



# MES in Biotech



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***The following Strategic Initiatives of MESA International are associated with this presentation:***

Lean Manufacturing

Quality & Regulatory Compliance

Product Lifecycle Management (PLM)

Real-Time Enterprise

Asset Performance Management (APM)

## General MES Implementation

Overview of typical MES implementation

## Biotech Specific Challenges

More detail on specific Biotech challenges

## Summary

Summary

General MES Implementation

Biotech Specific Challenges

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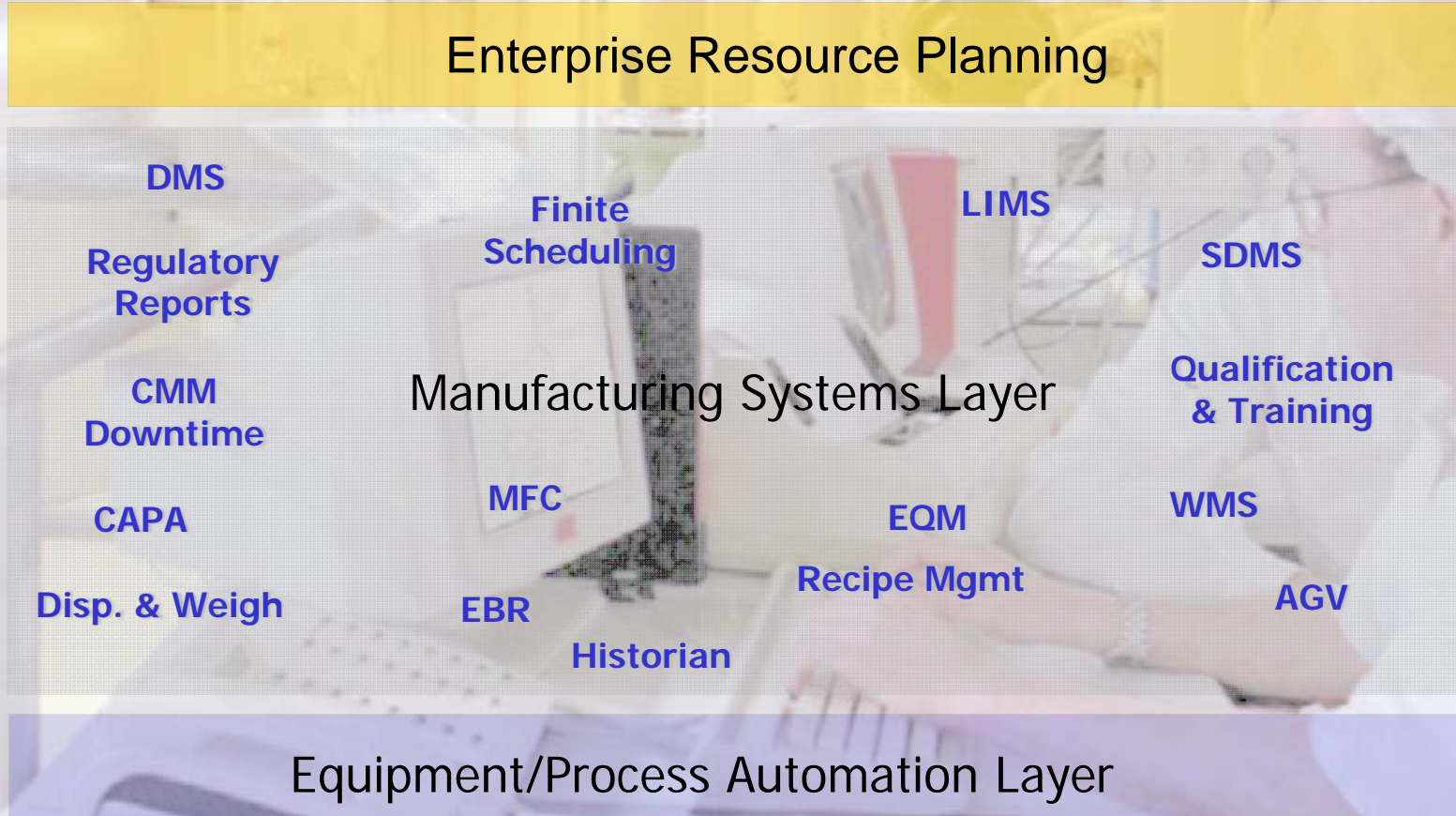
# Paper

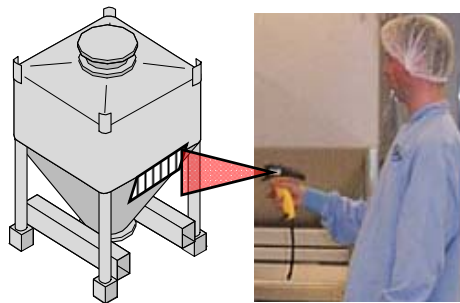


- 1,000 of signatures
- Attachments
- No visibility
- Poor RFT
- Arduous Review Cycle
- Wasted Effort
- Does not improve quality

