

Paperless QC Micro Webinar Series



Part 1: Automating Environmental Monitoring, Utility and Product Testing

Featuring

Robert Lutskus

QCMLS Supervisor

Co-sponsored by



ImClone Systems

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Co-sponsors



www.sqllims.com



www.hachultra.com

Today's Presenters



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



- **Bob Toal**
VP Marketing



- Company Overview
- MODA Software—Mobile Data Acquisition Platform
- Part 1: Automating EM, Utility & Product Testing
- ImClone Case Study, Featuring Robert Lutskus
- 15-minute Interactive Questions & Answers
- Wrap-up: Part 2 Focus Areas

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.

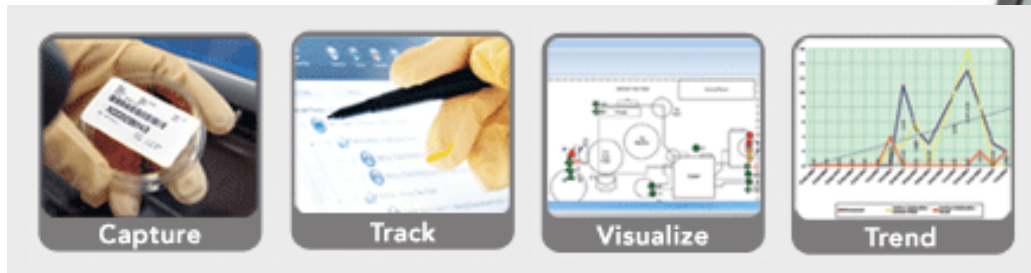
- Provide mobile data acquisition solutions that automate regulated manufacturing processes
 - Pharmaceuticals to consumer products
- Office locations
 - Wayne, PA Headquarters (suburban Philadelphia)
 - London, England
- World-wide sales in North America, Europe, and Asia
- Global technology partners

1. More science. Less paper.

- Move from paper-intensive QC Monitoring & Analysis quickly

2. Increase operational efficiency, improve quality, reduce costs

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



- Concepts for automation vs. paper-based QC process
- How mobile technology can overcome EM challenges
- Best practices requirements and real world success
- Decision support: reports, trending and visualization

The ImClone Story

Product Demand Drives Growth



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Previous: Raw Data Collection



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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



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Now: Automated Lab Processing



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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

