QC micro webinar series

Auxilium's QC micro automation using MODA™ solution

Lonza / 25 October 2011

Today's Presenters

- Bob Toal
  Segment Manager, Informatics
  Lonza Wayne

- Nicole Quinlan
  Sr. Manager, IT Laboratory Systems
  Auxilium Pharmaceuticals, Inc.

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

- State of the industry: Scope of a typical QC micro program
- Auxilium's paper-based processes & need for automation
- Auxilium's key requirements for a new solution
- Why Auxilium selected MODA™ solution; Implementation/validation of MODA™ platform
- Auxilium's current paperless QC micro program & plans for the future

Lonza and MODA™ Solution Overview

Lonza's Life-Science Platform

MODA™ Solution Value Proposition

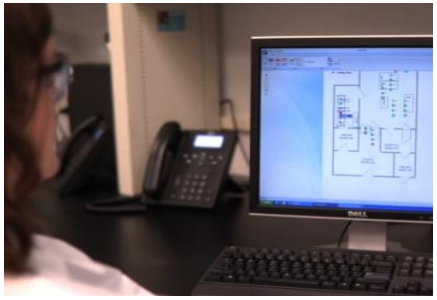
- **More science. Less paper.™**
  - Quickly move from paper-intensive QC Monitoring & Analysis

- **Increase operational efficiency, improve quality, reduce costs**
  - MODA-EM™ platform offers mobile computing technology & advanced visualization tools

Capture »

Track »

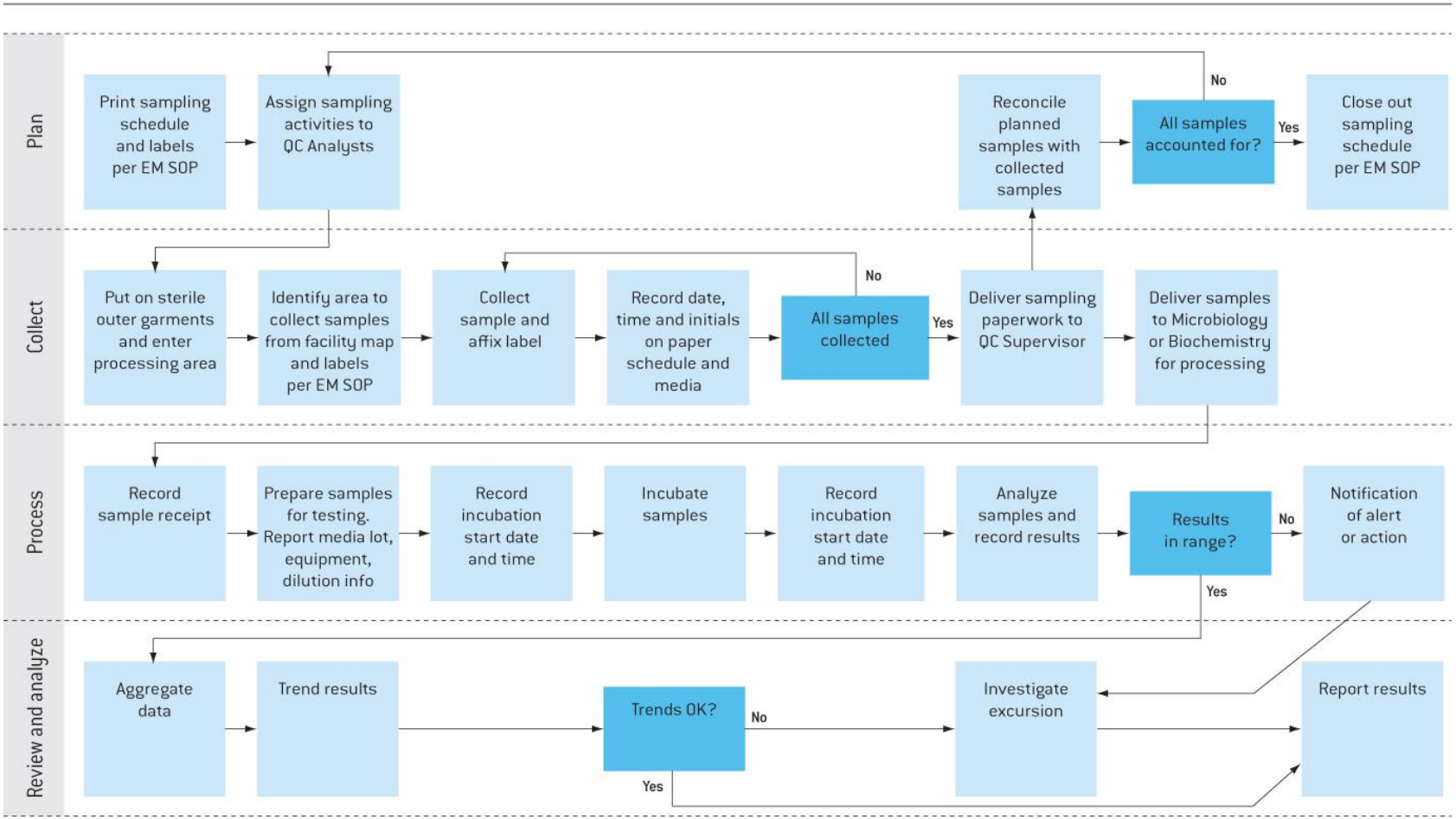
Visualize »



