999473 CF 2	1178 ajoly	room /location doesn't m
Nov 4, 20	10 06:36:35 PM	42666	Particle Count 0.5µ	R25_A1	Nov 4, 2010 01:39:04 PM	0.9996465 C 1	9746 ajoly	room /location doesn't m
Nov 4, 20	10 06:36:35 PM	42666	Particle Count 0.5µ	R25_A1	Nov 4, 2010 01:39:34 PM	0.2405608 C 2	5283 ajoly	room /location doesn't m
Nov 4, 20	10 06:36:35 PM	42666	Particle Count 5.0µ	R25_A1	Nov 4, 2010 01:33:18 PM	0.999473 CF 3	93 ajoly	room /location doesn't rr
Nov 4, 20	10 06:36:35 PM	42666	Particle Count 5.0µ	R25_A1	Nov 4, 2010 01:39:04 PM	0.9996465 C 2	:55 ajoly	room /location doesn't rr
<u>Nov 4, 20</u>	10 06:36:35 PM	42666	Particle Count 5.0µ	R25_A1	Nov 4, 2010 01:39:34 PM	0.2405608 C 2	548 ajoly	room /location doesn't rr
Nov 4, 20	10 06:42:30 PM	42666	Particle Count 0.5µ	R25_A1	Nov 4, 2010 06:41:39 PM	0.9997687 C 2	:3265 ajoly	room /location doesn't rr
Nov 4, 20	10 06:42:30 PM	42666	Particle Count 5.0µ	R25_A1	Nov 4, 2010 06:41:39 PM	0.9997687 C 2	39 ajoly	room /location doesn't rr
Nov 5, 20	10 12:10:45 PM	42666	Particle Count 0.5µ	R25_A1	Nov 5, 2010 12:12:37 PM	0.9997364 C 3	5097 sysadm	in error in sampling
Nov 5, 20	10 12:10:45 PM	42666	Particle Count 5.0µ	R25_A1	Nov 5, 2010 12:12:37 PM	0.9997364 C 3	25 sysadm	in error in sampling
Nov 5, 20	10 02:01:09 PM	42666	Particle Count 0.5µ	R25_A1	Nov 5, 2010 02:05:53 PM	6.612873E-0 3	0955 sysadm	in error in suction
Nov 5, 20	10 02:01:09 PM	42666	Particle Count 5.0µ	R25_A1	Nov 5, 2010 02:05:53 PM	6.612873E-0 3	63 sysadm	in error in suction
								Close
Number of	records: 14	0	APS NUM INS	11/5/2010	5:19 PM			
End Tim <none>       Media     OK     Close       Media I     <none>       Media T     <none>       Microganisms</none></none></none>								
	Serial Number	Row He	ight	Filter				Close

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

- ISO 14644-1 "Cleanrooms and Associated Controlled Environments - Part 1: Classification of Air Cleanliness", 1999
- www.particle.com
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### **Extra Reading Materials**



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# Thank You

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