

QC Micro Webinar Series

Lonza

Pfizer Achieves Efficiencies with Automated QC Micro

Rapid Testing Solutions / Lonza / 14 Dec 2010

Co-sponsor



www.labvantage.com

Today's Presenters

- **Bob Toal**
Segment Manager, Informatics
Lonza Wayne
- **Bob Voelkner**
Manager, Strategic Accounts
LabVantage Solutions, Inc.
- **Karen Grohalski**
Manager of Laboratory Operations, Quality Systems
Pfizer Global Manufacturing

60-Minute Agenda

- Lonza Overview
- 45-min Presentation
- 15-min Interactive Q&A
- Upcoming News/Events
- Wrap-up

A copy of this presentation will be made available through a follow up email.

Webinar Focus Areas

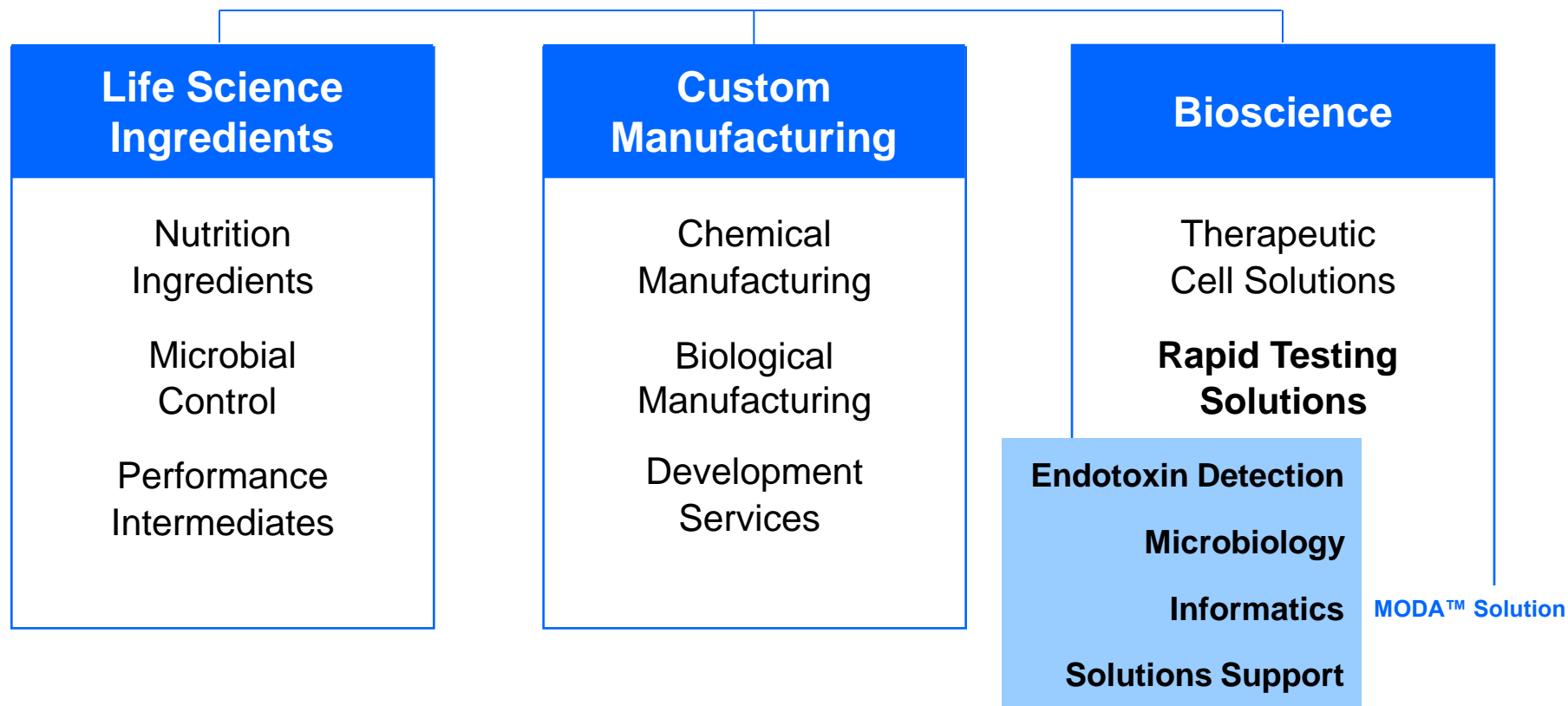
- Traditional LIMS solutions versus requirements for QC Micro
 - Need for Automation
 - Integration with LIMS
- LabVantage® and Lonza Vision to Integrate MODA™ Solution with LIMS
- Pfizer Case Study
 - Rationale to Augment LIMS with Purpose-built QC Micro Solution
 - Previous Processes; Need for Automation
 - Why Pfizer Selected LabVantage Micro/EM™, powered by MODA™
 - New Automated QC Micro Program
 - Plans for the Future