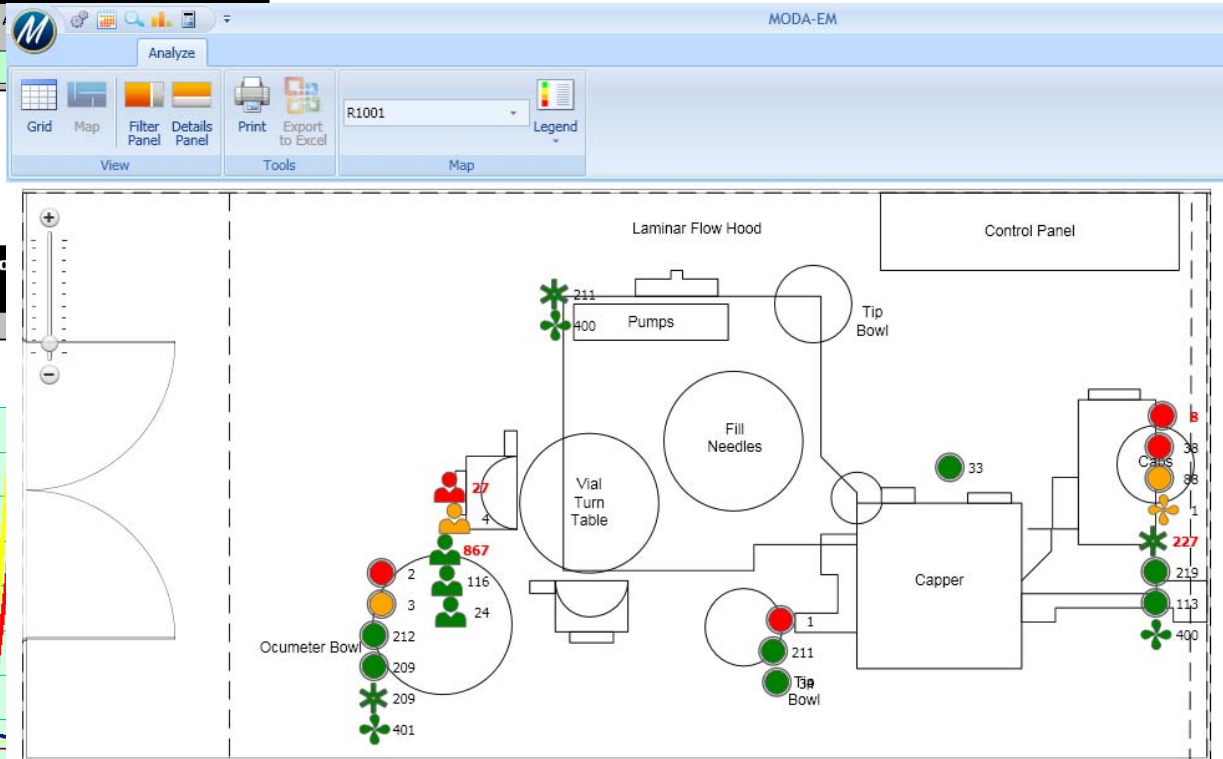
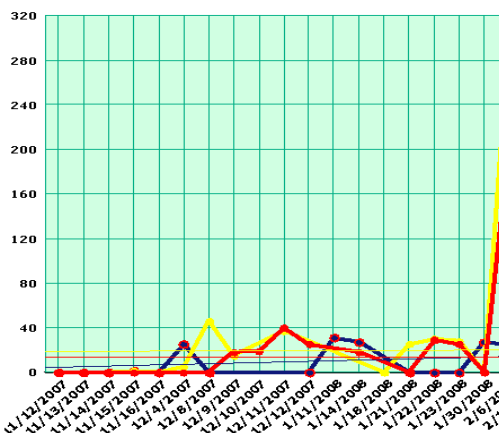
Chart as of 7/30/2008

SW

Bu

PEI

Location: Building 1000 R1001 - Fill Suite 1



