Business Process Improvement in Life Sciences Manufacturing through the Integration of Information and Production Management Systems and Automation

ANTHONY V SOLLAZO

Life Sciences Industry Solutions Manager

Rockwell Automation, Asia Pacific

Agenda

- Life Sciences Industry Concerns
- Business Process Improvement in Life Sciences
- Proof of the Concept
- Examples
- Summary of Results

Agenda

- **Life Sciences Industry Concerns**
- Business Process Improvement in Life Sciences
- Proof of the Concept
- Examples
- Summary of Results

Life Sciences Industry Challenges

In the Industry's Own Words:

- "Redefining our discovery and development process to yield new products more efficiently"
- "Reduce spending per brand by 15 to 20% in the U.S."
- "Reducing inventory by $400 million and saving $1.2 billion in procurement by 2008"
- "Redesigning all of our end-to-end processes"
- "Strengthened capabilities in vertical integration to secure future cost competitiveness"
- "Scale in manufacturing and infrastructure in low cost regions"
- "Integration of a global manufacturing network"
- "Globalization, centralization and standardization of clinical trial operations and data management"
- "Creation of one Pharmaceutical Development "center of excellence" between R&D and Manufacturing"

Source: Various life sciences manufacturing's investor relations presentations

The Time is Right

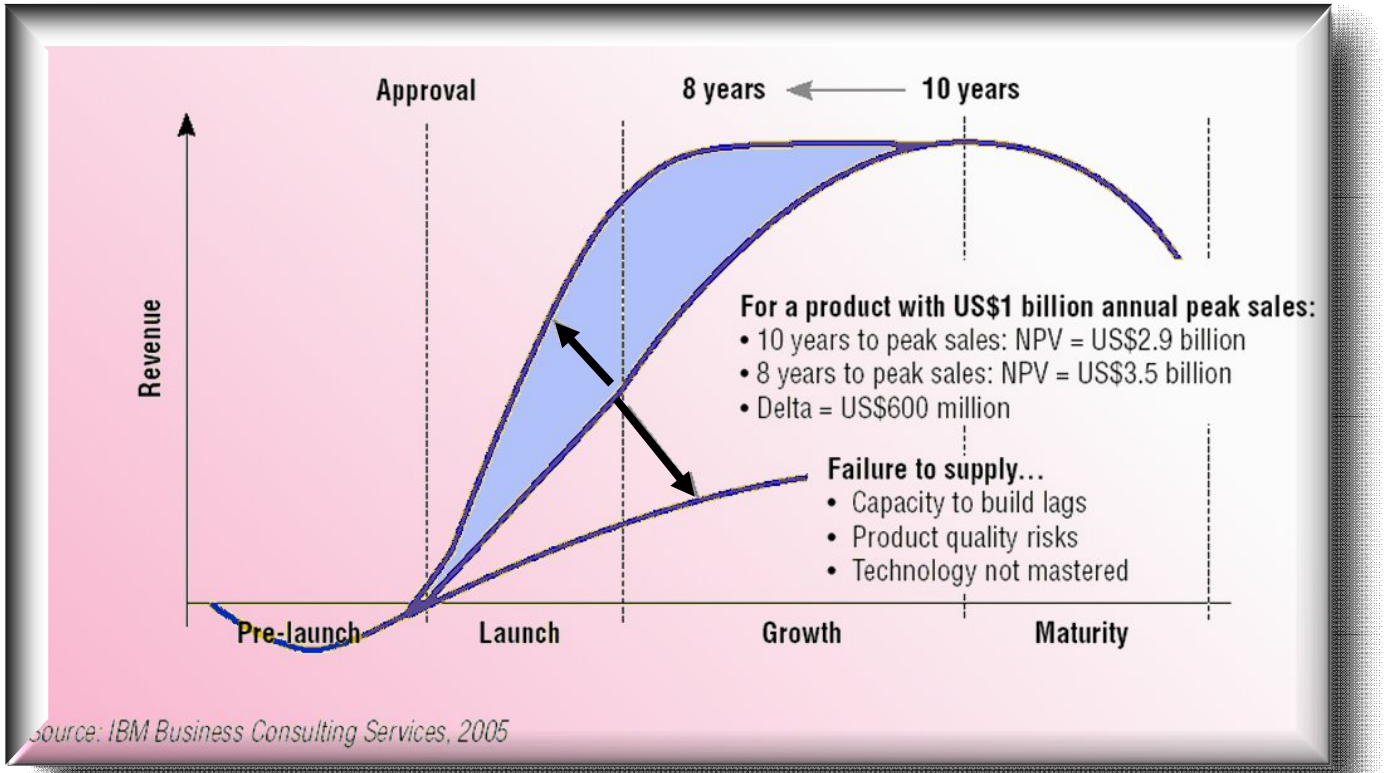
BUSINESS GOALS	Extremely important	Important
Boosting operating efficiency	66%	8%
Reducing mfg. costs	63%	10%
MANUFACTURING GOALS		
Improving efficiency	56%	7%
Reducing cycle time	73%	21%
Reducing set-up time	79%	17%
Increasing mfg. agility	64%	30%
QUALITY AND SERVICE IMPROVEMENT GOALS		
Reducing lead time	64%	21%
Improving on-time delivery	71%	21%