Trend »

Lonza

The Paper-based QC Process



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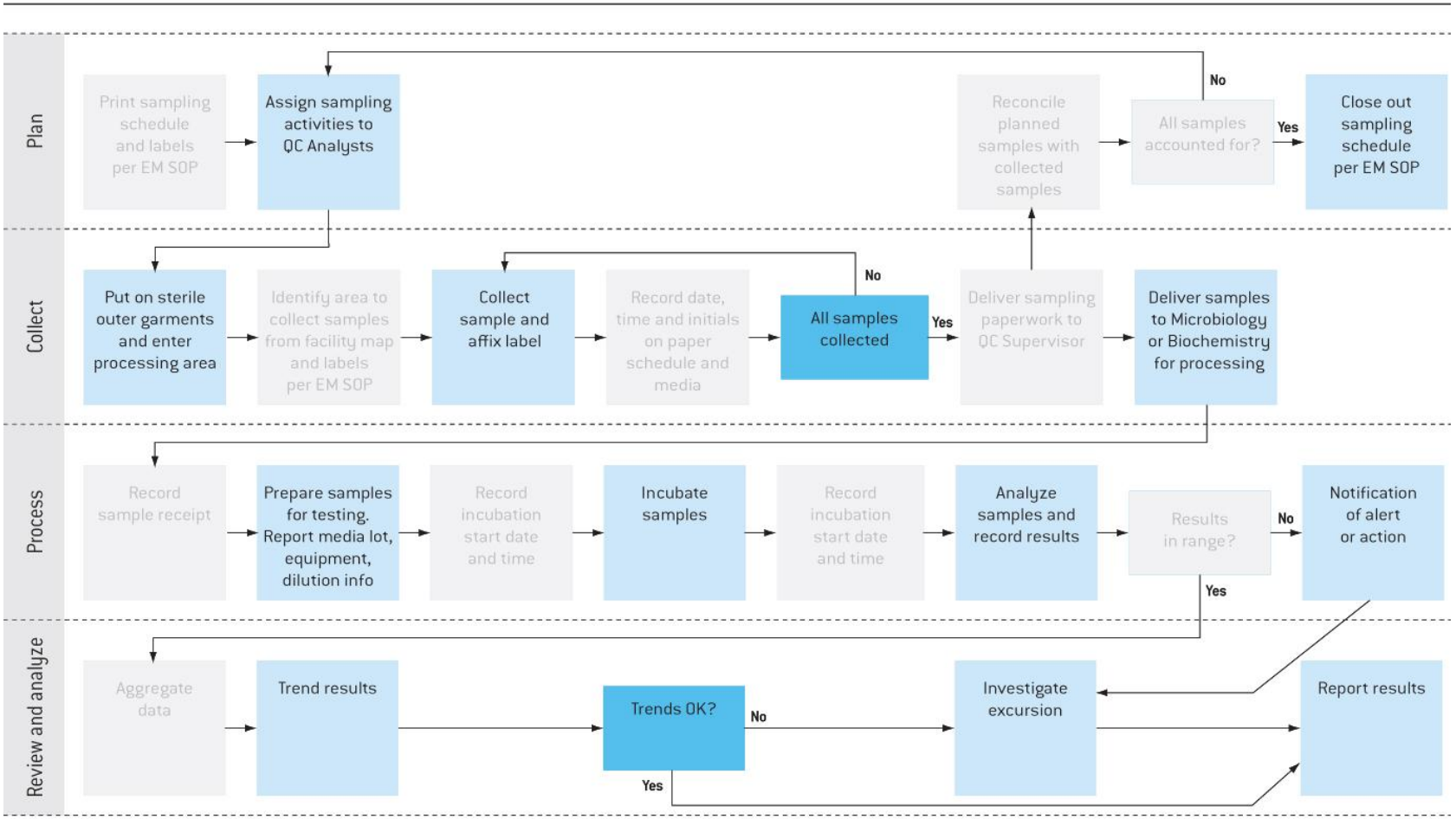
The Paperless QC Process—*11 Steps Removed*