Lonza and MODA™ Solution Overview

Lonza's Life-Science Platform

Lonza



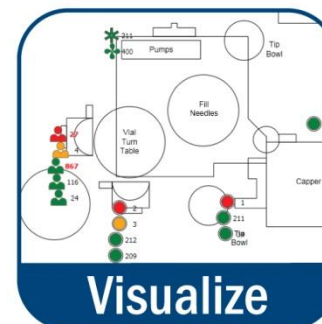
MODA™ Solution Value Proposition

■ More science. Less paper.™

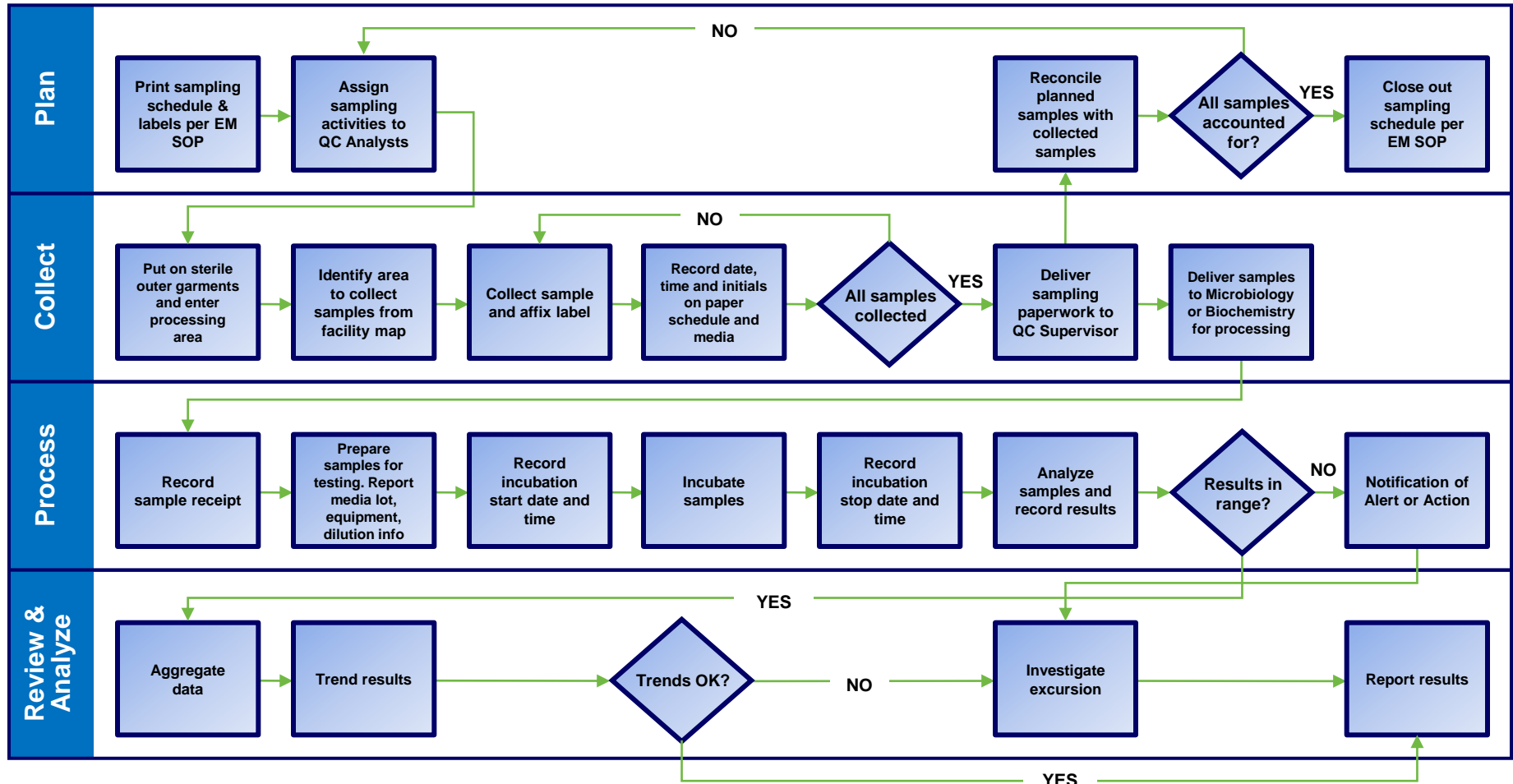
- Quickly move from paper-intensive QC Monitoring & Analysis

■ Increase operational efficiency, improve quality, reduce costs

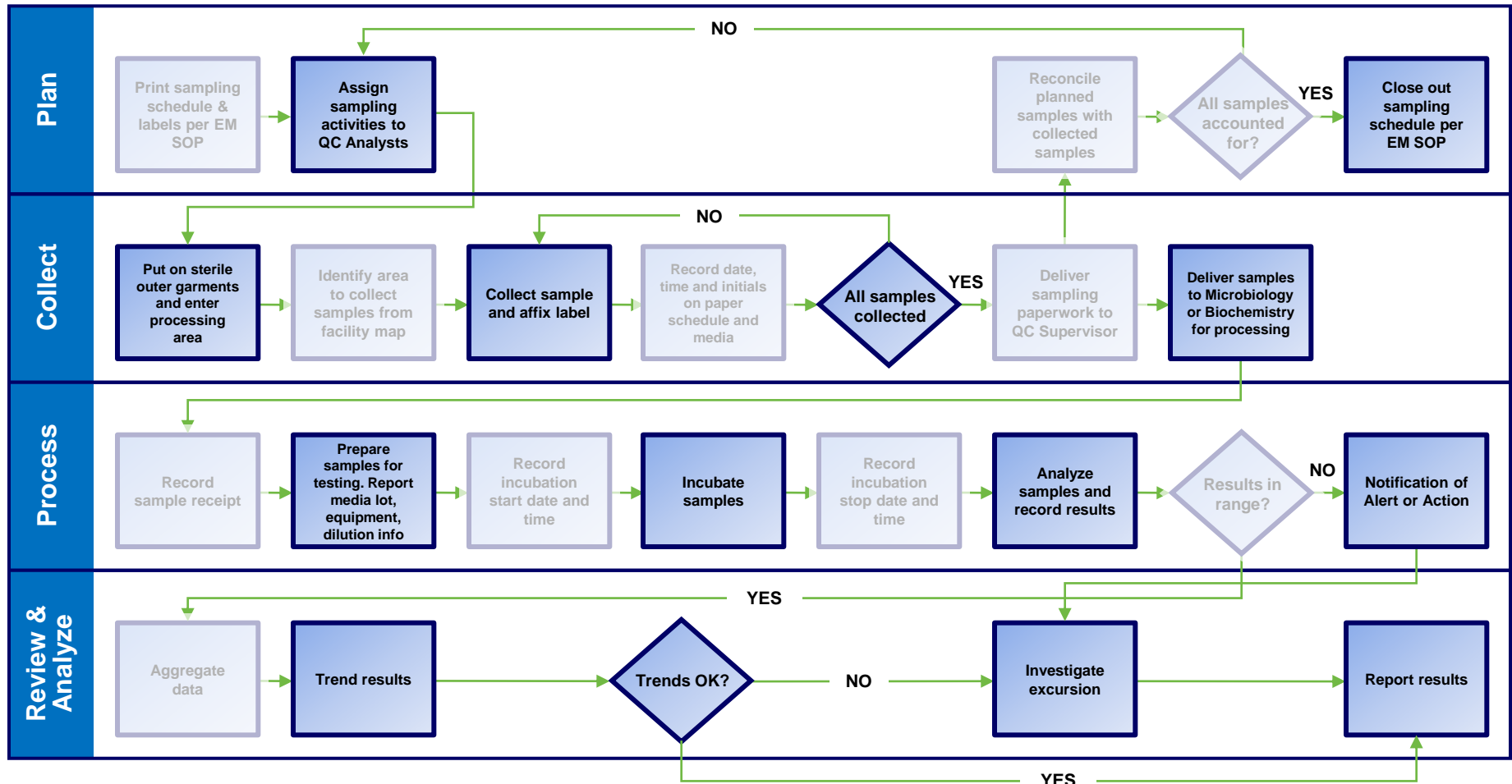
- MODA-EM™ platform offers mobile computing technology & advanced visualization tools