PharmaManufacturing June 2006

- Profit pressures require manufacturing to contribute
- Operational effectiveness on senior management radar
- Enables a compliant manufacturing environment that delivers product to plan with minimal cost and risk

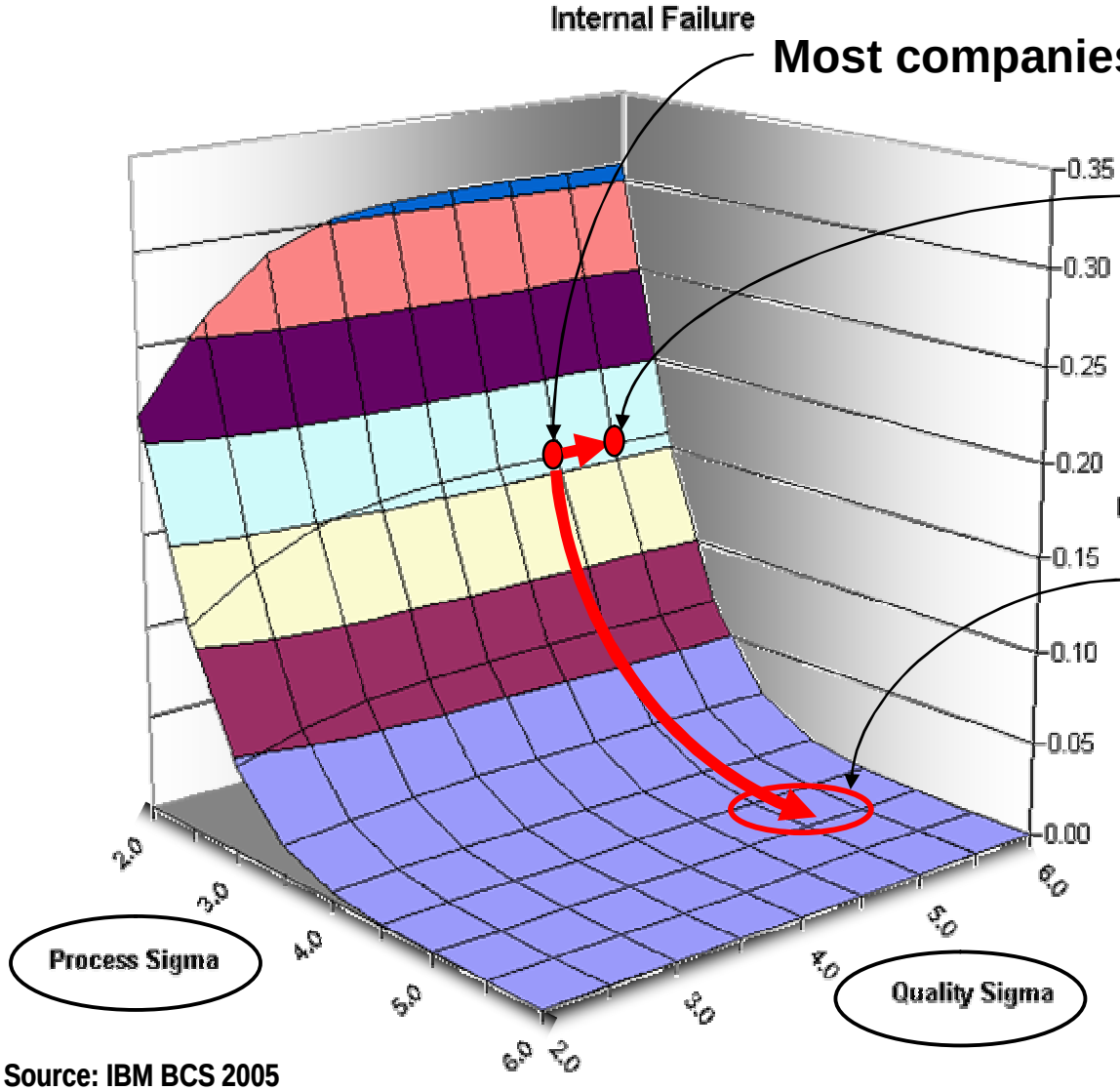
Time to Market

- Accelerating a product launch by 2 years could increase the revenue by $600 million
- An effective Clinical Trial Supply management can help to improve the product launch date



What are your delays costing you?

