

Paperless QC Micro Webinar Series



Part 2: Automating Environmental Monitoring, Utility and Product Testing

Featuring

Robert Lutskus

QCMLS Supervisor

Co-sponsored by



ImClone Systems

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Today's Presenters



- **Robert Lutskus**
QC Microbiology Laboratory
Systems Supervisor



- **Bob Toal**
VP Marketing



- MODA Overview
- Previous Webinar Part 1 Focus Areas (Feb 10)
- Part 2: Automating EM, Utility and Product Testing Featuring ImClone Case Study
- 15-minute Interactive Q&A
- Wrap-up, Next Webinar

A copy of this presentation and the movie of the live session will be available for download from the MODA website shortly after the presentation.

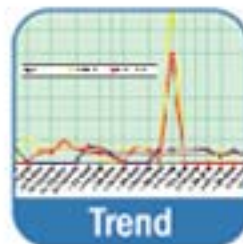
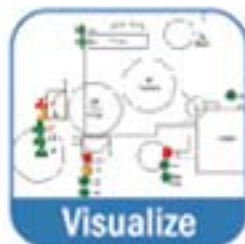
- Provide mobile data acquisition solutions that automate regulated manufacturing processes
 - Pharmaceuticals to consumer products
- Office locations
 - Wayne, PA Headquarters (suburban Philadelphia)
 - London, England
- World-wide sales in North America, Europe, and Asia
- Strategic partners

1. More science. Less paper.

- Quickly move from paper-intensive QC Monitoring & Analysis

2. Increase operational efficiency, improve quality, reduce costs

- MODA-EM™ offers mobile computing technology and advanced visualization tools



Representative Customers



Lonza



XOMA



Argos



Talecris
BIOTHERAPEUTICS

- Utility and product testing with instrument integration
- Process for non-viable air testing with instrument integration
- Reports, trending, visualization, and ROI/benefits

The ImClone Story

Product Demand Drives Growth



Previous: Raw Data Collection



ImClone Systems
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Now: Automated Field Data Capture



Featured: MODA-FDC Cart

- Stainless steel cart
- Ergonomic tablet PC
- Docking station
- Thermal label printer
- Barcode scanner gun
- Proximity reader for RF badges
- Space for equipment
- Space for growth media



ImClone Systems

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Now: Automated Lab Processing



ImClone Systems

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Now: Automated Reports & Analytics



Beta Pharma
Manager01

Deviation Summary

Report Period From 11/1/2007 12:00:00AM to 3/31/2008 12:00:00AM

MODA

7/30/2008 11:04:13AM

Deviation	Sample	Sample Date	Sampled By	Test	Result	Alert Limit
Building 1000 > R1001-Fill Suite 1						Alerts: 6
169	A00000040	12/9/2007 6:16:59PM	Analyst08	R1001.1 - Settling Plates	18.00cfu	1.00
174	A00000093	12/12/2007 6:38:00AM	Analyst08	R1001.1 - Settling Plates	25.00cfu	1.00
178	M00000106	1/14/2008 11:41:16AM	Manager01	R1001.1 - Settling Plates	18.00cfu	1.00
182	M00000263	1/23/2008 10:56:52AM	Manager01	R1001.1 - Settling Plates	25.00cfu	1.00
182	M00000263	1/23/2008 10:56:52AM	Manager01	R1001.1 - Settling Plates	25.00cfu	1.00
185	M00000036	12/11/2007 9:05:29AM	Manager01	R1001.1 - Settling Plates	40.00cfu	1.00

Beta Pharma
Manager01

Trend by System/R

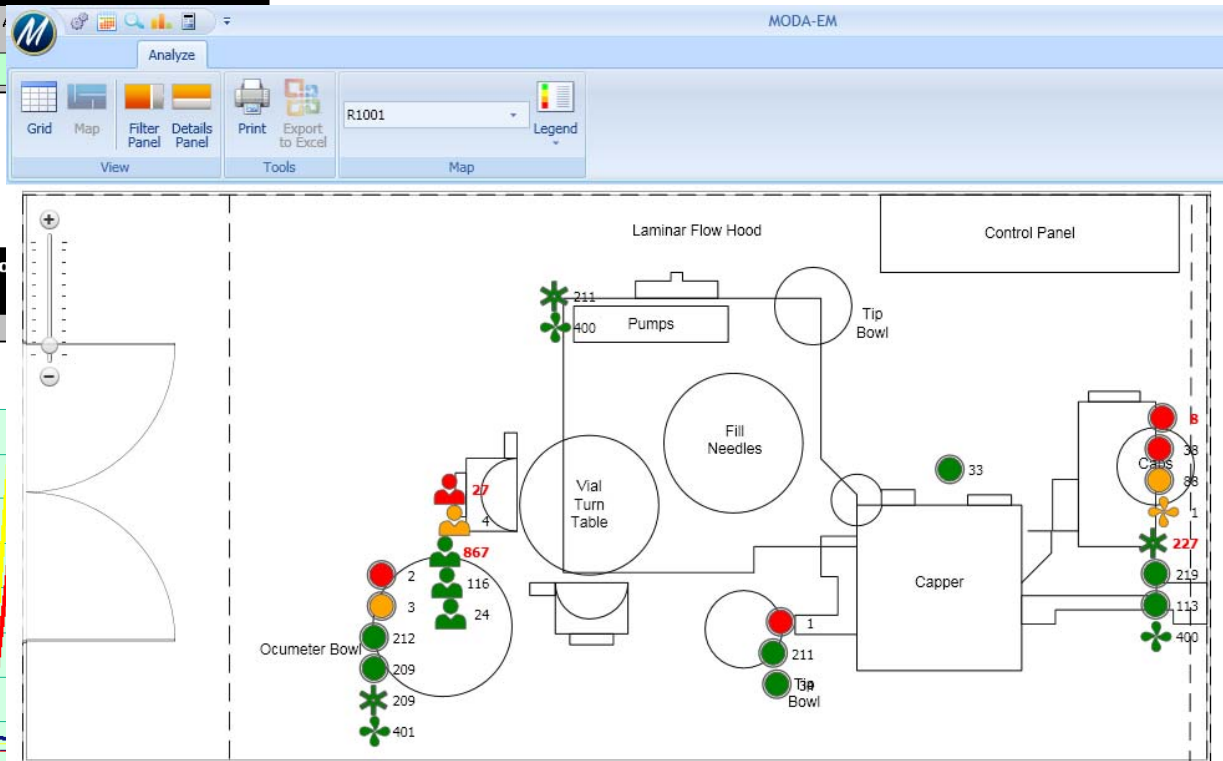
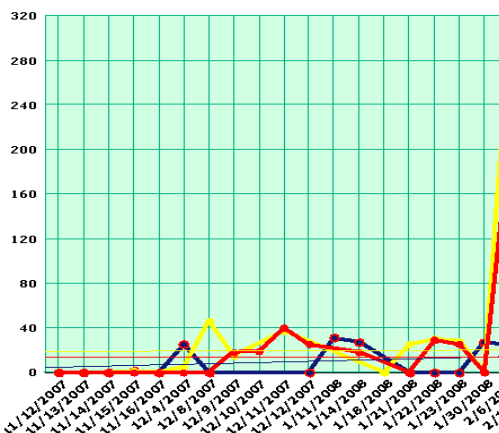
Chart as of 7/30/2008