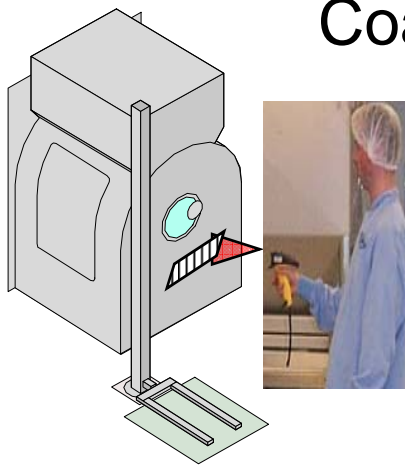


# Multitude of Systems

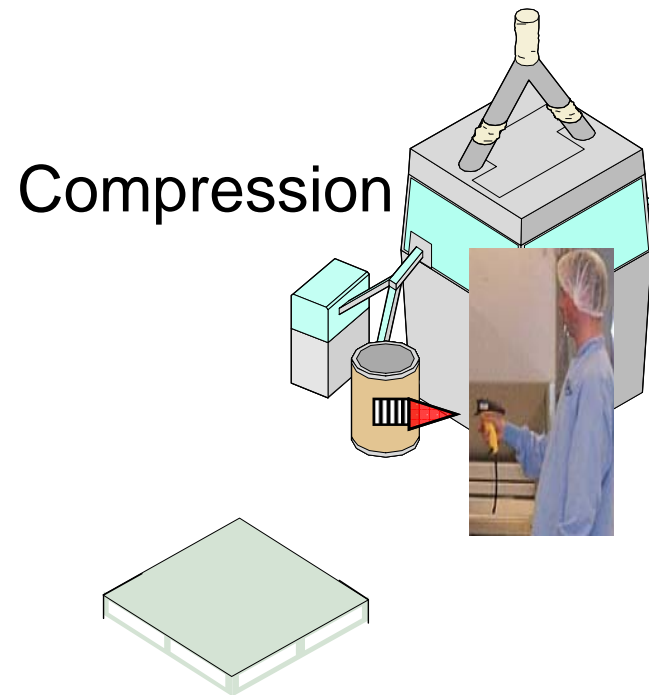




Blending



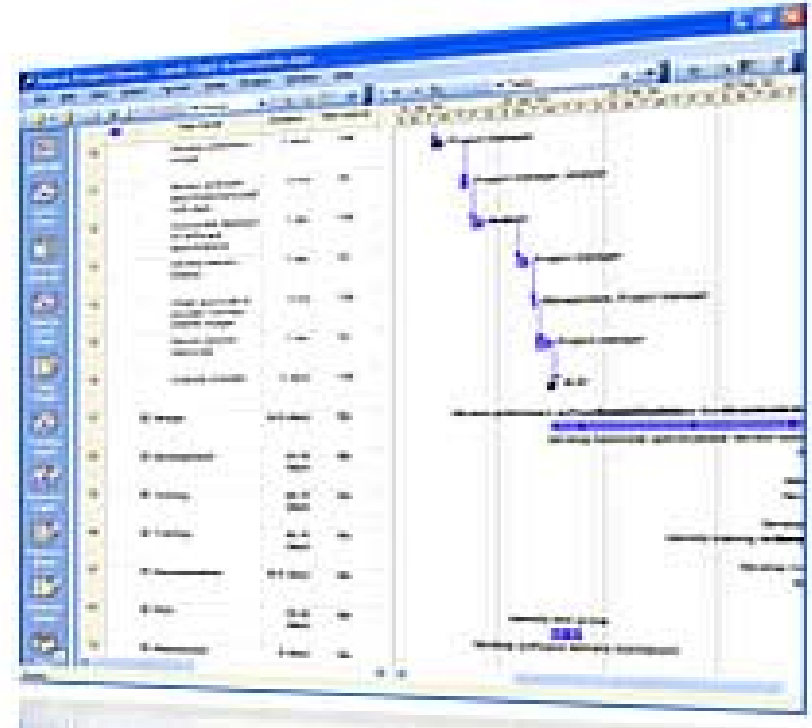
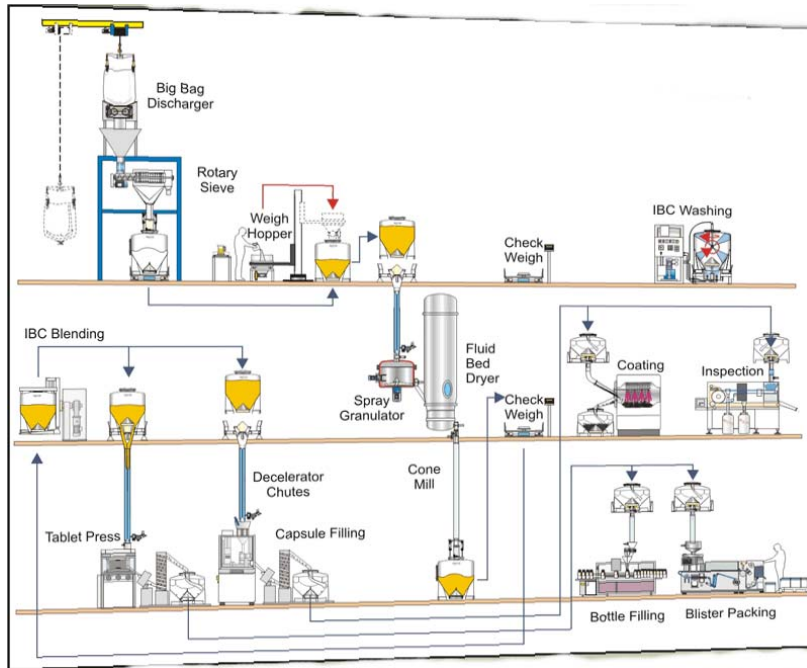
Coating

