Lonza's Paperless EM Success & Acquisition of MODA

Rapid Testing Solutions / Lonza / 20 July 2010

Today's Presenters

- **Douglas Danne**

  Head, Rapid Testing Solutions, Lonza Bioscience

- **Bob Toal**

  Segment Manager , Informatics, Lonza Wayne (formerly MODA)

- **Michael Goetter**

  Director, Informatics Strategy, Lonza Wayne (formerly MODA)

- **Susan Harrison**

  Senior Manager, Microbiology, Lonza Walkersville

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

- Lonza's acquisition of MODA Technology Partners

- MODA™ solution overview

- Paperless EM case study: Lonza's Walkersville facility

  - Update: Lean Six Sigma Initiative using MODA™ product line

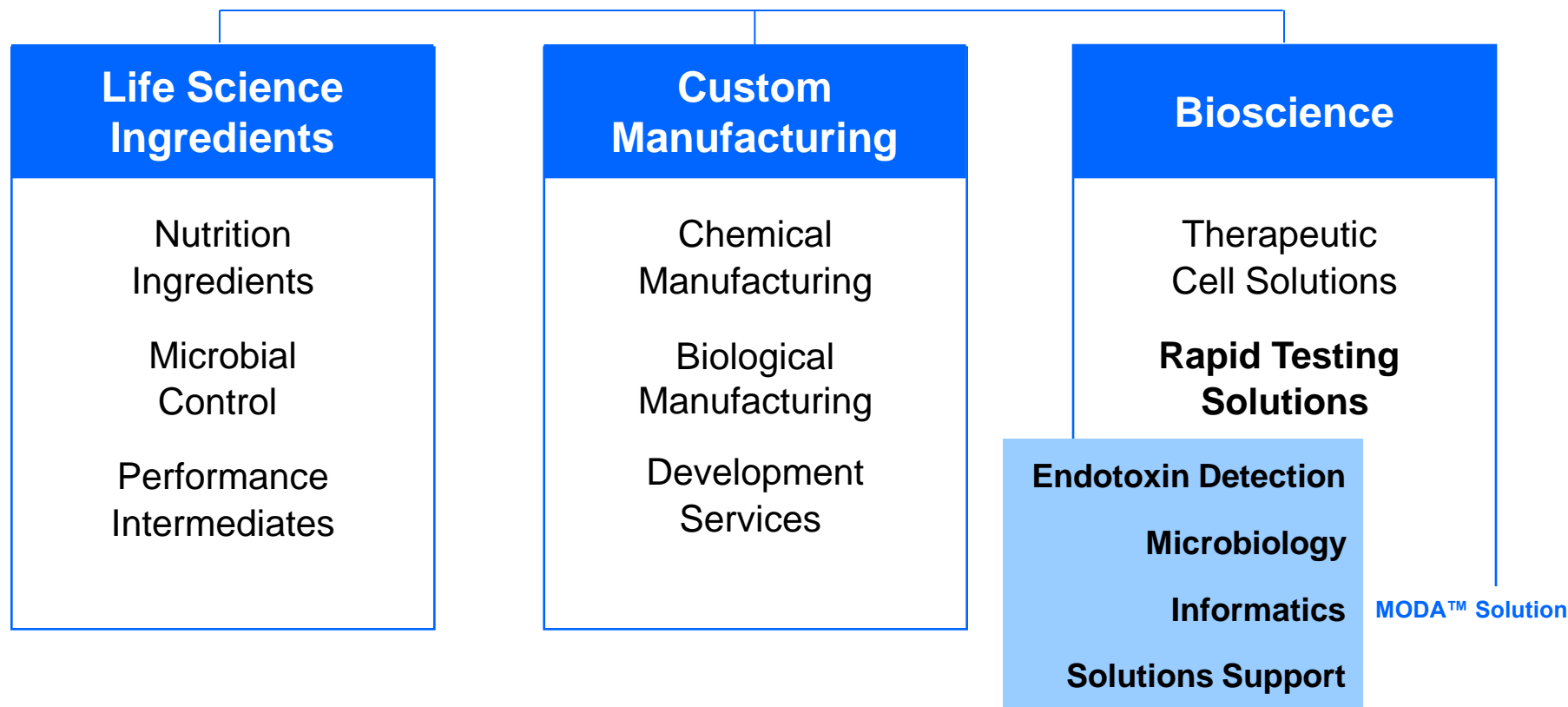 - ROI: Financial, Compliance, User Adoption