The Paper-based QC Process



The Paperless QC 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 |

Automated Field Data Capture

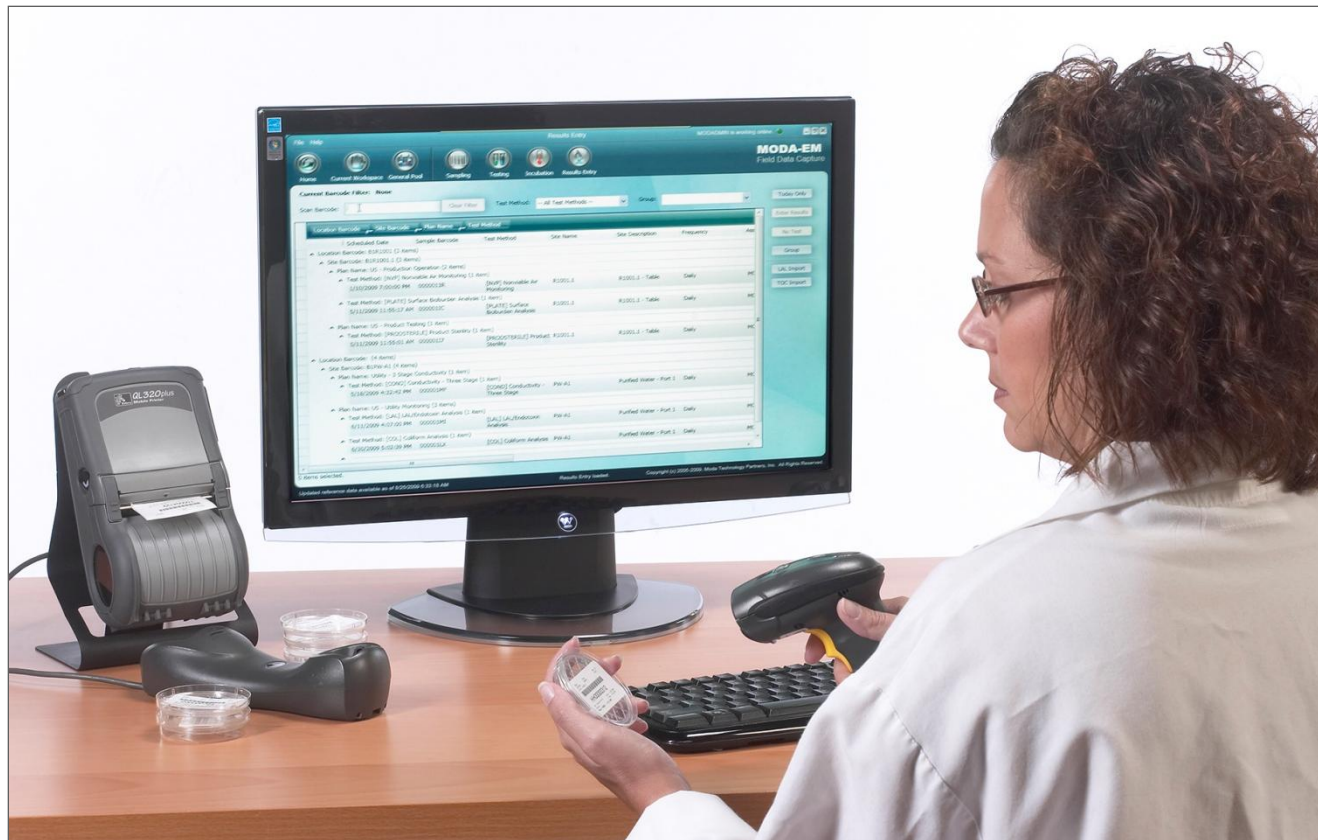


Featured: MODA-FDC™ platform, used for field data capture in clean room areas

- 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



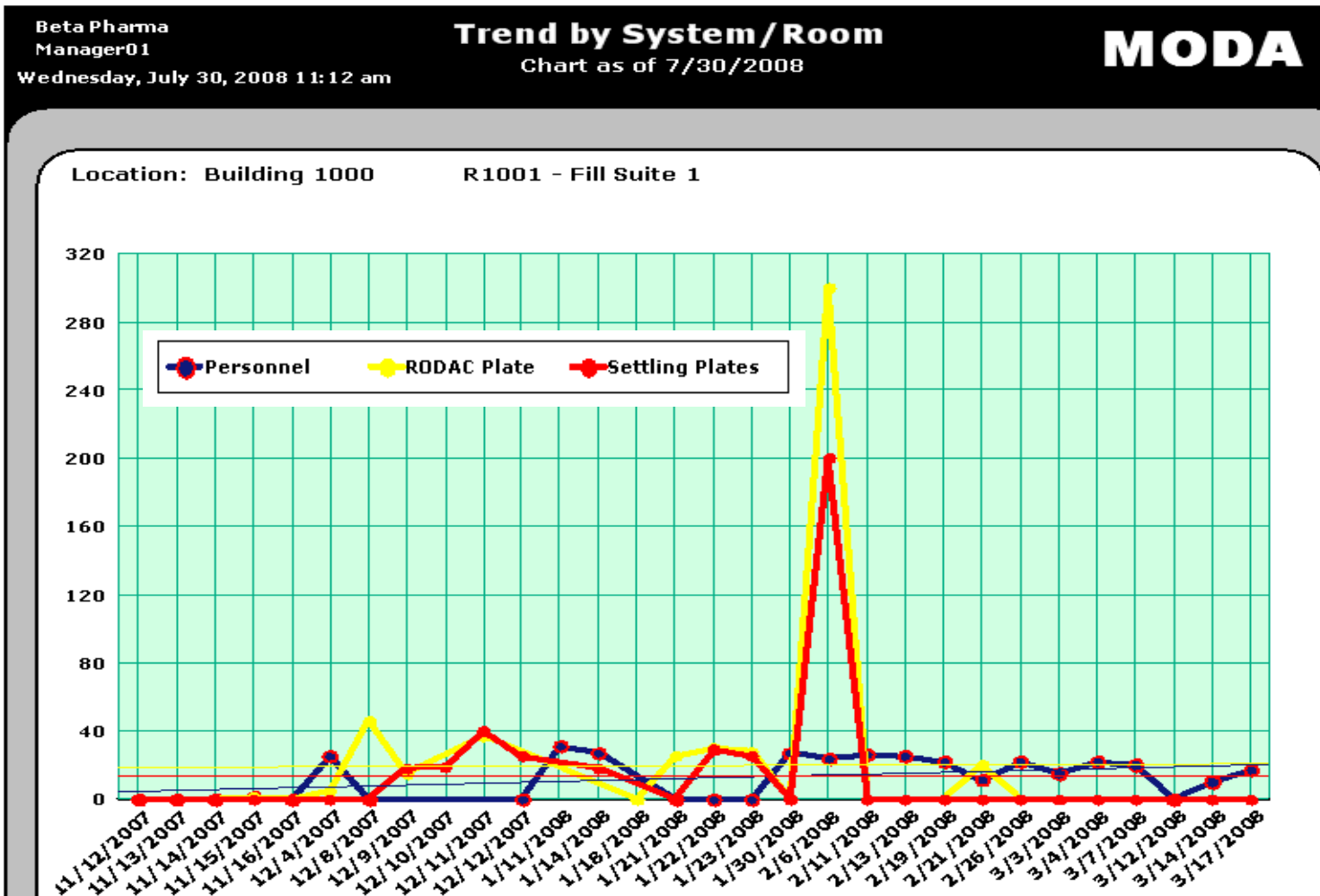
Automated Lab Processing and Reporting



Automated Reporting and Analytics

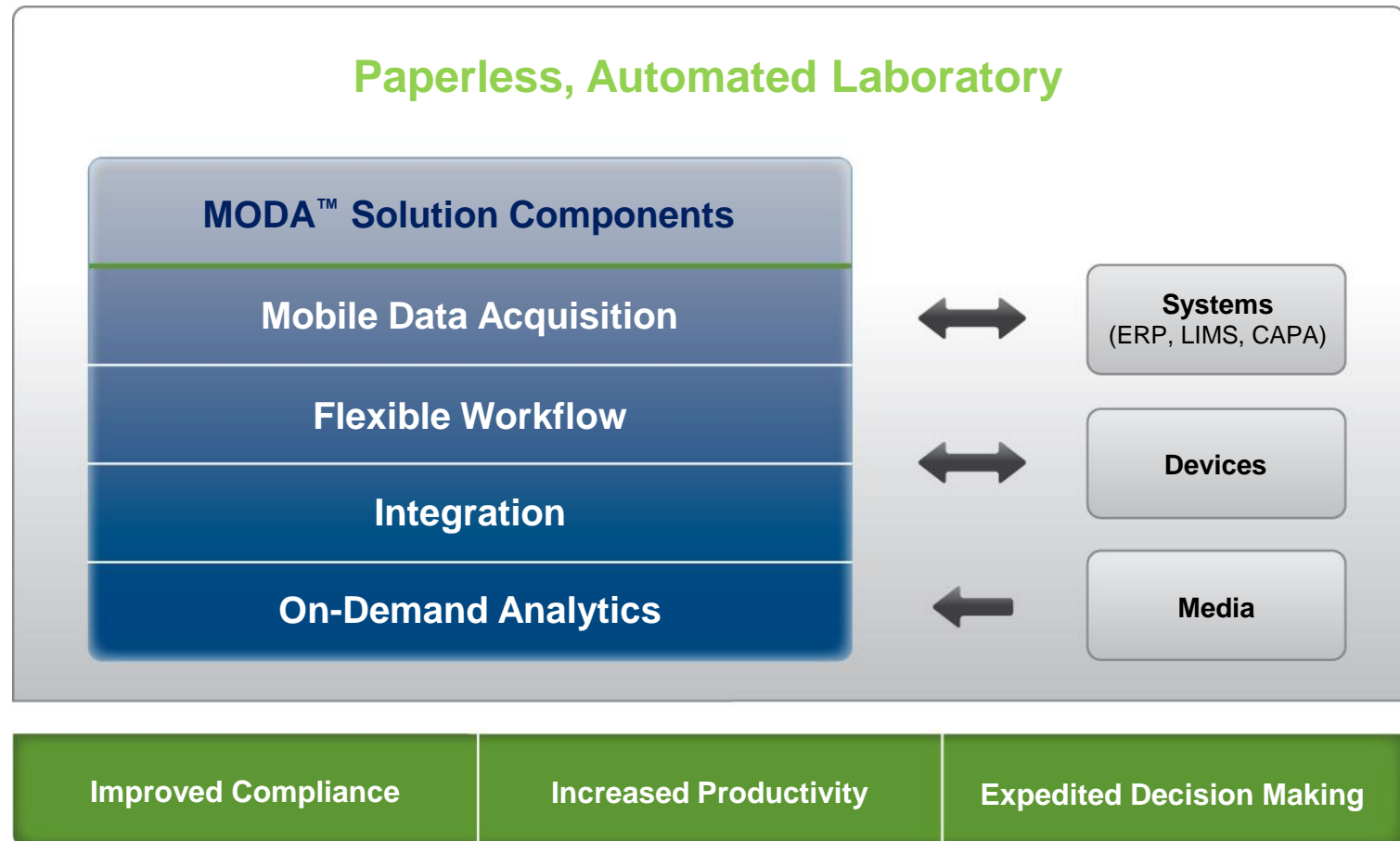
| <div> <div>Beta Pharma</div> <div>Manager01</div> <div>7/30/2008 11:04:13AM</div> </div> <div> <div>Deviation Summary</div> <div>Report Period From 11/1/2007 12:00:00AM to 3/31/2008 12:00:00AM</div> <div>MODA</div> </div> | | | | | | | | | | |
|---|-------------|----------------------|------------|---------------------------|-----------|-------------|--------------|---|----------------|-------------|
| Deviation | Sample | Sample Date | Sampled By | Test | Result | Alert Limit | Action Limit | Organism | Deviation Type | Environment |
| Building 1000 > R1001-Fill Suite 1 | | | | | Alerts: | 6 | Actions: | 50 | Total: | 52 |
| 169 | A00000040 | 12/9/2007 6:16:59PM | Analyst08 | R1001.1 - Settling Plates | 18.00cfu | 1.00 | 3.00 | | >= Action | D |
| 174 | A00000093 | 12/12/2007 6:38:00AM | Analyst08 | R1001.1 - Settling Plates | 25.00cfu | 1.00 | 3.00 | Bacillus licheniformis; Escherichia coli | >= Action | D |
| 178 | M00000106 | 1/14/2008 11:41:16AM | Manager01 | R1001.1 - Settling Plates | 18.00cfu | 1.00 | 3.00 | | >= Action | D |
| 182 | M00000263 | 1/23/2008 10:56:52AM | Manager01 | R1001.1 - Settling Plates | 25.00cfu | 1.00 | 3.00 | Escherichia coli | >= Action | D |
| 182 | M00000263 | 1/23/2008 10:56:52AM | Manager01 | R1001.1 - Settling Plates | 25.00cfu | 1.00 | 3.00 | Escherichia coli | >= Action | D |