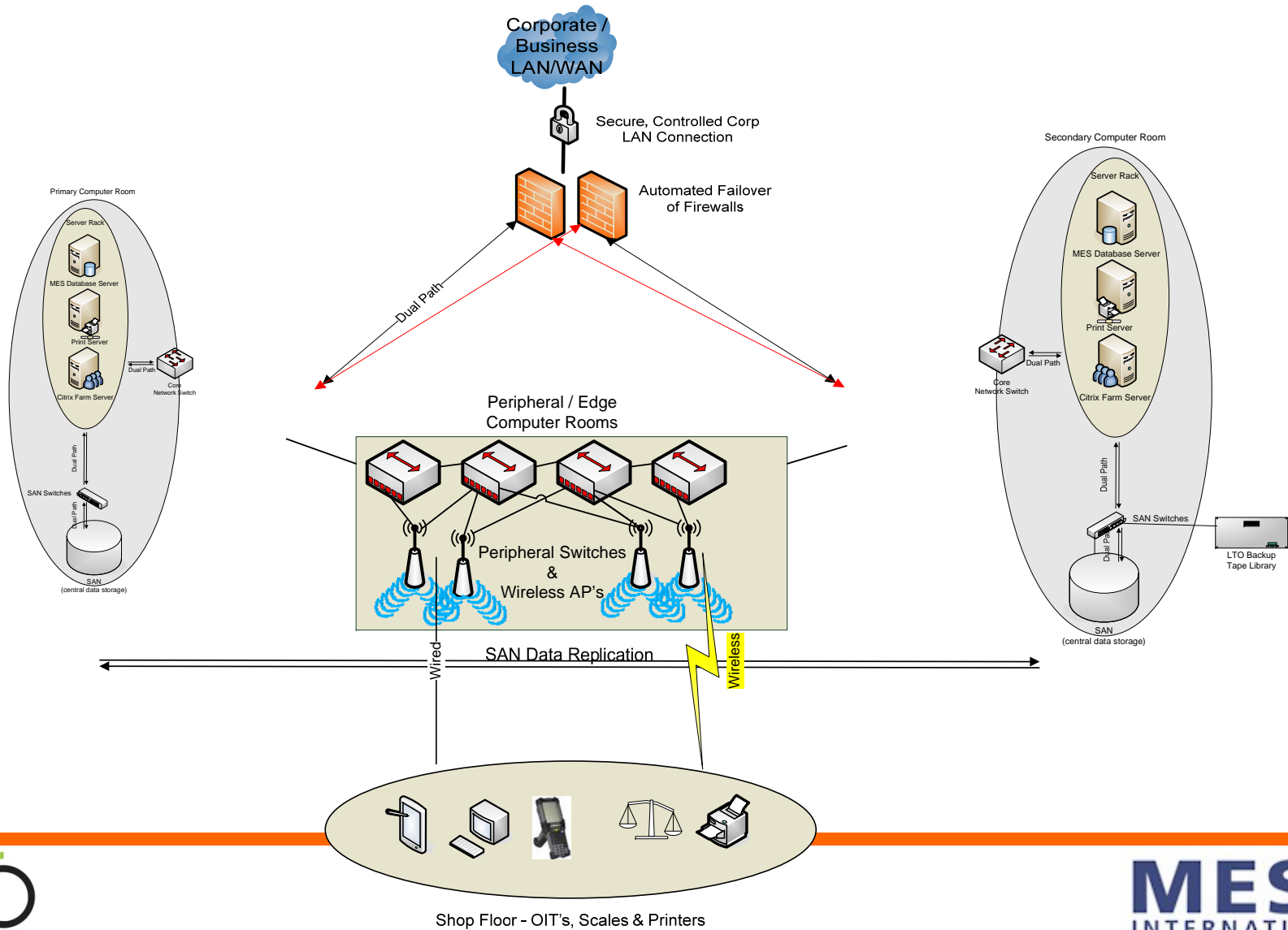


Compression



# Scheduling & Visibility







# Return On Investment

Labour



ROI

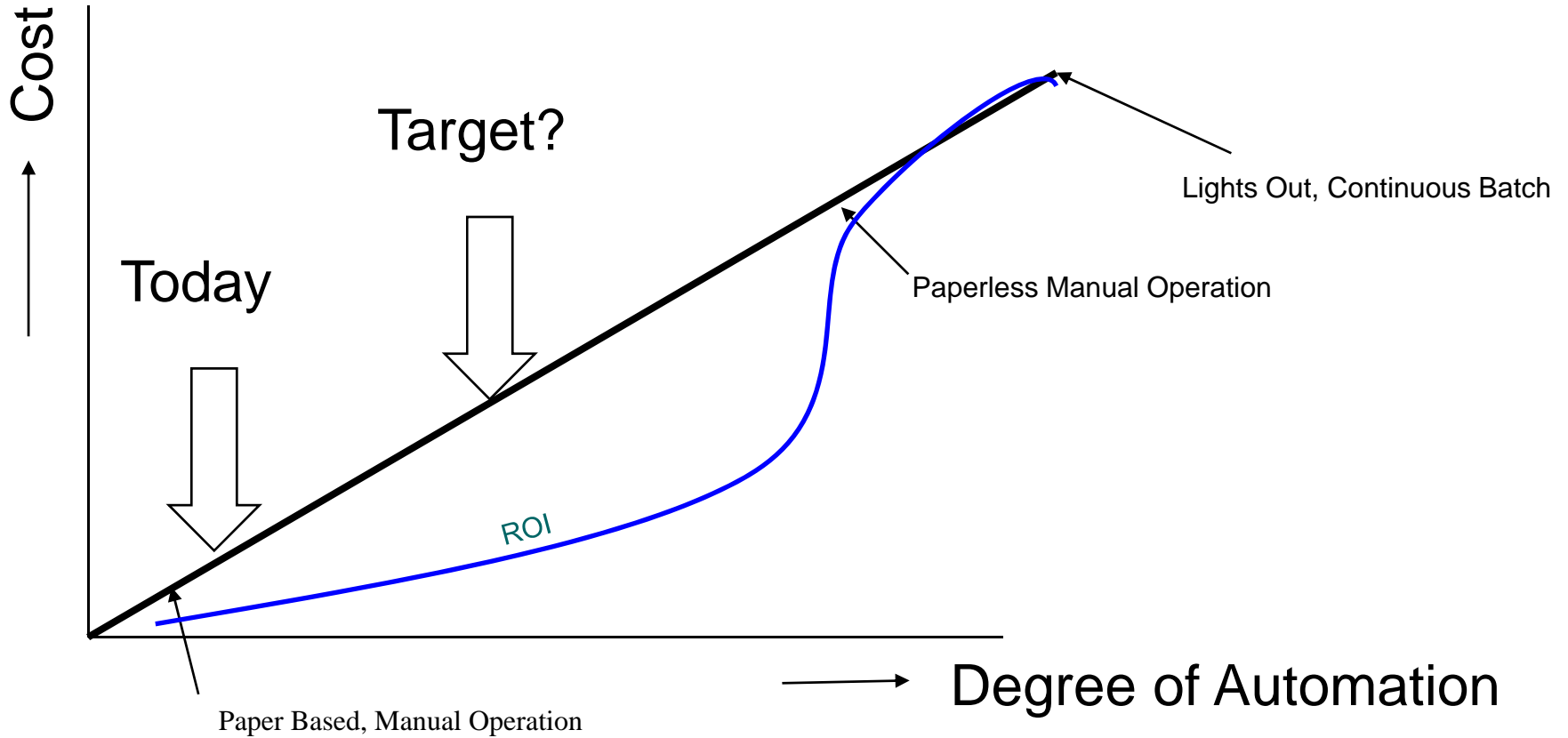
Materials



Equipment



# Level of Automation





# Overall System Landscape



Global

Enterprise Resource Planning System (ERP)

Variety of Reporting Systems

Laboratory Information Management System (LIMS)

Document Management System (DMS)

Personnel Qualification & Training (PQ&T)

Corrective And Preventative Action tracking (CAPA)

Warehouse Management (WM)

Detailed Scheduling & Planning

Material Tracking (MT)

Equipment & Container Management  
(ECM)

Recipe & Configuration Management

Weighing & Dispense (W&D)

Electronic Batch Record (EBR)

Data Historian (DH)

