

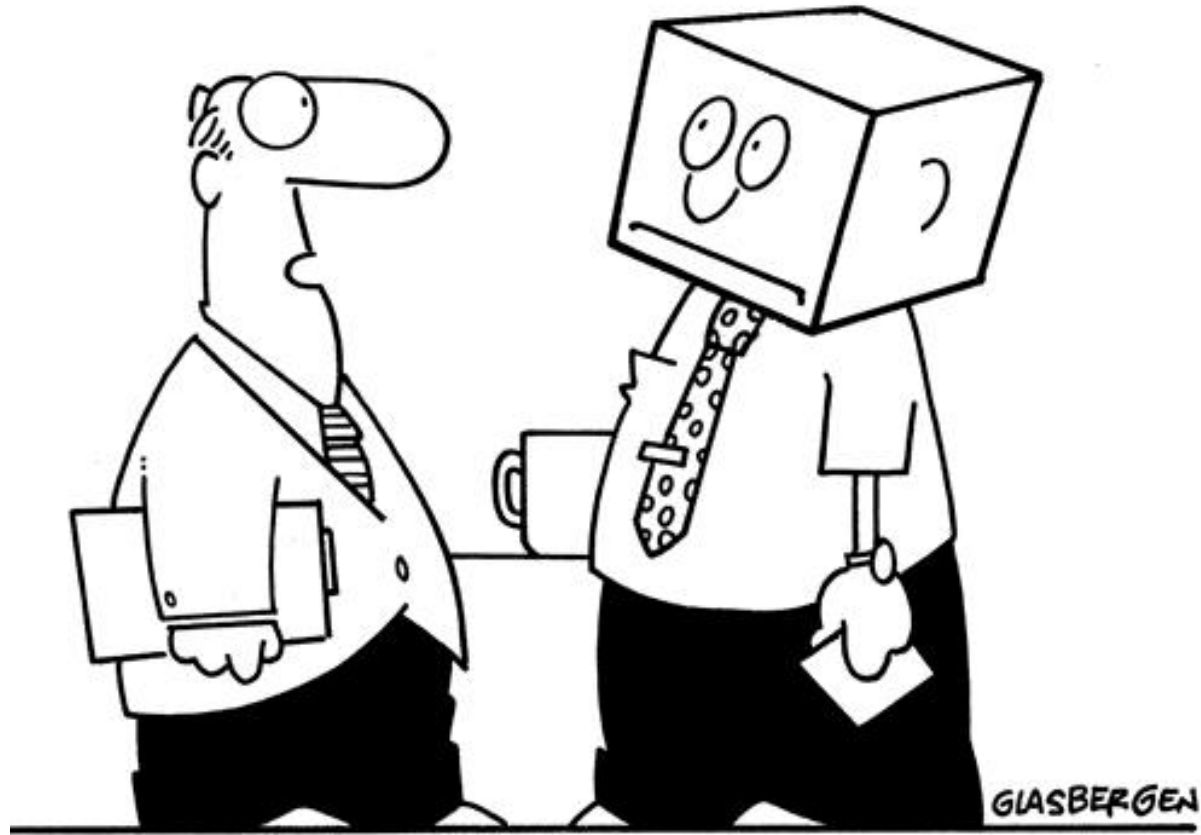


# You've bought a LIMS, now what?

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Presented by  
Charlotte Fort Findley

# You've implemented a LIMS, now what?



**"Thinking outside of the box is difficult  
for some people. Keep trying."**

# Why should you keep your LIMS current?

- Challenges of an outdated LIMS include:
  - Missed business opportunities
  - Need for additional systems to handle additional requirements
  - Software sprawl and user frustration
  - Time wasted performing tasks outside of the LIMS
- Benefits of a current LIMS:
  - Greater competitive advantage
  - Tighter integration of business applications and functions
  - A more engaged user community

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# Have you thought about?

- Future-proofing
- Maintaining
- Upgrading
- Enhancing
- Leveraging configurability

LIMS users should extend the system's functionality and keep it current with evolving organizational needs.