SW

Bu

PEI

Location: Building 1000 R1001 - Fill Suite 1



ImClone Systems

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- Version 2.2 expansion is complete
- 31 Tablets and 7 lab Workstations
- 2 to 3x more samples than pre-MODA days
- Planned Upgrade to latest MODA release in 2009
- **80+ users optimized with improved workflow**

- ✓ Eliminated data entry and transcription errors
- ✓ **Real time data entry**
- ✓ Eliminated scheduling errors
- ✓ **Part 11 Compliance**
- ✓ Reduced personnel related deviations
- ✓ Enhanced reporting and analytics capabilities
- ✓ **Instrument integration**
- ✓ No wasting time looking for paperwork/missing paperwork
- ✓ **Support for investigation activities**
- ✓ Less corrections
- ✓ Quicker reviews
- ✓ Notifications for deviations and missed samples

Utility Testing

Not easy. MODA-EM makes it easier.

A Disconnected Process for Many

- Utility Test Data coming from:
 - Manual sampling activities
 - Devices in the lab
 - Devices in production area (portable, in-line)

Information Management =

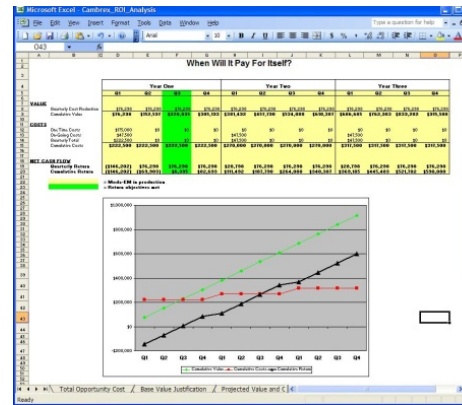
Laboratory



Paper



Spreadsheets

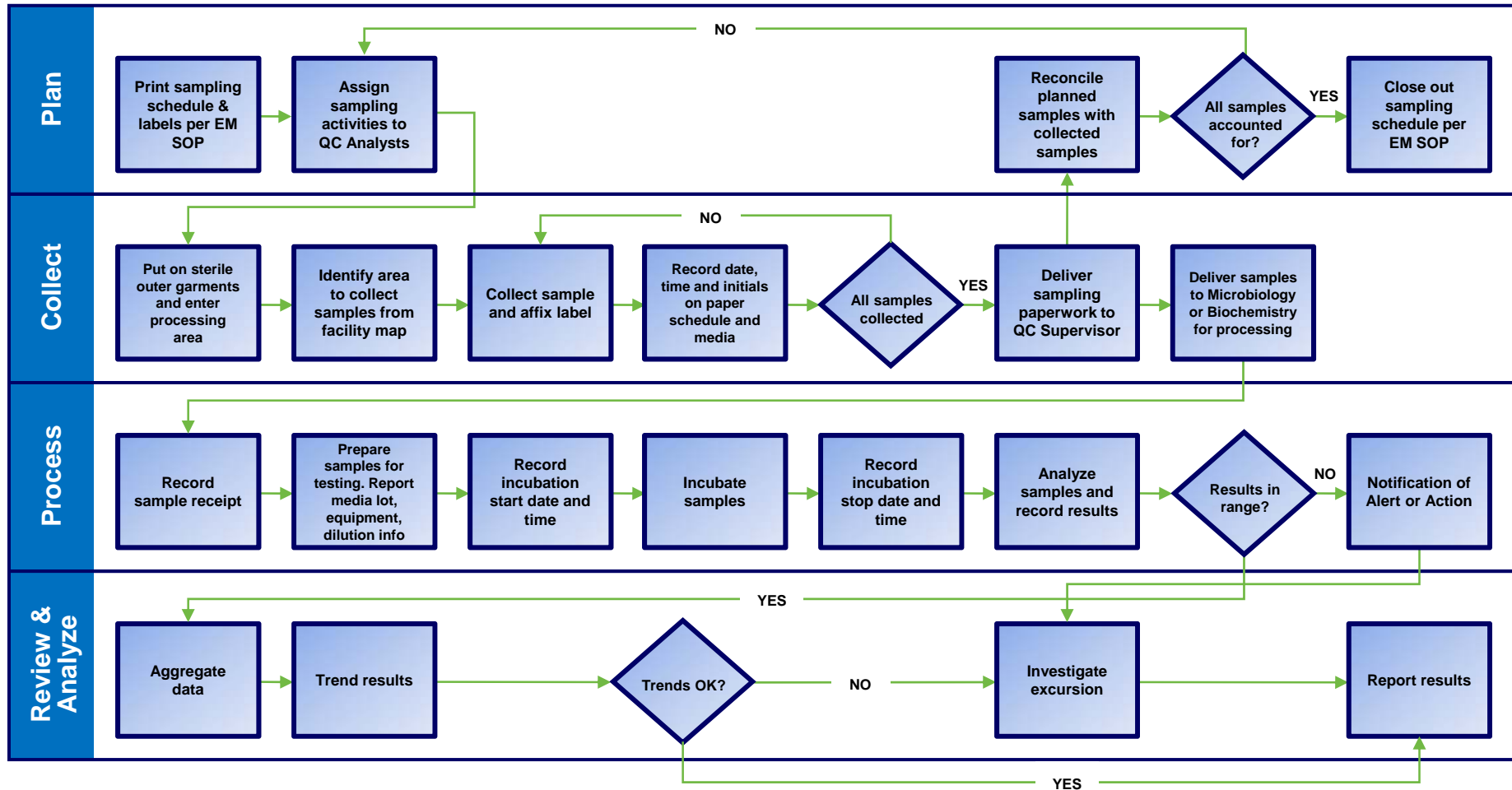


Office



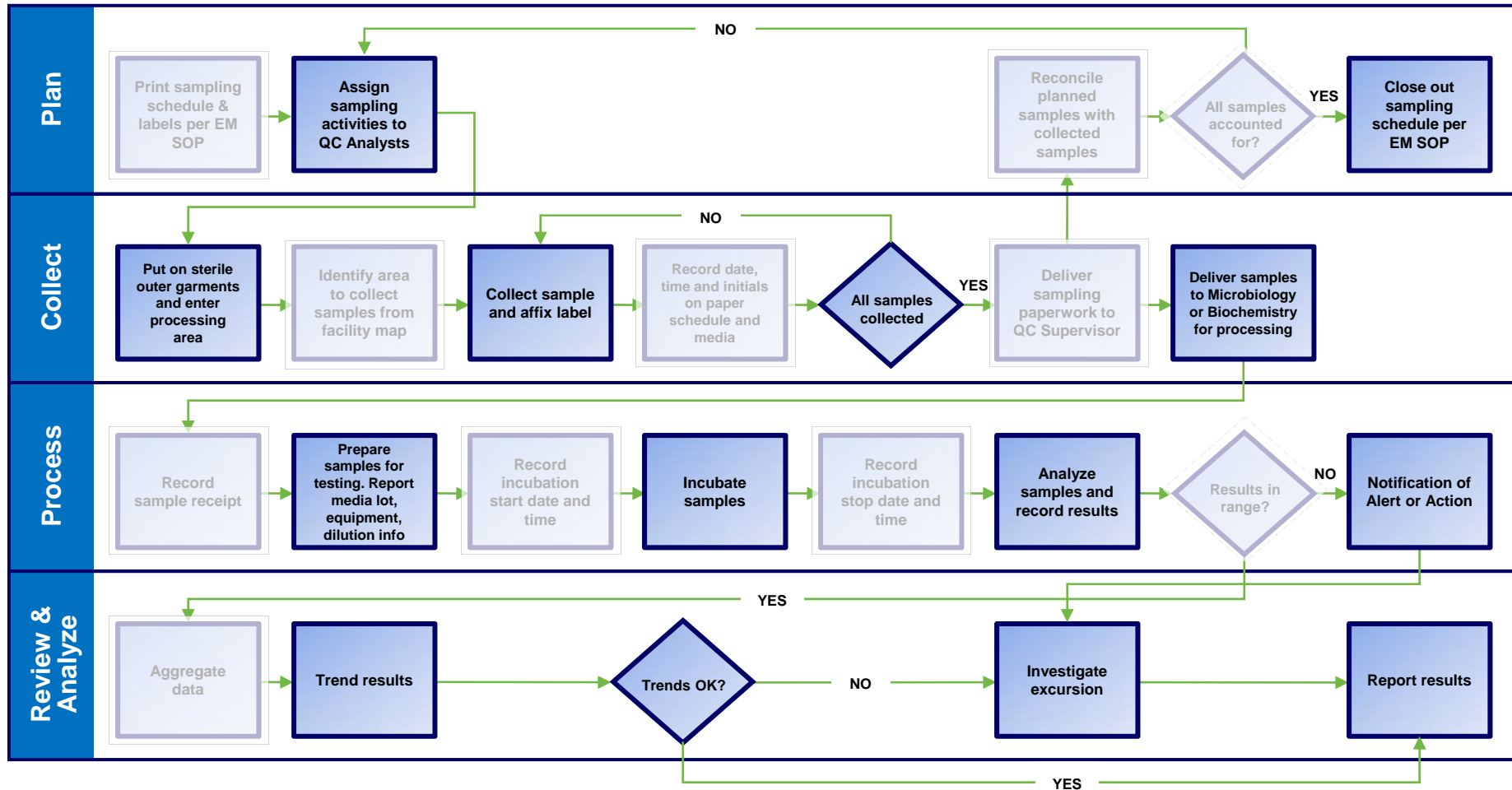
The Paper-based QC Process

Example: Manual Utility Sampling and Lab Processing









The Paperless QC Process

Example: Manual Utility Sampling and Lab Processing. **11 steps removed**



Paperless Efficiency Example

Record on paper template	Record media	Reconcile media and template	Enter data into Excel/LIMS
1: BB50, SS43, Water, IE5 2: BB50, SS43, RODAC, IP72/IP82 3: BB50, SS44, Water, IE5/IE7 4: BB50, SS44, Water, IE9/SP2 5: BB50, SS65, RODAC, IP74			
6 hours		1 hour	1 hour