Process Automation

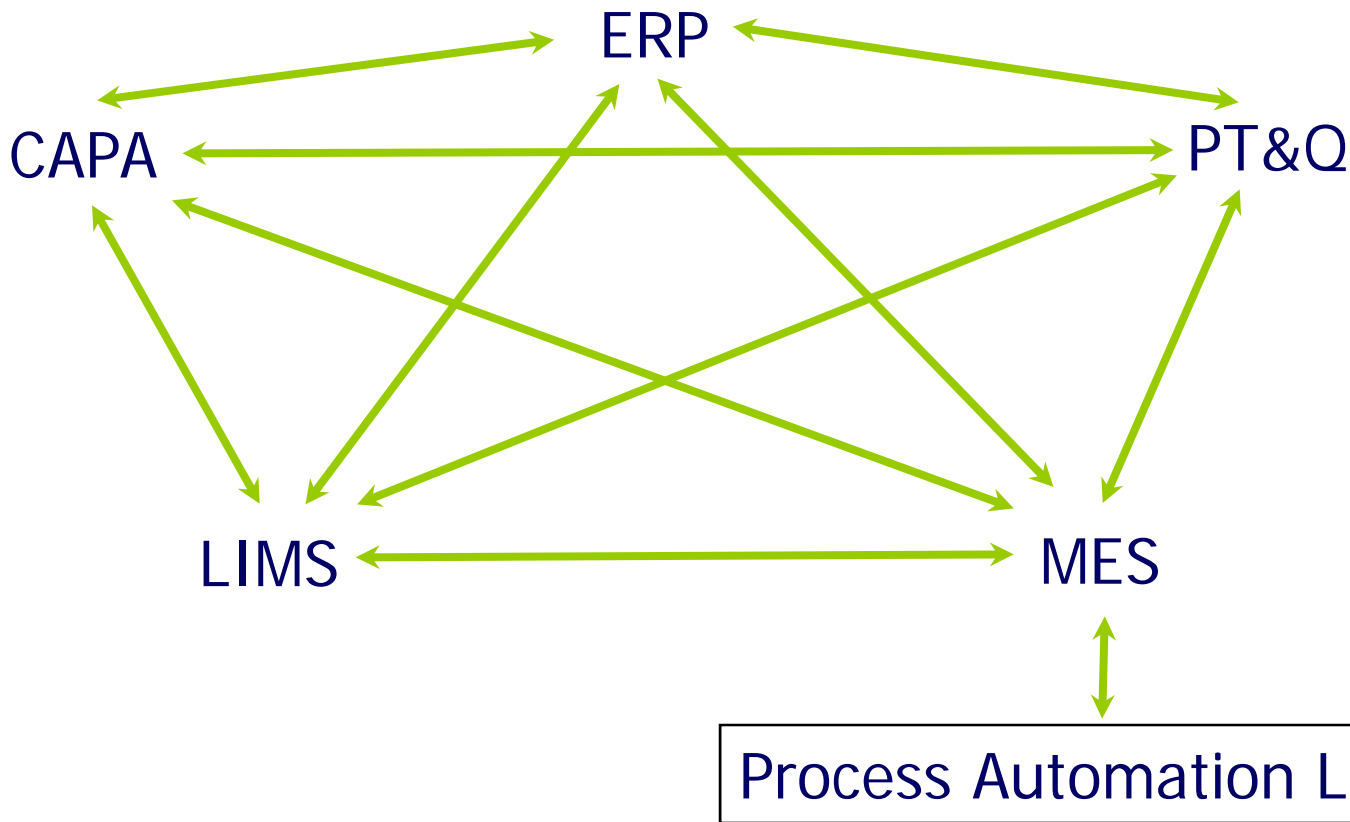


Plant



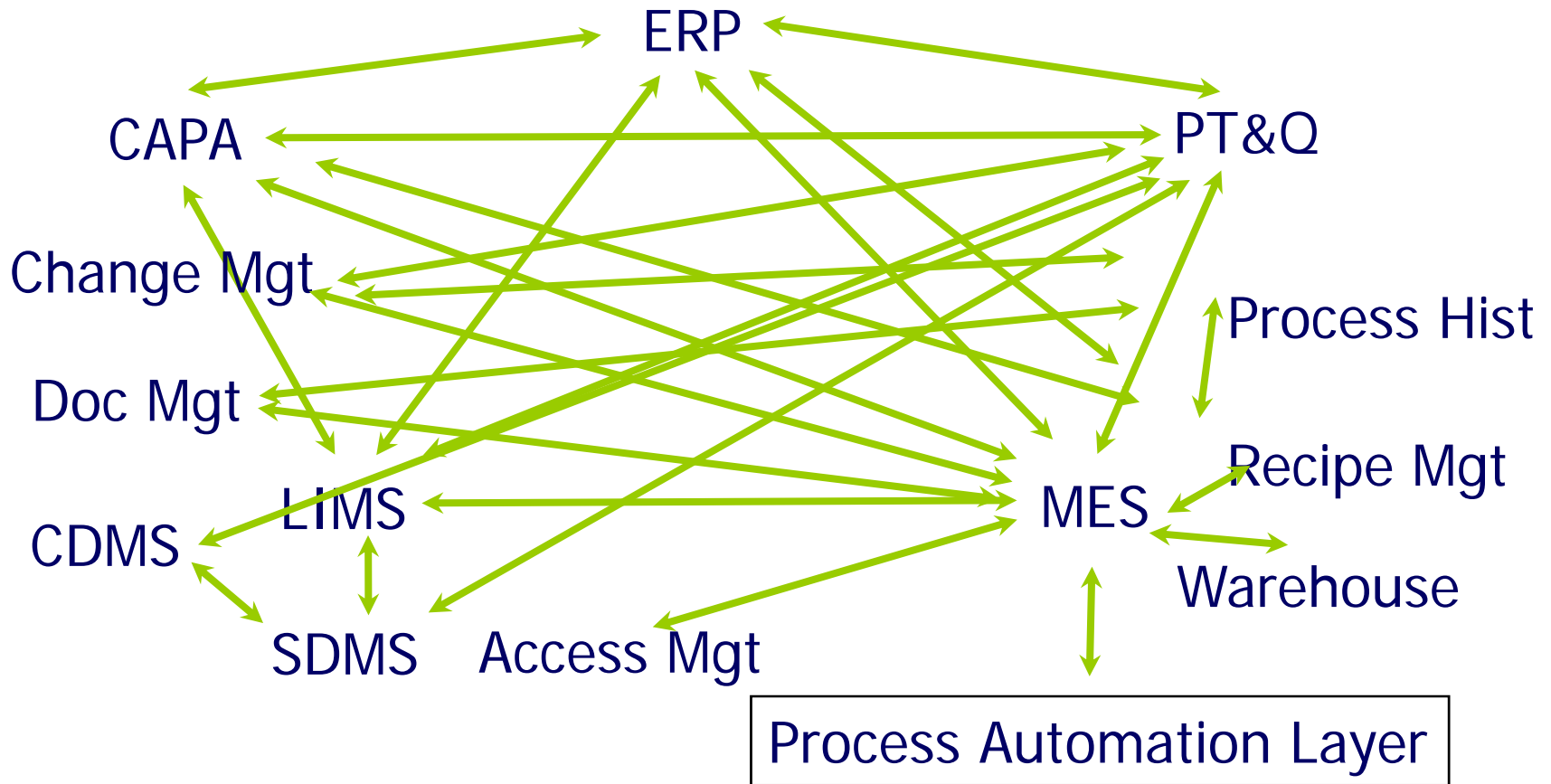
# Best of Breed v Integrated Approach

## Interfaces

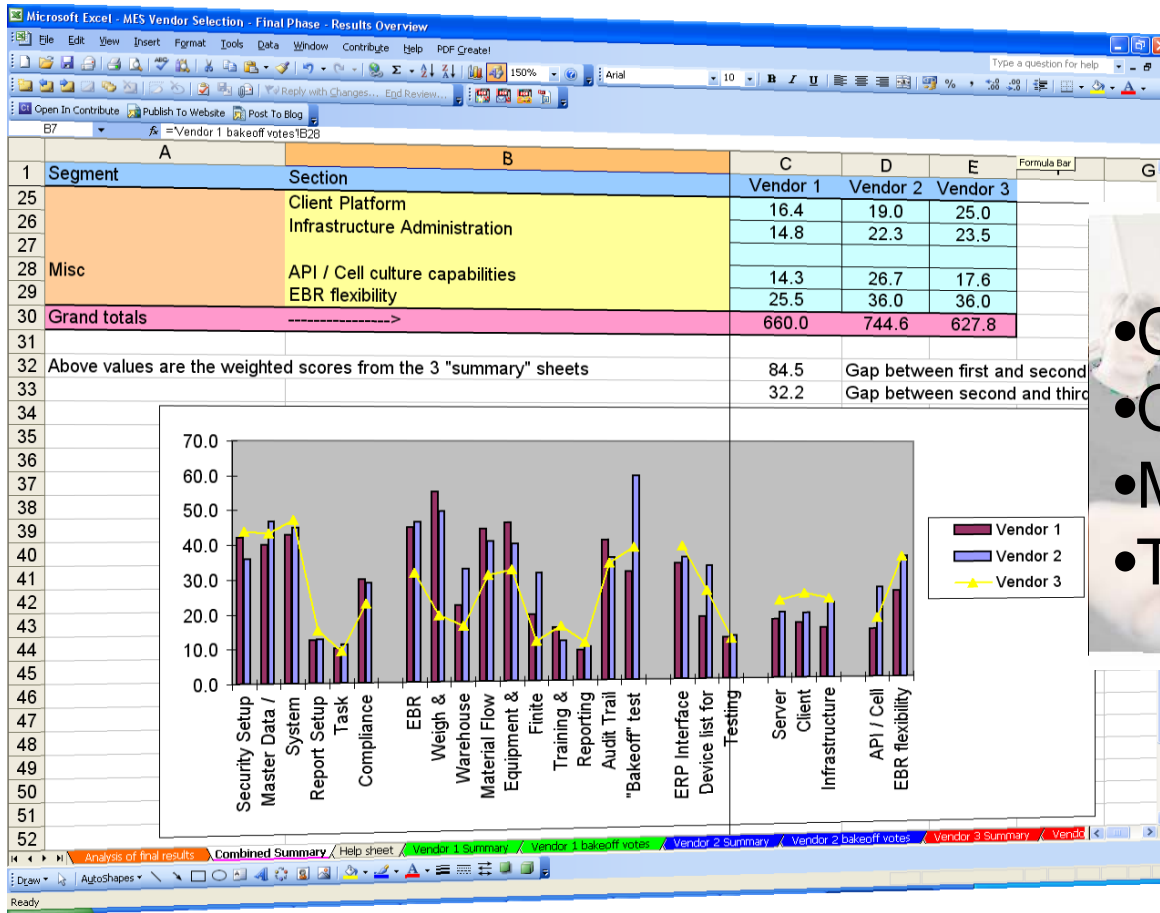


# Heading Towards

## Interfaces

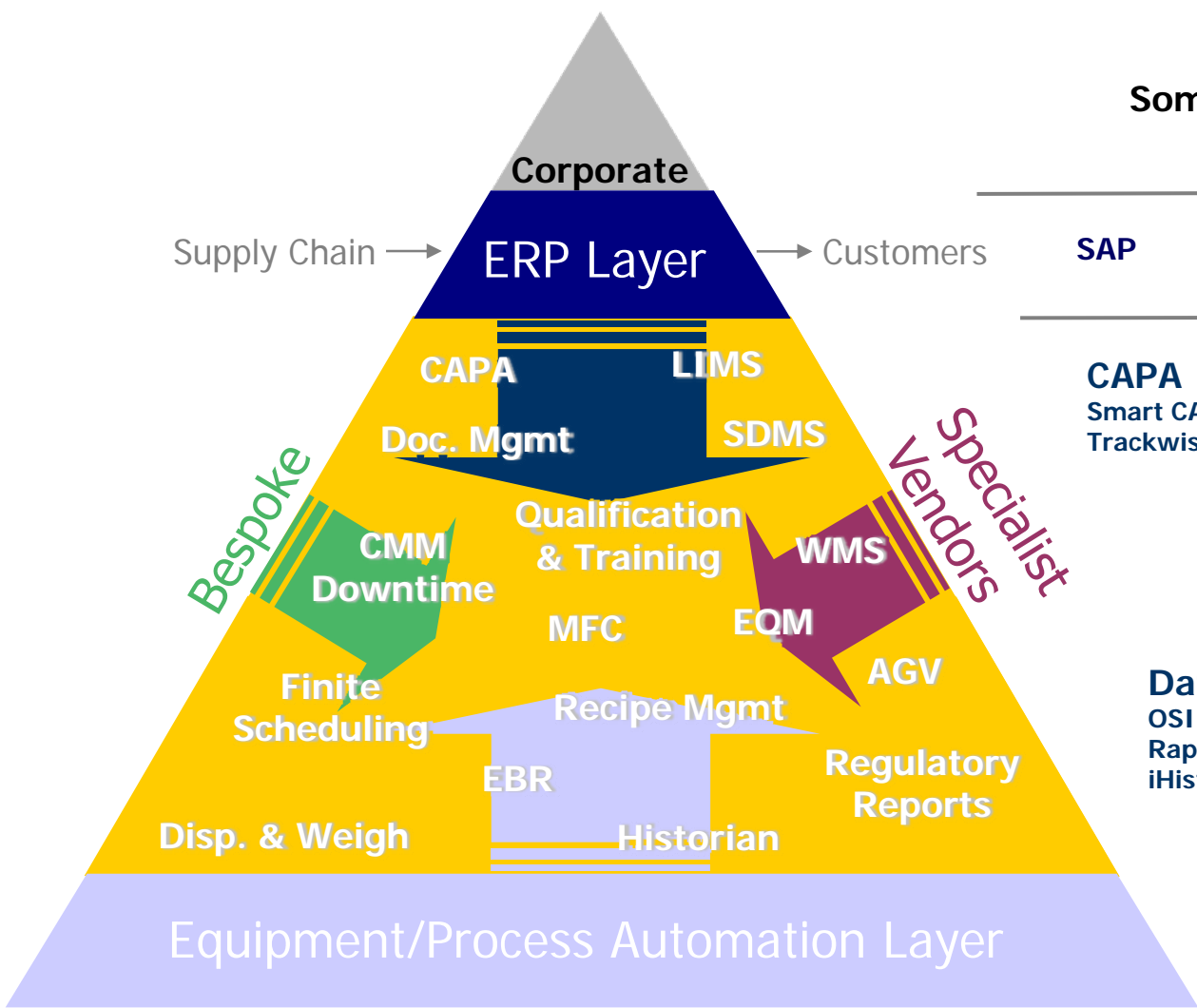


# Vendor Selection



- Corporate
- Quality
- Manufacturing
- Technical Services