ImClone Systems

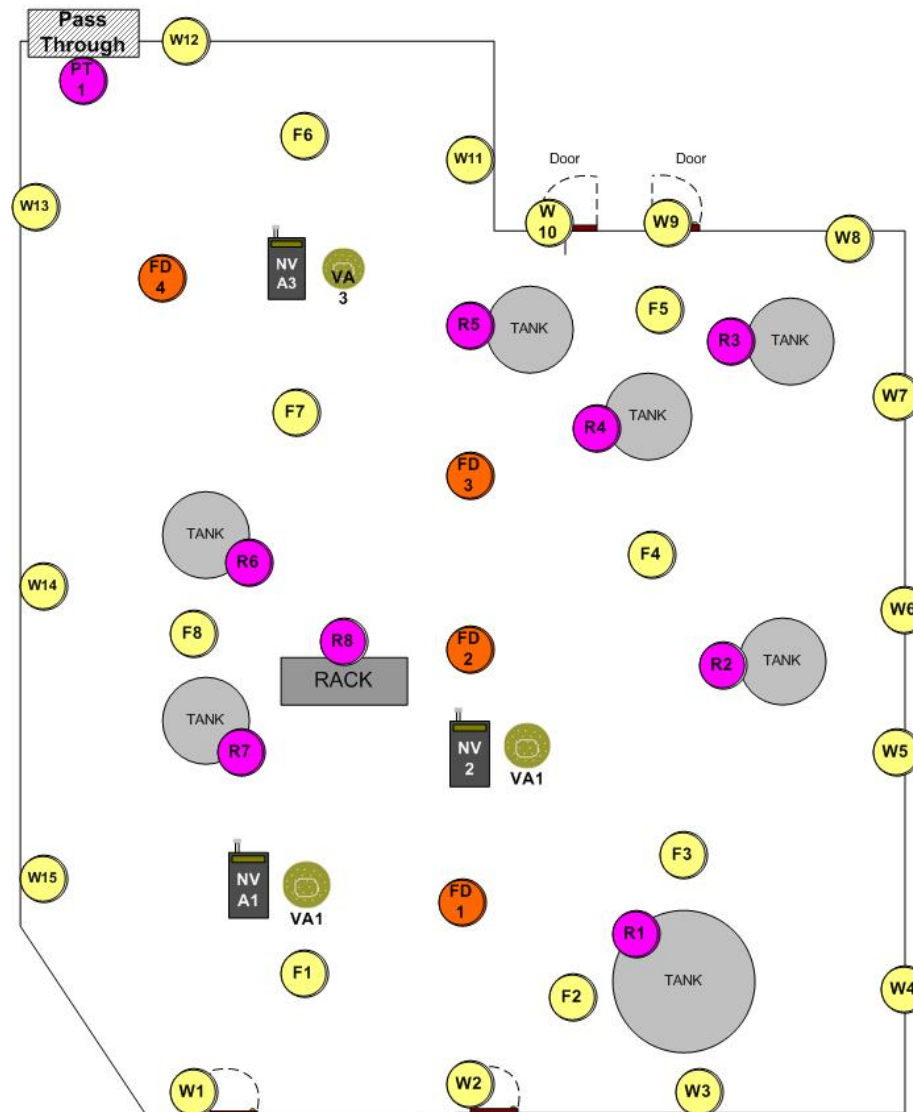
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State of the Industry

