

# Paperless QC Micro Webinar Series



## Improvement in QC Environmental Monitoring Processes with Paperless Data Capture System

**Presented by**

**Susan Harrison**

Senior Manager, Microbiology

**Jeremy Tanner**

QC Information System Specialist

Co-sponsored by



**Lonza**

# Co-sponsors



[www.drsarmo.com](http://www.drsarmo.com)



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# Today's Presenters



- **Susan Harrison**  
Senior Manager, Microbiology

- **Bob Toal**  
VP Marketing

- **Jeremy Tanner**  
QC Information  
System Specialist



# Lonza

# 60-Minute Agenda



- MODA Overview
- 45-Minute Presentation by Lonza
- 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.**

# Background: MODA



- 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

# MODA Value Proposition

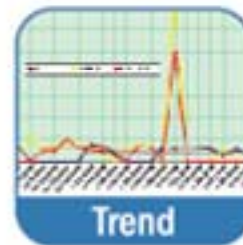
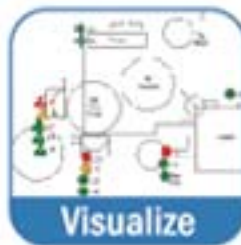


## 1. More science. Less paper.

- 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**

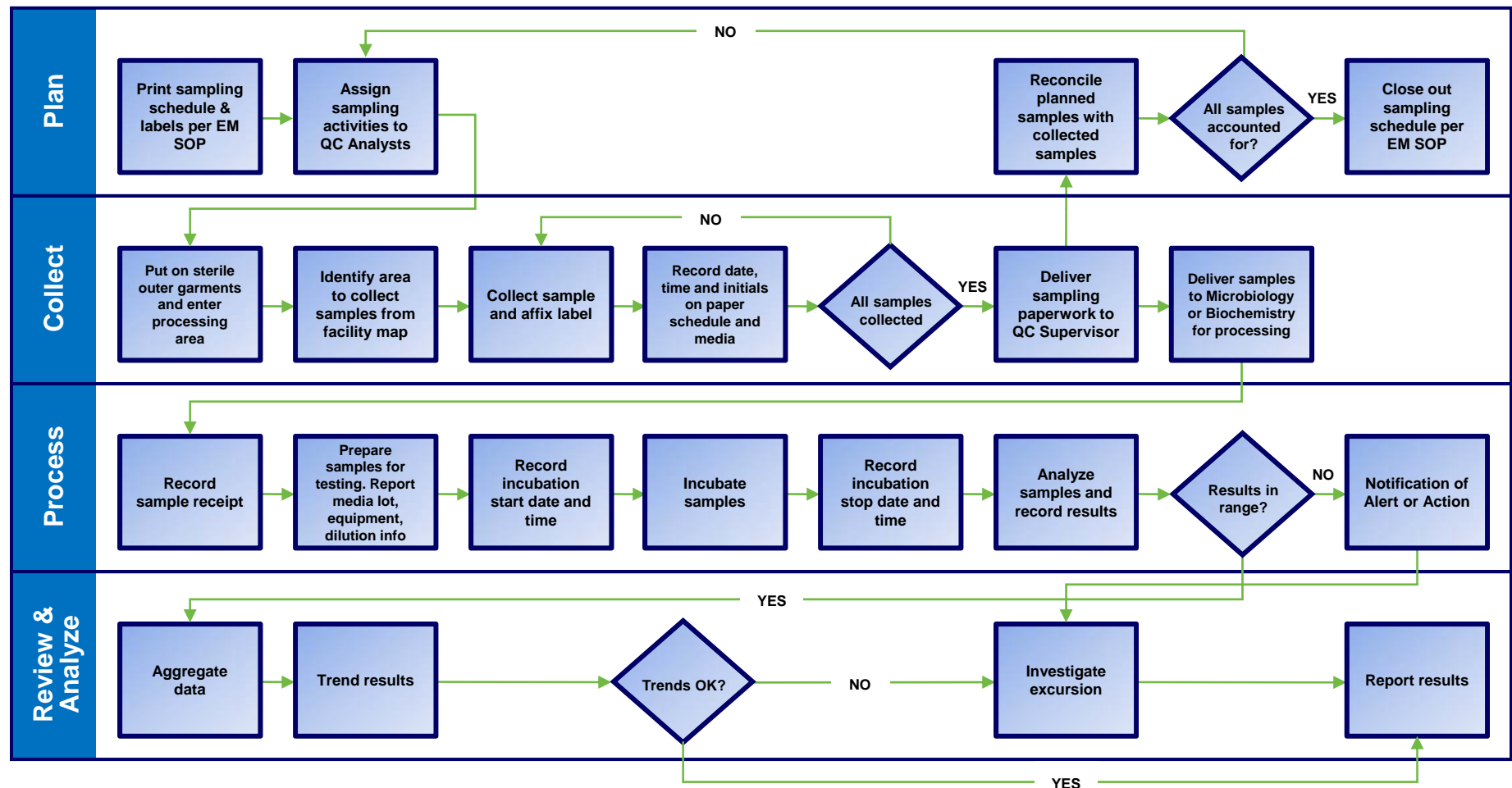


**Talecris**  
BIOTHERAPEUTICS

# The Paper-based QC Process



## Example: Manual Utility Sampling and Lab Processing

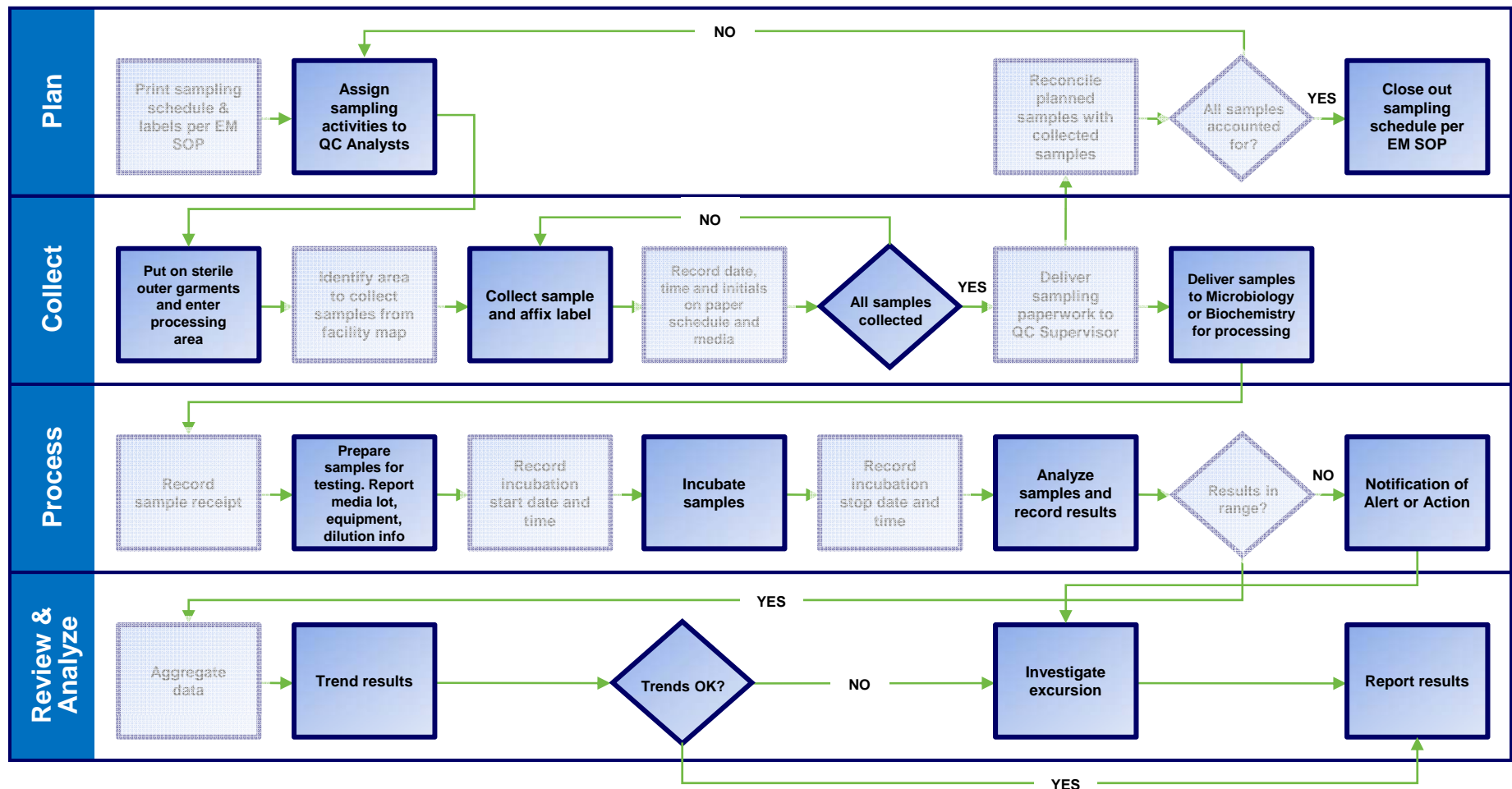




# The Paperless QC Process






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



# Paperless Efficiency Example

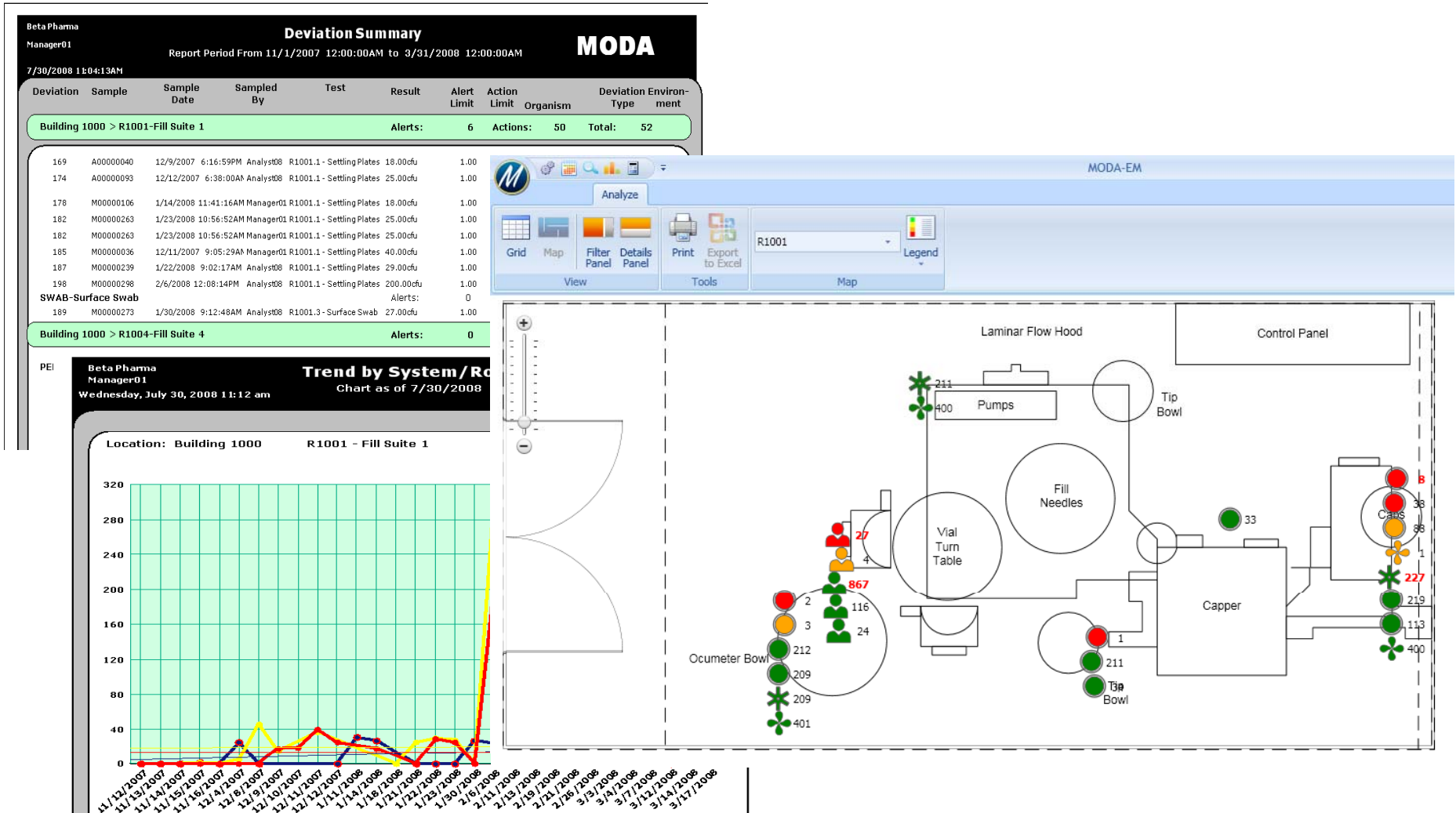


Record on paper template	Record on plate	Reconcile media and template	Enter data into Excel/LIMS
1: BB50, SS43, Water, IE5 2: BB50, SS43, RODAC, IP72/IP82 3: BB50, SS44, Water, IE5/IE7 4: BB50, SS44, Water, IE9/SP2 5: BB50, SS65, RODAC, IP74			
6 hours		1 hour	1 hour

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

	Paper	8 hours
–	Paperless	4 Hours
=	<b>Savings</b>	<b>4 Hours</b>

# Automated Reports & Analytics



# Webinar Focus Areas



- Lonza's Lean Six Sigma initiative
- Why MODA-EM for paperless QC Micro
- Lonza process improvements: reports, trending data, metrics
- Lonza ROI: Financial, Compliance, User Adoption
- Real-time Q&A with Lonza subject experts

- Evaluated LIMSystem(s)
  - Commercial off the shelf systems
  - Tablet PC system
- Didn't proceed
  - Corporate commitment
  - Investment
- MODA Technology Partners
  - Presentation at PDA Conference Summer '06
  - Offered solution specifically for Environmental Monitoring (EM)
  - Start-up company, flexible

# Lean Six Sigma (LSS) Initiative



- Company wide initiative
  - Eliminate Waste
  - Reduce Lead/Labor Time
- LSS Microbiology