# Vendor Selection



## Some of the Vendors ....

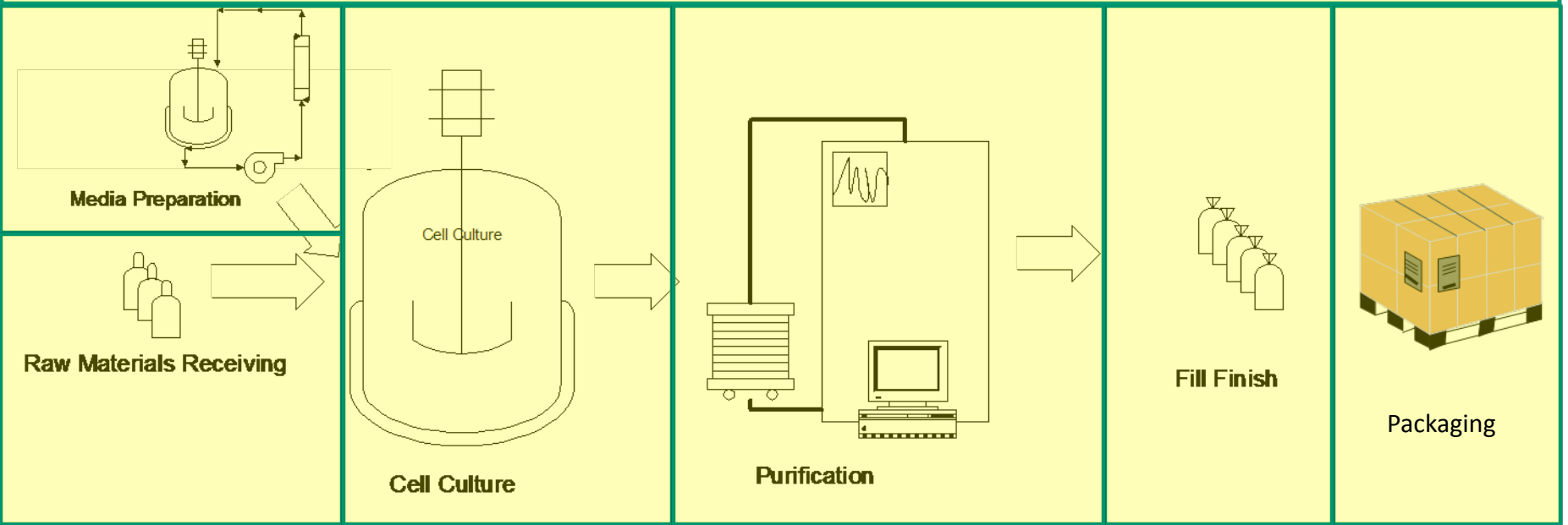
SAP	BPCS	JD Edwards	BAAN
<b>CAPA</b> Smart CAPA Trackwise	<b>MES</b> Camstar Elan POMS Propack Syncade Werum	<b>LIMS</b> SQL*LIMS LabWare SampleManager Thermo	
<b>Data Historian</b> OSI PI Rapid iHistorian		<b>Document Management</b> LiveLink Documentum	
<b>Siemens</b> <b>Rockwell</b>	<b>Honeywell</b>	<b>Emerson</b> <b>GE Fanuc</b>	