Lonza

Lonza Acquisition of MODA

D Danne / Lonza / 20 July

Lonza's Life-Science Platform

Lonza

Life Science Ingredients	**Custom Manufacturing**	**Bioscience**
Nutrition Ingredients	Chemical Manufacturing	Therapeutic Cell Solutions
Microbial Control	Biological Manufacturing	**Rapid Testing Solutions**
Performance Intermediates	Development Services	

Endotoxin Detection

Microbiology

Informatics — MODA™ Solution

Solutions Support

Rapid Testing Solutions

- **Endotoxin Detection** - LAL-based assays, sustainable recombinant Factor C technology, plate readers and robotic liquid handling systems

- **Microbiology** - Includes the microCompass™ system, a qPCR-based method that detects bacteria, yeast and mold in less than six hours with applications for sterility and bioburden testing

- **Informatics** - Integrated and flexible software solutions, including the WinKQCL® system and now the MODA™ solution providing results on demand, helping customers make intelligent decisions

- **Solutions Support** - Service programs, equipment and software validation, LIMS support, instrument training and lab testing services

Walkersville, MD (USA)

Lonza Walkersville, Inc.

- Area 2.8 ha
- Employees: Over 500
- Bioscience Headquarters
- Plants/Products
  - Liquid and powder media preparation and filling
  - Cell therapy and cell discovery
  - Rapid testing service
  - LAL processing
  - Contract services
- Products
  - Powdered media
  - Liquid media
  - Primary cells
  - Cell culture reagent
  - Endotoxin detection kits
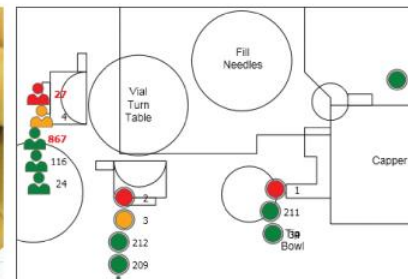 - Microbiology testing kits

QC automation just got greener!

MODA is now a Lonza company. More science. Less paper.™

Lonza's Rapid Testing Solutions now features mobile and wireless technologies by MODA—a paperless QC Micro solution. What started as a company-wide initiative to eliminate waste, reduce lead and labor time, and improve overall compliance, inspired a robust informatics platform for the life sciences industry. Automate your data collection. Gain improved insight into your manufacturing operation. Capture and upload test sample data for EM, utilities, and products at point of sample. Track and trend your data for immediate analytical reporting. Even see results through our visualization tools.

Rapid Testing Solutions. Go paperless today!
Explore our offerings at www.lonza.com/rts

MODA™ Solution
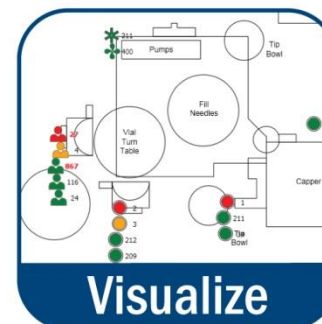
B Toal / Lonza / 20 July 2010