Building Product Quality Into The Process

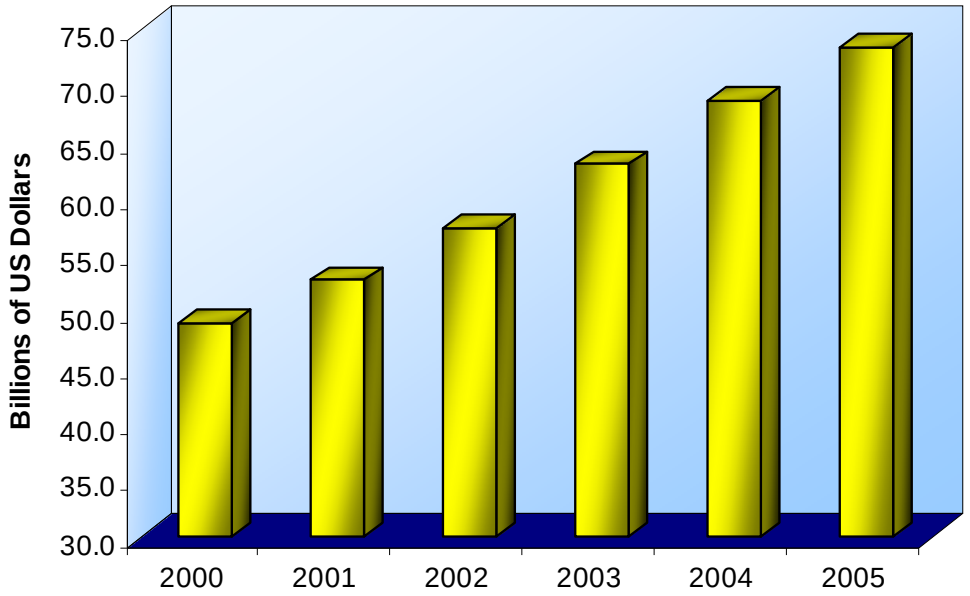


If a company were to invest to bring process sigma to 4.5 or greater (4.5, 5.0), the rate of change of failure would be reduced 1000-fold !

Source: IBM BCS 2005

Manufacturing Optimization

" Big pharma in manufacturing spends > $90 B / year, ~ 55% more than on R&D



Pharmaceutical Industry Plant Level Operations & Maintenance Expenditures, ARC

... a 1% savings in material costs from reduced waste [and WIP] could result in a $400 M benefit to a company's bottom line "

Mr. Raymond Scherzer, VP Engineering, Global Manufacturing & Supply, GSK from SalomonSmithBarney

Manufacturing Expenditures Drive Strategic Importance

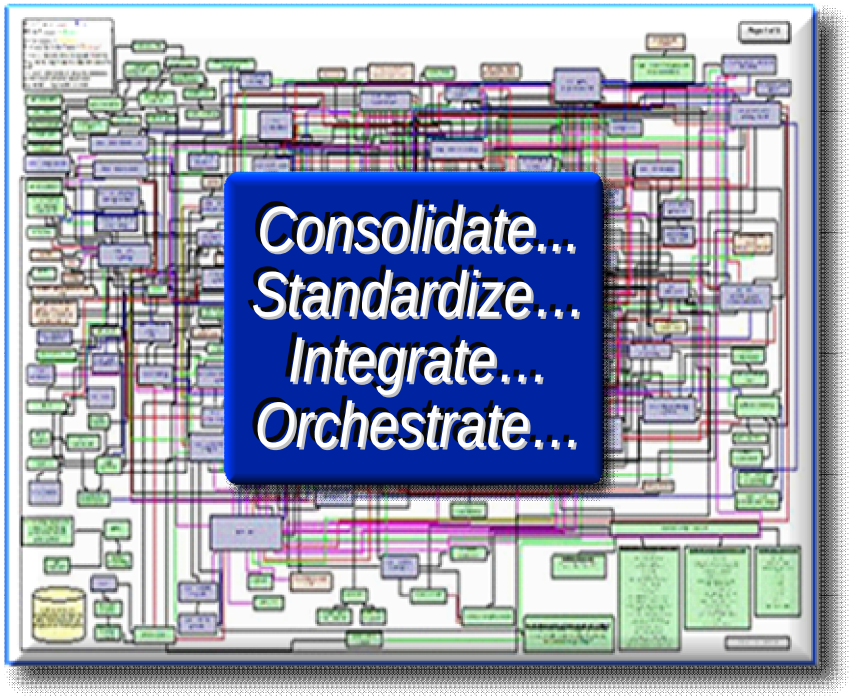
Potential Economic Returns

Measure	Average Pharma Industry*	Leading Pharma Factory*	A World Class Factory*	US Current Data**	Efficiency Improvement Impact ***	Potential Savin for a $1B Pharr Company
Stock turn	3 - 5	14	50	$21B Inv $/mon	$15B – $19B/ yr	$136M/ yr
On Time In Full -OTIF	60-80%	97%	99%	$110B Shipments	$30B - $33B / yr	$270M / yr
Right First Time -RFT	85-95%	96%	99%	$110B Shipments	$7B - $10B	$60M
Process Capability Index - CpK	1 - 2	3.5	3.2		>200% capacity	>200% capacit
OEE	30%	74%	92%		>200%	>200%
Cycle time (hrs)	720	48	8		$9B Cash conversion	$83M Cash conversion
Safety/ 100,000 hrs	0.100	0.050	0.001			