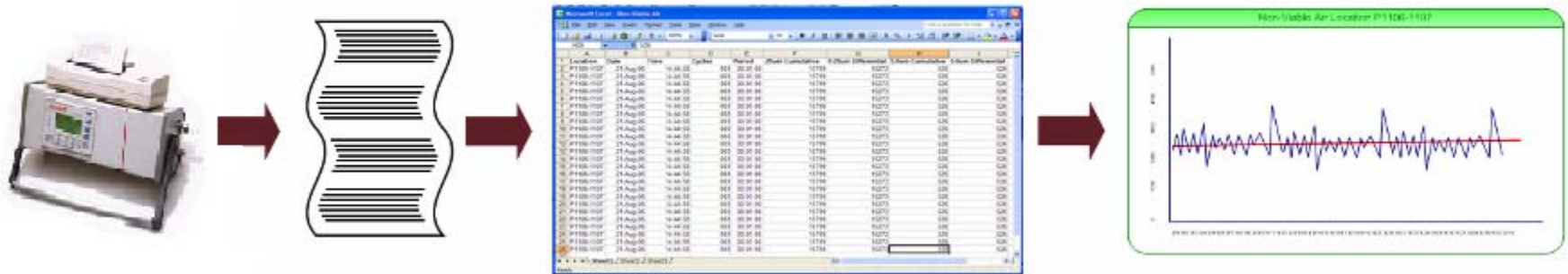
Scan room or site	Select sample and print labels	Send to repository
		
4 hours		Finished

	Paper	8 hours
–	Paperless	4 Hours
=	Savings	4 Hours

Lab Device Integration



The Paper-based Process



The Paperless Process



MODA-EM Product Tour

Test Methods – the “Heart” of Automated Workflows

Automated Capture and Lab Processing for Utility Testing

Scan or Enter Water Site Barcode



File Help Sampling - Print Labels Analyst08 is working online. MODA field data capture

Home Current Workspace General Pool Sampling Testing Incubation Results Entry

Current Barcode Filter: B1PW-A1 PW-A1 - Purified Water - Port 1 (Site)

Scan Barcode: B1PW-A1 Manual Entry Clear Filter Test Method: -- All Test Methods -- Today Only

Reprint Mode Select All Deselect All Print No Test View Diagram

Site Barcode	Plan Name	Test Method				
Scheduled Date	Workflow Step	Frequency	Test Method	Test Name	Site Barcode	Site Na
▼ Site Barcode: B1PW-A1 (2 items)						
▼ Plan Name: (2 items)						
▼ Test Method: [TPC] Total Plate Count (1 item)						
11/6/2007 12:00 PM	Sampling	Daily	[TPC] Total Plate Count	PW-A1 - Total Plate Co...	B1PW-A1	PW-A1
▼ Test Method: [COL] Coliform (1 item)						
11/6/2007 12:00 PM	Sampling	Daily	[COL] Coliform	PW-A1 - Coliform	B1PW-A1	PW-A1

0 items selected.

Updated reference data available as of 11/6/2007 5:13:23 PM Reprint mode disabled. Copyright (C) 2005-2007, Moda Technology Partners, Inc. All Rights Reserved.

Screen Display of Labels



Print Sample Labels

Labels User Fields

Water System	Test Type	Test		Media Lot	
Purified Water	TPC	20 PW-A1 - Total Plate Count	<input type="button" value="Add Note"/>	<input type="button" value="Select Media"/>	None None
Site: PW-A1				Sample Volume	1000 L
M00004617					
By: Analyst No 8		Date: 11/6/2007 Time: 5:49 PM			
<input type="radio"/> Static <input checked="" type="radio"/> Dynamic					

Water System	Test Type	Test		Media Lot	
Purified Water	COL	22 PW-A1 - Coliform	<input type="button" value="Add Note"/>	<input type="button" value="Select Media"/>	None None
Site: PW-A1				Sample Volume	1000 L
M00004618					
By: Analyst No 8		Date: 11/6/2007 Time: 5:49 PM			
<input type="radio"/> Static <input checked="" type="radio"/> Dynamic					

Select Media



Print Sample Labels

Labels User Fields

Media Lot None
None

Select Media From List

Media

Media Type

Lot Number	Media Type	Barcode	Name	Vendor	Expiration Date
▼ Media Type: RODAC Plates (1 item)					
M00001	RODAC Plates	M00001	M00001-RODAC	Becton Dickinson	12/31/2008
▼ Media Type: Sampling Bottle (1 item)					
M00002	Sampling Bottle	M00002	M00002-Bottle	Becton Dickinson	12/31/2008
▼ Media Type: TOC-Free Vials (1 item)					
M00003	TOC-Free Vials	M00003	M00003-TOC	Becton-Dickinson	12/31/2008
▼ Media Type: Settling Plates (1 item)					
M00004	Settling Plates	M00004	M00004-Setl	Becton Dickinson	12/31/2008
▼ Media Type: TSA (1 item)					
M00005	TSA	M00005	M00005-TSA	Becton Dickinson	12/31/2008
▼ Media Type: Swabs (1 item)					
M00006	Swabs	M00006	M00006-Swabs	Becton Dickinson	12/31/2008

Barcode: M00002 Expiration Date: 12/31/2008 12:00 AM
Name: M00002-Bottle Vendor: Becton Dickinson
Lot #: M00002

Scan Lot #:

Print Barcode Labels



Print Sample Labels

Labels | User Fields

Water System	Test Type	Test		Media Lot	
Purified Water	TPC	20 PW-A1 - Total Plate Count	<input type="button" value="Add Note"/>	<input type="button" value="Select Media"/>	M00002 12/31/2008
Site: PW-A1				Sample Volume	1000 L
M00004619					
By: Analyst No 8		Date: 11/6/2007 Time: 5:56 PM			
<input type="radio"/> Static <input checked="" type="radio"/> Dynamic					

Water System	Test Type	Test		Media Lot	
Purified Water	COL	22 PW-A1 - Coliform	<input type="button" value="Add Note"/>	<input type="button" value="Select Media"/>	M00002 12/31/2008
Site: PW-A1				Sample Volume	1000 L
M00004620					
By: Analyst No 8		Date: 11/6/2007 Time: 5:56 PM			
<input type="radio"/> Static <input checked="" type="radio"/> Dynamic					

E-Sig Required for Barcode Creation



The image shows a Windows-style dialog box titled "Electronic Signature Entry". It has a blue title bar with a small icon on the left and standard minimize, maximize, and close buttons on the right. Below the title bar is a header area with a notepad icon and the text "Electronic Signature Entry". The main content area is white and contains a red disclaimer paragraph, a red instruction line, and two input fields. The "Username:" field contains the text "Analyst08". The "Password:" field contains seven black dots. At the bottom right of the dialog are two buttons: "Sign" and "Cancel".