MODA™ Solution Value Proposition
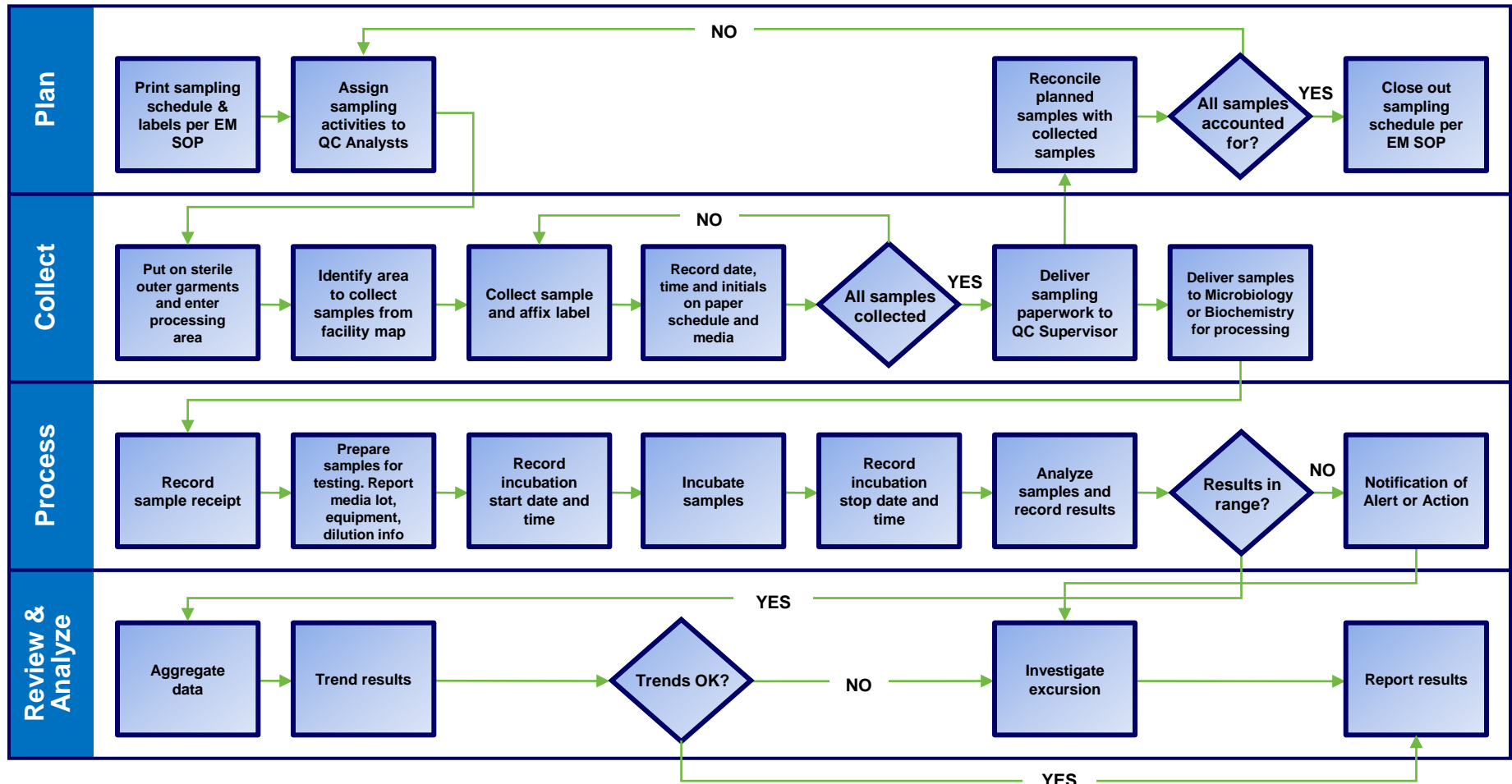
- **More science. Less paper.™**