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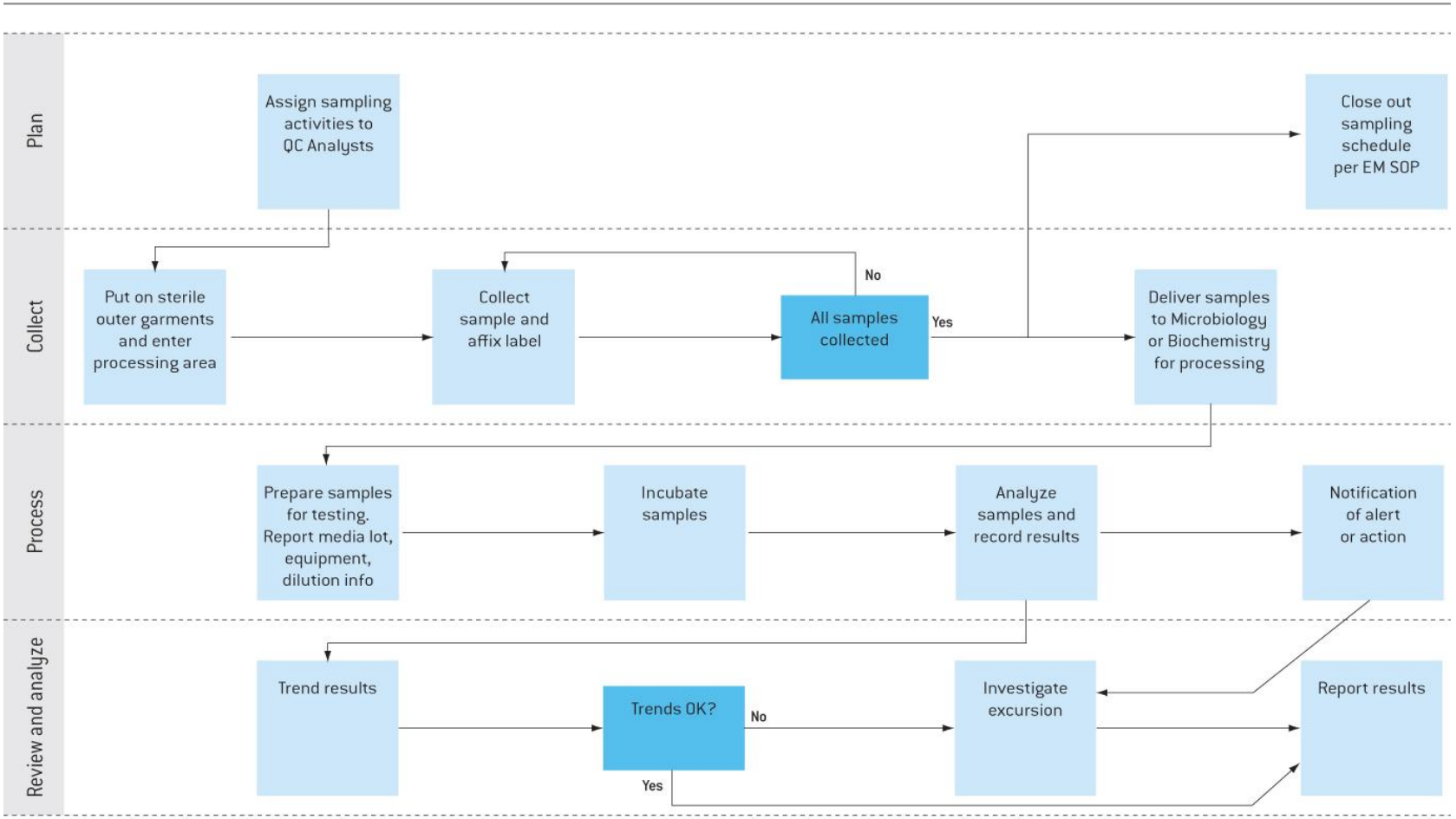
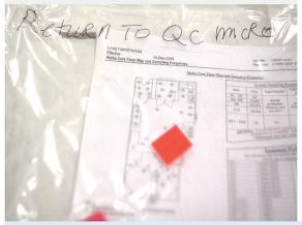
The Paperless QC Process



