

**Lonza**

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**Managing QC Challenges in an  
Ever-changing Industry with MODA™  
QC Micro Platform**

# Today's Presenters

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**Mike Goetter**

Innovation Director of Informatics

*Informatics, Lonza Bioscience*

**Rob Lutskus**

Product Delivery Manager of MODA

*Informatics, Lonza Bioscience*

# Forward Looking Statements

***Certain matters discussed in this presentation may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and Uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this presentation due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this presentation.***



# Lonza Overview

## A focused market leader

### Corporate Overview:

- Life sciences driven company
- Headquartered in Basel (Switzerland)
- Sales of CHF 2.692 billion in 2011

### Global operations:

- 45 major production and R&D facilities
- Employs over 11,000 people

### Global leader in microbial control and custom manufacturing:

- Biologics contract
- Cell Therapy and Viral Filling
- Hygiene
- Water treatment
- Active pharmaceutical ingredients both chemical and biological

### Leading positions in product market niches:

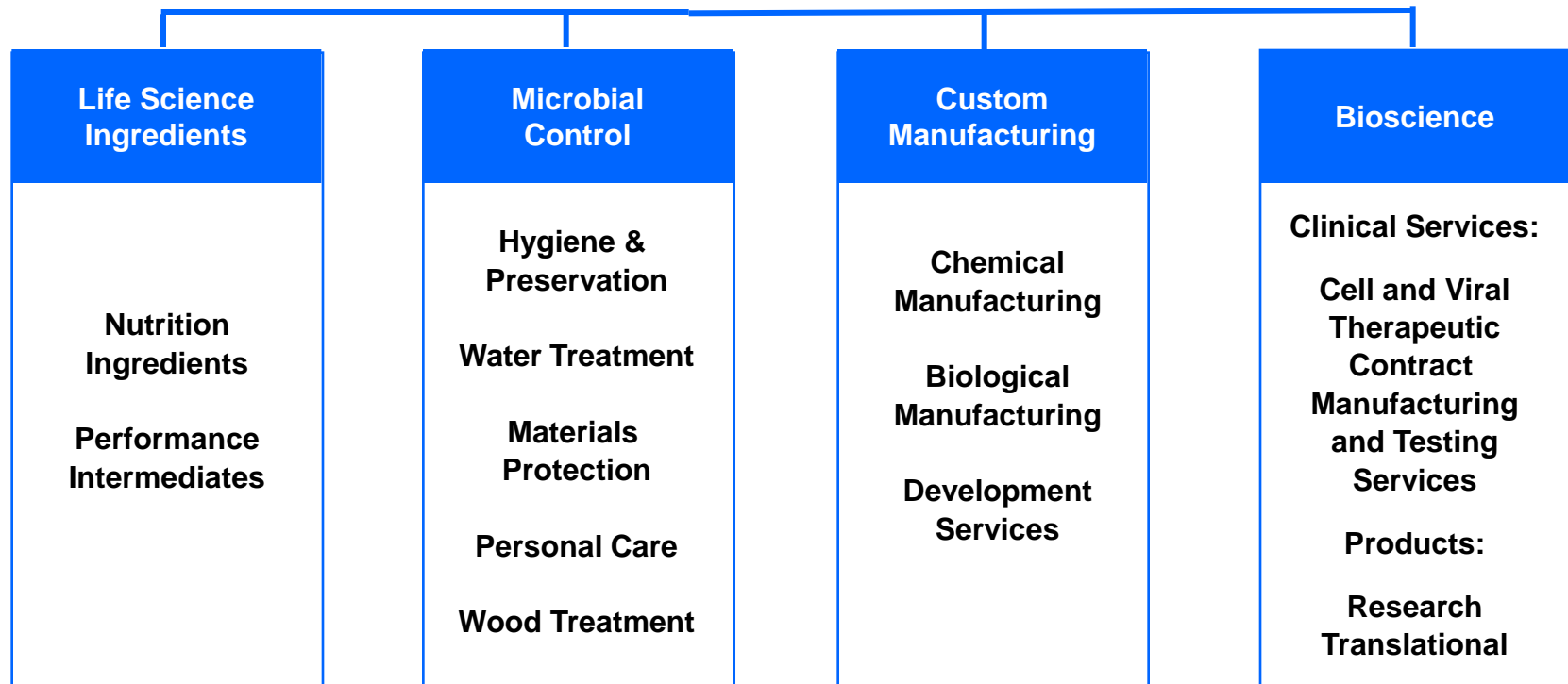
- Cell Therapy Manufacturing
- Endotoxin detection
- Cell-based research products
- Nutrition ingredients
- Performance intermediates



# Lonza's Interconnected Life-science Platform

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## **Lonza**



# Value Proposition

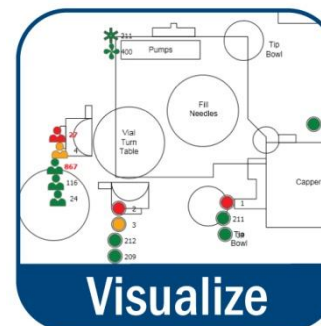
- More science. Less paper.
  - Increase operational efficiency, improve quality, reduce costs
  - Quickly move from paper-intensive QC monitoring/analysis
  - Gain measurable ROI and significantly enhance compliance



**Capture**



**Track**



**Visualize**



**Trend**

# Agenda

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- Recent regulatory guidance changes and their impacts on QC micro programs
- Managing requirements for monitoring and reporting in a global regulatory framework
- Meeting demands with limited resources: audits, excursion investigations, compliance deviations
- Cost savings and compliance improvement examples from MODA-EM™ customers
- What's new in MODA-EM™ version 3.1

## USP Chapter <1116> Revision

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- Microbiological Control and Monitoring of Aseptic Environments
  - Presents an entirely new perspective on environmental control relying on incident rates rather than action / alert levels
  - Reflects the uncertainty in microbial recovery, especially in the cleanest environments
  - Makes a clear distinction between environments for aseptic and other cleanroom applications



## USP Chapter <1116> Revision

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- Microbiological Control and Monitoring of Aseptic Environments relevant excerpts<sup>1</sup>:
  - “Since the early 1980s, manufacturers have established alert and action levels for environmental monitoring. In recent years, the numerical difference between alert and action levels has become quite small, especially in ISO 5 environments.”
  - “As a result of this inherent variability and in determinate sampling error, the supposed differences between, for example, an alert level of 1 cfu and an action level of 3 cfu are not analytically significant. Treating differences that are within expected, and therefore, normal ranges as numerically different is not scientifically valid and can result in unwarranted activities.”

1- United States Pharmacopeia, “<1116> Microbiological Control and Monitoring of Aseptic Processing Environments”, *USP 35-NF30*, 703, 2012.

## USP Chapter <1116> Revision

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- Microbiological Control and Monitoring of Aseptic Environments relevant excerpts<sup>2</sup> (cont.):
  - “Because of the inherent variability of microbial sampling methods, contamination recovery rates are a more useful measure of trending results than is focusing on the number of colonies recovered from a given sample.”
  - “The incident rate is the rate at which environmental samples are found to contain microbial contamination. For example, an incident rate of 1% would mean that only 1% of the samples taken have any contamination regardless of colony number. In other words, 99% of the samples taken are completely free of contamination”

2- United States Pharmacopeia, “<1116> Microbiological Control and Monitoring of Aseptic Processing Environments”, *USP 35-NF30*, 703-706, 2012.

## USP Chapter <1116> Revision

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Table 2: Suggested Frequency of Sampling for Aseptic Processing Areas<sup>3</sup>

Sampling Areas	Frequency of Sampling
Critical zone (ISO Class 5 or better) Active air Surface monitoring	Each operating shift At the end of the operation
Aseptic processing area adjacent to critical zone All sampling	Each operating shift
Other nonadjacent aseptic areas All sampling	Once per day

3- United States Pharmacopeia, "<1116> Microbiological Control and Monitoring of Aseptic Processing Environments", *USP 35-NF30*, 702, 2012.