<b>Standardized EM program (SOPs)</b> <b>Mistake-proofing (Forms)</b>	<ul style="list-style-type: none"><li>• Revised SOPs and Forms</li><li>• Maintenance of cleaning logs</li></ul>
<b>Reduce Lead and/or Labor Time</b>	<ul style="list-style-type: none"><li>• Production staff performs <b>all</b> routine monitoring</li><li>• Eliminated unnecessary sites</li><li>• Revised requirements for Bacterial ID (based on criticality)</li></ul>
<b>Implement MODA-EM™ module</b>	<ul style="list-style-type: none"><li>• Workshop held</li><li>• Three beta sites identified</li><li>• Timelines established</li><li>• Validated and implemented</li></ul>

- In support of
  - 13 existing clean room suites; Walkersville, MD
  - 1 clean room facility; Salisbury, MD
  - Unique requirements (cell therapy to crab bleeding)
  - Additional clean rooms to be built
- Program
  - Total Particulates, Viable Air, Settling, Contact, Personnel
  - Daily monitoring of Class 100 (ISO 5) & Class 10,000 (ISO 7)
  - Production staff (>100)
  - Perform most routine monitoring
  - QC Micro staff (13)
  - Plate enumeration, data review, trending, ID's
  - Perform validations (aseptic process, cleaning, gowning)

# Micro EM Volume 2006-2007

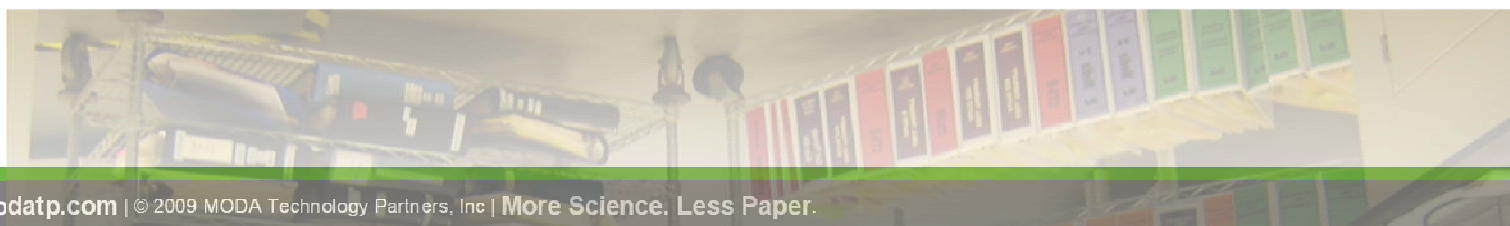


SOP	Description	Total (2006)	Total (2007)
918.238 1300.1606 1300.1607 1300.1609	Plate Enumerations <i>BioProducts</i> <i>Cell Therapy</i>	31,845 37,777	42,597 61,078
918.238 1300.1607	Total Particle Counts <i>BioProducts</i> <i>Cell Therapy</i>	8,650 4,291	11,258 7,833
918.239	Gowning Validations	178	219
Various	Aseptic Process Validations (APVs) <i>BioProducts</i> <i>Cell Therapy</i>	34 74	23 108
Various	Cleaning Validation Sessions (CVs)	70	36
<b>Total Testing</b>		<b>82,919</b>	<b>123,152</b>



- Paper based system (error prone)
- Duplication of effort
  - Completing paperwork
  - Data entry
- Timely data review (volume)
- Current database
  - Limited selection of reports
  - Time spent generating trending reports
  - Not validated or CFR21 Part 11 compliant
    - Requires data verification

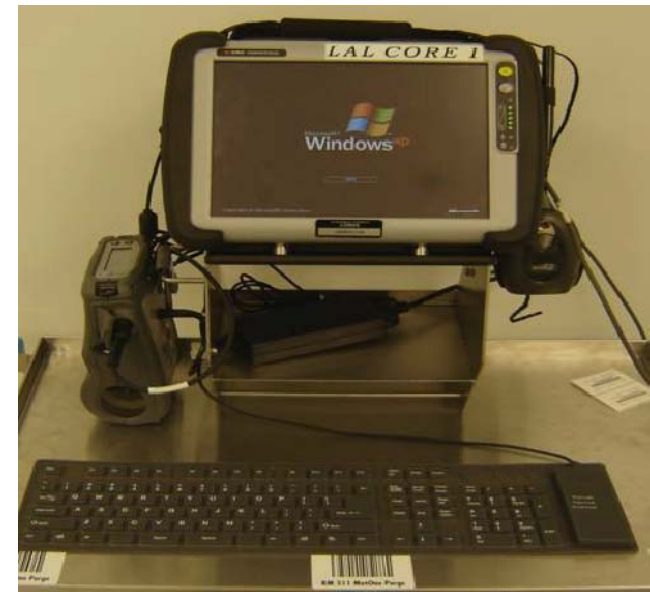
# Paper-Based Data...