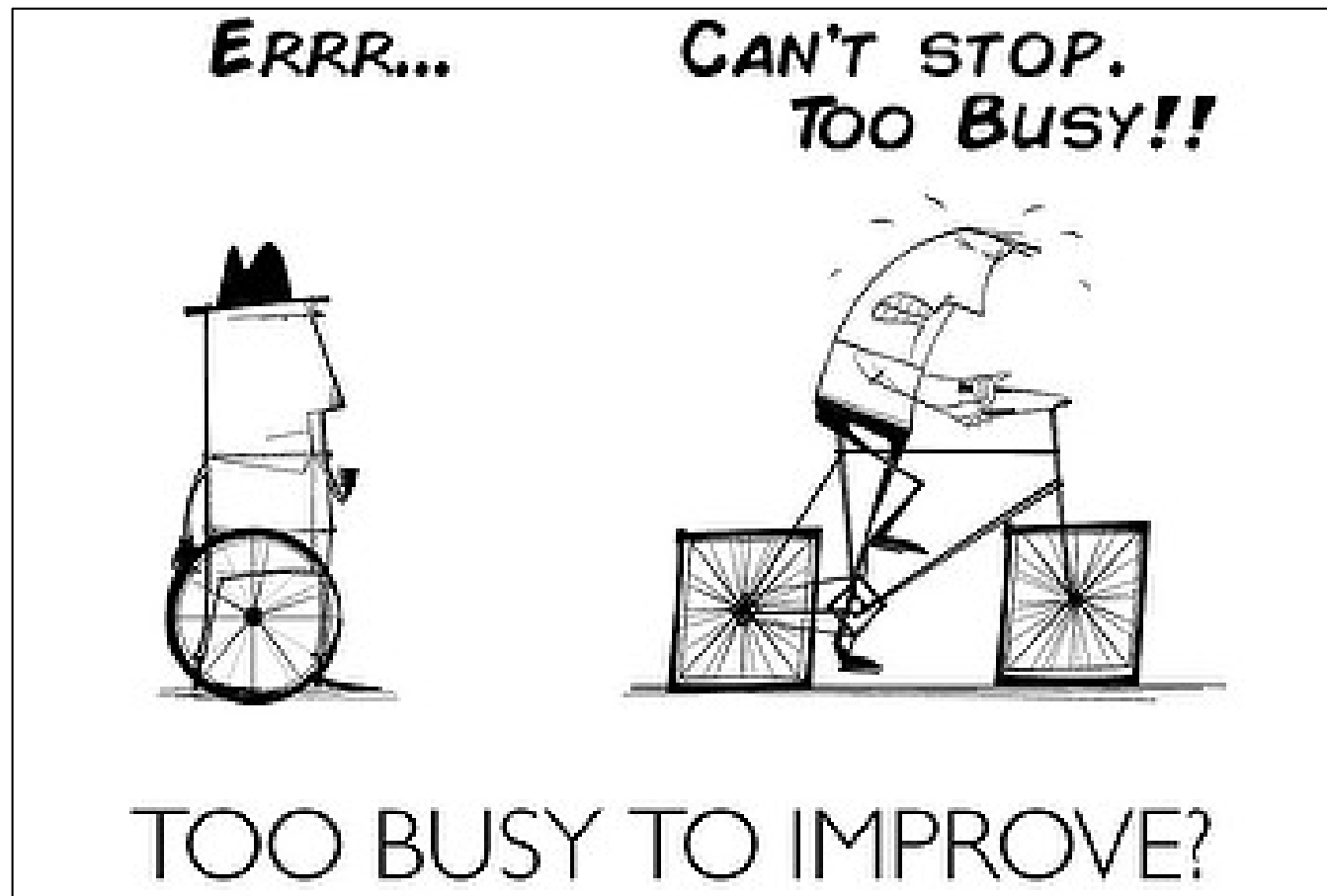
# Communicate, Communicate, Communicate

- Communicate with your LIMS team
- Communicate with your vendor
- Communicate with management
- Communicate with IT

ISO 4.1.6: Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.