* Source: R. S. Benson and D. J. MacCabe. From Good Manufacturing Practice to Good Manufacturing Performance. Pharmaceutical Engineering. July/August 2004.
** Source: US Census Bureau News 8/2/05
*** Source: Rockwell estimates calculated from above source data

The CIO's Reality

- Thousands of 'Point Solutions' from hundreds of vendors
- Interfaces everywhere with no upgrade path
- No "Single Version of the Truth"



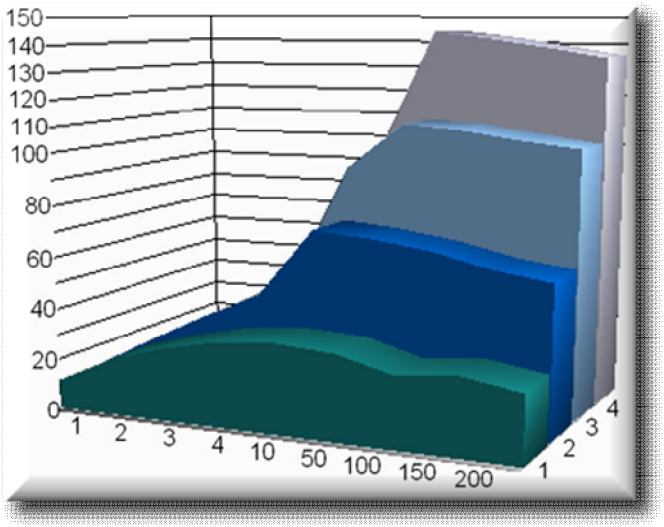
Source: IBM & Industry Studies; Customer Interviews 2004

Agenda

- Life Sciences Industry Concerns
- **Business Process Improvement in Life Sciences**
- Proof of the Concept
- Examples
- Summary of Results

What is Business Process Improvement in Life Sciences ?

- Encompasses initiatives like Right First Time, Six Sigma, PAT and Lean to be more successful by pulling all initiatives together under a **comprehensive common strategy**.
- A key element is **defining and mitigate risk** associated with regulations and non-performance.