| 185 | M00000036 | 12/11/2007 9:05:29AM | Manager01 | R1001.1 - Settling Plates | 40.00cfu | 1.00 | 3.00 | | >= Action | D |
| 187 | M00000239 | 1/22/2008 9:02:17AM | Analyst08 | R1001.1 - Settling Plates | 29.00cfu | 1.00 | 3.00 | | >= Action | D |
| 198 | M00000298 | 2/6/2008 12:08:14PM | Analyst08 | R1001.1 - Settling Plates | 200.00cfu | 1.00 | 3.00 | | >= Action | D |
| SWAB-Surface Swab | | | | | Alerts: | 0 | Actions: | 1 | Total: | 1 |
| 189 | M00000273 | 1/30/2008 9:12:48AM | Analyst08 | R1001.3 - Surface Swab | 27.00cfu | 1.00 | 3.00 | | >= Action | D |
| Building 1000 > R1004-Fill Suite 4 | | | | | Alerts: | 0 | Actions: | 4 | Total: | 4 |
| PERSON-Personnel | | | | | Alerts: | 0 | Actions: | 4 | Total: | 4 |
| 151 | R1419009301 | 11/6/2007 10:32:35PM | Analyst04 | R1004.6 - Personnel | 6.00cfu | 2.00 | 3.00 | | >= Action | D |
| 152 | R1419009302 | 11/6/2007 10:32:35PM | Analyst04 | R1004.6 - Personnel | 6.00cfu | 2.00 | 3.00 | | >= Action | D |
| 153 | R1419009303 | 11/6/2007 10:32:35PM | Analyst04 | R1004.6 - Personnel | 6.00cfu | 2.00 | 3.00 | | >= Action | D |
| 154 | R1419009304 | 11/6/2007 10:32:36PM | Analyst04 | R1004.6 - Personnel | 6.00cfu | 2.00 | 3.00 | | >= Action | D |

Automated Reporting and Analytics





MODA™ Solution Concept





Our Featured Speakers: LabVantage Solutions & Pfizer



Robert Voelkner / LabVantage / 14-Dec-2010

Robert Voelkner / LabVantage / 14-Dec-2010

LABVANTAGE BACKGROUND

- **Global provider of enterprise LIMS for over 25 years**
- **Fully independent company dedicated only to laboratory solutions**
- **Serve discovery, development, formulation, process research, raw material testing, biobanking, and quality management laboratories across multiple industries**
- **Extensive Global Presence - Dedicated Team Committed to World Class Customer Service**