# Implementation - Phasing

Enterprise Resource Planning

ERP

## Weigh & Dispense/Material handling



Field Level



Cell Culture

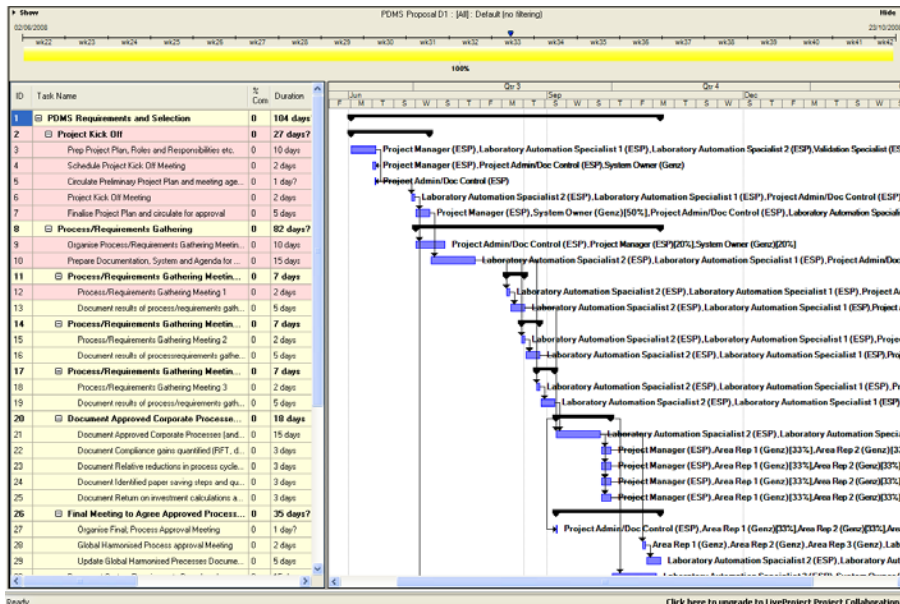
Fill Finish

DCS / PLC



# Project Plan & Resourcing

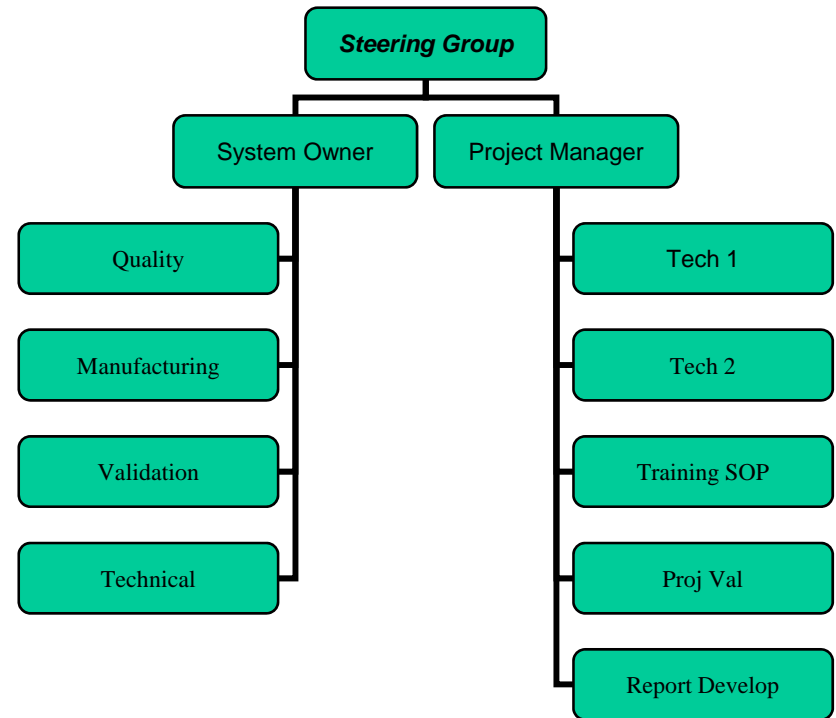
## Project Plan



## Resources

Business

External





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# Challenges

A: Complexity of the Process

B: Automation Layer Integration

C: Peripherals and Equipment Interfaces

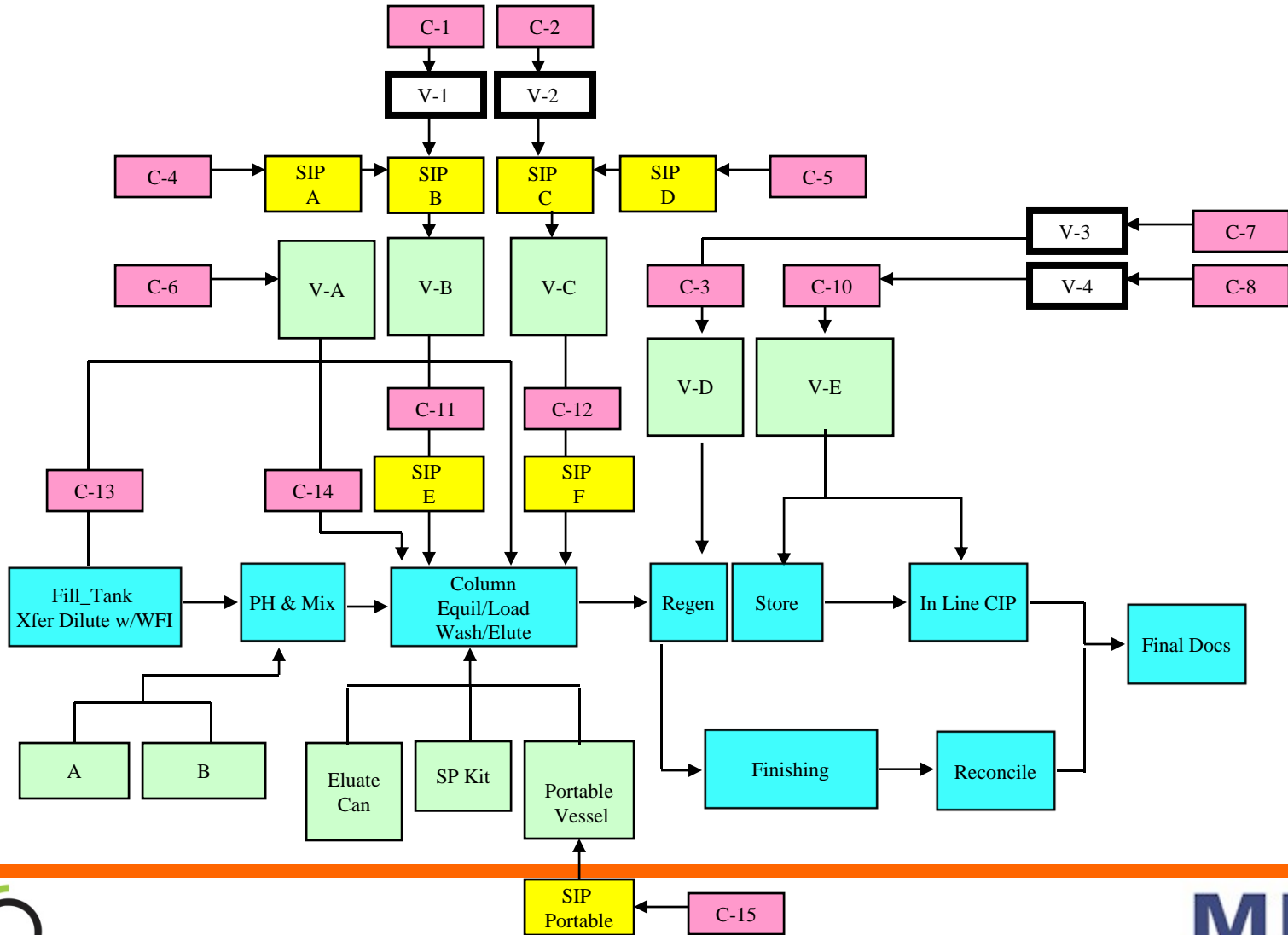
D: Cut Over in this complex environment