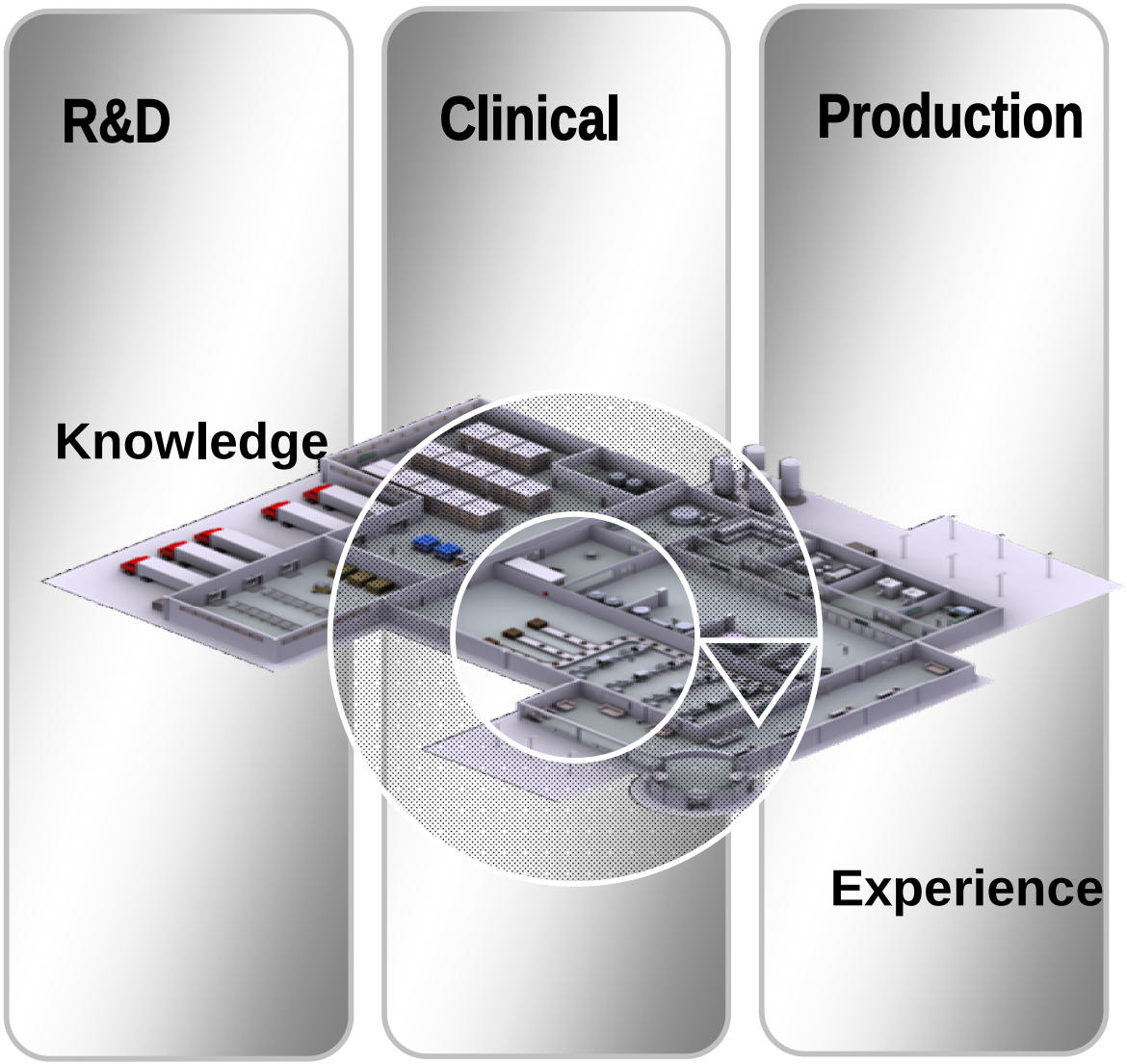


- Drive performance in Operational Effectiveness, Overall Equipment Effectiveness, Stock Turns, On Time in Full deliveries, and process capability.
- Establish Product Quality as a an Element of the Process

Execution

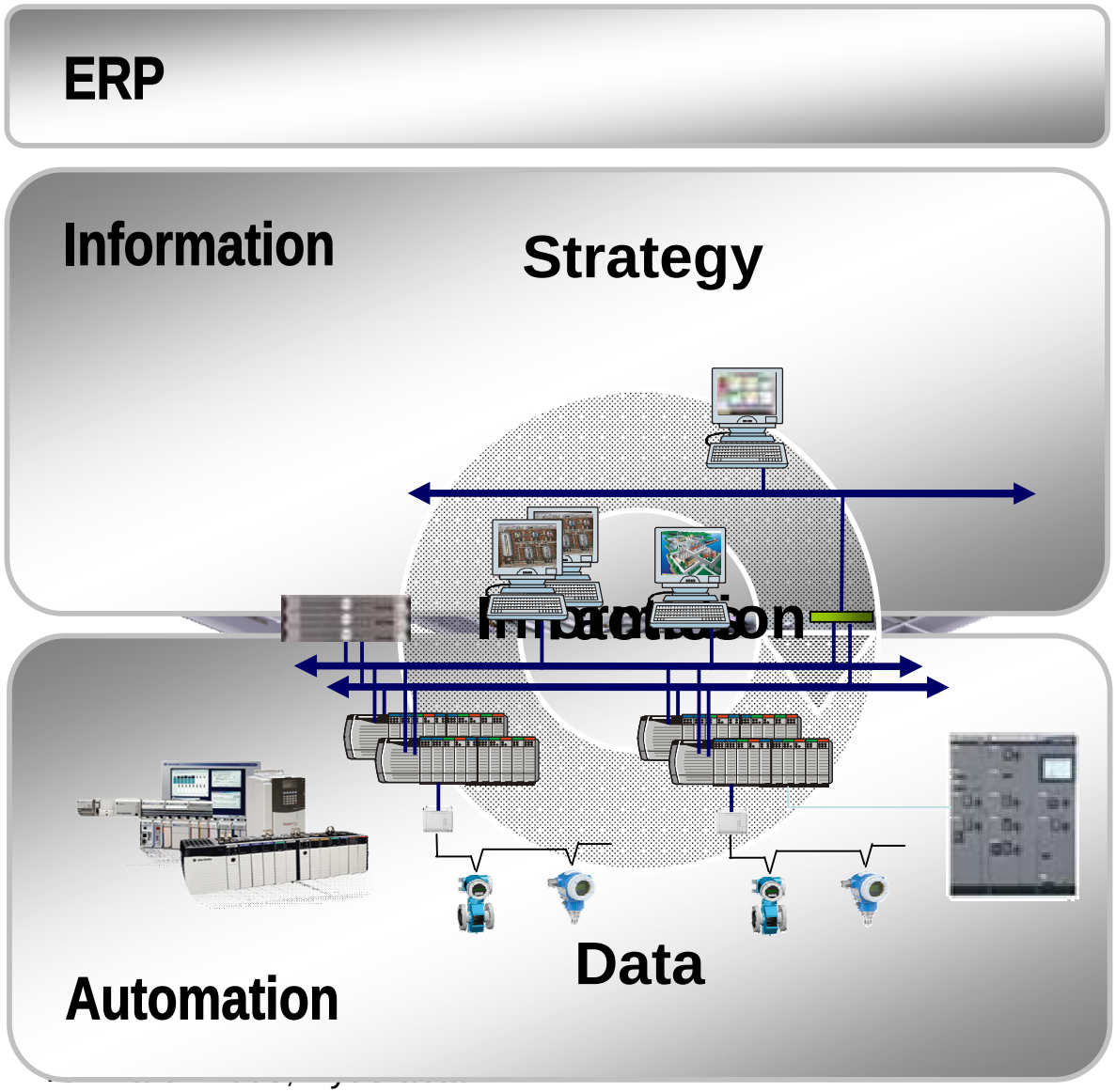
- A Strategy Execution must consider current needs and the future state
  - meet today's production demands within current GMP requirements
  - move towards a managed risk manufacturing environment (supporting PAT);
  - accomplish Lean Manufacturing in an effective & efficient manner
  - control manufacturing costs while market demands are served (Supply Chain Interoperability).