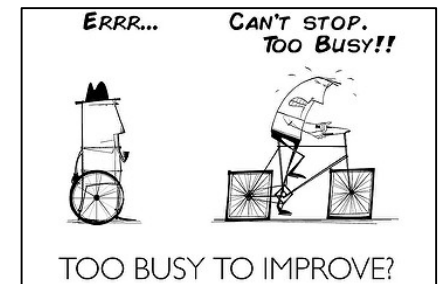
# Keep your head up!



# Moving forward!

## Think of your LIMS as a moving project

- Don't stop once you've gone live!
- Avoid LIMS becoming outdated
- If you are sitting still you will fall behind
  - The competition
  - Production
  - Efficiency



If a LIMS does not adapt to changing requirements, laboratory personnel will face additional challenges in effectively delivering results and complying with regulations and customer expectations.

# Maintaining

- Keeping up with technology
- Keeping up with changes in the laboratory
  - Expansion
    - New Processes?
    - New Testing?
    - Additional users?

Revisit the LIMS every 6 months to a year to determine if your processes have changed and if you need to adjust the LIMS based on those changes.

*ISO 4.1.6: Periodically conduct a review of the laboratory's management system*



# Enhancing...Making a List

- What should we do?
  - What regulations have changed?
  - What's working?
  - What's not working?
    - Make a list of changes and prioritize
      - Must have
      - Should have
      - Could have
      - Not required
- Did you leave off functions based on time, cost or resources?
  - Do you have already have a list of Phase Two requirements?



# Enhancing...Priorities, Priorities, Priorities

- Why should you define priorities?
  - Timeline
    - Outside events may effect the timeline
      - Regulations taking effect
      - Other projects
      - Employee changes
  - Scope, scope, scope
    - Change
      - Define how Change Control will be carried out
        - » Who, What, When, Where, Why and How?
    - Creep
  - Budget



# Enhancing...Functionality

- Barcodes

- Samples
- Chain of Custody
- Inventory



- Inventory

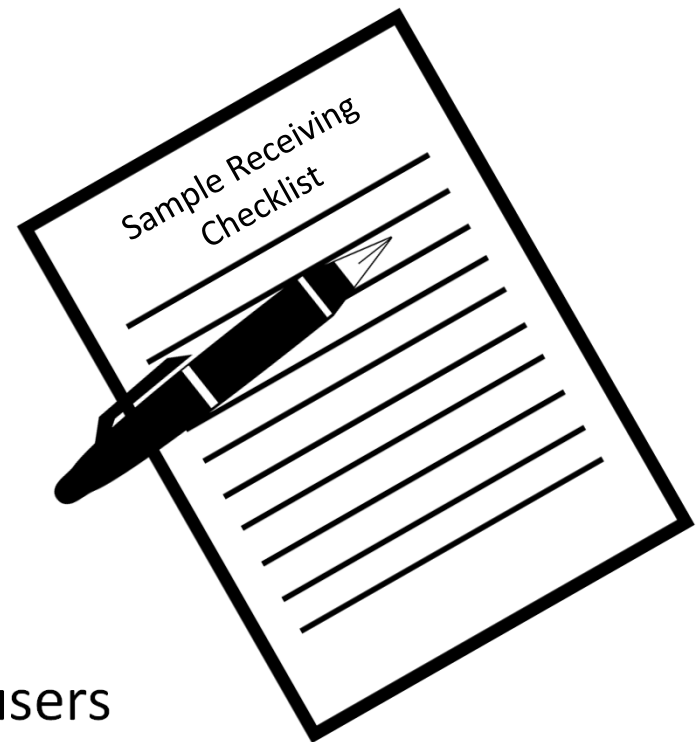
- Reagents
- Solutions
  - Track inventory used to create solutions
- Consumables
  - Attaching Safety Data Sheets/CofAs
- Reminders when it's time to reorder



# Eliminating Paper with Electronic Notebooks/Forms

What are you tracking outside of the LIMS using Excel or other paper forms?

- Replacing hardbound notebooks
- Replacing forms
  - Checklists
  - Daily walkthroughs
  - Safety
  - Chain Of Custody
    - Internal
    - External
      - Contract Labs
      - Sample Collectors
- Easy access to multiple/concurrent users
- Audit trail



# ISO Regulations and Quality Management Functions

- Improvement (ISO/IEC 17025:2005, Clause 4.10)

The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.