- **Experienced with complex LIMS deployments with a heavy focus on highly regulated laboratories**
- **9 of top 10 pharmaceuticals use LabVantage products**
- **Over 80,000 active daily users**



LIMS – BEST FIT APPLICATION AREAS

- ❖ **Quality Management** – Complete traceability throughout the production process
- ❖ **Analytical & Testing Services** – Improving customer satisfaction and quality
- ❖ **Research & Development** – Improving new product discovery and development
- ❖ **Stability & Shelf Life Analysis** – Automating long-term shelf life studies and analysis
- ❖ **Inventory Management** – Facilitating long-term storage & enterprise location tracking
- ❖ **BioBanking & BioSpecimen Management** – Centralized biological specimen management
- ❖ **eNotebook** – Replacing paper lab worksheets with online interactive notebooks
- ❖ **Instrument Automation** – Automatically capturing and posting analytical instrument results into LIMS
- ❖ **Business Intelligence** – Data mining and analytics for lab decision support

LIMS – NOT DESIGNED FOR QC MICRO

- ❖ For years, the micro lab has not benefited the same way as the analytical lab has using commercial LIMS
- ❖ The QC micro workflow is complex and very different compared to what a LIMS does well for the analytical lab
- ❖ Historically, QC micro has either been ignored by LIMS projects or unsuccessfully forced into the same LIMS environment as the analytical lab
- ❖ As a result, manual paper-based processes have been used in QC micro to work around gaps in generic analytical LIMS
- ❖ Test results are usually manually transcribed into LIMS, spreadsheets or stored in shelves of paper binders
- ❖ The volume of samples processed at one time by a QC micro technician is much higher compared to the analytical lab making manual transcription painfully slow and error prone