Paperless Efficiency Example

Paper-based

Record on paper template	Record on plate	Reconcile media and template	Enter data into Excel/LIMS
			
6 hours		1 hour	1 hour

Paperless

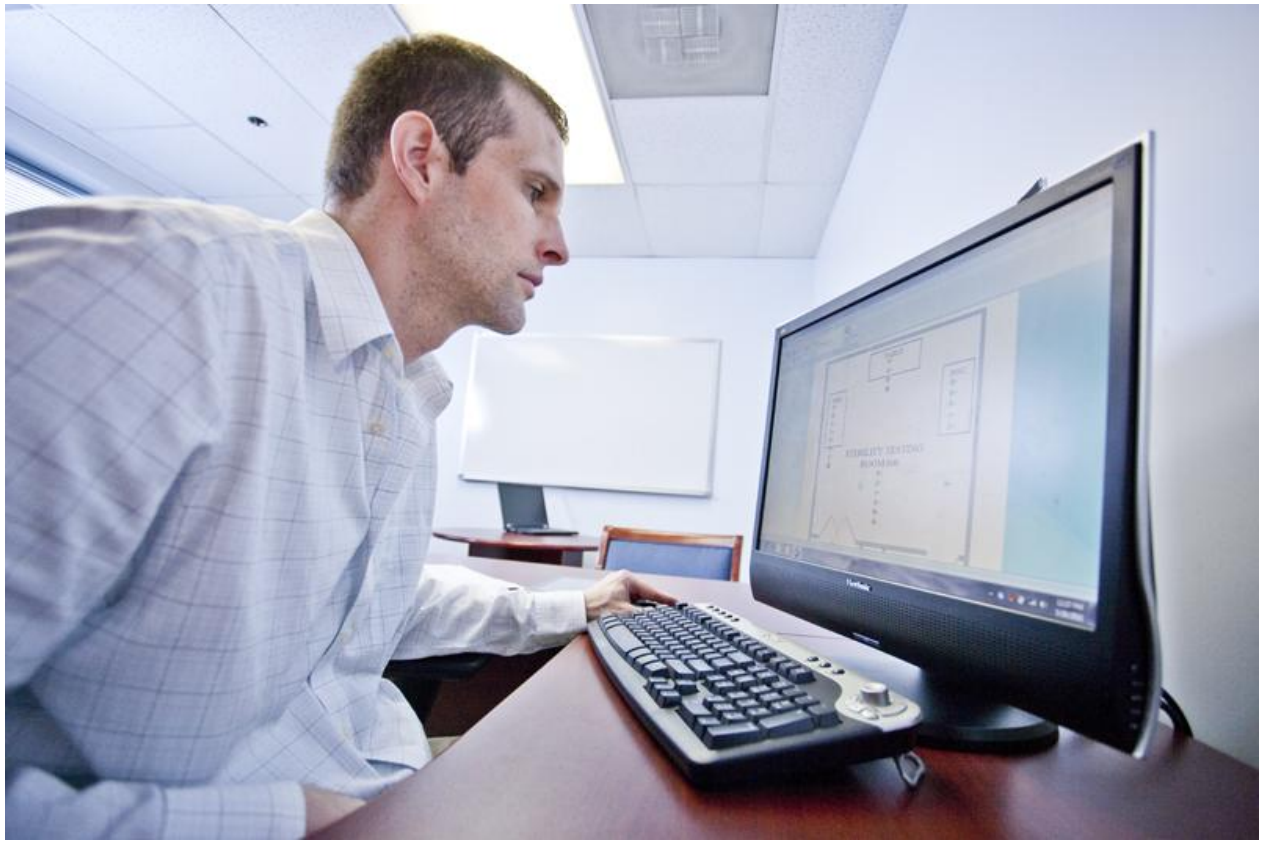
Scan room or site	Select sample and print labels	Send to repository	
			Paper-based **8 hours** – Paperless **4 hours** = Savings **4 hours**
4 hours		Finished	