How are most QC Micro programs managed today?

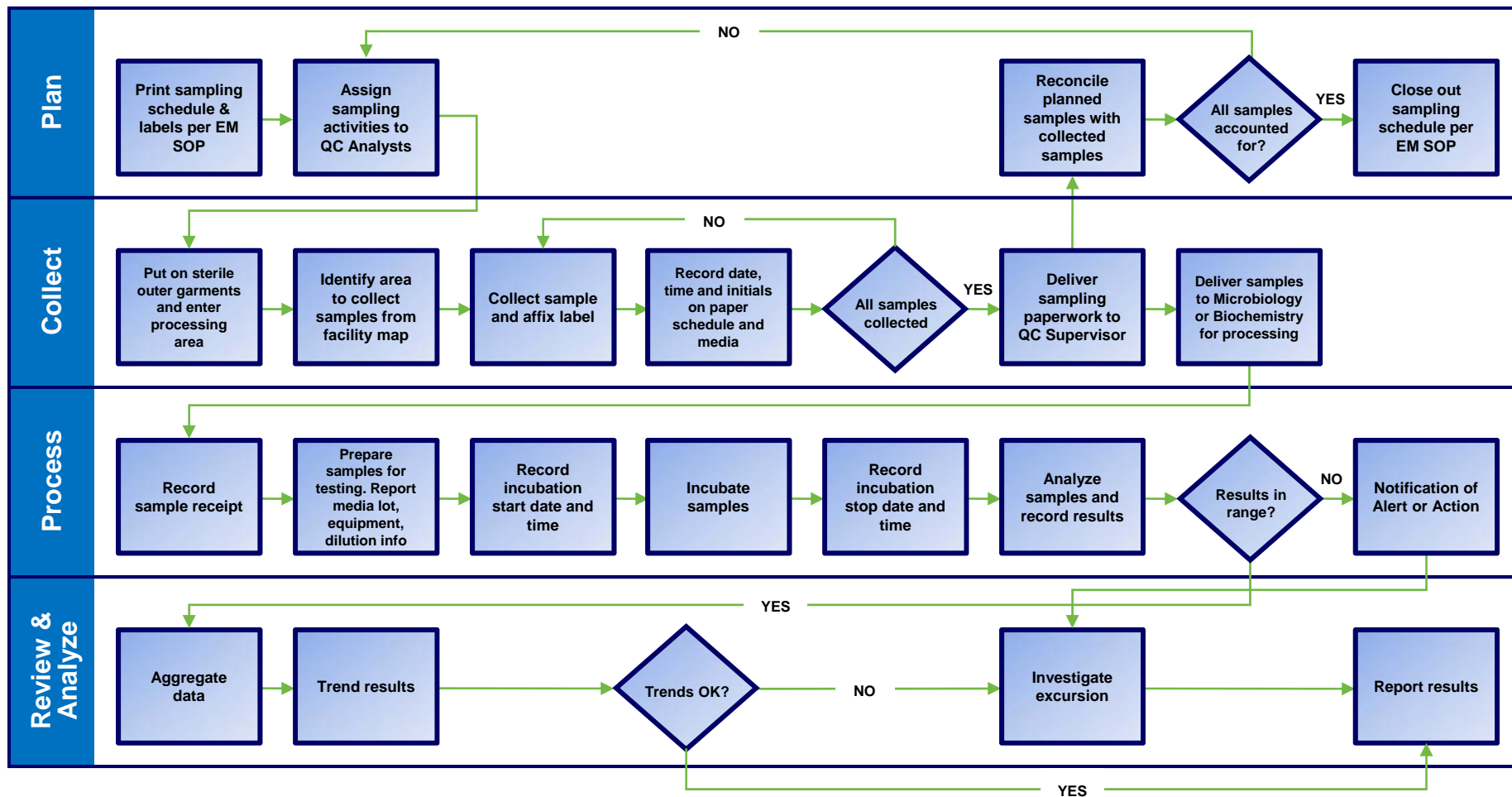
EM Sampling Sites

Example: Fill Suite



The Paper-based QC Process

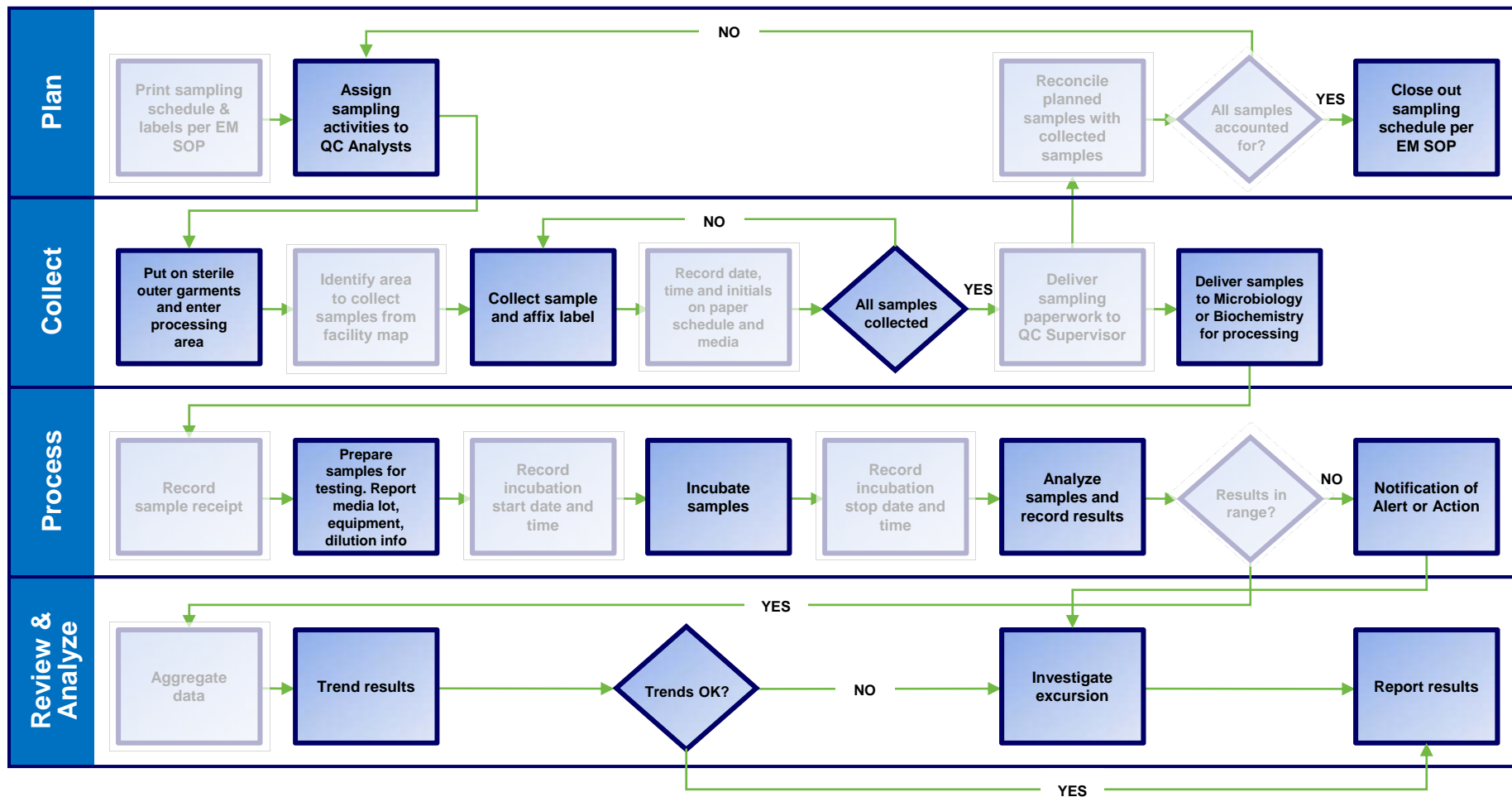
Example: Control Monitoring Process






The Paperless QC Process



Example: Control Monitoring Process. 11 steps removed



Paperless Efficiency Example

Record on paper template	Record on plate	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

Live Demonstration: Efficiencies of Paperless QC

1. [Automated Data Capture](#)
2. [Automated Reports and Analytics](#)

For the screen cams associated
with this portion of the Webinar,
email Bob Toal, btoal@modatp.com



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”

Challenges	Solutions: Mobile Technology
<p>Computers, like all other equipment in an aseptic environment, must be sanitized</p> <p>Heat, radiation and chemical disinfectants cannot be used on standard business computers</p> <p>Rugged computers that can be sanitized exist, but are typically deployed as a fixed workstation (kiosk) used to control or monitor a specific operation</p> <p>Fixed workstations cause increased foot traffic and body movement resulting in higher levels of personnel borne contaminants</p>	<p>Ideal device is small, lightweight, transportable, durable and can be sanitized</p> <p>Must not introduce particulates into the air</p> <p>Leverages wireless or radio-frequency (RF) technology</p> <p>Can read and print barcodes and RFID tags to eliminate need for paper schedules and hand-written sample labels and records</p>