QC MICRO REQUIREMENTS FOR PROCESS WORKFLOW

- ❖ **Location based data collection – not just fixed lab instruments**
- ❖ **Complex scheduling and workflow – routine and event based**
- ❖ **Paperless – No preprinted lists of tasks for sample collection**
- ❖ **Track, prevent and reduce exceptions to SOPs**
 - ❖ Track and schedule retests
 - ❖ Prevent missed samples
 - ❖ Reduce SOP non-compliance like expired media, incubation times
- ❖ **Aseptic environment (clean room) platform**
 - ❖ Data capture at point of sample collection
 - ❖ Ability to work disconnected from network
 - ❖ Specialized equipment and user interface

QC MICRO REQUIREMENTS FOR REPORTING AND ANALYTICS

- Track and trend by location, room, sampling site, person, organism, product batch/lot and any combination

Beta Pharma
Manager01

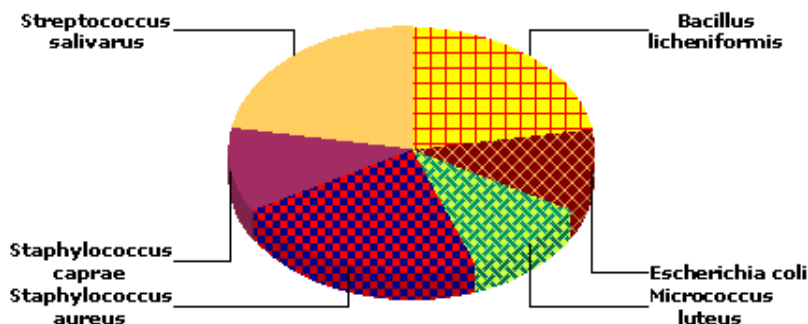
12/12/2010 6:46:38PM

Organisms By Location

Report Period from 12/1/2009 to 12/31/2010

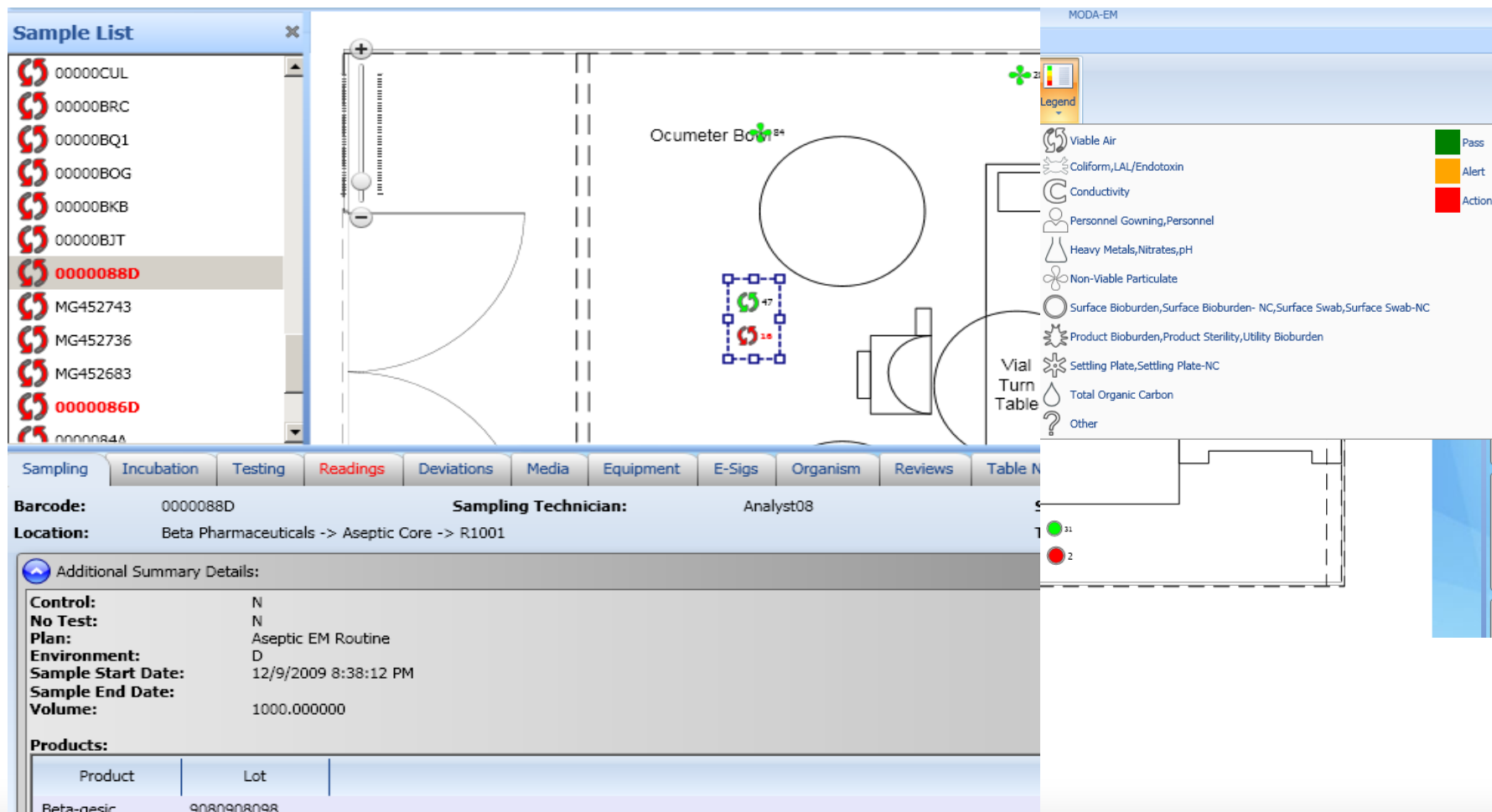
| Sample Date | Sample Barcode | Sampled By | Organism Description | Organism Characterization | Found Date | Isolate: |
|------------------------|----------------|------------|------------------------|---------------------------|------------|----------|
| Aseptic Core | | | | | | |
| R1001 | | | | | | |
| Bacillus licheniformis | | | | | | |
| 5/10/2010 12:38:58PM | 00000CY7 | Analyst08 | Bacillus licheniformis | Gram - Rods | 5/10/2010 | 10 |
| 4/30/2010 11:38:45AM | 00000CU8P1S2 | Analyst08 | Bacillus licheniformis | Gram - Rods | 4/30/2010 | 3 |
| Escherichia coli | | | | | | |
| 2/3/2010 1:52:32PM | 00000B78 | Analyst08 | Escherichia coli | Gram - Cocci | 2/3/2010 | 1 |
| Micrococcus luteus | | | | | | |
| 12/9/2009 9:28:05PM | 00000B8RP1S1 | Operator01 | Micrococcus luteus | Gram - Rods | 12/10/2009 | 5 |
| Staphylococcus aureus | | | | | | |
| 1/22/2010 4:17:45PM | 00000BQ8 | Analyst08 | Staphylococcus aureus | Gram - Rods | 1/22/2010 | 7 |