Electronic Signature Entry

I acknowledge that my signature executed electronically through this computerized system is the legally binding equivalent of my handwritten paper-based signature. Further, I understand that sharing components of my non-biometric electronic signature, using an electronic signature not my own, and/or misuse or falsification of electronic signature may result in disciplinary action and/or dismissal.

Please sign by entering your username and password below:

Username:

Password:

Lab Processing - Scan Barcode Label for Total Plate Count (TPC) Test



Current Barcode Filter: **M00004617** (Sample)

Scan Barcode:

Manual Entry

Clear Filter

Test Method: -- All Test Methods --

Today Only

Location Barcode Site Barcode Plan Name Test Method

Test

Sample Barcode	Scheduled Date	Workflow Step	Test Method	Site Name	Site Description
▼ Location Barcode: (1 item)					
▼ Site Barcode: B1PW-A1 (1 item)					
▼ Plan Name: (1 item)					
▼ Test Method: [TPC] Total Plate Count (1 item)					
M00004617	11/6/2007 5:54 PM	Testing	[TPC] Total Plate Count	PW-A1	Purified Water - Port 1

Select the Sample and click Test.

1 items selected.

Setup of Dilutions for TPC



File Help Testing Analyst08 is working online.

Home Current Workspace General Pool Sampling Testing Incubation Results Entry

MODA
field data capture

Site Barcode: B1PW-A1 Site Name: PW-A1 Test Method: [TPC] Total Plate Count Sample Barcode: M00004617

Dilutions Equipment Media

#	Volume (mL/g)
1	10
2	100
3	250

Print
No Dilutions
No Test
Cancel

Updated reference data available as of 11/8/2007 5:13:23 PM Testing loaded. Copyright (C) 2005-2007, Moda Technology Partners, Inc. All Rights Reserved.

Print dilution labels.

Click to enter No Dilutions where dilutions are normally required.

No Test this stage, which requires a note indicating the reason for No Test.

Enter each dilution here.

Display of Dilution Sample Labels



Print Labels

Labels

Water System	Test Type	Test	
Purified Water	TPC	20 PW-A1 - Total Plate Count	Add Note
M00004617D1			
By: Analyst08		Date: 11/6/2007 Time: 11:32 PM	
<input type="radio"/> Static <input checked="" type="radio"/> Dynamic			

Water System	Test Type	Test	
Purified Water	TPC	20 PW-A1 - Total Plate Count	Add Note
M00004617D2			
By: Analyst08		Date: 11/6/2007 Time: 11:32 PM	
<input type="radio"/> Static <input checked="" type="radio"/> Dynamic			

Water System	Test Type	Test	
Purified Water	TPC	20 PW-A1 - Total Plate Count	Add Note
M00004617D3			
By: Analyst08		Date: 11/6/2007	

Attach Note **Print** **Cancel**

Adds a note to the sample.

Click to add a note to all samples in the preview list..

Click to ESig and print labels.

Lab Processing - Scan Barcode Label for Coliform Test



Current Barcode Filter: M00004620 (Sample)

Scan Barcode:

Manual Entry

Clear Filter

Test Method: -- All Test Methods --

Today Only

Location Barcode Site Barcode Plan Name Test Method

Sample Barcode	Scheduled Date	Workflow Step	Test Method	Site Name	Site Description
▼ Location Barcode: (1 item)					
▼ Site Barcode: B1PW-A1 (1 item)					
▼ Plan Name: (1 item)					
▼ Test Method: [COL] Coliform (1 item)					
M00004620	11/6/2007 6:09 PM	Testing	[COL] Coliform	PW-A1	Purified Water - Port 1

Test

1 items selected.

No Dilutions for Coliform Test



Site Barcode: B1PW-A1 Site Name: PW-A1 Test Method: [COL] Coliform Sample Barcode: M00004620

Equipment Media

Equipment Type

Location	Equipment Type	Barcode	Control Number	Name	Description
----------	----------------	---------	----------------	------	-------------

Scan Equipment Barcode

Select Equipment Manual Entry Remove All Remove

Test No Test Cancel

Select Media for Coliform Test



Site Barcode: B1PW-A1 Site Name: PW-A1 Test Method: [COL] Coliform Sample Barcode: M00004618

Equipment Media

Media Type

Lot Number	Media Type	Barcode	Name	Vendor	Expiration Date
------------	------------	---------	------	--------	-----------------

Media Type: Colisure (1 item)

M00007	Colisure	M00007	Colisure	Beta Media	12/31/2008
--------	----------	--------	----------	------------	------------

Select Media From List

Media

Media Type

Lot Number	Media Type	Barcode	Name	Vendor	Expiration Date
------------	------------	---------	------	--------	-----------------

Media Type: RODAC Plates (1 item)

M00001	RODAC Plates	M00001	M00001-RODAC	Becton Dickinson	12/31/2008
--------	--------------	--------	--------------	------------------	------------

Media Type: Colisure (1 item)

M00007	Colisure	M00007	Colisure	Beta Media	12/31/2008
--------	----------	--------	----------	------------	------------

Barcode:	M00007	Expiration Date:	12/31/2008 12:00 AM
Name:	Colisure	Vendor:	Beta Media
Lot #:	M00007		

Scan Lot #:

Manual Entry

Select

None

Scan Media Lot #

Select Media

Manual Entry

Remove All

Remove

Perform Incubation – Select Samples and Equipment



Current Barcode Filter: None

Scan Barcode: Test Method: -- All Test Methods --

Location Barcode Site Barcode Plan Name Test Method

Sample Barcode	Dilutions	Scheduled Date	Workflow Step	Test Method	Site Name
▼ Location Barcode: (2 items)					
▼ Site Barcode: B1PW-A1 (2 items)					
▼ Plan Name: (2 items)					
▼ Test Method: [TPC] Total Plate Count (1 item)					
M00004617	M00004617D1, M0000461...	11/6/2007 11:35 PM	Incubation	[TPC] Total Plate Count	PW-A1
▼ Test Method: [COL] Coliform (1 item)					
M00004618	None	11/7/2007 12:10 AM	Incubation	[COL] Coliform	PW-A1

2 items selected.