  - Quickly move from paper-intensive QC Monitoring & Analysis

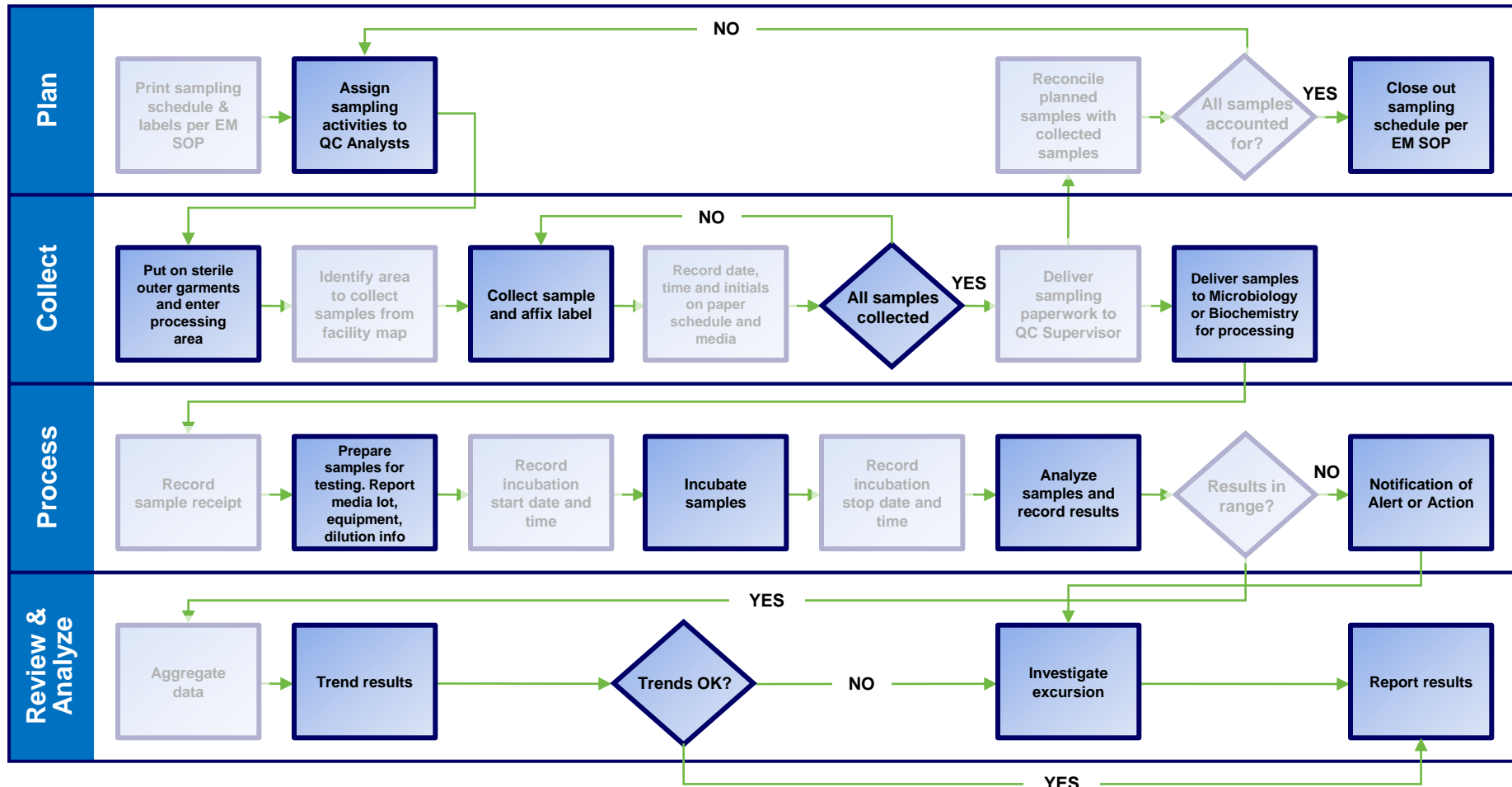- **Increase operational efficiency, improve quality, reduce costs**

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

Capture **Track** **Visualize** **Trend**

Example: QC Sampling and Lab Processing

The Paper-based QC Process

Example: QC Sampling and Lab Processing

Lonza

The Paperless QC Process—*11 Steps Removed*

Plan
- Print sampling schedule & labels per EM SOP
- Assign sampling activities to QC Analysts
- Reconcile planned samples with collected samples
- All samples accounted for? — YES — Close out sampling schedule per EM SOP
- NO

Collect
- Put on sterile outer garments and enter processing area
- Identify area to collect samples from facility map
- Collect sample and affix label
- Record date, time and initials on paper schedule and media
- All samples collected — YES — Deliver sampling paperwork to QC Supervisor
- Deliver samples to Microbiology or Biochemistry for processing
- NO

Process
- Record sample receipt
- Prepare samples for testing. Report media lot, equipment, dilution info
- Record incubation start date and time
- Incubate samples
- Record incubation stop date and time
- Analyze samples and record results
- Results in range? — NO — Notification of Alert or Action

Review & Analyze
- Aggregate data
- Trend results
- Trends OK? — NO — Investigate excursion
- Report results
- YES

slide 13

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
	P1106-1107	
4 hours		Finished

	Paper	8 hours
–	Paperless	4 Hours
=	**Savings**	**4 Hours**

Automated Reports & Analytics

Now: MODA™ Solution Concept

Paperless, Automated Laboratory

MODA™ Solution Components

- Mobile Data Acquisition ⟷ Systems (ERP, LIMS, CAPA)
- Flexible Workflow
- Integration ⟷ Devices
- On-Demand Analytics ⟵ Media

Improved Compliance	Increased Productivity	Expedited Decision Making

Now: MODA™ Solution Concept

Looking Forward: MODA™ Solution Vision

Lonza

MODA™ Solution Components		
Mobile Data Acquisition	↔	
Flexible Workflow	↔	
Integration		
On-Demand Analytics	↔	