Solutions for Manufacturing Competitiveness



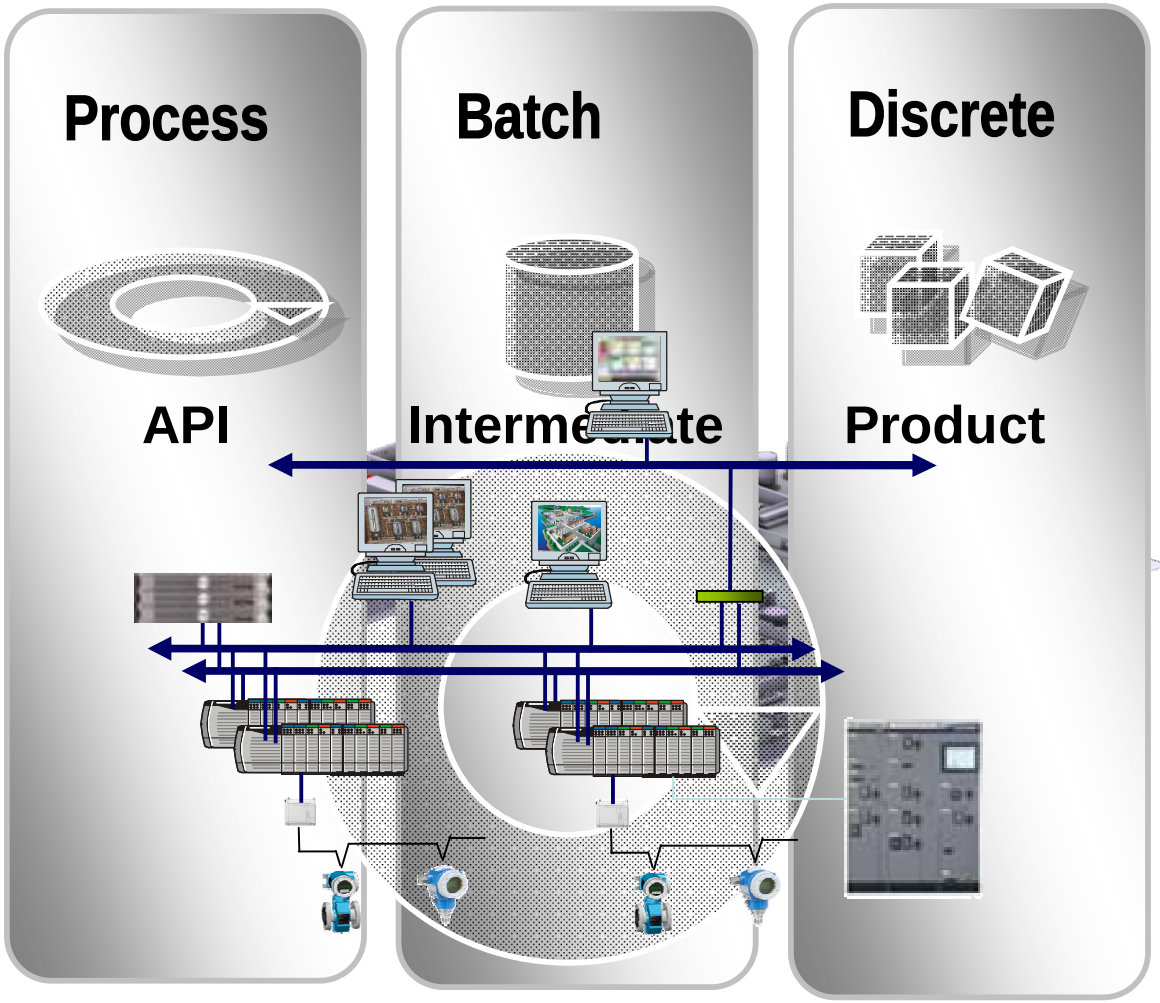
- **From R&D thru Clinical to Commercial Manufacturing**