## ...or Paperless Data



- MODA (Mobile Data Acquisition)
  - Paperless Environmental Monitoring system
  - Records same information as our current paper system
  - Capable of generating trend reports
  - User-friendly interface
- Selected three beta sites
  - Sterility Core II
  - LAL Core I
  - CTS 209



# Current System vs. MODA



- Current System

- Particle-generating paper autoclaved into clean room
- Data capture onto paper
- Redundant Entry of data information in access/excel
- Numerous Corrections for Omissions and Errors
- Trending is manual, time-consuming and limited in scope

- MODA

- Clean room compatible  
\*No paper\*
- Real-Time electronic data capture
- One-Step Data Capture of information
- Reduces corrections through mandatory fields/dropdowns
- System generates a variety of automatic trend reports

# Implementation Timeline



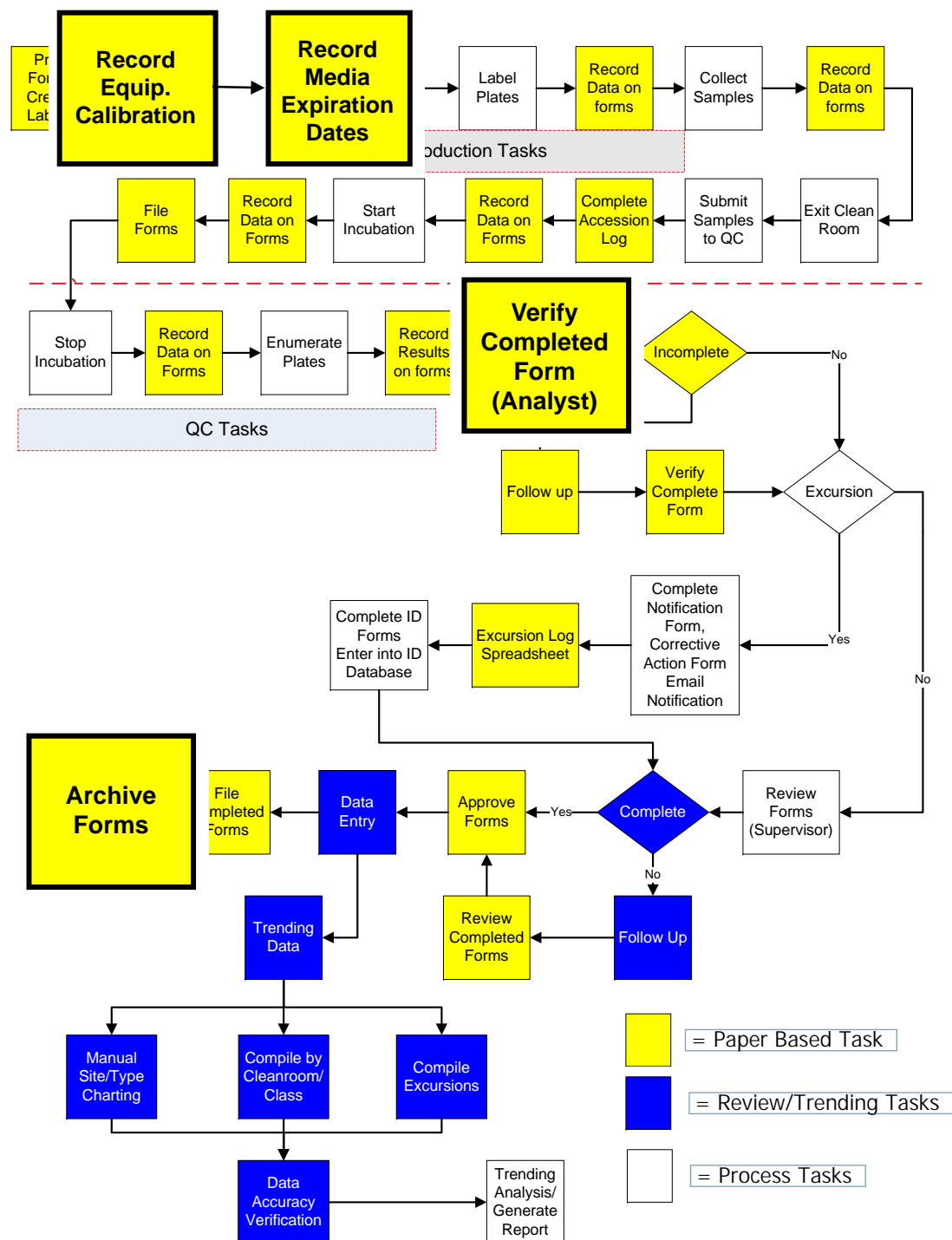
Sep 06	Vendor demo
Dec 06	Discussed configuration
Jan 07	Project kickoff
Apr –Aug 07	IT Transition delays <ul style="list-style-type: none"><li>• Server requirements</li><li>• Computer hardware/software transition</li><li>• IT Support</li></ul>
Jul 07	Software installed in test environment
Oct 07	Installation Qualification (IQ) completed
Nov 07	Operation Qualification (OQ) completed
Dec 07	Performance Qualifications (PQ's) <i>completed</i>