Mobile Data Acquisition Devices



**Rugged Wireless
Tablet PC with
Touch Screen**



**Wireless Barcode
Scanner**



**Rugged Wireless
Thermal Barcode
Printer with
Sterile Label Stock**

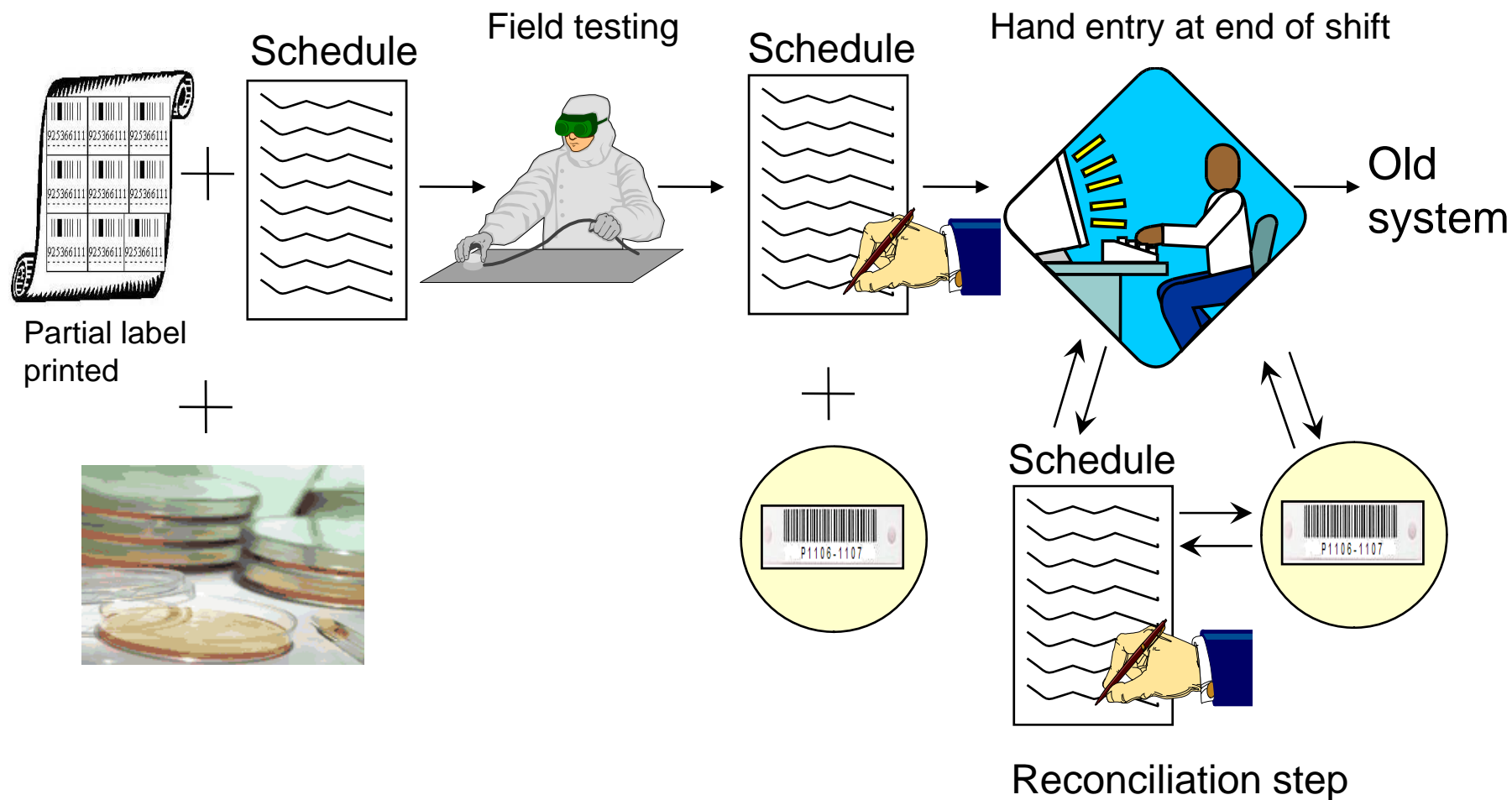


Case Study

ImClone Systems is a fully integrated global biopharmaceutical company committed to advancing oncology care by developing and commercializing a portfolio of targeted biologic treatments designed to address the medical needs of patients with a variety of cancers.

ImClone is a wholly-owned subsidiary of Eli Lilly and Company that utilizes the MODA-EM platform for improved Environmental Monitoring and Utility Testing.

Before: Paper-Heavy, Manual Processes



After: Streamlined Data Entry



Field Testing: data entered on tablet
in clean room at point of sample



Complete Label Printed



MODA-EM



- ✓ 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

- 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

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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.

- **Next Webinar: Part 2, Tuesday, March 31**
 - Utility and product testing
 - Instrument integration
 - Process for non-viable air testing
 - Delve deeper into reports, trending, visualization, and ROI/benefits
- **Personal consultation:**
Bob Toal, btoal@modatp.com, (484) 253-1000 x133
- **Learn more:** www.modatp.com

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