Improved Compliance	Increased Productivity	

Looking Forward: MODA™ Solution Vision

Comprehensive Quality Data Management Solution

MODA™ Solution Components

Mobile Data Acquisition	⬌ **Laboratory**
Flexible Workflow	⬌ **Production Line and Facilities**
Integration	
On-Demand Analytics	⬌ **Services and Suppliers**

Improved Compliance | **Increased Productivity**

Looking Forward: MODA™ Solution Vision

Comprehensive Quality Data Management Solution

MODA™ Solution Components

Mobile Data Acquisition ⟷ Laboratory

Flexible Workflow

Integration ⟷ Production Line and Facilities

On-Demand Analytics ⟷ Services and Suppliers

| Improved Compliance | Increased Productivity | Expedited Product Release |

Walkersville Case Study - MODA-EM™ Platform

S Harrison / Lonza / 20 July 2010

Walkersville MODA™ System Implementation

- **12-2007:** Beta-Site implementation
  - 3 cleanrooms using Environmental Monitoring
  - Previous MODA software version

- **04-2009:** Site-wide Environmental Monitoring implementation
  - 13 cleanroom suites
  - Current MODA software version

- **04-2010:** Utility Monitoring implementation
  - 5 current water loops
  - 3 new loops added in Q2

Before MODA™ Solution – Recurring Issues

- **Paper based system (labor intensive)**

- **Duplication of effort**
  - Completing paperwork
  - Data entry

- **Timely data review (volume)**

- **Paper-Based MS Access database**
  - Limited selection of reports
  - Excessive time spent generating trending reports
  - Not validated or CFR21 Part 11 compliant
    - Requires data verification

Paper-Based System vs. MODA™ Solution

■ **Paper-Based 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™ Solution**

✓ **Clean room compatible: "*No paper*"**

✓ **Real-time electronic data capture**

✓ **One-step data capture of information**

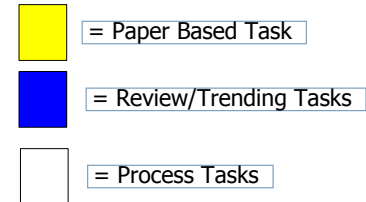✓ **Reduces corrections through mandatory fields/dropdowns**

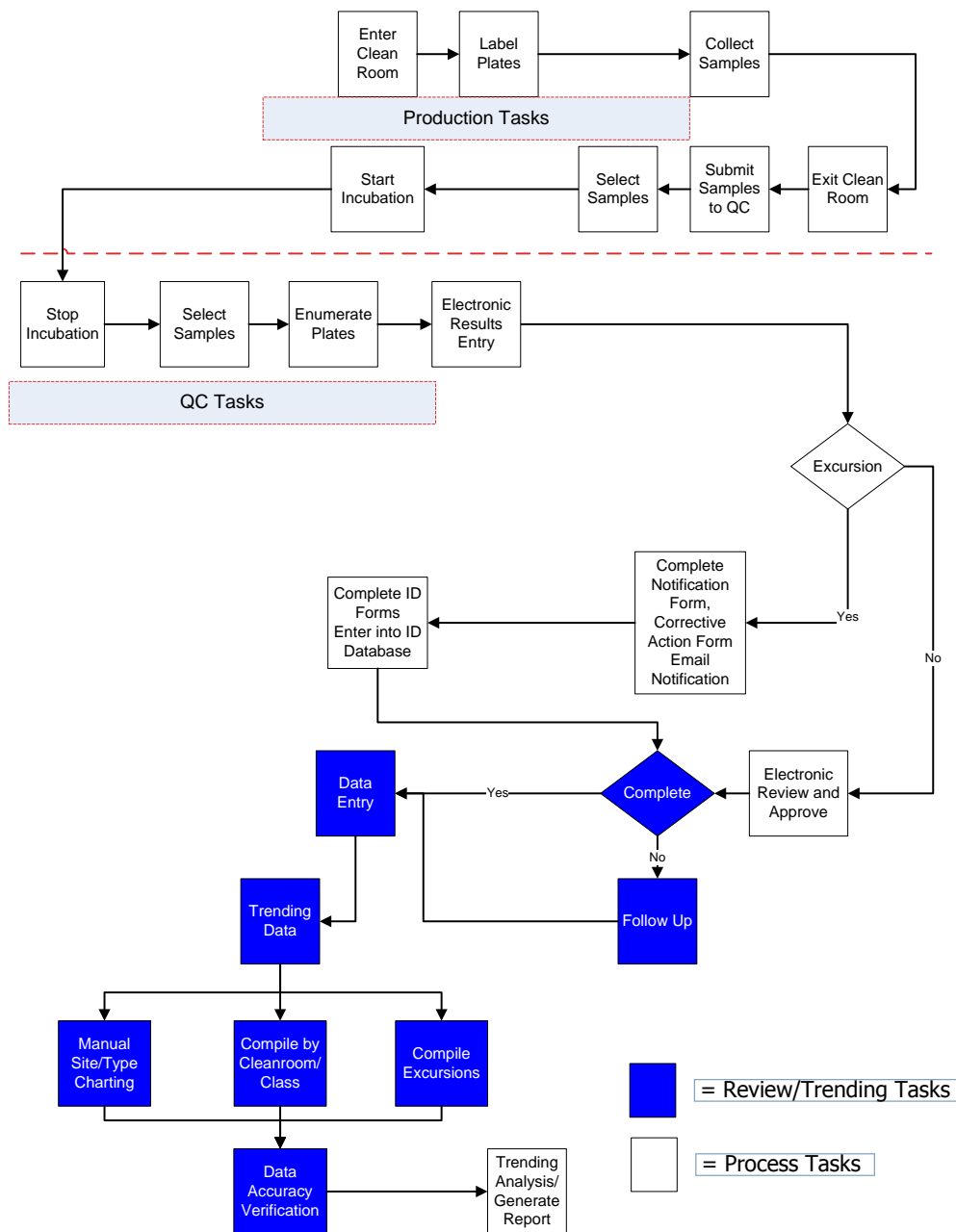✓ **System generates a variety of automatic trend reports**