Solutions for Manufacturing Competitiveness



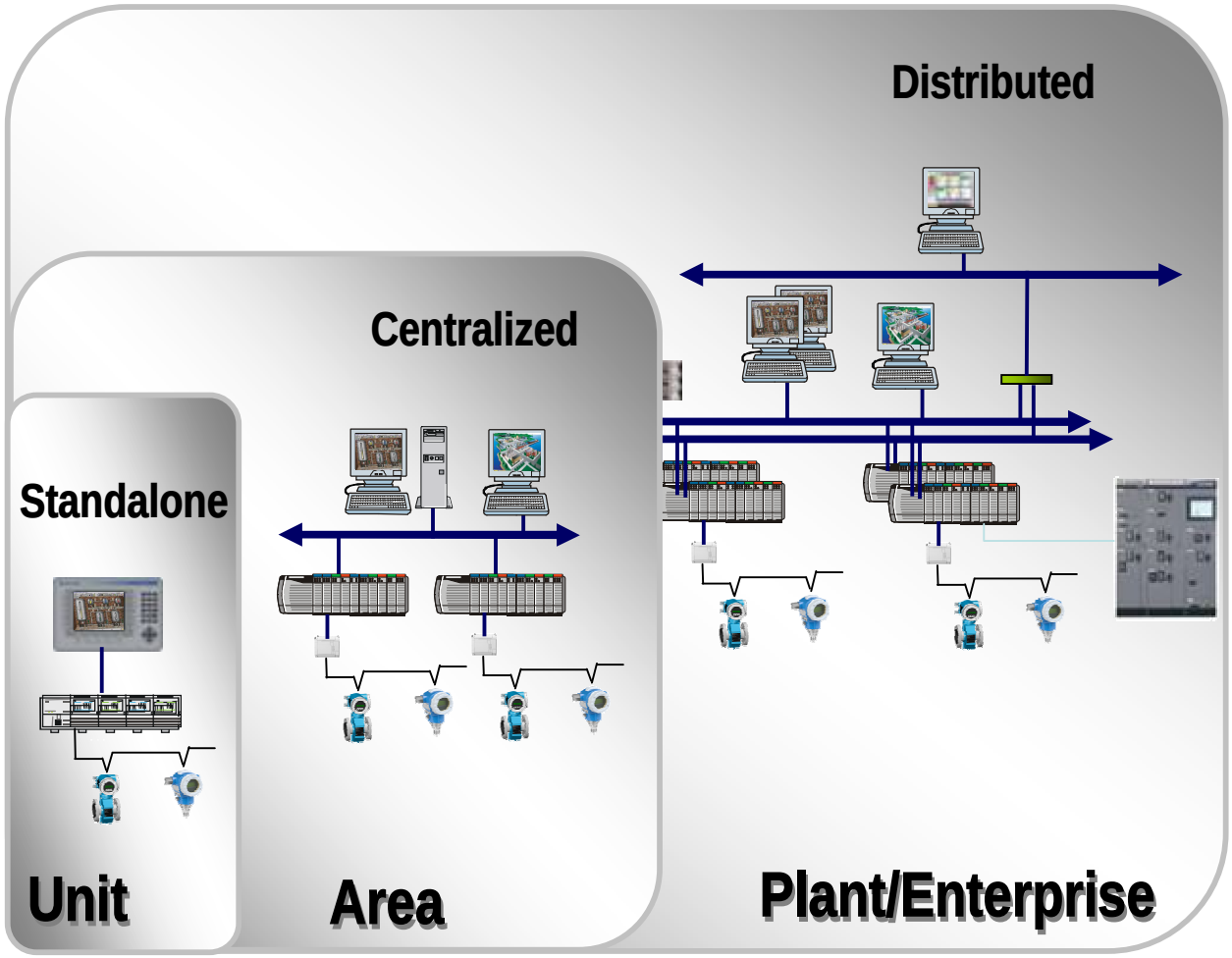
- **From R&D thru Clinical to Commercial Manufacturing**
- **Connect plant floor to business system**