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

Beta Pharma
Manager01
7/30/2008 11:04:13AM

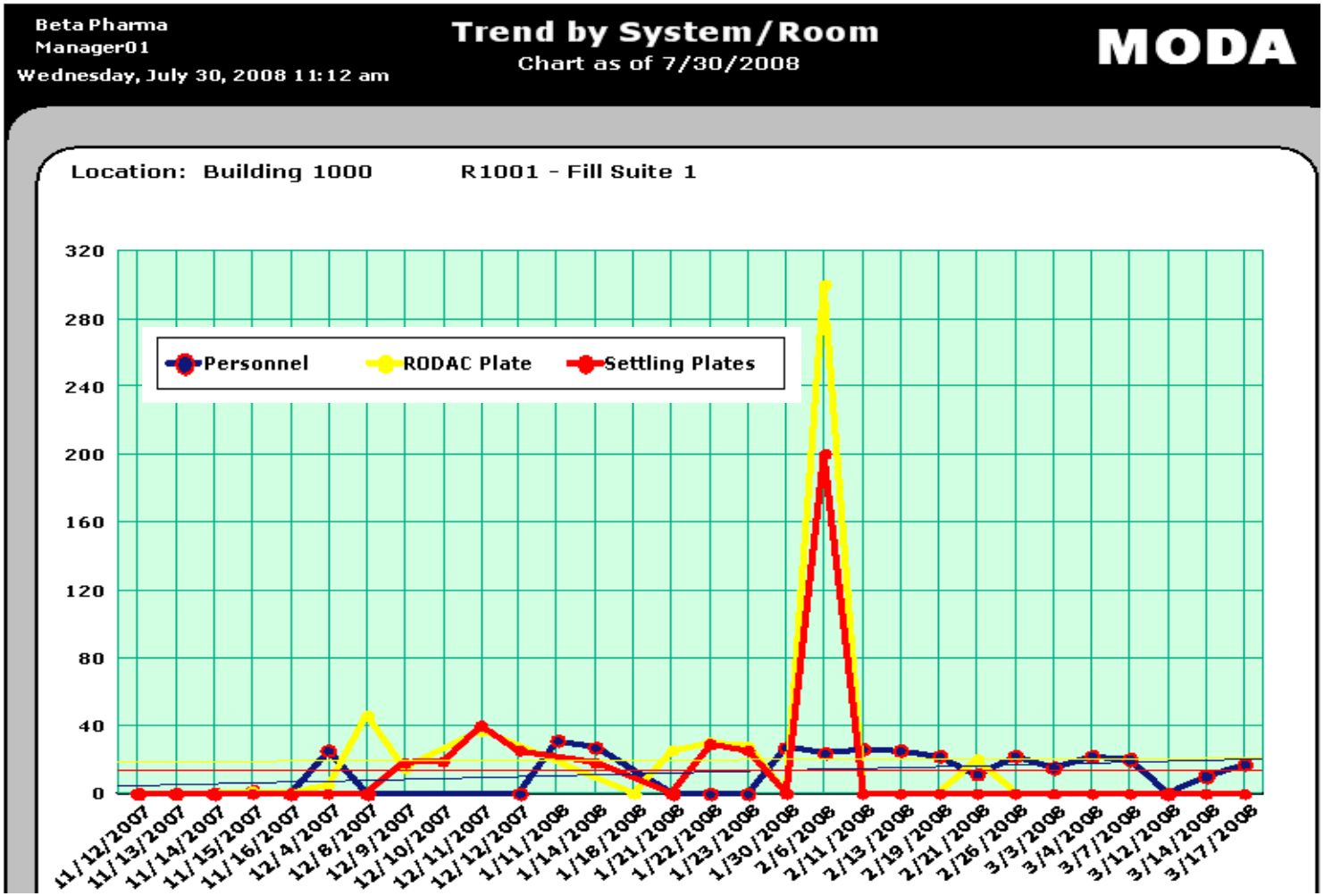
Deviation Summary

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

