AACC Laboratory Automation
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If You Build It, Automation Will Come: A Builder's Checklist

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Financial Disclosures

- None

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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.

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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

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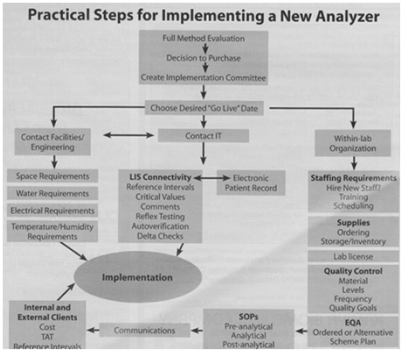
Practical Considerations for Implementing a New Lab Analyzer
Julie Shaw, PhD
Clinical Laboratory News, November 2012



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Practical Steps For Implementing Lab Automation

Establish Lab Need

↓

Define Automation Goals

↓

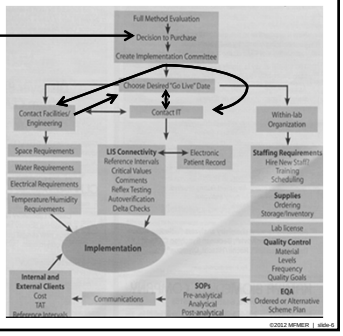
RFP

↓

Evaluate Vendor Proposals

Facility/Engineering Specs

- Space
- Water
- Electrical
- HVAC
- Humidity
- Phone/Data
- LIS/Middleware



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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

Dimensions	Water Needs	LIS/Middleware	HVAC

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

- Important requirements:
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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**

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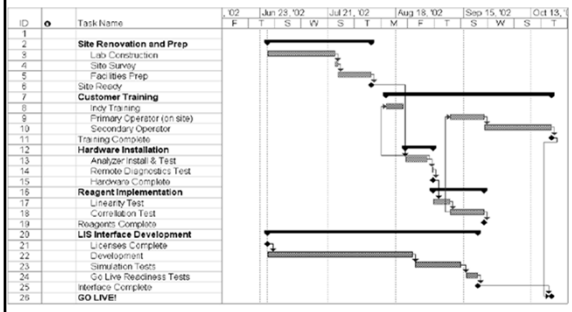
Gantt Chart

(One Example of a Helpful Project Management Tool)



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Now You Have Selected A Vendor... What's the Next Step?

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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:

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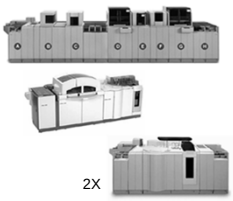
Initiation Phase: Project Scope Defined

- Final equipment configurations/layouts

Roche Automation/Instrumentation



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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

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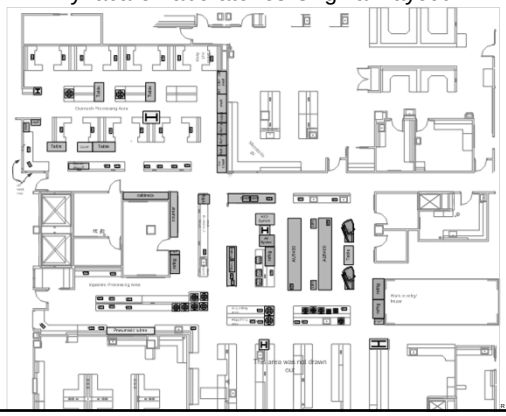
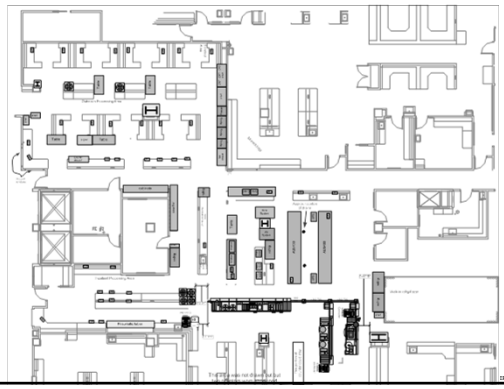
Dynacare Laboratories Original Layout

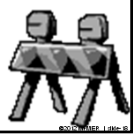


Dynacare Laboratories Layout-Phase 1



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
- Nov16th – Nov 20th: Mock "Go Live" activities
- Nov 23rd: Go live

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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

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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

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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

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

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

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Summary

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

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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

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The Conclusion

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

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