# MODA Improves EM Processes



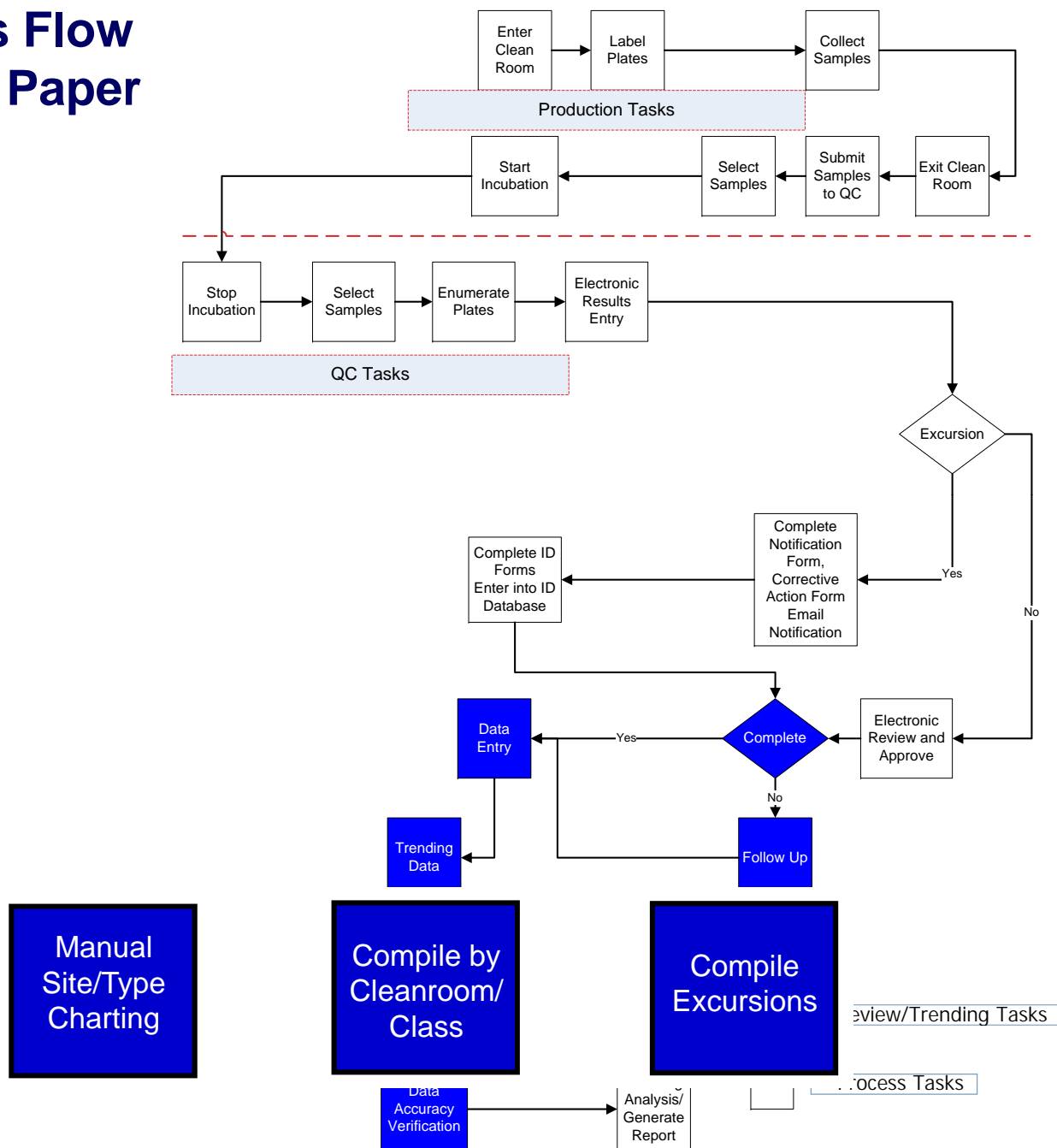
- Eliminates several steps from the paper-based EM Process
- Reduces Task and Process Time
  - Task Time – Hands-on time to complete each task
  - Process Time – Turn Around Time
- Data readily available
- Improves overall compliance