# Quality Management Functions in LIMS

- Quality Assurance Aspects
  - Employee Training
    - Competency
    - Employee
  - Audits
    - Internal
    - External
  - Customer Service
    - Emails
    - Phone calls
  - Corrective Action/Preventive Action (CA/PA)
    - Initiate Investigation
    - Link to specific sample/test
    - Record Details
    - Approve Investigation



# Controlled Documents

Controlled Documents : Management

**Search Criteria**

From : 29/07/2010

To : 29/07/2016

By : \*

Filename : \*

Title : \*

Description : \*

Category : \*

Reset Search

Revise

# ▼▲	Ver. ▼▲	Title ▼▲	Ref. ▼▲
AS-2012-0001	2	TEST 1234	abc
AS-2012-0002	1	FIVE THINGS YOU NEVER KNEW	Things
AS-2012-0003	1	COC DOCUMENT	
AS-2012-0004	1	SINGLE SAMPLE REPORT	Sample
AS-2012-0005	1	CEF DOC	1
AS-2013-0002	1	WORD VERSION 21 CFR 11 AND AUTOSCRIBE SOFT...	21 CFR 11v
AS-2013-0015	1	DOCUMENT MANAGER	
AS-2013-0023	1	A	LIMS
AS-2013-0025	1	USER REQUIREMENTS CHECKLIST	All
AS-2013-0030	1	FEATURES LIST MATRIX GEMINI LIMS	LIMS
AS-2013-0031	1	HARDWARE REQUIREMENTS MATRIX GEMINI V5.3	LIMS
AS-2013-0034	1	FEATURES LIST MATRIX EXPRESS	Express
AS-2013-0035	1	FAMILY - MATRIX LIMS	All

Awaiting Approval  
Obsolete Document

- Upload/Store
  - SOPs
  - Test Methods
  - Training Documents
- Track versions
- Review dates

- Circulate for employee review
- Mark as read and understood

# Instrument Calibration/Maintenance

- Track calibration and maintenance details
- Assign instrument types to tests
- Associate specific instrument ID number to samples/tests
  - Only current instruments will be displayed available for selection.





# Outside the Laboratory

- Web Interface
  - Users can log into the LIMS and complete any tasks they normally complete from inside the laboratory.
  - Sample collectors can connect directly to LIMS and enter field information or complete other tasks.

The screenshot displays the 'Result Entry' window of the LIMS software. The interface includes a top toolbar with icons for Save, Retest, Details, Menu, Text Document, Cross test, History, Calc, Limits, Attachment, Sample Test Comments, and Exit. Below the toolbar are buttons for 'Refresh All QC Calculations', 'Refresh QC By Sample', 'Include in Report', 'Fill Down', and 'Refresh All Cross Test Values'. A 'Change Method' button is also present. On the left, there are dropdown menus for 'SampleCode' (showing 'F17072301') and 'TestCod...' (showing 'PH-FLD...'). The main data entry area contains a table with the following structure:

METER MODEL NO.:		METER ID:	
	pH 4.00:	pH 7.00:	pH 10.00:
STANDARD INFO:			
CALIBRATION:			
VERIFICATION CHECK:			

At the bottom right of the main area, there are fields for 'Active Cell's Units' (set to 'A1') and 'RunCode:'. Below these are buttons for 'Select MPN' and 'Select SimPlate MPN'.