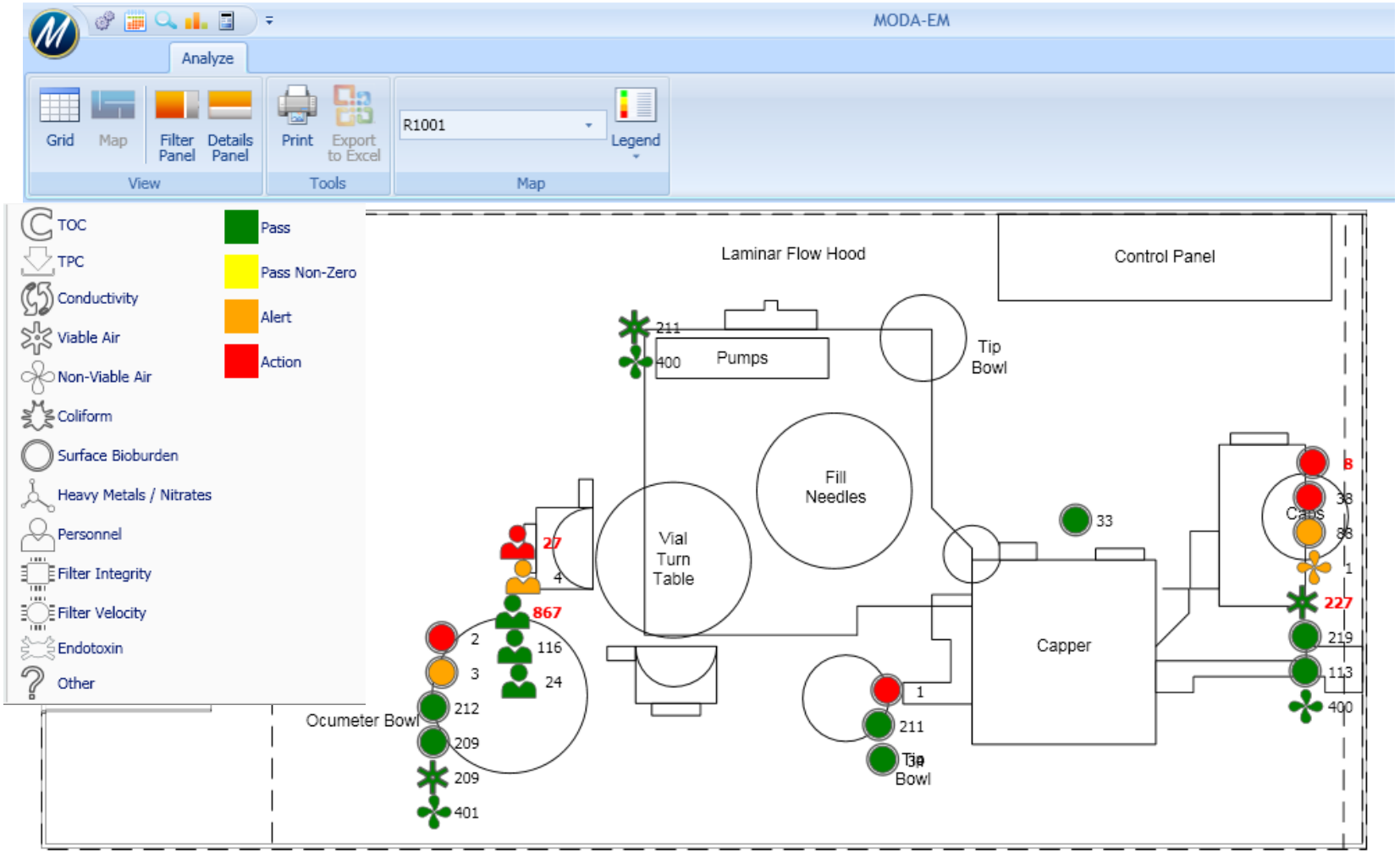
MODA

Deviation	Sample	Sample Date	Sampled By	Test	Result	Alert Limit	Action Limit	Organism	Deviation Type	Environ-ment
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