Organism Description



| | | |
|--------------------------|---|--------|
| Bacillus licheniformis | 2 | 22.2% |
| Escherichia coli | 1 | 11.1% |
| Micrococcus luteus | 1 | 11.1% |
| Staphylococcus aureus | 2 | 22.2% |
| Staphylococcus caprae | 1 | 11.1% |
| Streptococcus salivarius | 2 | 22.2% |
| Total: | 9 | 100.0% |

- Visualization – trend and correlate environment, process (i.e. water loop), across multiple tests over specified time frames



WHY NOT LIMS?

❖ Not out of the box

- ❖ No standard QC micro workflows (scheduling, sampling, incubating, testing)
- ❖ No simple answer to the variability of personnel monitoring
- ❖ Data entry not geared toward how QC micro works

❖ Higher Cost – Extra configuration work and possible customizations needed

- ❖ Workflows
- ❖ Special rules
- ❖ Reports
- ❖ Charts
- ❖ Instrument interfaces
- ❖ Ongoing support

❖ Insufficient mobile field data capture capabilities

- ❖ No off-line capabilities
- ❖ User interface not designed for gowned and gloved users
- ❖ No built-in, out of the box instrument integration



LABVANTAGE AND LONZA VISION: A BEST OF BREED TOTAL SOLUTION

LABVANTAGE AND LONZA – CLOSE WORKING RELATIONSHIP

- ❖ In 2007, LabVantage became a partner with Lonza to provide MODA™ EM with our LIMS solutions
- ❖ A purpose-built standard solution was seen as more advantageous for our customers than customizing our LIMS solution
- ❖ LabVantage has a close, trusted partnership with Lonza
 - ❖ Rebranded version of MODA™ solution by Lonza
 - ❖ Work jointly to develop new capabilities and integrations
 - ❖ LabVantage sells, implements, validates and supports the MODA™ solution for our LIMS customers
- ❖ Closely integrated solution for our SQL*LIMS and SAPPHIRE LIMS platforms

LABVANTAGE MICRO/EM™ - RIGHT TOOL FOR THE JOB

❖ Out of the box means no customization

- ❖ Purpose-built to solve needs of QC micro lab (not forced fit into LIMS)
- ❖ Fixed price best practices implementation service reduces risk and cost
- ❖ Project scope and timeline are well controlled

❖ All data (micro and analytical) reside in one database

- ❖ One single system of record for all QC/QA information
- ❖ QC micro data viewable during analytical lot release

❖ Meet IT and Lab needs

- ❖ Leverage current LIMS IT support – *Key Benefit for IT Department*
- ❖ Familiar UI with purpose built tools – *Key Benefit for QA and QC Users*

LABVANTAGE MICRO/EM™ - BUSINESS BENEFITS

| BENEFIT | DESCRIPTION |
|--|--|
| Cost Reduction | Significantly less personnel hours on data entry, paperwork, and other clerical functions. |
| Productivity Improvements | Collect and process more samples with the same or fewer personnel. Refocus personnel on value-added activities. |
| Enhanced Compliance | Reduced errors and process deviations; faster turnaround of information for CAPA activities and product release. |
| Enhanced Reporting and Analysis | Capability to report on combined set of QA and QC data for product/batch release. Reporting and analysis tools existing users are familiar with. |

LABVANTAGE MICRO/EM™ - INFORMATION TECHNOLOGY BENEFITS

| BENEFIT | DESCRIPTION |
|-------------------------------|---|
| Ease of Implementation | COTS software built for regulated environments with full complement of validation accelerators versus custom alternatives |
| Ease of Administration | Single data base server to administer and support for QA and QC organizations |
| Ease of Audit | Solution provides a single system of record with complete audit trail for all QA and QC data |
| Ease of Support | LabVantage provides a single, first line of support for LIMS and MICRO/EM |



K Grohalski / Pfizer / 14-Dec-2010

K Grohalski / Pfizer / 14-Dec-2010

QUICK FACTS: PFIZER

- ❖ **World's largest research based pharmaceutical company**
- ❖ **Headquarters based in New York, NY**
- ❖ **Manufacturing facilities around the world**
- ❖ **Our global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products**
- ❖ **2006 Project initiation to develop a global approach to roll-out SQL*LIMS**
- ❖ **December 2008 first site goes live with LabVantage SQL*LIMS – 25 sites live**
- ❖ **2008 Project initiation to provide a complete environmental solution**
- ❖ **May 2009 – MODA™ solution (LabVantage Micro/EM™) goes live in our first region**

SCOPE OF PFIZER WATER UTILITY TESTING PROGRAM

Scope of program - typical facility:

❖ Water Utility Program consists of monitoring:

- ❖ Water for injection (WFI), distilled water, potable water, purified water etc.

