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

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Financial Disclosures

• 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.
Outline
A Builder’s Checklist for Laboratory Automation

Builder's Checklist

- Permits
- Space requirement
  - Analyzers
  - Countertop/Bench space for techs/computers
- Electrical requirement
  - Analyzers
  - Accessory equipment
  - Centrifuges/Barcode label printers/Computers
- Water requirement
  - Analyzers (water/drains)
  - Spigot to reconstitute reagents/QC/Calibrators
- HVAC/Humidity requirement
  - Analyzers
  - Accessory equipment
- Phone/Data jacks
  - Analyzers
  - Accessory equipment & computers
- LIS/Middleware requirements
- Storage requirements
  - Room Temperature supplies
  - Refrigerated supplies
  - Frozen (-20C, -70C) supplies
Practical Steps For Implementing Lab Automation

1. Establish Lab Need
2. Define Automation Goals
3. RFP
4. Evaluate Vendor Proposals
   - Facility/Engineering Specs
     - Space
     - Water
     - Electrical
     - HVAC
     - Humidity
     - Phone/Data
     - LIS/Middleware

Flowchart: Full Method Evaluation → Decision to Purchase → Create Implementation Committee → Choose Desired “Go Live” Date → Electronic Patient Record → Staffing Requirements → Supplies → Quality Control → SOPs → Internal and External Clients → Communications → LIS Connectivity → Reference Intervals → Critical Values → Comments → Reflex Testing → Autoverification → Delta Checks → Temperature/Humidity Requirements → Electrical Requirements → Water Requirements → Space Requirements
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

<table>
<thead>
<tr>
<th>Company</th>
<th>Proposed Orientation</th>
<th>Dimensions</th>
<th>Water Needs</th>
<th>LIS/Middleware</th>
<th>HVAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic</td>
<td>Top/Bottom 2038</td>
<td>46 x 17.5 x 40</td>
<td>250 ml-1000 ml</td>
<td>2-15 times daily</td>
<td>24 hour (marginal)</td>
</tr>
<tr>
<td>Sigma</td>
<td>G3003G</td>
<td>46 x 17.5 x 40</td>
<td>250 ml-1000 ml</td>
<td>2-15 times daily</td>
<td>24 hour (marginal)</td>
</tr>
<tr>
<td>Eppendorf</td>
<td>1-1001, 2-1004</td>
<td>46 x 17.5 x 40</td>
<td>250 ml-1000 ml</td>
<td>2-15 times daily</td>
<td>24 hour (marginal)</td>
</tr>
<tr>
<td>Emultex</td>
<td>2-1001, 3-1003</td>
<td>46 x 17.5 x 40</td>
<td>250 ml-1000 ml</td>
<td>2-15 times daily</td>
<td>24 hour (marginal)</td>
</tr>
<tr>
<td>Beckman Coulter</td>
<td>2-1101, 3-1103</td>
<td>46 x 17.5 x 40</td>
<td>250 ml-1000 ml</td>
<td>2-15 times daily</td>
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</tr>
<tr>
<td>Thermo Fisher</td>
<td>2-1101, 3-1103</td>
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Step 1: Before Making Your Final Decision, Work with Vendors to Get All the Facts

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  - Water
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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 Robotic
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/added, 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
Summary

• Use your builder’s checklist to identify potential logistical, engineering, and/or regulatory hurdles/issues early

• 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!!!