Automated Reporting and Analytics



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Our Featured Speaker:

Nicole Quinlan – Auxilium Pharmaceuticals

AUXILIUM

Innovations for Life®

Transition to a Paperless QC Microbiology Laboratory

Agenda

- Scope of the Auxilium QC Micro Program
- Previous Processes & Need for Automation
- Key Requirements for New Solution & Selection Process
- Implementation & Validation
- Current State & Plans for Future

Quick Facts:
Auxilium Pharmaceuticals, Inc.

- Auxilium was founded in 1999 (NASDAQ: AUXL)
- Specialty Biopharmaceutical Company
- Corporate Headquarters in Malvern, PA
- Xiaflex® Manufacturing and QC Laboratories in Horsham, PA
- Our Products:
  - **TESTIM®** is used to treat adult males who have low or no testosterone
  - **Xiaflex®** is the only FDA approved nonsurgical treatment for adults with Dupuytren's Contracture with a palpable cord
    - Xiapex® (our EU partner's brand name) received European Union approval from the European Commission in 2011

Regulatory Expectations – FDA

- "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"
- "Written procedures should define the system whereby the most responsible managers are regularly informed and updated on trends and investigations"

* *Guidance for Industry*
Sterile Drug Products Produced by Aseptic Processing
– Current Good Manufacturing Practice

Regulatory Expectations – Electronic Records

- Regulations and Guidance's
  - 21CFR Part 11 *Electronic Records ; Electronic Signatures – Scope and Application*
  - Annex 11 *Computerized Systems*
  - ISPE *GAMP 5 A Risk Based Approach to Compliant GXP Computerized Systems*
  - PIC/S *Good Practices for Computerized Systems in Regulated "GXP" Environments*
  - PDA Technical Report No. 31 *Validation and Qualification of Computerized Laboratory Data Acquisition Systems*

Regulatory Expectations – Electronic Records

- Ensure the accuracy, integrity, and security of the data
- Ensure data is retrievable in an agency inspection compatible format
- Validation Model
  - Based on a scientific, documented, risk assessment
  - Based on an understanding of the supported process and products
  - Verifies the system is fit for use based on the user requirements

Scope of QC Micro Program

EM & Utility Monitoring

- Microbial and Particulate Monitoring for Manufacturing Facility & Personnel
- Microbial, Endotoxin, and Chemistry testing of all critical utilities: WFI, RO water, Clean Steam, Nitrogen, Compressed Gases

In Process Product Testing

- Microbial and Endotoxin testing of all in process product
- Working and Master Cell Bank testing
- Final Product Release testing

8 Analysts working across 1.5 Shifts in 2 Micro Labs

Paper Based Processes

- Scheduling and work assignment performed manually by shift supervisor
- Controlled Paper Forms used to record results
- All reports compiled manually, requiring data verification
- All trending performed manually

Automation Justification

- **Large volume of paperwork** increases probability of data handling and paperwork errors
- **Data entry and data review** for reporting & trending was 100% manual
- **Manual paperwork review process** resulted in a measureable lag time between test completion and final reporting

Key Rqts: New Solution (1 of 2)

Paperless EM lifecycle	**All sample and testing information is entered directly into computerized system at time of occurrence ("real time"). No reconciliation of transcription process required.**
Immediate access to EM results	**Process owners will have access to test results immediately after final readings due to results being entered directly into system.**
Greater flexibility in trending and reporting results	
"User Friendly"	**Designed for use by lab technicians actually performing EM work.**
Automatic notification of excursions through the use of system generated emails	

Key Rqts: New Solution (2 of 2)

Mobile work stations for technicians to access system from manufacturing cleanrooms in the plant.

Custom and ad hoc reporting for real-time and historical data analysis.

Automatic tracking of sample and EM process.

Scheduling of tasks; barcode label printing; sample collection; incubation; and testing.