# Current Paper-Based Process Flow



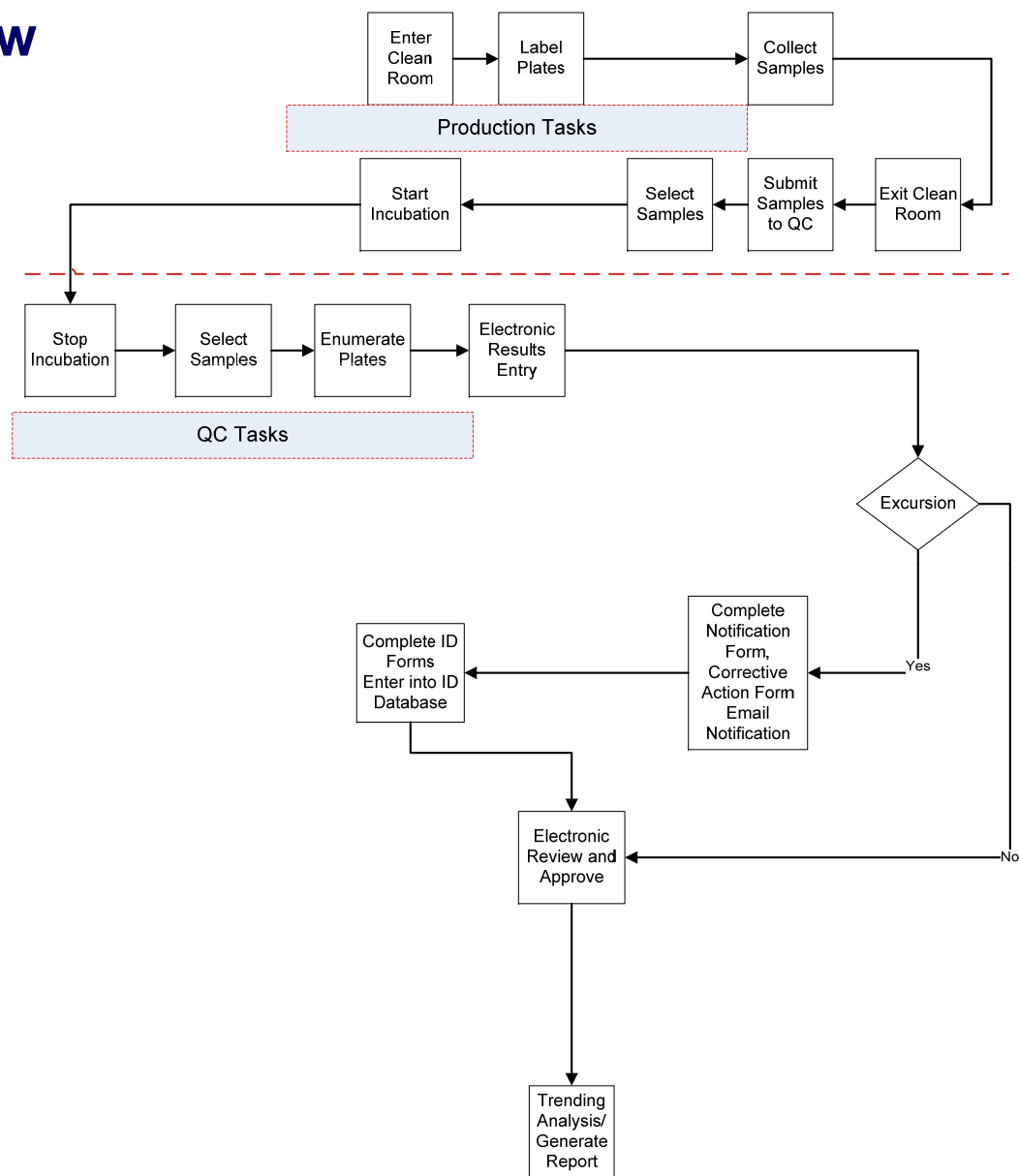



# Process Flow without Paper Tasks





# Process Flow with MODA



 = Process Tasks

- Sampling, Incubation and Results Entry
  - Prep Work
  - Sampling
  - Incubation
  - Corrections
  - Enumeration
- Report generation
  - Monthly Trending
  - Quarterly Trending
  - Plate Counts
  - Audit Report
- Review and Approval
  - Review and Approve
  - Corrections

- Sampling and Incubation (Production)
  - Prep Work
  - Perform EM
  - Incubation
  - Corrections
- Results Entry (QC Micro)
  - Prep
  - Enumeration
  - Data Entry
  - Corrections
- Review and Approval
  - Corrections
- Trending
  - Monthly
  - Quarterly
  - Organism

# Estimated Time Savings



Task	Time Saved Per person per day	Number of Users per day	Total Time Savings per day for Three cores
<b>Sampling and Incubation</b>	<b>3 minutes</b>	<b>3</b>	<b>9 minutes</b>
Results Entry	36 minutes	3	108 minutes
Review and Approve	8 minutes	3	24 minutes
Monthly Trending	13 minutes	5	65 minutes
Quarterly Trending	17 minutes	1	17 minutes
Excursion/Organism Trending	22 minutes	1	22 minutes
<b>TOTALS</b>			<b>4 hours</b>