# Sample Collectors

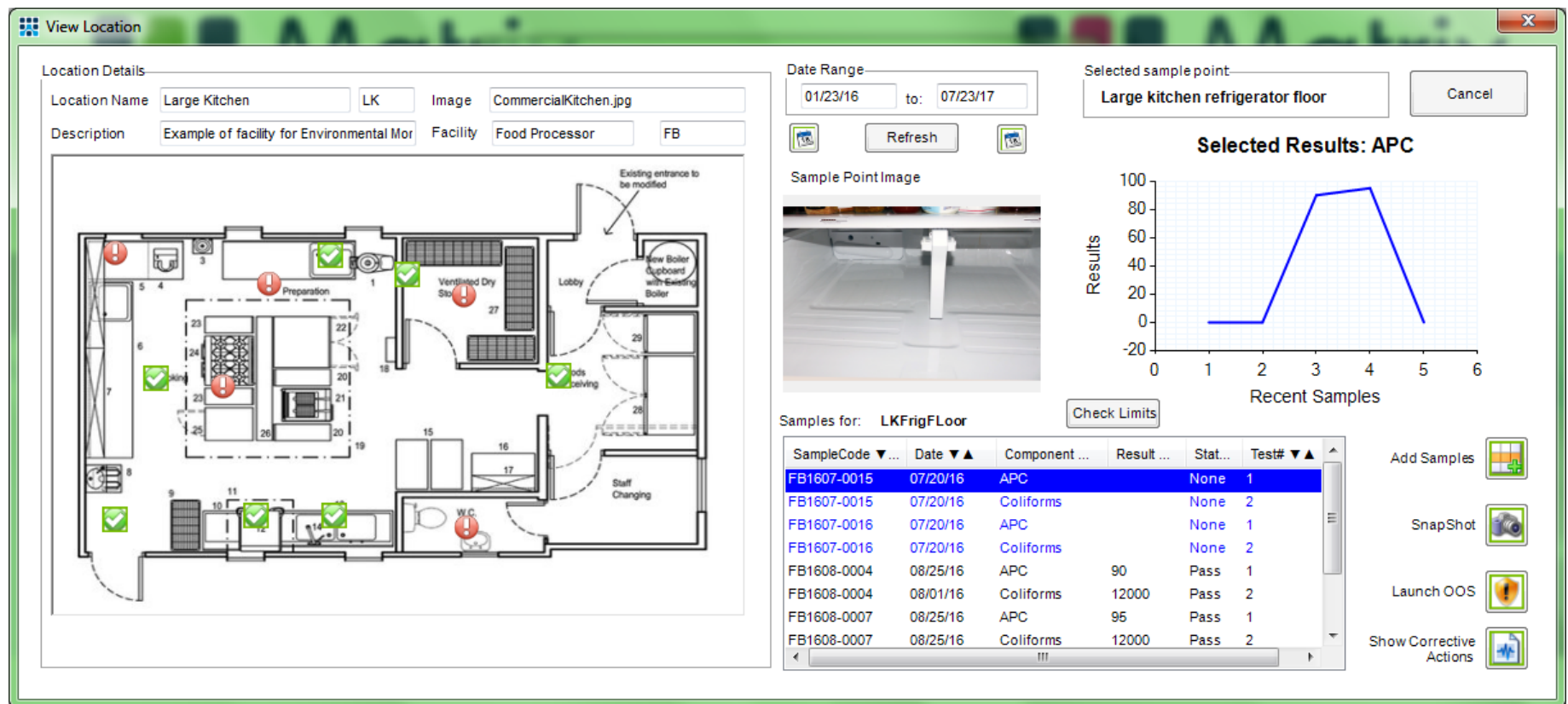
## Out in the Field Without Internet Connection

- Field Analytics Application
  - A Field Analytics System enables users to select the sample information they want and download it, edit that sample data and record relevant test results while isolated from the Internet or mobile data connection.