Select Equipment

Scan Barcode:

Equipment Details:

Barcode: E518

Type: Incubator

Name: Incubator 1001

Description: Incubator 1001 (20-25)

Results Entry for Coliform Test



Results Entry: [M00004618] COL - Coliform

MODA
field data capture

Scan Sample Barcode:

Location Barcode: Location Name: Purified Water Site Barcode: B1PW-A1 Site Name: PW-A1 Classification:

Results Sample Media Information Sample/Incubation Times Equipment Media

Measurements

Measurement	Sign	Value	Unit of Measure	Descriptor
Coliform	= <input type="text"/>	POSITIVE <input type="text"/>		
E. Coli	= <input type="text"/>	NEGATIVE <input type="text"/>		

Results Entry for Total Plate Count Test



Results Entry: [M00004617] TPC - Total Plate Count

MODA
field data capture

Scan Sample Barcode: Manual Entry Auto Save Mode

Location Barcode: Location Name: Purified Water Site Barcode: B1PW-A1 Site Name: PW-A1 Classification:

Results Sample Media Information Sample/Incubation Times Equipment Media

Measurements

Dilution M00004617D1, 10.0 mL

Measurement	Sign	Value	Unit of Measure	Descriptor
Bacteria	=	0	cfu	
Mold	=	0	cfu	
Sample Volume	=	1	mL	
Reportable	=	YES		

Dilution M00004617D2, 100.0 mL

Measurement	Sign	Value	Unit of Measure	Descriptor
Bacteria	=	0	cfu	
Mold	=	0	cfu	
Sample Volume	=	1	mL	
Reportable	=	NO		

Dilution M00004617D3, 250.0 mL

Measurement	Sign	Value	Unit of Measure	Descriptor
Bacteria	=	0	cfu	

Attach Note Zero Counts Save & Close Save Result Cancel

Batch E-Sig of Results Entered



Batch Electronic Signature Preview

Batch Electronic Signature Results

Drag a column header here to group by that column.

Exp	Type	Test Type	Site/Room	Sample	Value	# Readings
	WATER	Coliform	B1PW-A1	M00004618	1	2
	WATER	Total Plate Count	B1PW-A1	M00004617	0,0,0	12

Discard

Sign

Cancel

Select All

Deselect All

Results Entry

No Test

LAL Import

TOC Import


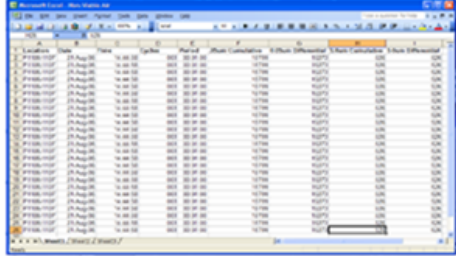
2 Items waiting for electronic signature.

Enter Signature

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Efficient, Portable Particle Monitoring



Record on template Transcribe printout to log book	Enter data into spreadsheet Reconcile spreadsheet and printout
 A diagram showing a particle counter device on the left, an arrow pointing to a stack of paper printouts in the middle, and another arrow pointing to a spreadsheet application window on the right.	 A screenshot of a Microsoft Excel spreadsheet showing multiple columns of data, including dates, times, and numerical values.
3 hours	5 hours

Manual Methods
Paper-based data
acquisition and data entry

Scan room or site. Invoke particle counter from mobile data acquisition tablet.	Automatic upload of results to server
 A diagram showing a particle counter device on the left, connected by a cable to a ruggedized tablet computer in the middle. The tablet screen displays a landscape image.	 A diagram showing a server tower on the right with three curved lines representing a wireless signal being transmitted from the tablet area on the left.
2 hours	Finished

Labor-Saving Method
Paperless, automated
data acquisition

Benefits: Eliminate Paper Records



- Increased productivity

- Save labor in sample collection
- Save labor in data entry
- Save labor in data analysis
- Save labor in porting data to ERP/LIMS

