If You Build It, Automation Will Come: A Builder’s Checklist

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• None

Objectives
After this session, the attendee will be able to:
• Describe some of the technical/engineering considerations, logistical issues, and regulatory requirements that are important to consider when remodeling your lab to accommodate automation.
• Identify key internal and external resources to gather the necessary information and keep the project on target.
• Recognize potential hurdles early in the remodeling process so you can prepare a realistic timeline and "go live" date.
• Understand the importance of communication throughout the process.
A Builder’s Checklist for Laboratory Automation

• Analyzers
• Countertop/Bench space for techs/computers
• Analyzers
• Accessory equipment
• Centrifuges/Barcode label printers/Computers
• Analyzers (water/drains)
• Spigot to reconstitute reagents/QC/Calibrators
• Analyzers
• Accessory equipment & computers
• Analyzers
• Accessory equipment
• Room Temperature supplies
• Refrigerated supplies
• Frozen (-20C, -70C) supplies

Practical Considerations for Implementing a New Lab Analyzer
Julie Shaw, PhD
Clinical Laboratory News, November 2012

Practical Steps for Implementing a New Analyzer

Evaluate Vendor Proposals
Facility/Engineering Space
- Space
- Water
- Electrical
- HVAC
- Humidity
- Phone/Data
- LIS/Middleware

Establish Lab Need
Define Automation Goals
RFP
Step 1: Before Making Your Final Decision, Work with Vendors to Get All the Facts

- Important requirements:
  - Space
  - Electrical
  - Water
  - HVAC
  - Data/Phone
  - LIS/Middleware
  - Storage (RT, Refrigerated, Frozen)

Comparison Chart of Vendors Solutions

Step 1: Before Making Your Final Decision, Work with Vendors to Get All the Facts

- Important requirements:
  - Space
  - Electrical
  - Water
  - HVAC
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- Inquire about the vendor’s project management tools and support (they have great expertise/experience)
Dynacare Laboratories:
Roche Diagnostics Was Selected Solution

Project Management Tools

- Communications Management
  - Weekly Team Meetings, Project updates
- Scope Management
  - Document SOW, Change Management Protocols
- Risk Identification and Management
  - Risk Analysis, Communications
- Issues Management
  - Issue Tracking and Closure

Gantt Chart
(One Example of a Helpful Project Management Tool)

Now You Have Selected A Vendor...
What's the Next Step?
Installation of Laboratory Automation

- **5 Phases:**
  1. Initiating Phase:
     - Project is defined
  2. Planning Phase:
     - Site Prep
  3. Implementation Phase:
     - Installation
     - Validation
     - Training
  4. “Go Live” Phase:
  5. Follow-up Phase:

Initiation Phase: Project Scope Defined

- Final equipment configurations/layouts

Initiation Phase Continued

- Architectural plans drawn up by vendor
- Institutional review/approval
- State/Regulatory approval
  - Department of Commerce
  - Department of Health & Human Services
- Renovation timeline
  - Power, Drain, Water, Data, HVAC, etc…
- Training (Automation and Chemistry Analyzers)
  - Off-site key operators
  - On-site operator training
Phase 2: Site Prep/Construction

- Risk Management (Preparing for the unexpected):
  - Hidden obstacles beneath floors/behind walls
  - Outdated/discrepant electrical/plumbing plans
  - Special heating/cooling components & capacity
  - Availability of critical/emergency power
  - Working environment during construction
  - Ordering LIS interfaces/Middleware
    - Ex: Cerner Millennium Robot
Phase 3: Implementation Dates/Activities

- Prior to Sept 28th: All site prep tasks completed
- Sept 28th – Oct 2nd: Install MPA, Cobas-CE, Modular-EE; Off-site key operator training
- Oct 5th - Oct 23rd: Technical validations begin
- Oct 19th– Nov 6th: Interfacing activities (MPA, CE, EE)
- Oct 26th – Nov 6th: On-site training activities
- Nov 9th – Nov 13th: Wrap up outstanding tasks
- Nov 16th – Nov 20th: Mock “Go Live” activities
- Nov 23rd: Go live

Identify Potential Hurdles/Delays

- Determine all preparatory tasks needed for analyzer installations, order of events:
  - Counters/bench space removed/additional, workstations, etc.
  - Confirm availability of utilities (water, power, drain, data connections, etc.)
  - Determine implementation plan for LIS & Middleware (installation components required, network connections, staff training, etc.)
  - Determine validation plan for analyzers (pull & save high/low samples for correlation of low volume tests)
  - Storage of reagents/supplies (RT, Refrigerated, Frozen)
  - Confirm purchase and expected delivery date of key LIS components
    - Cerner Millennium “Robotics” interface

Other Items to Consider/Plan For

- Complete required vendor paperwork:
  - MPA System Configuration Book agreement
- Determine your validation plan and acceptance criteria
- Develop technical installation scope of work
- Develop a clear LIS interface scope document
- Identify Risks
  - On-going process
Phase 4: Go-Live

• Inform hospital/physicians when “Go Live” is
• Adequate On-site support:
  • LIS
  • Vendor
  • Lab leadership
  • Staffing
• Identify and report any issues immediately
• Prepare back-up contingency plan

Phase 5: Follow-up and Optimization
Post “Go Live”

• Continue to monitor any issues
• Regular communication w/ vendor, staff, physicians/clients, hospital administration

Summary

• Use your builder’s checklist to identify potential logistical, engineering, and/or regulatory hurdles/issues early
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• Communicate expectations and issues clearly with all parties
  • Vendor
  • Lab/Hospital Administration
  • Physicians/ Clients
  • Contractors

• Take advantage of vendor resources, tools, and experience

The Conclusion

• Being prepared, well-informed, and in constant communication with all parties will lead to a successful outcome!!!