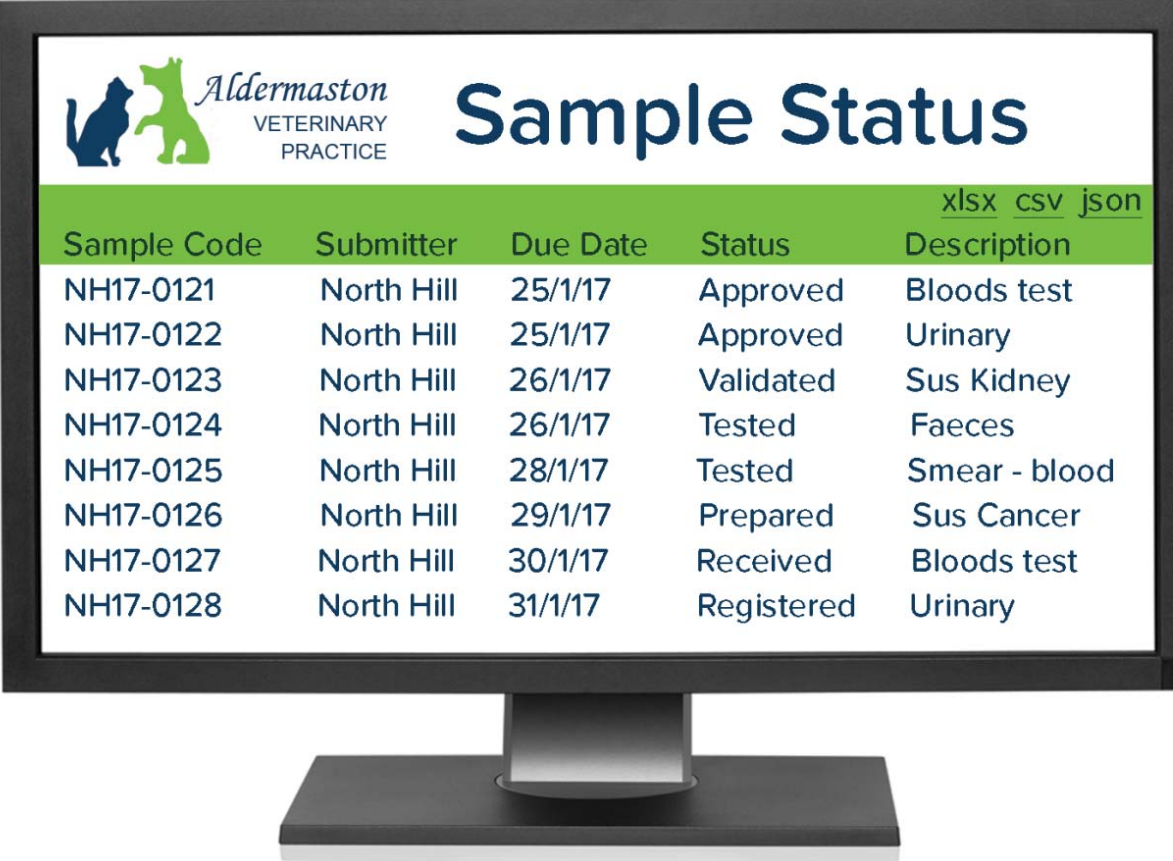
# Environmental Monitoring

## Visual sample mapping



# Web Portal

Customer access without LIMS username/password



**Aldermaston**  
VETERINARY  
PRACTICE

## Sample Status

[xlsx](#) [csv](#) [json](#)

Sample Code	Submitter	Due Date	Status	Description
NH17-0121	North Hill	25/1/17	Approved	Bloods test
NH17-0122	North Hill	25/1/17	Approved	Urinary
NH17-0123	North Hill	26/1/17	Validated	Sus Kidney
NH17-0124	North Hill	26/1/17	Tested	Faeces
NH17-0125	North Hill	28/1/17	Tested	Smear - blood
NH17-0126	North Hill	29/1/17	Prepared	Sus Cancer
NH17-0127	North Hill	30/1/17	Received	Bloods test
NH17-0128	North Hill	31/1/17	Registered	Urinary

# Management Reports

- What do you spend time researching that could be viewed in a report?
  - Ad-Hoc Searching
  - Specific customer information?
  - Historical Results?



# Leveraging Configurability

## Do you have a flexible LIMS?

- Who can make the changes?
  - You
    - Are you trained?
  - Vendor
  - You and the Vendor
    - Cost/timeline involved?
- Have you contacted the Vendor?
  - Partnership
    - List of requirements?
    - Desired timeline?

# Upgrading...What do you do?

- The process
  - Defined internally
  - SOPs
- Change control practices
  - Define how Change Control will be carried out
    - Who
    - What
    - When
    - Where
    - Why
    - How
- Development environment
  - Why do you need a development environment?
  - Testing
  - Migration

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# Questions?





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**Slow and steady...**

No need for giant leaps because small steps lead to the same finish line!





Delivering Configurable Future-Proof Solutions

Thank you for your time and attention!

Charlotte Fort Findley  
[cfortfindley@autoscribeinformatics.com](mailto:cfortfindley@autoscribeinformatics.com)  
910.512.6325