Notify lab supervisors if scheduled samples are not collected.

Automatic rescheduling of samples based on limits.

Permit lab supervisors to easily schedule ad hoc & repeat samples.

Implementation & Validation

1. Install MODA in Development Environment
2. Configure MODA with Test Methods & Master Data (incl. Sites, Alerts/Actions, Sampling Plans, etc.)
3. Test Method walkthrough reviews with Micro SMEs
4. Micro SMEs perform hands on evaluation & configuration review
5. Prepare full SDLC documentation for a configured system (GAMP5 Category 4)
6. Fully validate in the QA environment (IQ, OPQ)
7. Conduct End User Training
8. Perform Installation Qualification in Production
9. Conduct Parallel Testing in Production Environment
10. Execute Cutover Plan & Go Live

Current Status

- ✓ Install MODA in Development Environment
- ✓ Configure MODA with Test Methods & Master Data (incl. Sites, Alerts/Actions, Sampling Plans, etc.)
- ✓ Test Method walkthrough reviews with Micro SMEs
- ✓ Micro SMEs perform hands on evaluation & configuration review
- ✓ Prepare full SDLC documentation for a configured system (GAMP5 Category 4)
6. Fully validate in the QA environment (IQ, OPQ)
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Looking Forward

- Future Benefits and Sustainable Compliance

Our Future

- Automated field data capture
- Automated lab processing
- On-demand reporting

Benefits of MODA-EM™ Solution

- Workflow driven per SOPs and Test Methods
- Eliminated data entry and transcription errors
- Real time data entry – with or without network connectivity
- MetOne Nonviable integration
- EM results available to process owners faster
- Eliminated scheduling errors
- Part 11 / Annex 11 compliance
- Reduced personnel related deviations
- No wasted time locating paperwork
- Advanced support for investigation activities
- Fewer corrections and documentation errors
- Quicker reviews
- Notifications and automatic rescheduling for deviations
- Preventive notifications before samples are missed
- System generated final results reports for LIMS submission
- Enhanced reporting and analytics capabilities
- Visualization – results overlaid on facility maps

cGMP Compliance

Paper-Based System

Significant number of documentation errors

Long turn around time for processing data

Paper presents particulate and microbial contamination risk

GMP Compliance Risk

MODA™ Solution

- ✓ **Eliminates documentation errors**
- ✓ **Short-turn around time for processing data**
- ✓ **Clean room compatible equipment reduces contamination risk**
- ✓ **Sustainable GMP compliance**

21 CFR Part 11 / Annex 11 Compliance

Paper-Based System

Spreadsheets for data reporting is not validated

No control of changes in spreadsheets

No electronic signature for changes and approvals

All users have all privileges

Data stored in binders that are stored on and off site

MODA™ Solution

- ✓ **Validated system**
- ✓ **Audit trail tracks all changes/records**
- ✓ **Electronic signature for all major steps to enable quick and clear traceability**
- ✓ **Varying levels of access to system dependent upon job function**
- ✓ **Data stored on servers that are backed up daily**

Trending/Report Generation Compliance

Paper-Based System

Substantial QC and QA hours per month after data entry

Limited Scope of Trending Reports

No Formal way of tracking growth

Difficult to extract lot-specific data

All trending performed by QC for QA and Manufacturing

MODA™ Solution

- ✓ **Quick and efficient trending in real time**
- ✓ **Wide array of trend report formats**
- ✓ **Growth can be trended by person, site, room, facility**
- ✓ **lot-specific reporting for Contract Manufacturing**
- ✓ **Ease of trending allows others (QA, Manufacturing) to perform their own trending**

Our Justification

- **Large volume of paperwork** increases probability of data handling and paperwork errors
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Our Future

- **No paperwork**
- **cGMP compliant real time data acquisition** to decrease probability of data handling errors
- **21CFR11 and Annex 11 compliant** records reduce data entry & transcription reviews
- **Real-time report generation** to eliminate non value adding lag time between test completion and final reporting

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.

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Questions & Answers

Upcoming News & Events

Future webinars (topics under consideration)

- Non-sterile manufacturing quality control
- Process optimization – making the business case

Wrap-up

Personal consultation

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

Lonza

Thank You