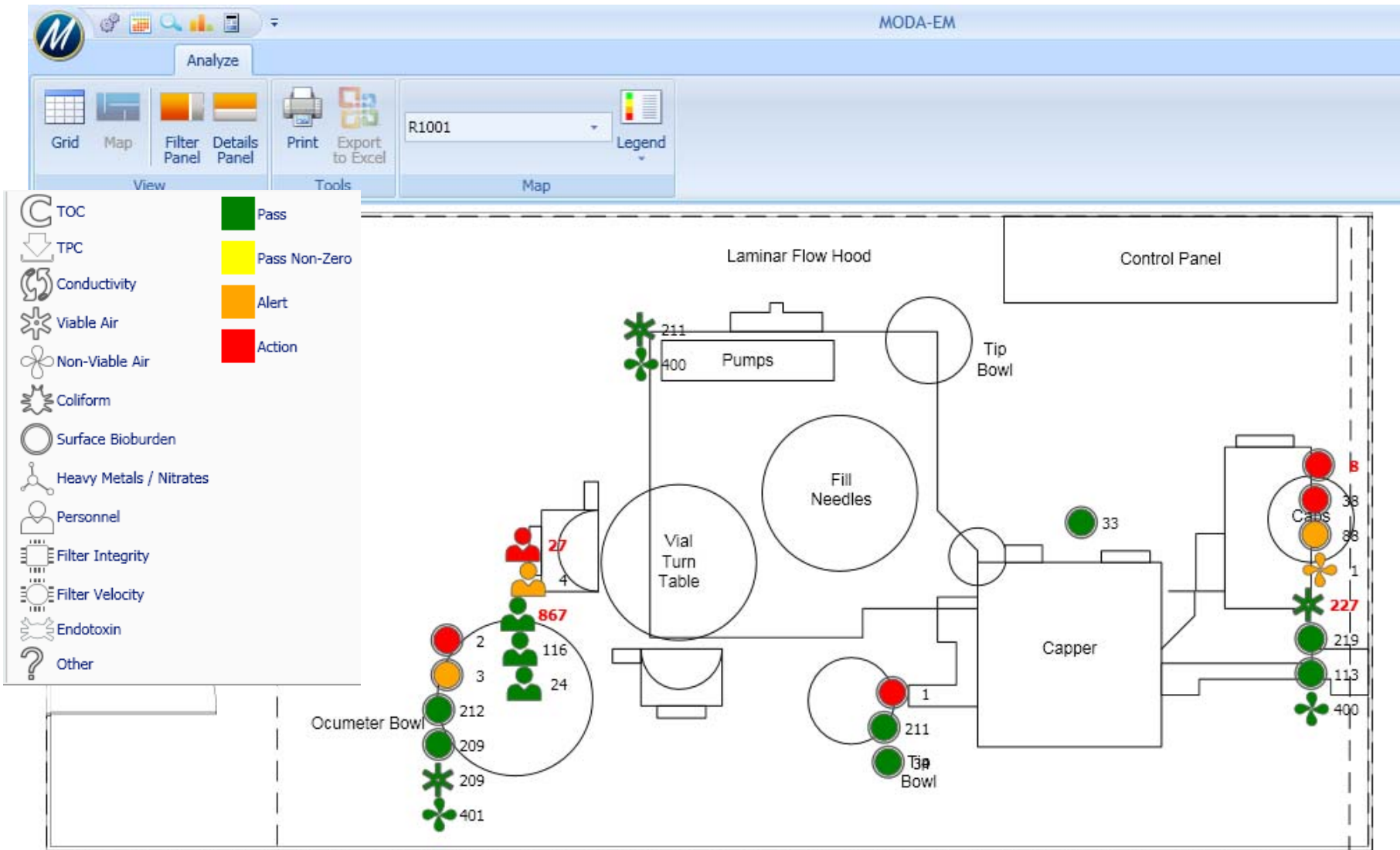
- Improved compliance

- Improve consistency of SOP implementation
- Get immediate notification of non-compliant samples
- Eliminate human data-entry errors
- Reduce human bio-burden during sample collection

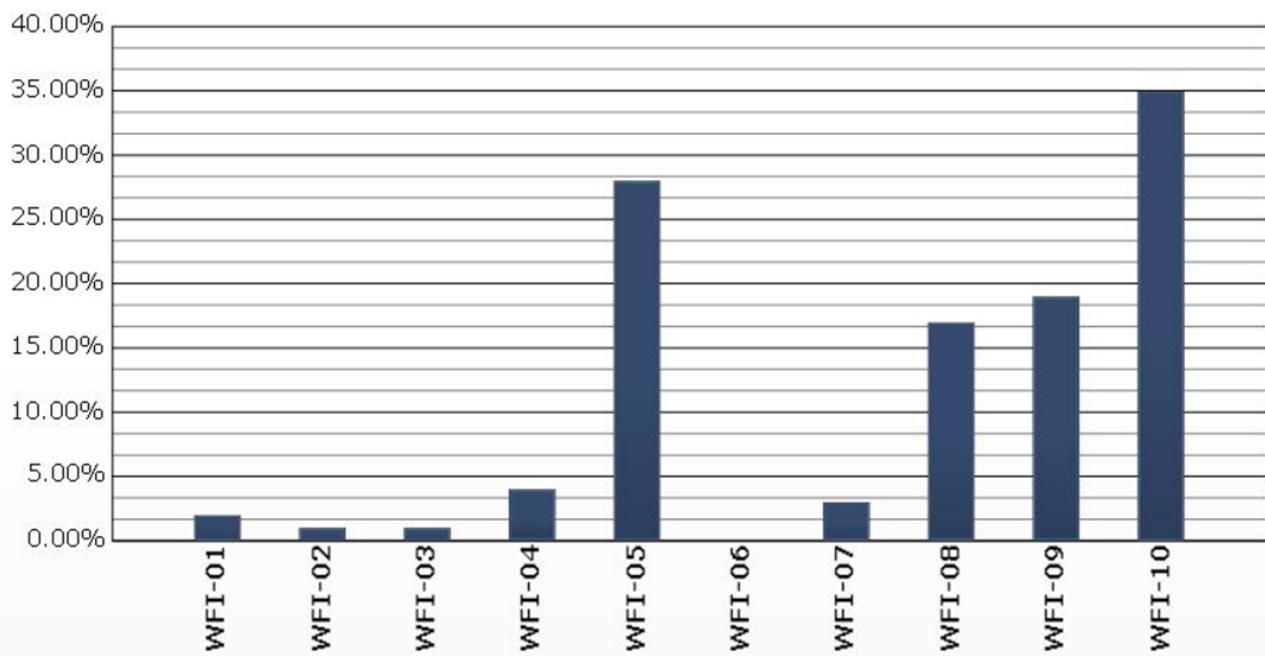
Reports Trending Visualization ROI/Benefits

The Payoff: More Science. Less Paper.