MODA™ Solution Improves EM Processes

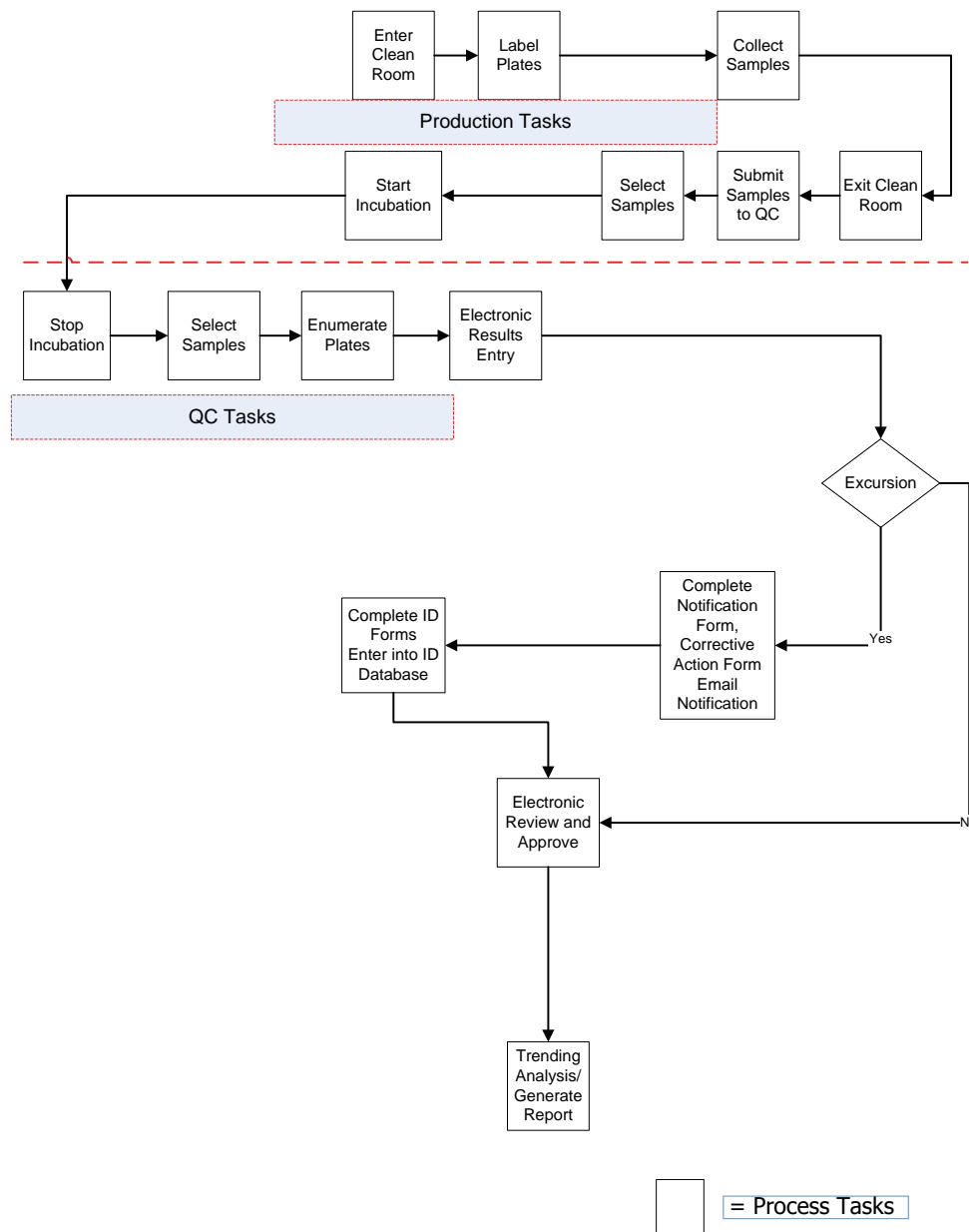- **Eliminates several steps from the paper-based EM Process**