## USP Chapter <1116> Revision

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Table 3: Recommended Contamination Incident Rates<sup>4</sup>

Grade	Active Air	Settle Plate (4 hr Exposure)	Contact Plate or Swab	Glove or Garment
Isolator (ISO 5 or better)	<0.1%	<0.1%	<0.1%	<0.1%
ISO 5	<1%	<1%	<1%	<1%
ISO 6	<3%	<3%	<3%	<3%
ISO 7	<5%	<5%	<5%	<5%
ISO 8	<10%	<10%	<10%	<10%

4- United States Pharmacopeia, "<1116> Microbiological Control and Monitoring of Aseptic Processing Environments", *USP 35-NF30*, 703, 2012.

## USP Chapter <1116> Revision

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- Microbiological Control and Monitoring of Aseptic Environments relevant excerpts<sup>5</sup> (cont):
  - “Excursions beyond approximately **15 cfu** recovered from a single ISO 5 sample, whether from airborne, surface, or personnel sources, should happen very infrequently. When such ISO 5 excursions do occur, they may be indicative of a **significant loss of control** when they occur within the ISO 5 critical zone in close proximity to product and components. Thus, any ISO 5 excursion >15 cfu should prompt a careful and thorough investigation. A key consideration for an abnormally high number of the recovered colonies is whether this incident is isolated or can be correlated with other recoveries. Microbiologists should review recovery rates for at least two weeks before the incident of abnormally high recovery so that they can be aware of other recoveries that might indicate an unusual pattern. The **identity of the organisms** recovered is an important factor in the conduct of this investigation.”

5- United States Pharmacopeia, “<1116> Microbiological Control and Monitoring of Aseptic Processing Environments”, *USP 35-NF30*, 703, 2012.

# Addressing These Changes

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- Significant time investment
  - Rewriting SOPs
  - Reclassifying “incidents” and “trends”
  - New quarterly reports, excursion reports and investigation procedures
- Resource investment
  - Personnel to evaluate and make changes
  - Multi-department agreement on changes

# What Part Does MODA Play?

- Test Based and Site Based Frequency Limits
  - Limits based on adverse trends for a given test or for all test methods at a site.

**Locations**

- Global Pharmaceuticals
  - Global Facility I
    - Aseptic Core
      - R1001**
      - R1003
      - R1004 Combined Room
      - R1010
    - Bulk Mfg.
    - Laboratory
    - Product Line 1
    - Source Feed Loop
    - WFI Supply Loop
  - Z- Test Building
- Global Facility II
- Global Facility III

**Sites**

Drag a column header here to group by that column.

Name	Description	Site Type	Classification
R1001.1	R1001.1	Air Site	A
R1001.2	R1001.2	Filling Equipment	A

**Add Frequency Limit**

Limit Type: Incident Description: 1% Incident Rate

☒ Source Limit Type ☐ Source Limit

Source Limit Type:  Source Limit:

Occurrence Count: 3 Period: Day(s)

Period Count: 30

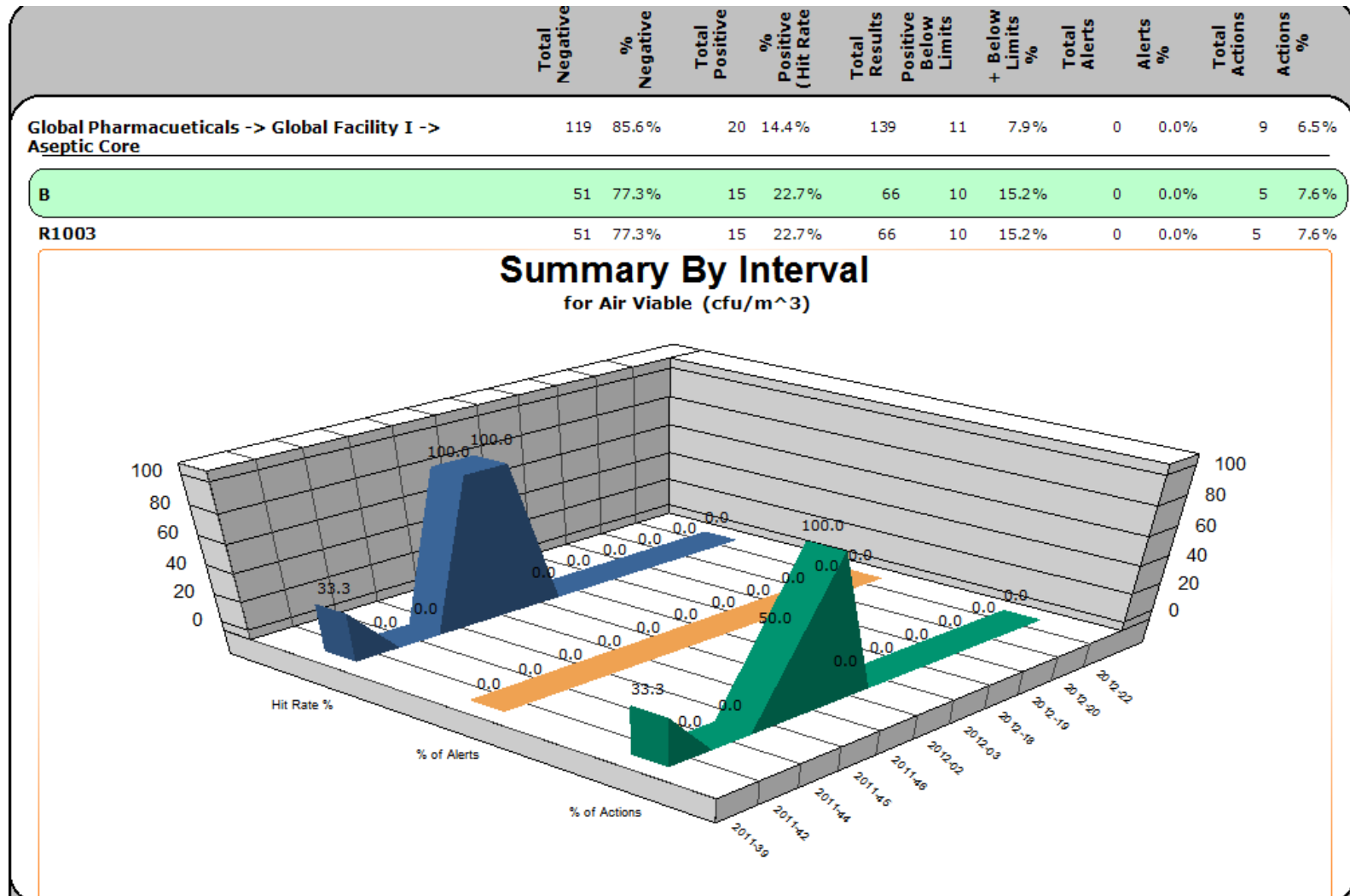
☒ Deviation ☐ Reschedule 0 Work Items

☒ Email Notification 0 Minutes from deviation

☒ Count Toward Frequency Limits ☐ Reset Frequency Limit Count

OK
Cancel

# What Part Does MODA Play?





# What Part Does MODA Play?

The screenshot displays the MODA-EM software interface. The main window is titled 'MODA-EM™' and features a menu bar with 'File', 'Dashboard', 'Admin', 'Schedule', 'Review/Approve', 'Analyze', and 'Report Gallery'. Below the menu bar is a toolbar with icons for various functions: Plan, General Pool, Issue Resolution, Save, Save As..., Plan, Work Item, Select All, Add Work Item(s) to Pool, Dev Mode, Fill Pool, Withdraw from Pool, and Print.