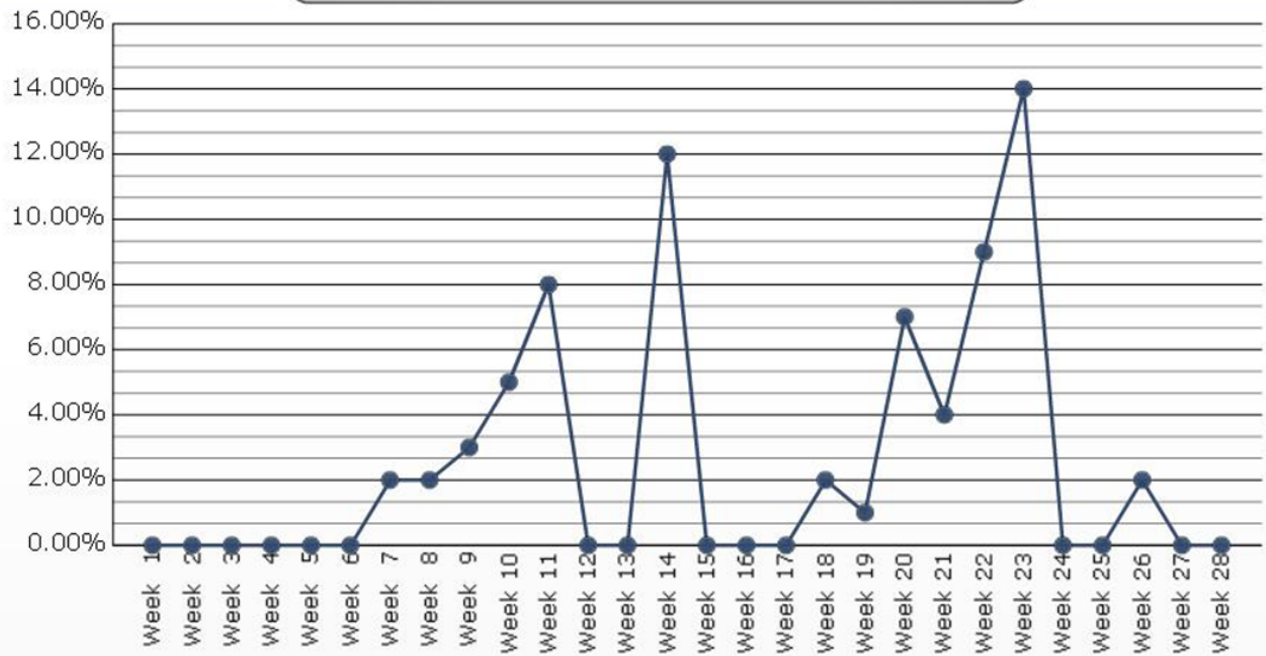
Automated Reporting & Analytics



Percent Non-Zero by Site



Percent of Samples with Counts > 0



- Large-scale pharmaceutical manufacturer of hematology and cardiology products
- QC (EM & Utility) program is paper-based
- 360,000 samples per year across 10 locations
- Monthly trending reports required 30 person-days to produce

Data Acquisition Savings



Average annual cost of testing professional (salary and benefits)	\$80,000
Annual work days per testing professional (1920 hours / 8 hour day)	240
Cost per day per testing professional (\$80K / 240 work days)	\$333
Number of QC personnel performing data acquisition activities (24 current + 6 additional for new facility)	30
Annual number of days for current and projected QC activities (30 professionals x 240 work days)	7,200
Total Annual QC Data Acquisition Costs	\$2,400,000
Daily hours saved per testing professional – eliminating batch data entry Total daily hours saved – eliminating batch data entry (30 professionals x 3 hours)	3 90
Daily hours saved – reduction of problem or missed samples (10 problem/missed samples per day x 1 hour corrective action per sample)	10
Daily hours saved – elimination of template-to-media reconciliation (2 hours per day x 3 shift supervisors)	6
Total work days saved per year (Daily hours saved / 8 hour day) x 240 work days per year)	3180
Total Annual Data Acquisition Savings	\$1,060,000

Data Analysis/Reporting Savings



Average annual cost of data analysis professional (salary and benefits)	\$80,000
Annual work days per testing professional (1920 hours / 8 hour day)	240
Cost per day per testing professional (\$80K / 240 work days)	\$333
Number of data analysis professionals	6
Days per month spent producing QC reports	5
Number of days annually required to produce monthly QC reports (6 professionals x 5 days / month x 12 months)	360
Total Annual QC Report Production Costs	\$120,000
Days saved per data analysis professional to produce monthly QC reports	4
Number of days saved annually producing monthly reports (4 days x 6 analysts x 12 months)	288
Total Annual Data Analysis/Reporting Savings	\$96,000

- Version 2.2 expansion is complete
- 31 Tablets and 7 lab Workstations
- 2 to 3x more samples than pre-MODA days
- Planned Upgrade to latest MODA release in 2009
- **80+ users optimized with improved workflow**

THE REAL PAYOFF: ImClone expanded their production facilities; increased their manufacturing volume; and tripled their EM activities without the need to increase QC Micro staff.



Source: Environmental Monitoring
A Comprehensive Handbook, Volume 1

“...cleanroom touch pads or computer terminals that allow for automated data entry IN THE ROOM.”

“...palm-pilot-type of data collection devices... that can directly download to the computer system and allow for direct data transfer without risk of contamination.”

“...real time data for many of the chemistry and microbiology tests that must be performed.”



Source: Environmental Monitoring
A Comprehensive Handbook, Volume 2

“...analysis and trending of environmental data is essential to aid in the interpretation of process stability and assess overall control performance.”

EM Reports must be “...accurate, traceable, timely, and well-documented”

Bob Toal

MODA

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Robert Lutskus

ImClone Systems

robert.lutskus@imclone.com

Questions & Answers

→ **To submit a question, use the “Q&A” feature of WebEx** (bottom right of your screen). If we do not answer a question online, we will be sure to follow up with an e-mail.

- **Additional Customer-Focused Events in 2009**

- Topics being considered:

- Bridging the gap between LIMS and EM needs
 - Advancements in automated Endotoxin testing
 - Advancements in automated Air Testing
 - Application of Lean Six Sigma principles to QC Micro
 - Use of Pre-Barcoded Media in QC Micro

- **Personal consultation:**

Bob Toal, btoal@modatp.com, (484) 253-1000 x133

- **Learn more:** www.modatp.com

A copy of this presentation and the movie of the live session will be available for download from the MODA website shortly after the presentation.