- **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**

Previous Paper-Based Process Flow

Lonza

Process Flow without Paper Tasks

Lonza

slide 27

Lonza

Process Flow with MODA™ Solution

Enter Clean Room → Label Plates → Collect Samples

Production Tasks

Exit Clean Room → Submit Samples to QC → Select Samples → Start Incubation

Stop Incubation → Select Samples → Enumerate Plates → Electronic Results Entry

QC Tasks

Excursion

Complete Notification Form, Corrective Action Form Email Notification

Complete ID Forms Enter into ID Database

Yes

No

Electronic Review and Approve

Trending Analysis/ Generate Report

☐ = Process Tasks

Financial Benefits

- **Estimated**
  - 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

- **Realized**
  - Staff Reduction from 11 to 8 FTE's (~25%)
  - Miscellaneous savings (binders, paper, ink, particle-counter tape, autoclave costs, archiving and storage of data)
  - Shift of resource to other value-added activities

- **Favorable ROI**

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 Compliance

- **Paper-Based System**

  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™ 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 on a routine basis**

Trending/Report Generation Compliance

■ Paper-Based System

- 5 Analysts 8-10 hours per month after data entry

- Limited Scope of Trending Reports

- No Formal way of tracking flora

- Difficult to extract client-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**

- ✓ **Flora can be trended by person, site, room, facility**

- ✓ **Client-specific reporting for Contract Manufacturing**

- ✓ **Ease of trending allows others (QA, Manufacturing) to perform their own trending**

Benefits of MODA™ Solution

- ✓ 21 CFR Part 11 compliant

- ✓ Instant data entry eliminating paper transpositions

- ✓ Generation of timely trending reports

- ✓ Equipment Interface (MetOne Particle counter)

- ✓ Eliminates duplication of efforts in data entry and trending

- ✓ Storage of paper documentation eliminated

- ✓ Clean room compatible equipment

- ✓ Provide Superior Quality System to our clients (potential revenue generation)

- ✓ Severability: Continues sampling process without wireless internet connection