The interface is divided into two main sections: 'Plans' on the left and 'Work Items' on the right. The 'Plans' section shows a tree view of plans, including 'Aseptic EM Routine' (with sub-items v18 Draft, v15 Effective, v14 Superceded, v13 Superceded) and 'Product Bioburden' (with sub-items v6 Draft, v5 Effective, v4 Superceded, v3 Superceded). The 'Work Items' section shows a list of work items, grouped by location name. The 'Location Name: R1003 (9 items)' group includes items like R1003.S01-NVP, R1003.S01-ACTIV..., R1003.S03-NVP, R1003.S03-ACTIV..., R1003.S04-ACTIV..., R1003.S08-SETTLE, R1003.D01-PLATE, R1003.F01-PLATE, and R1003.W01-PLATE. The 'Location Name: R1001 (11 items)' group includes items like R1001.1-ACTIVEAIR, R1001.2-NVP, R1001.3-NVP, R1001.3-ACTIVEA..., R1001.3-ACTIVEA..., R1001.3-ACTIVEA..., R1001.5-PERS, R1001.6-SETTLE, R1001.8-PLATE, R1001.WS1-PLATE, and R1001.WS2-PLATE.

An 'Edit Work Item' dialog box is open, showing the 'Work Item Detail' for a selected item. The dialog box has tabs for 'Frequency' and 'Limits'. The 'Frequency' tab is active, showing the following details:

- Test Method: Air Viable
- Test Site: R1003.S01
- Name: R1003.S01-ACTIVEAIR
- Description: R1003.S01-Viable Air
- Environment: Dynamic
- Frequency Type: Daily
- Frequency: every 1 days on
- Days: ☐ Sunday, ☒ Monday, ☒ Tuesday, ☒ Wednesday, ☒ Thursday, ☒ Friday, ☐ Saturday
- at 6:00
- Top of the hour (x:00)

The dialog box has 'OK' and 'Cancel' buttons at the bottom.

# What Part Does MODA Play?

- Powerful reports and analytics that identify adverse trends and correlate results across tests

Enter Time (days) for Previous Results:

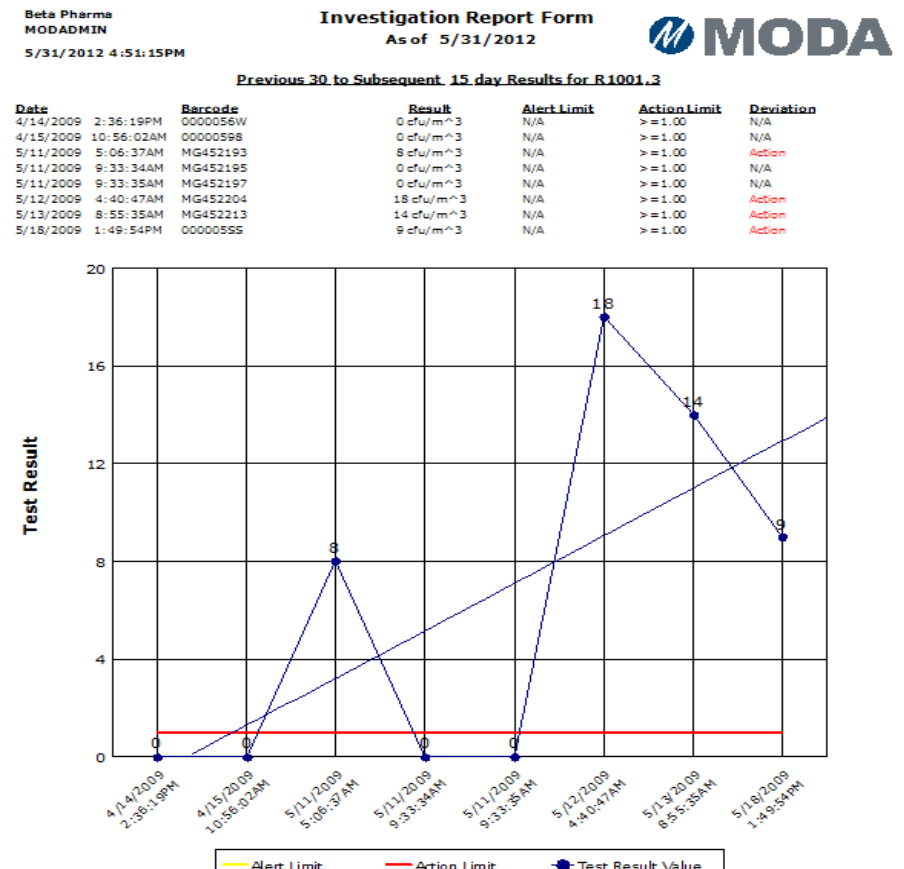
Enter Time (days) for Excursion Results:

Enter Time (days) for Isolates:

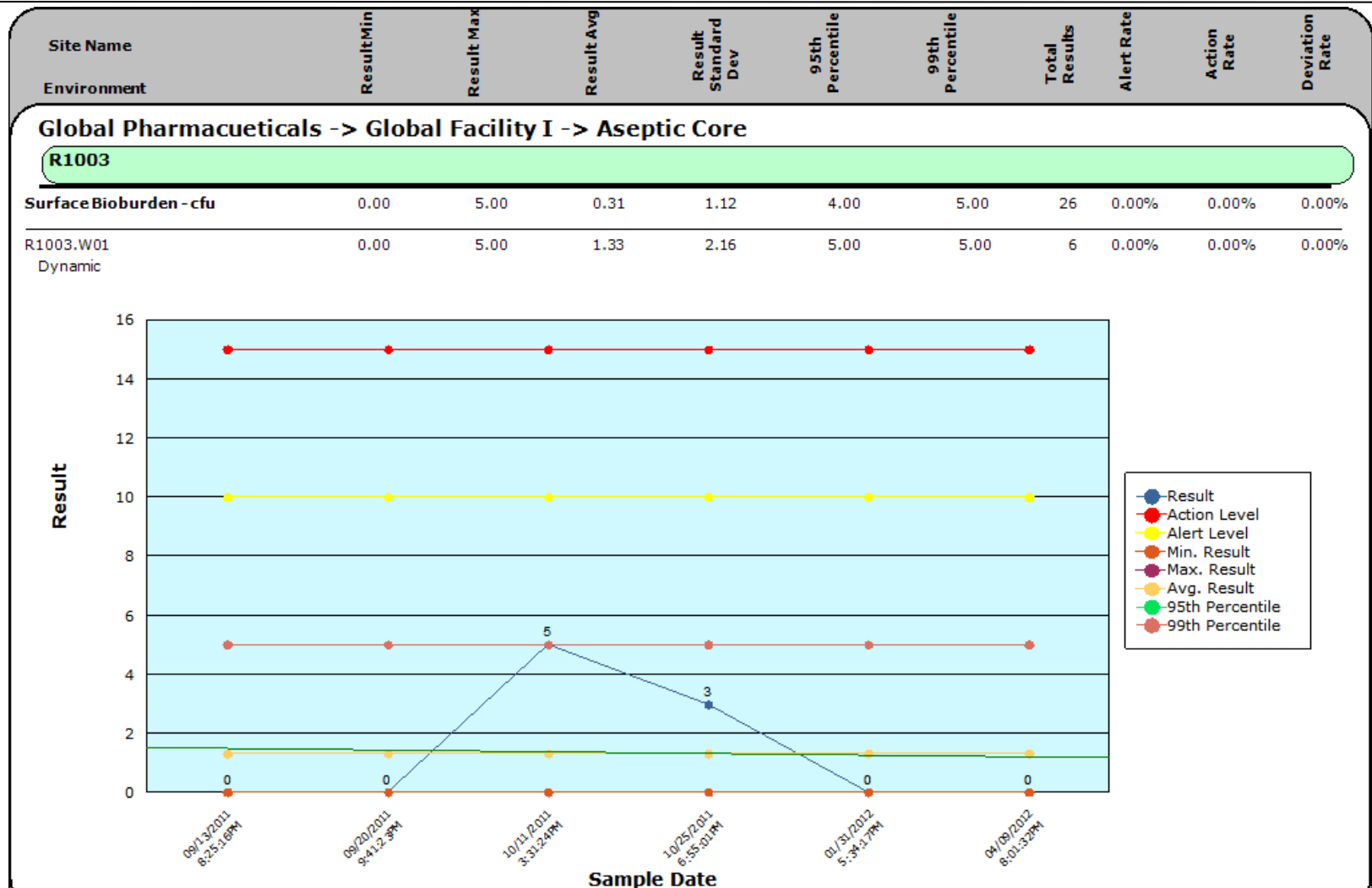
Enter Time (days) for Subsequent Results:

Enter Time (days) for Subsequent Organisms:

Enter Time (days) for Subsequent Excursions:



# What Part Does MODA Play?



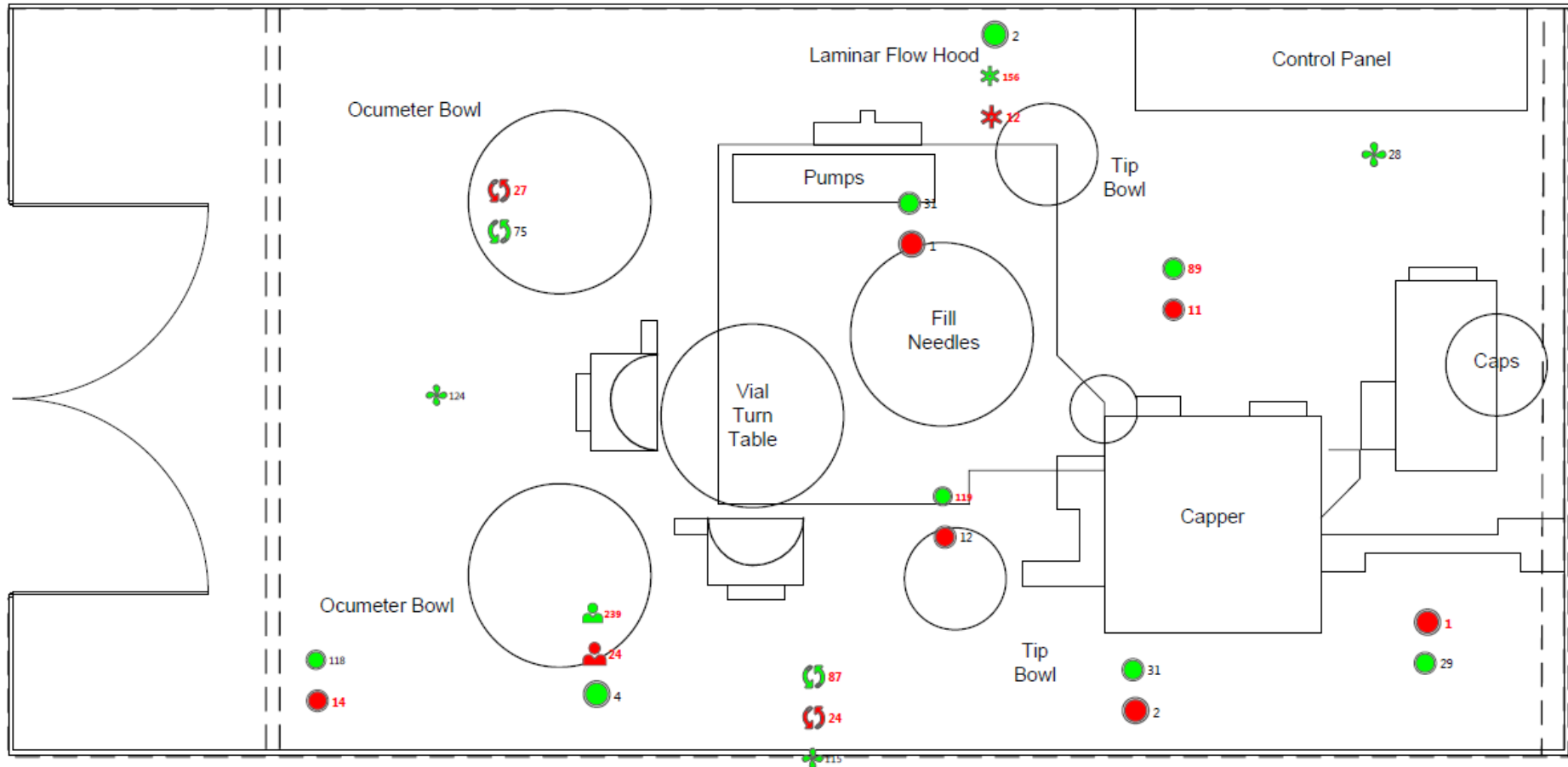
Previous 90 to Subsequent 15 day Excursions for Room /System (R1001)

<u>Date</u>	<u>Barcode</u>	<u>Site Name</u>	<u>Result</u>	<u>AlertLimit</u>	<u>ActionLimit</u>	<u>Deviation</u>	<u>Deviation Number</u>
<b>AirViable-cfu/1000L</b>							
03/16/2010 2:09:20PM	00000BYS	R1001.1	17 cfu/1000L	N/A	>=1.00	Action	N/A
<b>AirViable-cfu/m^3</b>							
03/30/2010 7:20:31PM	00000C68	R1001.1	19 cfu/m^3	N/A	>=1.00	Action	N/A
03/31/2010 11:57:57AM	00000BR2	R1001.3	17 cfu/m^3	N/A	>=1.00	Action	N/A
04/13/2010 3:14:18PM	00000C8K	R1001.3	20 cfu/m^3	N/A	>=1.00	Action	N/A
05/17/2010 5:28:02PM	00000CD4	R1001.3	18 cfu/m^3	N/A	>=1.00	Action	N/A
05/18/2010 11:01:54AM	00000CDM	R1001.3	18 cfu/m^3	N/A	>=1.00	Action	N/A
05/21/2010 2:49:26PM	00000CG1	R1001.3	19 cfu/m^3	N/A	>=1.00	Action	N/A
<b>Personnel Monitoring-cfu</b>							
02/18/2010 2:40:02PM	00000BRQP1S1	R1001.5	16 cfu	N/A	>=1.00	Action	N/A
03/30/2010 7:20:27PM	00000C5VP1S1	R1001.5	15 cfu	N/A	>=1.00	Action	N/A
05/17/2010 5:27:58PM	00000CD2P1S2	R1001.5	8 cfu	N/A	>=1.00	Action	N/A
05/18/2010 11:01:18AM	00000CDKP1S1	R1001.5	17 cfu	N/A	>=1.00	Action	N/A
<b>SettlePlates-cfu</b>							
03/30/2010 7:20:31PM	00000C62	R1001.6	8 cfu	N/A	>=1.00	Action	N/A
05/13/2010 11:01:45AM	00000CB5	R1001.6	27 cfu	N/A	>=1.00	Action	N/A
<b>SurfaceBioburden-cfu</b>							
03/18/2010 8:46:34PM	00000BZK	R1001.8	25 cfu	N/A	>=1.00	Action	N/A
03/19/2010 4:52:11PM	MG453022	R1001.WS1	23 cfu	N/A	>=1.00	Action	N/A
03/22/2010 6:32:56AM	MG453037	R1001.WS1	14 cfu	N/A	>=1.00	Action	N/A
03/30/2010 7:20:31PM	00000CSY	R1001.WS1	13 cfu	N/A	>=1.00	Action	N/A
03/30/2010 7:20:31PM	00000CSZ	R1001.WS2	6 cfu	N/A	>=1.00	Action	N/A
04/13/2010 1:59:01PM	00000C60	R1001.8	23 cfu	N/A	>=1.00	Action	N/A
05/17/2010 5:28:02PM	00000CD0	R1001.8	6 cfu	N/A	>=1.00	Action	N/A

Isolate Information for Room/System (R1001)