❖ Test methods include:

- ❖ Total viable content (TVC), Endotoxin, E-coli, Total organic compounds (TOC), Heavy metals, Nitrates, and includes stage 1,2 and 3 Conductivity testing etc.
- ❖ Mini-tab reporting for annual and quarterly water reports
- ❖ Water Certificate of Analysis to facilitate inter-company testing

Water samples:
52,000 samples tested per year (once qualified)

Chemistry/Micro and Production labs:

8 x 5 with ~100 employees supporting production operations

SCOPE OF PFIZER QC MICRO ASEPTIC PROGRAM

Scope of program - typical aseptic facility:

- ❖ **QC Micro program consists of monitoring:**
 - ❖ All classified facilities (non-aseptic areas)
 - ❖ Can facilitate all grade areas
 - ❖ All critical utilities: WFI, Reverse osmosis (RO) water, Clean Steam, Compressed Gases
 - ❖ Aseptic fill facilities
 - ❖ Personnel monitoring
 - ❖ Process equipment, in-process product bioburden
- ❖ **Test methods include:**
 - ❖ Microbial and particulate testing for facilities
 - ❖ Microbial and endotoxin testing for process equipment
 - ❖ Microbial, endotoxin, and USP/EP/JP chemistry testing of critical utilities

QC workload:
360,000+ samples
tested each year

QC/Micro. lab:
24 x 7 with ~70
employees
supporting
production
operations

PAST PROCESSES AT PFIZER

- ❖ **SQL*LIMS Scheduler was used for sample scheduling and data entry/reporting**
 - ❖ The SQL*LIMS application was not designed for Environmental Monitoring workflow
- ❖ **EM data were distributed over several different platforms**
- ❖ **The following additional systems were being used as part of the Environmental Monitoring solution:**
 - ❖ *Excel Spreadsheets*—used for recording and trending In-Process sample results
 - ❖ *Microsoft Access DB*—used for storing Microbial Identification test results
 - ❖ Certificate of Analysis were manually written (inter-company testing)

NEED FOR QC AUTOMATION

ISSUE

- ❖ Paper-intensive process for EM and Water/Utility sampling
- ❖ Compliance errors resulting in additional paperwork and time for corrective actions
- ❖ Significant time delays in generating needed reports and analysis for management and CAPA activities
- ❖ Trending was a significant activity at sites and took approximately 2.5 months each year to complete.
- ❖ Sample labels were manually written

SOLUTION REQUIREMENT

- ❖ Remove paper and clerical steps from the QC Micro Process
- ❖ Enforced compliance via automated workflows with validation checks at each step
- ❖ Increase availability of report and analysis tools and reduce the time to produce meaningful information
- ❖ Mini-tab interface used to generate reports instantly
- ❖ System generated labels and reports

NEED FOR QC AUTOMATION

ISSUE

- ❖ **Difficulty coordinating and harmonizing QC procedures and practices across sites**
- ❖ **Fragmented array of systems and automation across sites; difficulty planning, implementing, and supporting information technology for QC Micro. on a global basis**

SOLUTION REQUIREMENT

- ❖ **Standardize and harmonize QC Micro monitoring test procedures**
- ❖ **Capability for global deployment**
- ❖ **Integrate with corporate Statistical process control (SPC) tools**
- ❖ **Integrate with the global LIMS platform for C of A and other reports**
- ❖ **Allow centralized IT planning and support of QC Micro operations by global LIMS group**
- ❖ **Coordinate releases and features with the global LIMS release strategy and across individual sites**

PFIZER'S SELECTION PROCESS

- ✓ **Worked with business to determine needs**
- ✓ **Evaluated existing LabVantage SQL*Scheduler module and identified gaps**
- ✓ **LabVantage proposed integrated solution with LabVantage Micro-EM™ solution (powered by MODA™)**
- ✓ **Evaluated other available software solutions**
- ✓ **Demonstrated LabVantage Micro/EM capabilities for key PGM QC Micro sites**
- ✓ **LabVantage Micro/EM was best fit for key requirements and user needs**
- ✓ **Acquired management approval and funding**

PFIZER GLOBAL QC AUTOMATION PROJECT

- ❖ **Integrated with global SQL*LIMS instances**
- ❖ **Began with a regional implementation in Europe**
- ❖ **Solution is installed at Pfizer's regional data centers and supported and managed by Global Support team**
- ❖ **Have a rollout plan for Manufacturing's aseptic production facilities**

CURRENT STATUS WITH PFIZER GLOBAL DEPLOYMENT

- ❖ **Validation completed 1st Quarter 2009**
- ❖ **6 sites using MODA™ solution (LabVantage Micro/EM™) in production**
- ❖ **Aseptic processing go live scheduled for 1st quarter 2011**
- ❖ **System is operated and maintained by site EM personnel**
 - ❖ IT is available for system support and troubleshooting.

NOW: AUTOMATED FIELD DATA CAPTURE

LabVantage Micro/EM™ with 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



BENEFITS SUMMARY AT PFIZER

- ✓ Reduced data entry errors
- ✓ Real time data entry
- ✓ EM results available to process owners faster
- ✓ Eliminated scheduling errors
- ✓ Part 11 Compliance
- ✓ Reduced personnel related deviations

✓ Enhanced reporting and analytics capabilities

✓ Template setup for test methods via automated tool

✓ Support for investigation activities

✓ Fewer corrections and documentation errors

✓ Quicker reviews

✓ Notifications for deviations and missed samples

✓ Instrument integration

PFIZER PATH FORWARD

- ❖ **Investigating potential to expand use of application in manufacturing process control areas**
- ❖ **Looking to LabVantage/Lonza to integrate particle counters into system to allow automatic download of nonviable test results directly into MODA™ software.**

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.

Lonza

Questions & Answers

Upcoming News & Events

- **2011 Lonza QC Micro Webinar Series**
 - Jan 19: *Innovations in QC Using PyroGene™ rFC Assay*
 - Other customer-focused topics under consideration for 2011
 - Advancements in Automated Water Testing
 - Non-sterile Manufacturing Quality Control
- **Global QC Automation Tour featuring MODA™ solution**
 - Starts in Feb 2011 in city near you; look for Evite
 - Excellent opportunity to learn more and network
- ***Pharmaceutical Technology* article**
 - Jan 2011: *Improving the Quality of Product Release: The Role of Quality Control Automation*

Wrap-up

Personal Consultation

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MODA Test Drive. Do you qualify?

www.lonza.com/testdrive

Learn more about MODA Solution: www.lonza.com/moda

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Thank You