- ✓ Added bonus: DMS access through PC tablets
  - ✓ i.e. Documentum, NovaManage
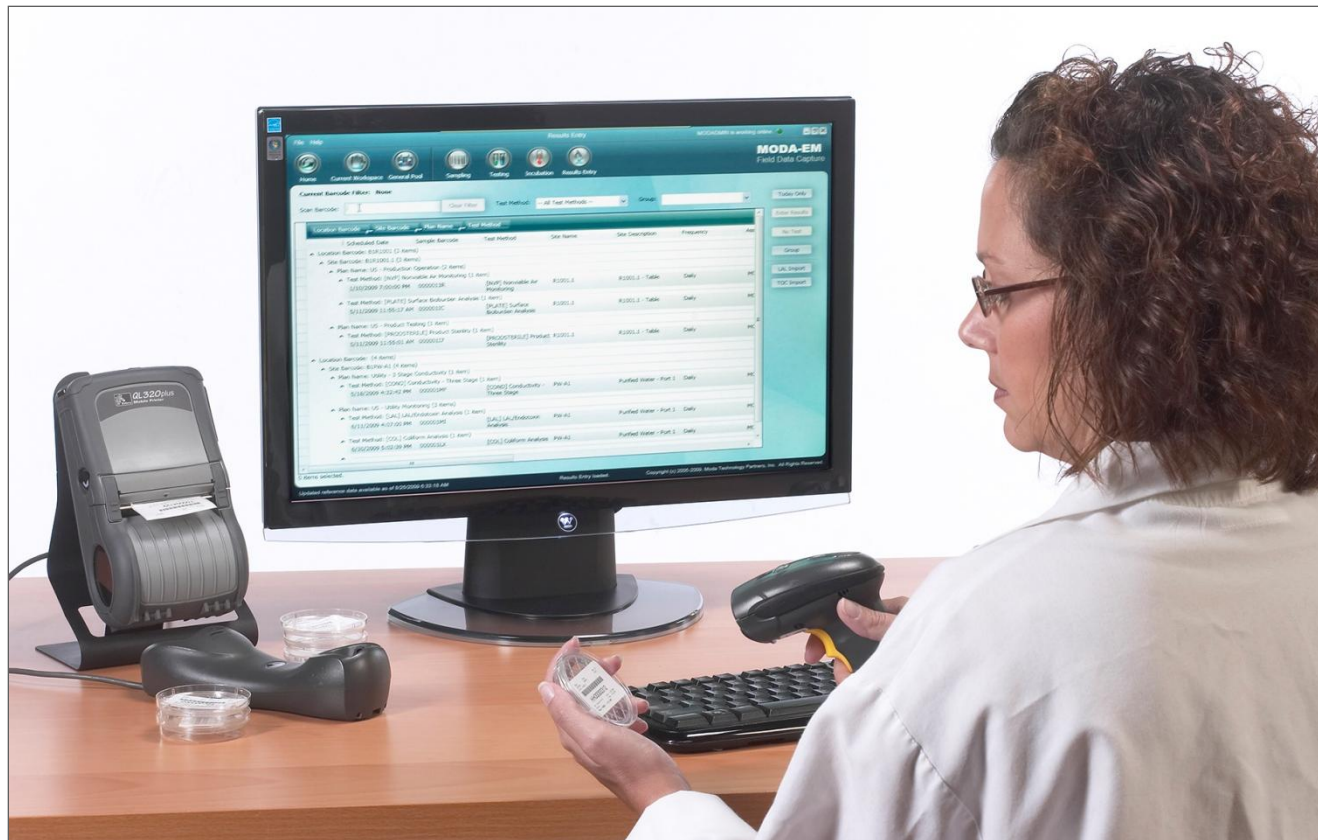
Now: Automated Field Data Capture

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

Now: Automated Lab Processing

Today's Cleanroom

"…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 1

Today's QC Micro Lab

"…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."

Source: Environmental Monitoring A Comprehensive Handbook, Volume 1

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

Lonza

Week of Nov 8

- 2-day QC Automation Training Workshop, Walkersville, MD

See Lonza and MODA™ solution in action

- Sep 21-24: ILMAC, Basel
- Sep 28-30: ScanLab, Copenhagen
- Oct 5-8: Biotechnica , Hannover, Germany
- Oct 18: Quality in BioPharma (QBC), Raleigh, NC
- Oct 25-28: PDA Microbiology, Washington DC
- Nov 4: Paperless Lab, Bonn, Germany
- Nov 14-19: AAPS, New Orleans
- Nov 15-17: IVT ACE, Europe

Sep 2010

- Feature Article in Pharma Technology

Upcoming Webinars

Sept 2010

- IT Perspective on Automated Quality Control

Late Fall (topics under consideration)

- Advancements in Automated Water Testing
- Non-sterile Manufacturing Quality Control
- Client Case Studies

Wrap-up

Personal Consultation

Bob Toal - Segment Manager, Informatics

Phone: +1 484 253 1000 x133

Email: robert.toal@lonza.com

Learn More
Web: www.lonza.com/rts

Lonza

Thank You