<u>Date</u>	<u>Sample</u>	<u>Location</u>	<u>IsolateName</u>
02/18/2010 2:40:32PM	00000BU3	R1001.3	Escherichiacoli
03/22/2010 6:32:56AM	MG453037	R1001.WS1	Aspergillusglaucus
04/13/2010 1:59:01PM	00000C60	R1001.8	Staphylococcus caprae
05/13/2010 11:01:45AM	00000CB1	R1001.WS1	Chryseobacterium indologenes
05/18/2010 11:01:54AM	00000CDM	R1001.3	Staphylococcus aureus
05/21/2010 2:49:26PM	00000CG1	R1001.3	Staphylococcus aureus

# What Part Does MODA Play?



# What Part Does MODA Play?



Beta Pharma

MODADMIN

02/21/2012 9:18:23PM

## Deviation Summary

Report Period from 01/01/2011 to 12/31/2011

Deviation	Sample	Sample Date	Sampled By	Site Name	Site Class	Result	Alert Limit	Action Limit	Deviation Type	Environment
Beta Pharmaceuticals -> Aseptic Core						Alerts: 1	Actions: 29	Total: 30		
R1001						Alerts: 0	Actions: 12	Total: 12		
Air Viable (cfu/m <sup>3</sup> )						Alerts: 0	Actions: 8	Total: 8		
838	00000K87	10/11/2011 11:31:24AM	Analyst02	R1001.1	A	50 cfu/m <sup>3</sup>		1	Action	D
818	00000J05	05/27/2011 3:05:58AM	Analyst08	R1001.1	A	36 cfu/m <sup>3</sup>		1	Action	D
778	00000IT7	02/07/2011 11:47:37AM	Analyst08	R1001.3	A	31 cfu/m <sup>3</sup>		1	Action	D
782	00000IT6	02/07/2011 11:47:37AM	Analyst08	R1001.3	A	42 cfu/m <sup>3</sup>		1	Action	D
779	00000IT8	02/07/2011 11:47:37AM	Analyst08	R1001.3	A	1 cfu/m <sup>3</sup>		1	Action	D
Organism: Staphylococcus Aureus,										
773	00000IRL	01/18/2011 6:07:11AM	Analyst08	R1001.3	A	31 cfu/m <sup>3</sup>		1	Action	D
Organism: Staphylococcus Aureus,										
772	00000IQ6	01/12/2011 10:03:10AM	Analyst08	R1001.3	A	1 cfu/m <sup>3</sup>		1	Action	D
Organism: Staphylococcus Epidermidis,										
771	00000IQ5	01/12/2011 10:03:10AM	Analyst08	R1001.3	A	20 cfu/m <sup>3</sup>		1	Action	D
Settle Plates (cfu)						Alerts: 0	Actions: 3	Total: 3		
823	00000JWH	06/08/2011 1:54:30PM	Analyst08	R1001.6	A	44 cfu		1	Action	D
802	00000J5U	03/17/2011 3:16:05PM	Analyst08	R1001.6	A	220 cfu		1	Action	D
770	00000IOE	01/05/2011 4:25:14PM	Analyst08	R1001.6	A	15 cfu		1	Action	D
Organism: Bacillus Cereus,										
Surface Bioburden (cfu)						Alerts: 0	Actions: 1	Total: 1		
813	00000J51	05/23/2011 8:52:06PM	Analyst08	R1001.8	A	70 cfu		1	Action	D
R1003						Alerts: 1	Actions: 17	Total: 18		

# What Part Does MODA Play?

Beta Pharma  
MODADMIN  
02/21/2012 9:14:49PM

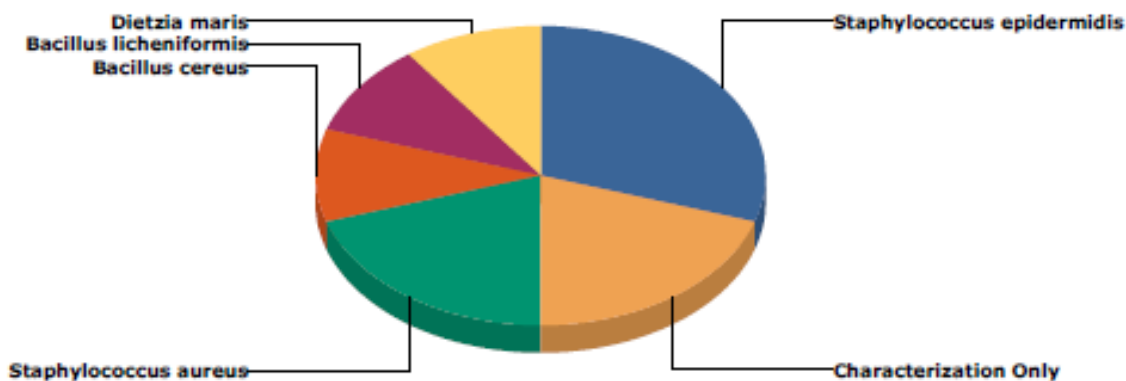
## Organisms By Location Chart

Report Period From 01/01/2011 to 12/31/2011



R1001

### Organism Description



Staphylococcus epidermidis	3	30.0%
Characterization Only	2	20.0%
Staphylococcus aureus	2	20.0%
Bacillus cereus	1	10.0%
Bacillus licheniformis	1	10.0%
Dietzia maris	1	10.0%
Total:	10	100.0%

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Page 3 of 3

## Doing More with Less

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- Most of the industry has experienced layoffs, hiring freezes or cutbacks at some level
- Less analysts doing the same or additional work
- More frequent and more demanding audits and audit requests
- Operating according to Lean Six Sigma practices



# Measurable Cost Savings

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## Lonza Walkersville

### ■ 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

## Measurable Cost Savings

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### Mid-sized biotech:

- Opened new building which doubled sample volume in 2006
- Installed MODA™ QC Micro Platform to coincide with building approval
- Gained efficiencies, improved workflow, and reduced redundancies without increasing staff
- Upgraded to MODA™ 3.0 platform in 2010
- Further process improvements realized with upgrade

## Lonza's Global MODA™-EM Deployment

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- There were two sites using MODA™ QC Micro Platform locally prior to the global project
- The main global project goal was to implement seven additional sites using the centralized approach as well as providing the capability to move the two local installations onto the corporate system
- This would also provide a platform to expand the global system to other Lonza sites in the future

## Currently There Are Eight Sites Live

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Tuas - Singapore



Walkersville, MD (USA)



Verviers - Belgium



Porriño - Spain



Visp - Switzerland



Hopkinton, MA (USA)



Portsmouth, NH (USA)



Kouřim, Czech Republic

## With Two Additional Sites for Future Installs

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Slough, UK



Houston, TX (USA)



# The Solution

MODA-EM™: Automates QC micro data collection & management



## Measurable benefits

Improve regulatory compliance	Increase worker efficiency	Make sound product quality & release decisions
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# MODA™ Solution: Components