# Typical Purification Step

Complexity of Process



## One Process Step (part of MBR with 10 Steps)

- 8 Column prep Steps
- 10 Buffers and Solutions
- 7 SIP
- 14 CIP



# Plant/Process Model

Complexity of  
Process

- Planning and Scheduling
- ERP interface
- One Big WO or many small ones.
  - CIP/SIP
  - Colum Prep and Filter Prep
  - Filter Testing, Integration of FIT
  - Buffer and solution prep
  - Pooling and splitting
  - Batch genealogy

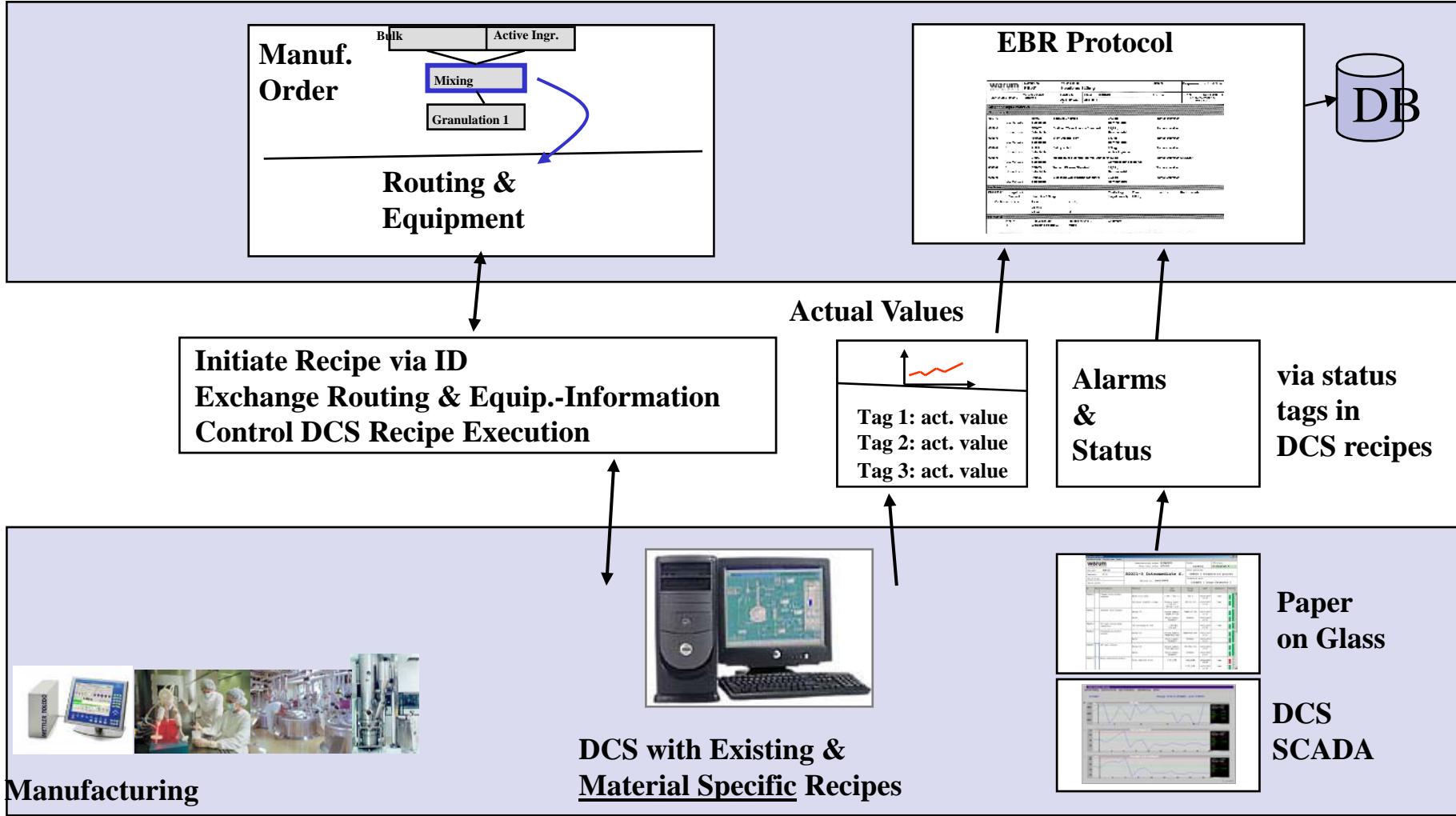
- Management of room and equipment status.
  - Appropriate room/equipment model