**Total Savings: 1 hour 20 minutes per core per day**

# Model of Financial Benefits



- 1.3 hours/day x 3 beta sites = 3.9 hours/day
- 1.3 hours/day x 11 clean room suites = 14.3 hours/day
- 18.2 hours/day ÷ 8 hours day/analyst = 2.25 FTEs
- Miscellaneous savings (binders, paper, ink, particle-counter tape, autoclave costs, archiving and storage of data)
- Favorable ROI

## Current System

- Significant number of documentation errors
- Long Turn around time for processing data
- Paper presents particulate and microbial contamination risk

## MODA

- Eliminates documentation errors
- Short-turn around time for processing data
- Clean room compatible equipment reduces contamination risk

# 21 CFR Part 11 Compliance



## Current Database

- Access database for data storage is not validated
- No control of changes in access database
- No electronic signature for changes
- All users have all privileges.
- Data stored in binders that are stored on and off site.

## MODA

- Validated system
- Audit trail tracks all changes/records
- Electronic signature for all major steps to ensure traceability
- Varying levels of access to system dependent upon job function
- Data stored on servers that are backed up on a routine basis

# FDA Aseptic Processing Guide Regulatory Expectations\*



- The quality control unit should provide routine oversight of near-term (e.g., daily, weekly, monthly, quarterly) and long-term trends in environmental and personnel monitoring data”
- “Trend reports should include data generated by location, shift, room, operator, or other parameters”
- “The quality control unit should be responsible for producing specialized data reports (e.g., a search on a particular isolate over a year period) with the goal of investigating results beyond established levels and identifying any appropriate follow-up actions. Significant changes in microbial flora should be considered in the review of the ongoing environmental monitoring data”

**\* Guidance for Industry: Sterile Drug Products Produced by  
Aseptic Processing—Current Good Manufacturing Practice**



# Trending/Report Generation Compliance



## Current System

- 5 Analysts 8-10 hours per month after data entry
- Limited Scope of Trending Reports
- No Formal way of tracking flora
- Limited Time frames
- All trending performed by QC for QA and Manufacturing

## MODA

- Quick and efficient trending in real time
- Wide array of trend report formats
- Flora can be trended by person, site, room, facility
- Time frame can be specified
- Ease of trending allows others (QA, Manufacturing) to perform their own trending

# Benefits of MODA



- Clean room compatible equipment
- Instant data entry eliminating paper transpositions
- Eliminates duplication of efforts in data entry and trending
- Equipment Interface (MetOne Particle counter)
- 21 CFR Part 11 compliant
- Generation of timely trending reports
- Storage of paper documentation eliminated
- Severability: Continues sampling process without wireless internet connection
- Added bonus: DMS access through PC tablets
  - i.e. Documentum, NovaManage

# Recommendation



- Based on potential cost savings, compliance, and end-user satisfaction, we recommended site-wide implementation of MODA

- Phased site-wide implementation
- Cell Therapy
- Media (Core, TBS, Hood, Sterilization & PMPD)
- LAL (Core II, Formulation & Salisbury)
- QC (Sterility Core I, Sterility Hood, Micro & backup/training)
- Other sites (QA Inspection, Utilities)
- Site Licensure
- Transition to new version
- Including VIP module
- Possible implementation at other company sites

- Employed LSS tools to identify areas for improvement
- Used EM Program requirements to justify the need for a software solution
- Selected MODA-EM for beta site evaluation
- Demonstrated benefits
- Financial
- Compliance
- End-user satisfaction
- Corporate support for site-wide implementation

# Acknowledgments



- QC MODA Project Team
  - Jeremy Tanner, Susan Harrison, Sue Stoops, Valerie Williams, Jennifer Lesko, Melissa McLearen, Joe Matta & Jason Smith
- Others
  - QA: Vijaya Rangavajhula, Ward Broadrup, Heath Coats
  - IT: Maria Hess, Makiese Lukama, Nicole Norwood, Greg Jilek
  - Production: Kara Anlauf, Mike Shutty, Monyque Bruchey
- MODA Technology Partners
  - Brad Turner, Michael Marshall, Steve Kirsch, Nicole Quinlan & Mike Desiderio

# Today's Cleanroom



**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.”

# Today's QC Micro Lab



**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”



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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.

- **Additional Customer-Focused Events in 2009**
  - Topics being considered:
    - Bridging the gap between LIMS and EM needs
    - Advancements in automated Endotoxin testing
    - Use of Pre-Barcoded Media in QC Micro
    - Advancements in automated Air Testing
- **Personal consultation:**  
Bob Toal, [btoal@modatp.com](mailto:btoal@modatp.com), (484) 253-1000 x133
- **Learn more:** [www.modatp.com](http://www.modatp.com)

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