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## **MODA-EM™ Client**

Software to manage the entire lifecycle of EM samples without paper

## **MODA-FDC™**

Mobile Field Data Capture platform for sampling in all critical areas

## **MODA-EM™ Server**

Database to store, administer, and report all EM data

## **MODA-VIP™**

Visual Intelligence Portal, advanced visualization of EM data



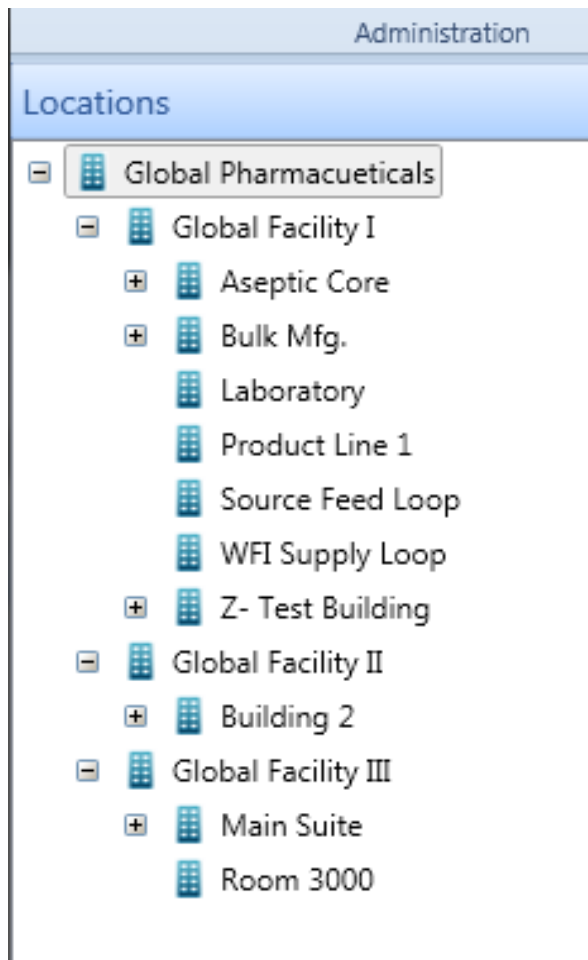
## Global/Multi-site Deployment

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MODA™-EM can be deployed as an enterprise application. Instances are typically site or cluster-specific, however:

- Server can reside either per-site placement or in datacenter
- Single or multi-server architecture supported through server virtualization
- Instances can be stored on a single database server (one schema per instance)
- Web service components can be hosted on a single IIS web server instance
- Authentication integrated with Active Directory and LDAP
- Authorized users can login between instances
- Reports can be deployed via Business Objects Enterprise Server or Crystal Reports Server

# Global/Multi-site Deployment



- Users' rights are granted by a combination of user role and location
- A user in the US can sample just the US sites, while a global administrator in the EU can see all locations and have rights to modify them

The screenshot shows the 'Edit User' dialog box with the 'User Detail' tab selected. The dialog contains the following fields and controls:

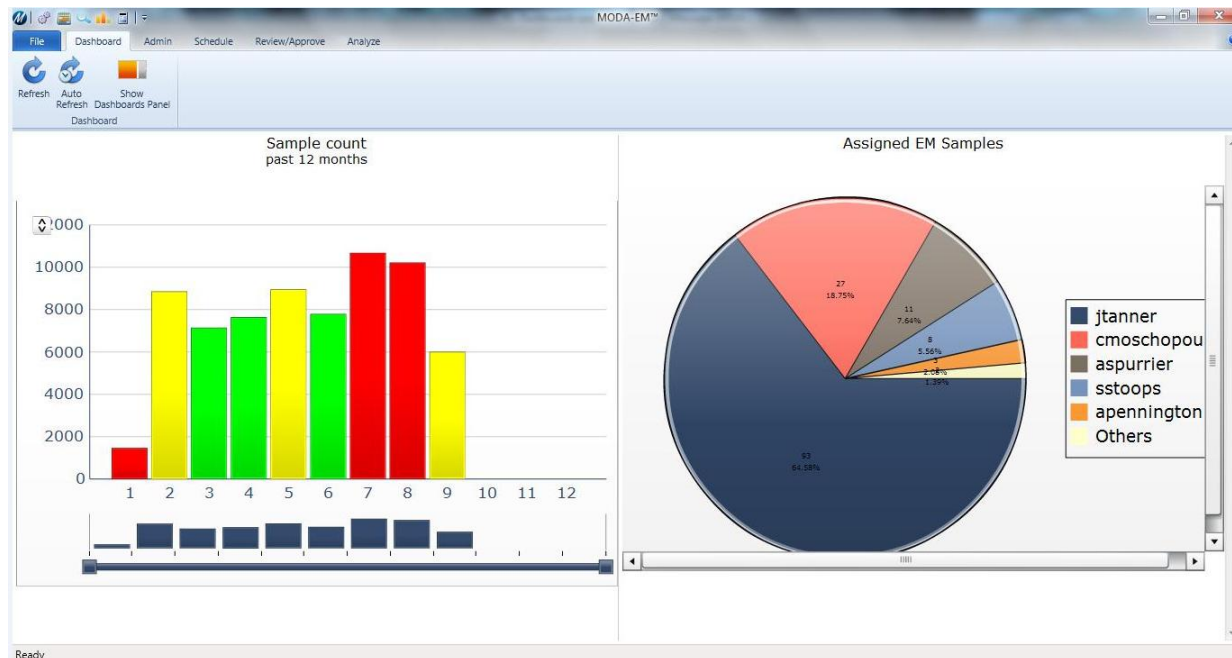
First Name:	Facility	Locked:	<input type="checkbox"/>
Last Name:	Manager01	Reset Password:	<input type="checkbox"/>
Title:		Department:	Manufacturing
User Name:	FacManager01	Location:	Beta Pharmaceuticals
User Password:		Personnel Monitoring:	Yes
Retype Password:		Last Monitored Date:	
Employee Id:	FacManager01	Initial Qualification Date:	12/31/2008 7:00:00 PM
E-mail:		Next Qualification Date:	03/30/2009 8:00:00 PM

At the bottom of the dialog are 'OK' and 'Cancel' buttons.

# MODA™-EM Version 3.1

Major update to address:

- New analytical tools and revamped reporting suite
- Customer-driven usability and paperless efficiency features
- Global rollout capabilities and improvements



## Major Features/Objectives:

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- Multi-language support- support for eight languages (English, German, French, Italian, Spanish, Czech, Japanese, Portuguese -Brazil) with framework to rapidly add more
- Dashboard – Live monitoring tool to capture real time data in a configurable format
- Ad-hoc reports – Excel® plug-in that allows a secure, password required connection to the MODA™ software to harness the power of the Excel® charting features
- Report improvements and updates – numerous report enhancements and additional reports
  - 3D charts, product release reports and hit rate analysis

## Major Features/Objectives (cont.):

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- Filtering and editing enhancements – Updates to the interface allow more data to be edited within the application, with ease. The additional filters support supervisor responsibilities in searching for data or samples
- Session defaults – set the media, equipment and product at the beginning of the sampling/testing session and the system will apply it automatically to all applicable samples
- Site based frequency limits – trigger notifications based on all sampling done at a site, previously this was done on a per test basis

# MODA™-EM Version 3.1

File View Help
Home
MODA-FDC™  
Field Data Capture

Home Current Workspace General Pool Sampling Testing Incubation Results Entry

**Working Online**  
Last update as of 04/23/2012 5:31:46 PM  
Offline processing status: 0 in queue.

**MODADMIN**  
Roles: Administrator

**Wireless Signal (dbM)**  
Strong Weak 

99 %

**Scan Barcode:**

**Current Workspace**  
Sampling: 1  
Incubation: 0  
Testing: 0  
Results Entry: 1

**Default Equipment**

Test Stage	Equipment Type	Equipment	Delete
Sampling	Active Air Sampler	Biotech RCS High Flow	
Incubation	Incubator 30-35	Incubator 3001 (30-3...	
*			