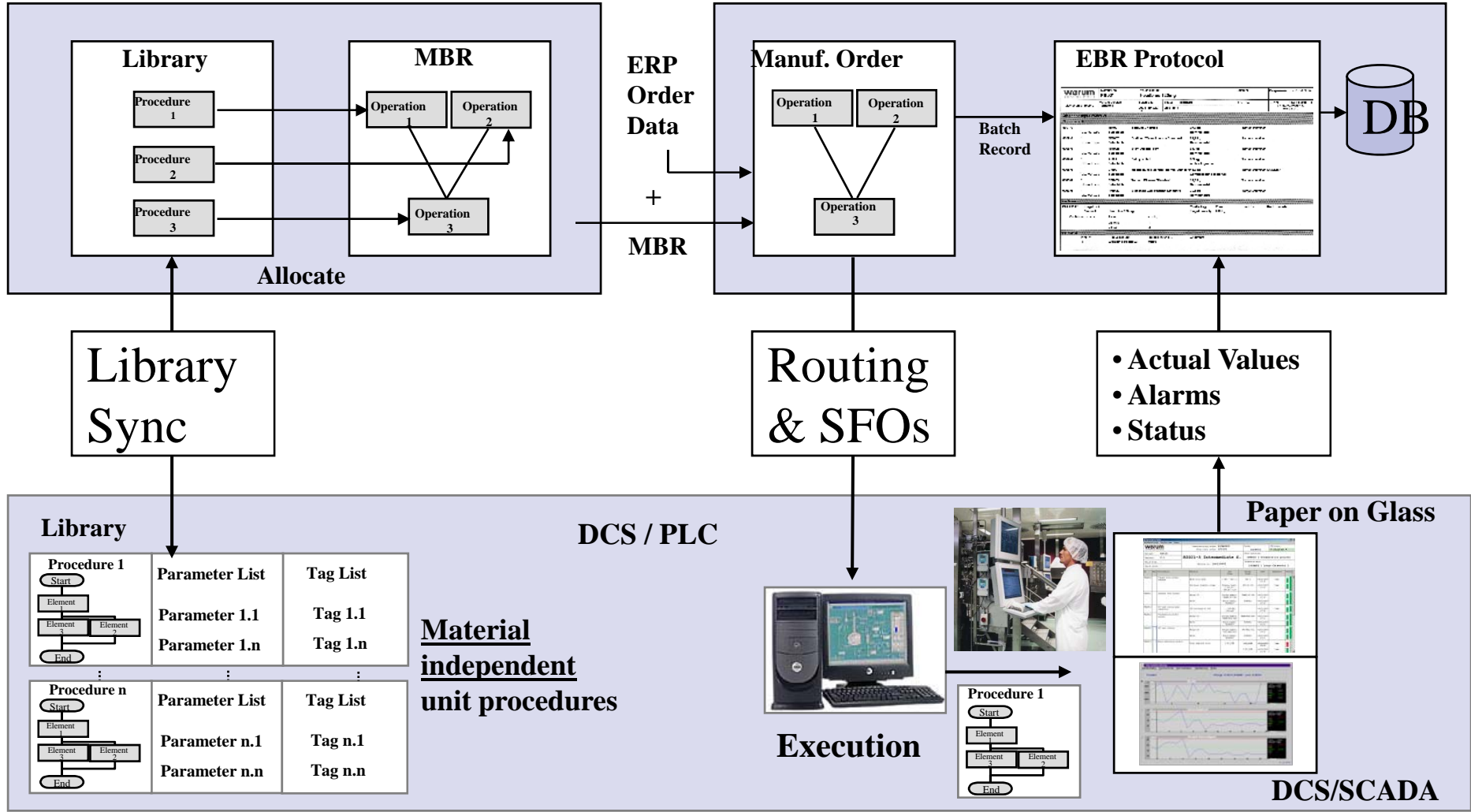
- Automation Layer Integration
  - Batch Structure
  - Synchronisation
  - Alarms and Events
  - RBE
  - ‘Light Touch’ or deep integration
  - No Material Specific Information at DCS layer?
  - New plant or ‘cut over’



# Basic DCS Interface

Automation Layer Integration

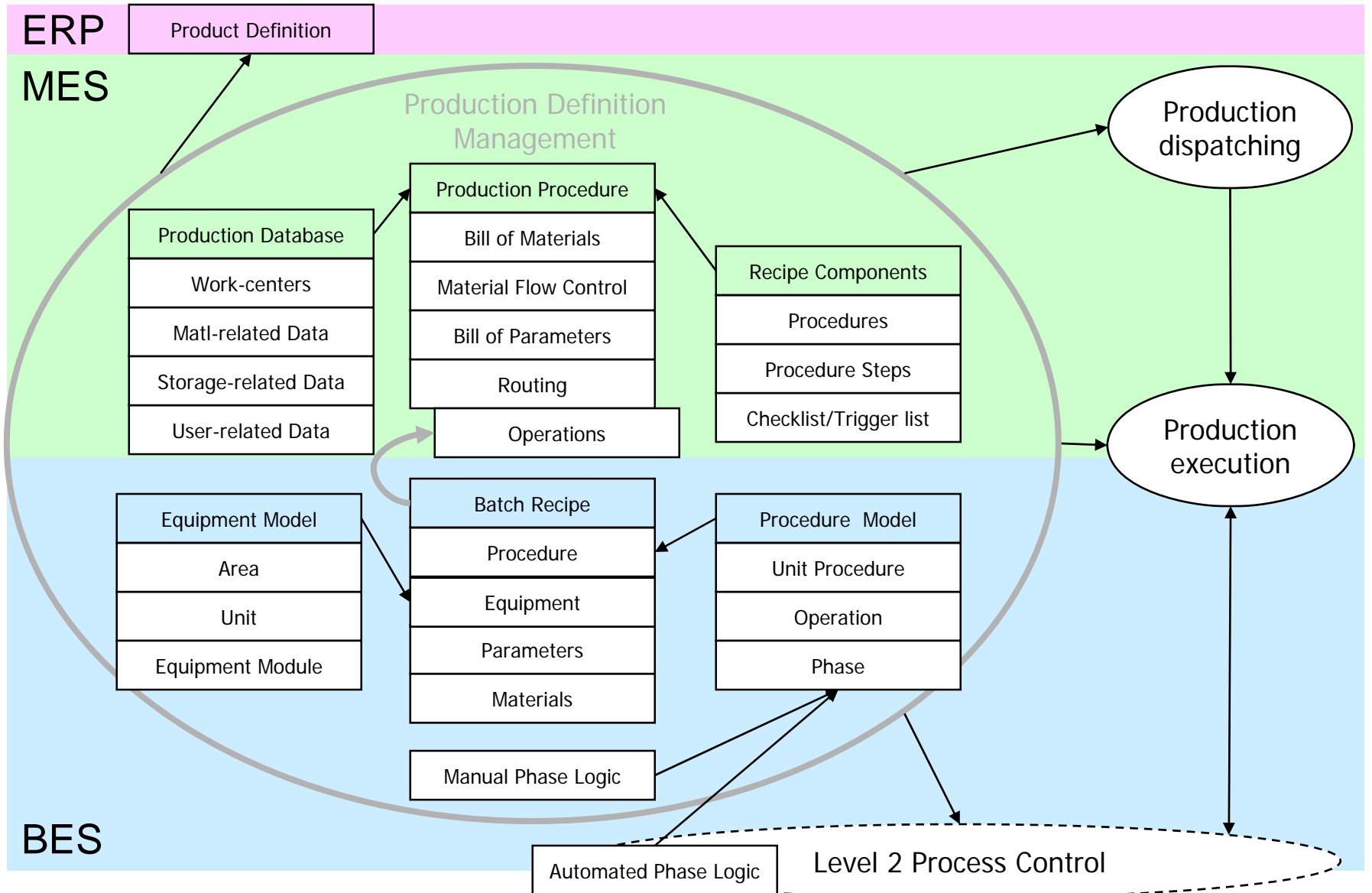




# Integration of Batch Functionality

Challenge B

Automation  
Layer  
Integration



- HMI/Scanner in Sterile Area
- Sharing HMI with SCADA/DCS
- Printers
- Interface with Test Equipment
  - FIT
  - Analytical equipment
  - Get interfaces from MES vendor or use middleware?



BGA

pH



ViCell

Conductivity



Osmometer

Refractive Index



- Cut Over in this complex environment
  - Material and Equipment Management in Hybrid State
  - Operator Training
  - Schedule disruption



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# Any Questions?

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