**Default Media**

Test Stage	Media Type	Media	Delete
Sampling	TSA Contact Plates	TSA 123456	
*			

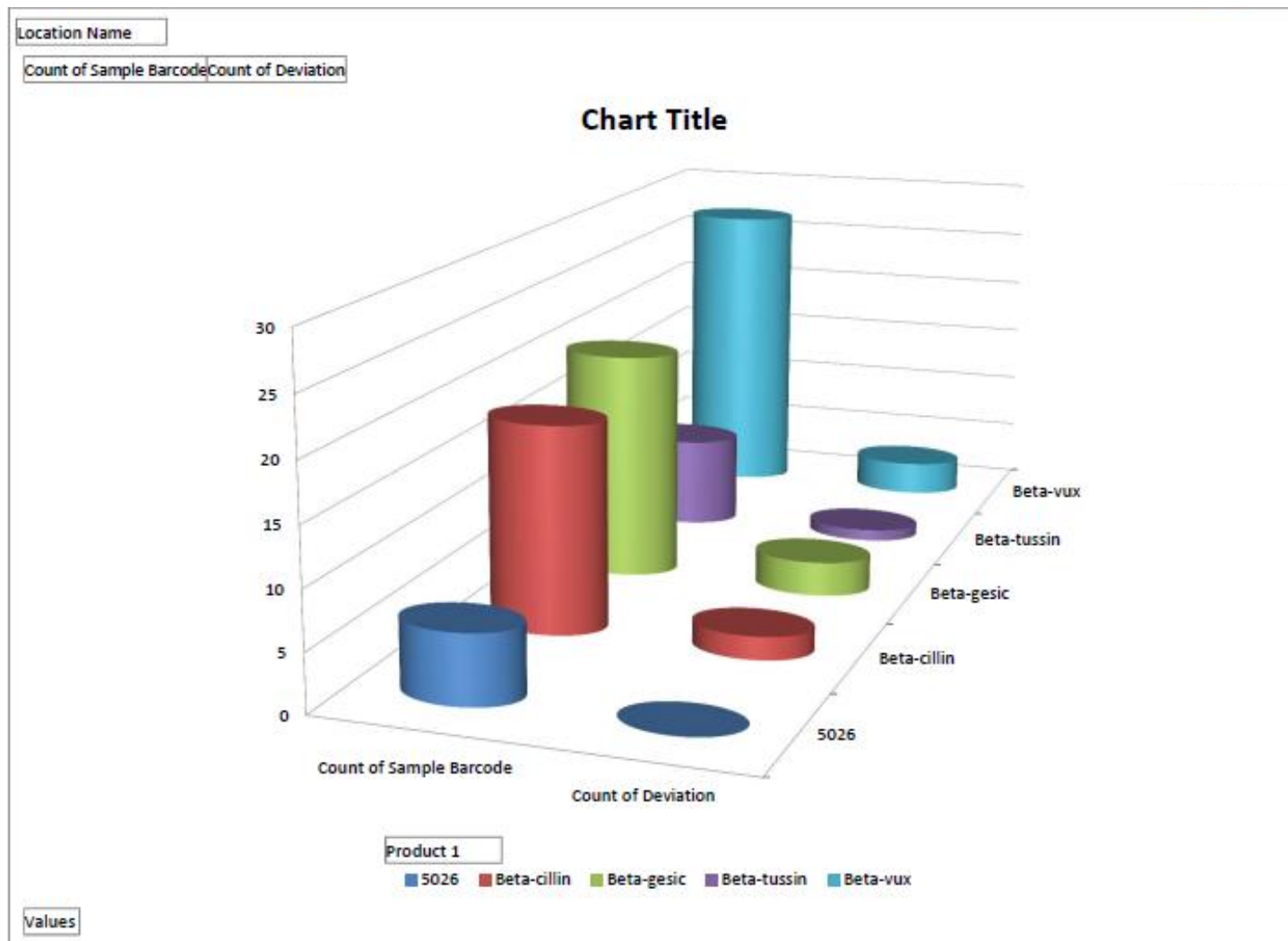
**Default Products**

Product	Batch/Lot Number	Delete
Beta-vux	Y12R45A	
*		

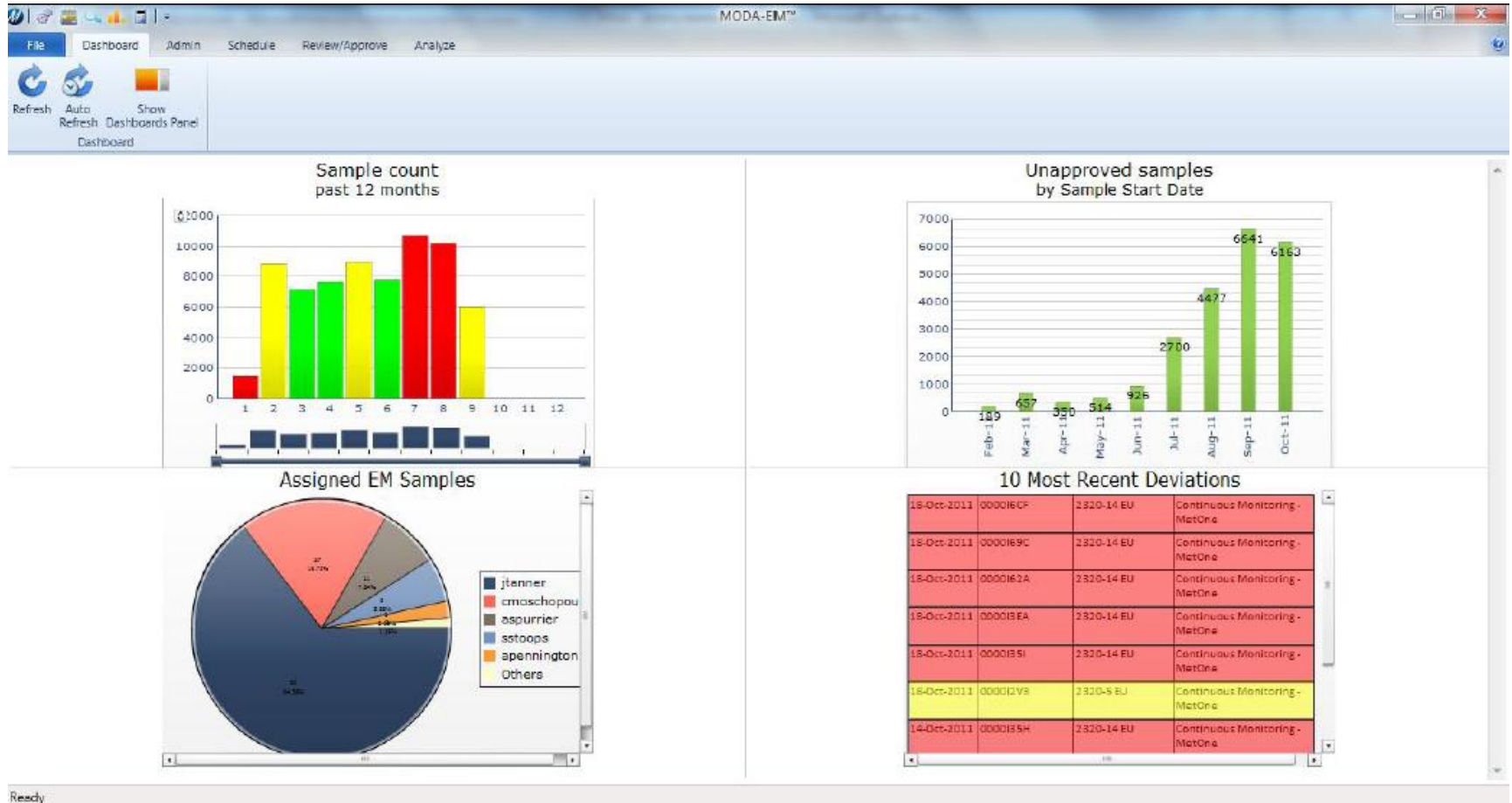
Clear All Session Defaults

MODADMIN is working online.
Home Panel loaded.
Copyright © 2011 Lonza Walkersville, Inc.

# MODA™-EM Version 3.1



# MODA™-EM Version 3.1



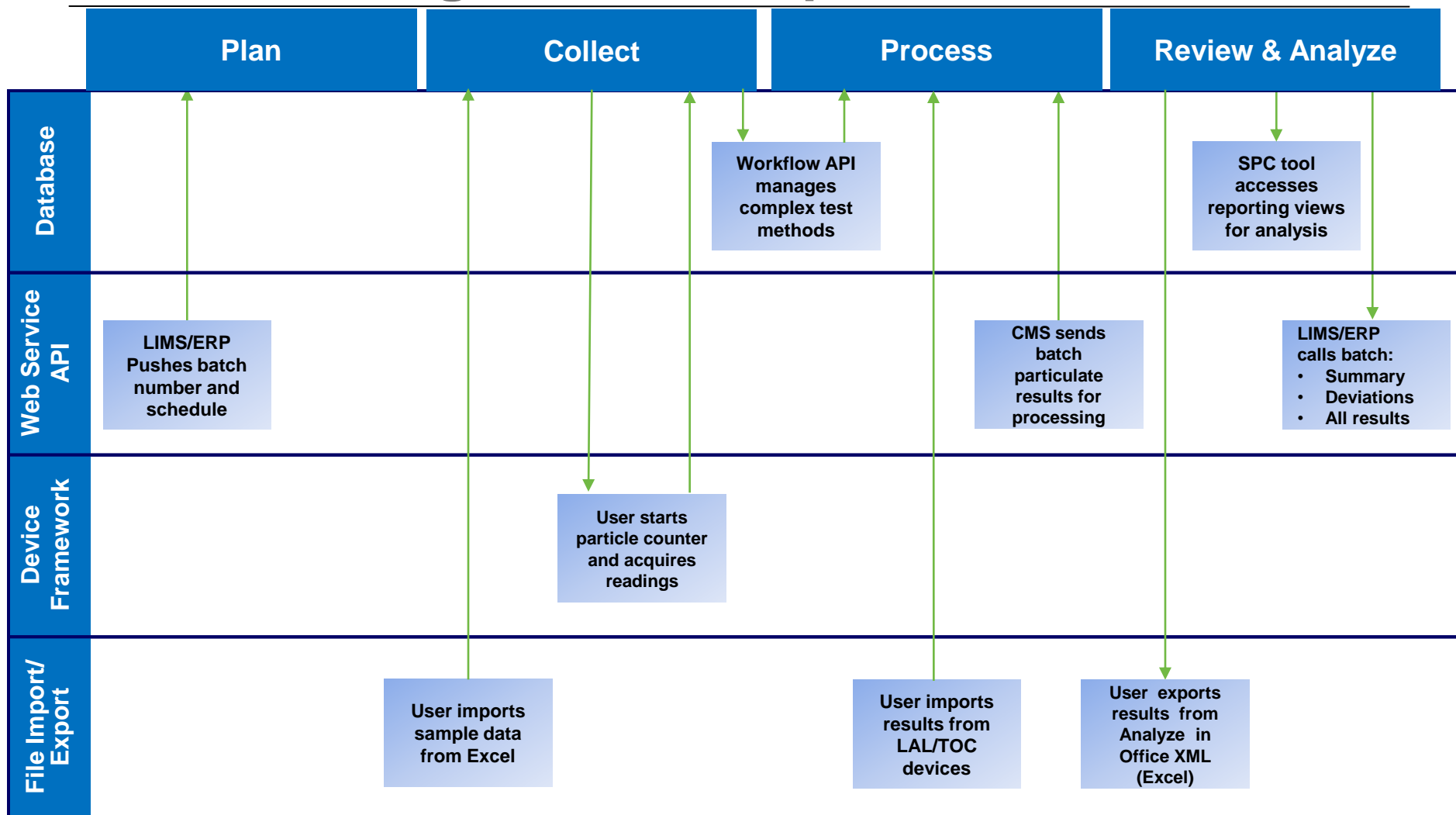


## Major Features/Objectives (cont.):

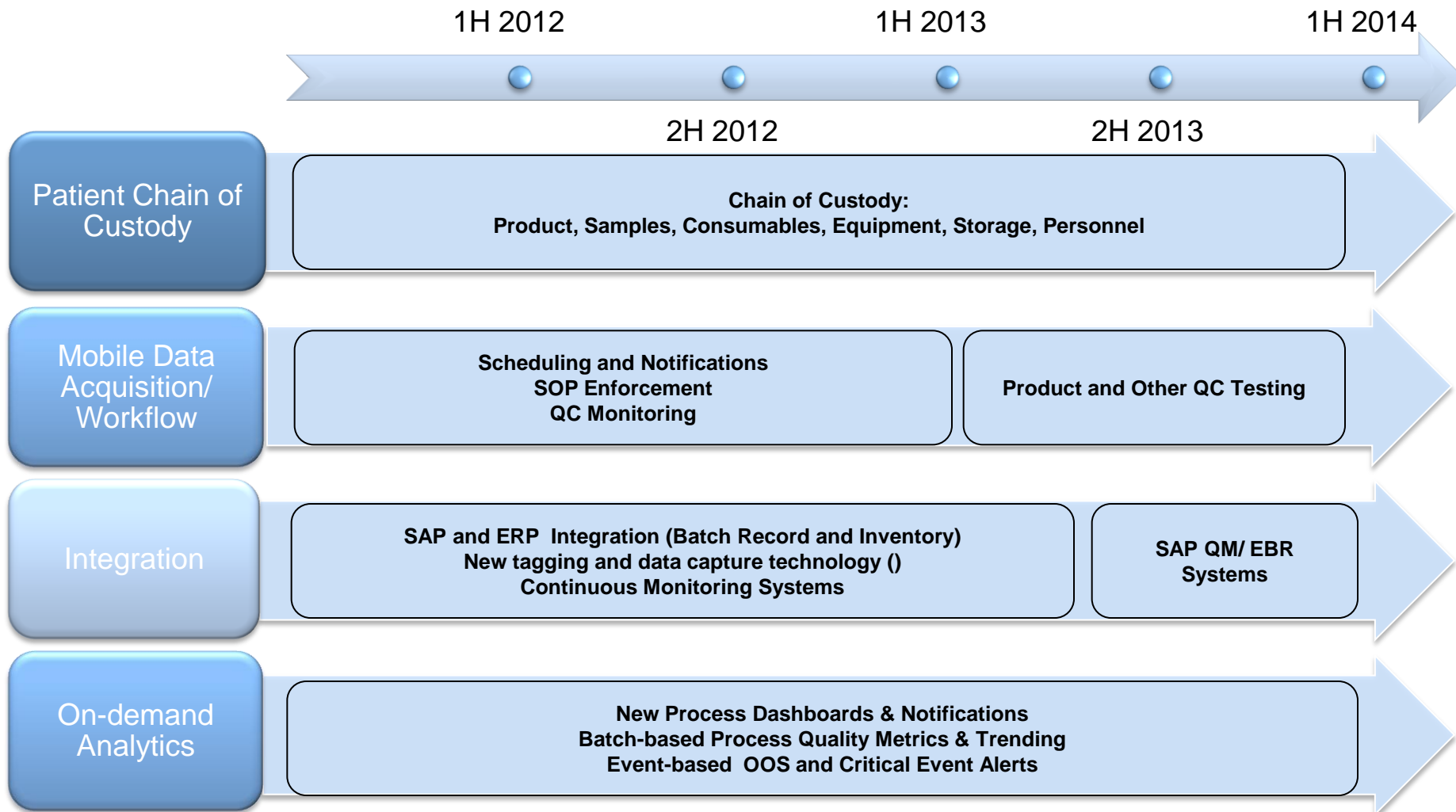
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- Data import/export tools – end user interface to import to or export from MODA™ QC Micro Platform to other systems, including LIMS and spreadsheets
- SOP linkage – connection to document management systems to connect your SOPs to the end users
- Complete API – exchange data with other systems to the MODA™ platform using a service-oriented architecture with no end-user interaction
- New devices- numerous new device integrations (particle counters, conductivity meters, TOC analyzers) new tablet support, and improved support for WinKQCL™ software
- New notification services – increased configurability of the notifications allowing time and frequency setting along with additional notification types

# MODA™ Integration Examples



# MODA-EM Version 4.0



**To submit a question,** use the “Ask Presenter a Question” feature (left side 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 Webinars

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**Topic: Cell-based Potency Assays—Expectations & Realities**

Category: Viral-based Therapeutics

Date: Tuesday, July 10

Look for your invitation shortly!

## Wrap-up: More Information

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**Thank You**