Solutions for Manufacturing Competitiveness



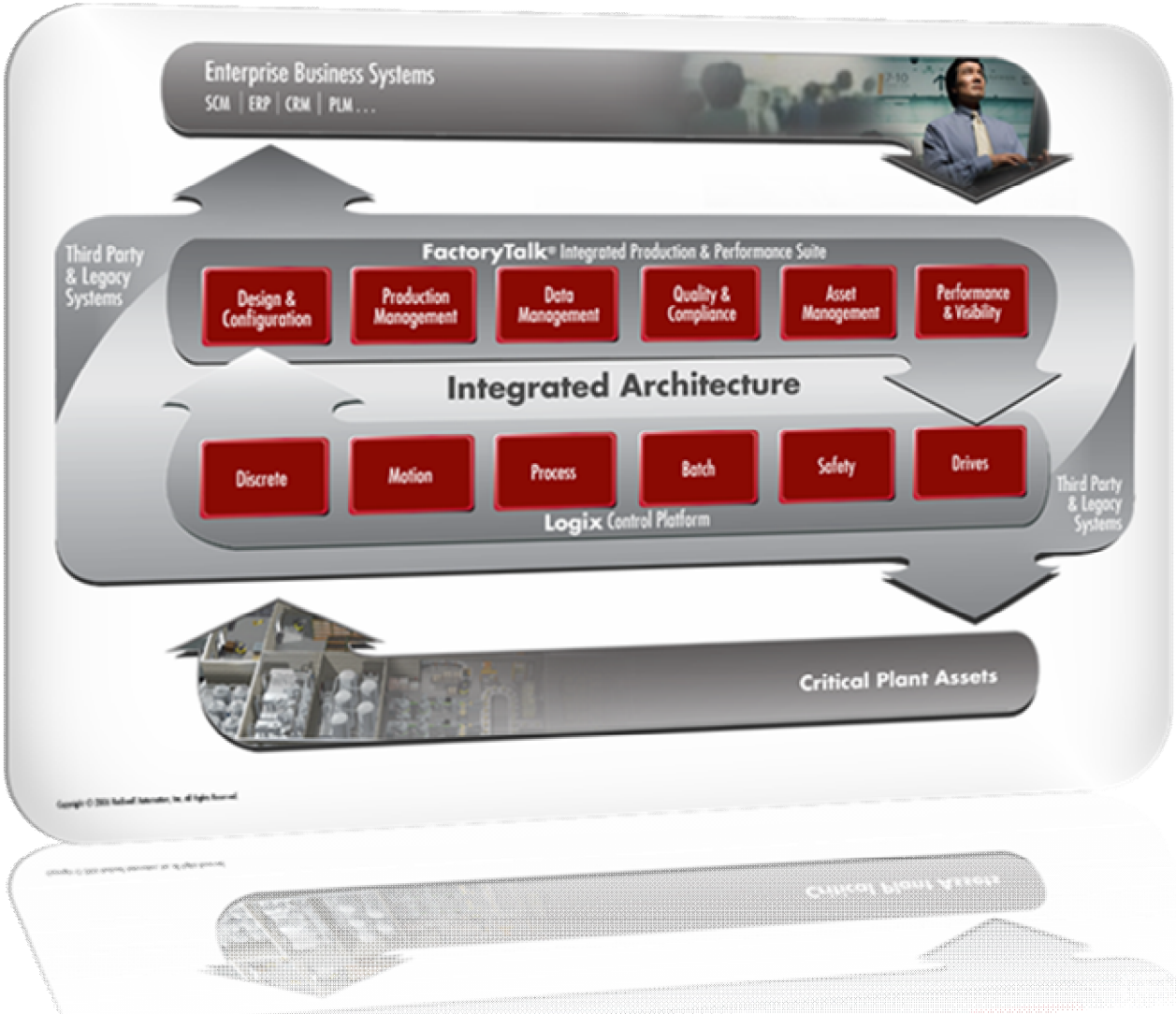
- From R&D thru Clinical to Commercial Manufacturing
- Connect plant floor to business system
- One single platform for multiple disciplines

Solutions for Manufacturing Competitiveness



- From R&D thru Clinical to Commercial Manufacturing
- Connect plant floor to business system
- One single platform for multiple disciplines
- Scalable from OEM to Enterprise solutions
- Standardize KPIs & Reporting capabilities across the enterprise

Solutions for Manufacturing Competitiveness



- **From R&D thru Clinical to Commercial Manufacturing**
- **Connect plant floor to business system**
- **One single platform for multiple disciplines**
- **Scalable from OEM to Enterprise solutions**
- **Standardize KPIs & Reporting capabilities across the enterprise**
- **Enabled by Industry Standards and Superior Technology**

Path to Success

- Manufacturing Strategy
  - A complete and common approach and architecture across all lines of business
  - Value based/Risk Managed Approach
- Manage Operations Effectively
  - Executing Production schedules and generating batch record documentation for efficient product release.
  - Delivering on what is key for real-time and interoperating with ERP, LIMS, BAS…
- Control Key Parameters in Real-time - Plant Automation
  - Integrated real-time knowledge based control
  - Predicting and avoiding problems
  - Feedback control based on measured input
  - Feed forward control based on material information

Path to Success

- Manage the Assets
  - Effectively coordinate calibration, status, availability,… of critical plant assets
- Product Life Cycle- Close the loop for Continuous Improvement
  - Design for Manufacturability – closing the loop with manufacturing with timely information presented in a relevant manner.
- Consider all Areas that Impact Costs
  - Power and Energy Management - coordinated energy conservation strategy supporting an effective and compliant manufacturing strategy
- Project & Program Management
  - effectively deliver throughout the organization
- Tied Into The Corporate/Business Infrastructure
  - ERP, LIMS, DMS Interoperability

Agenda

- Life Sciences Industry Concerns
- Business Process Improvement in Life Sciences
- **Proof of the Concept**
- Examples
- Summary of Results

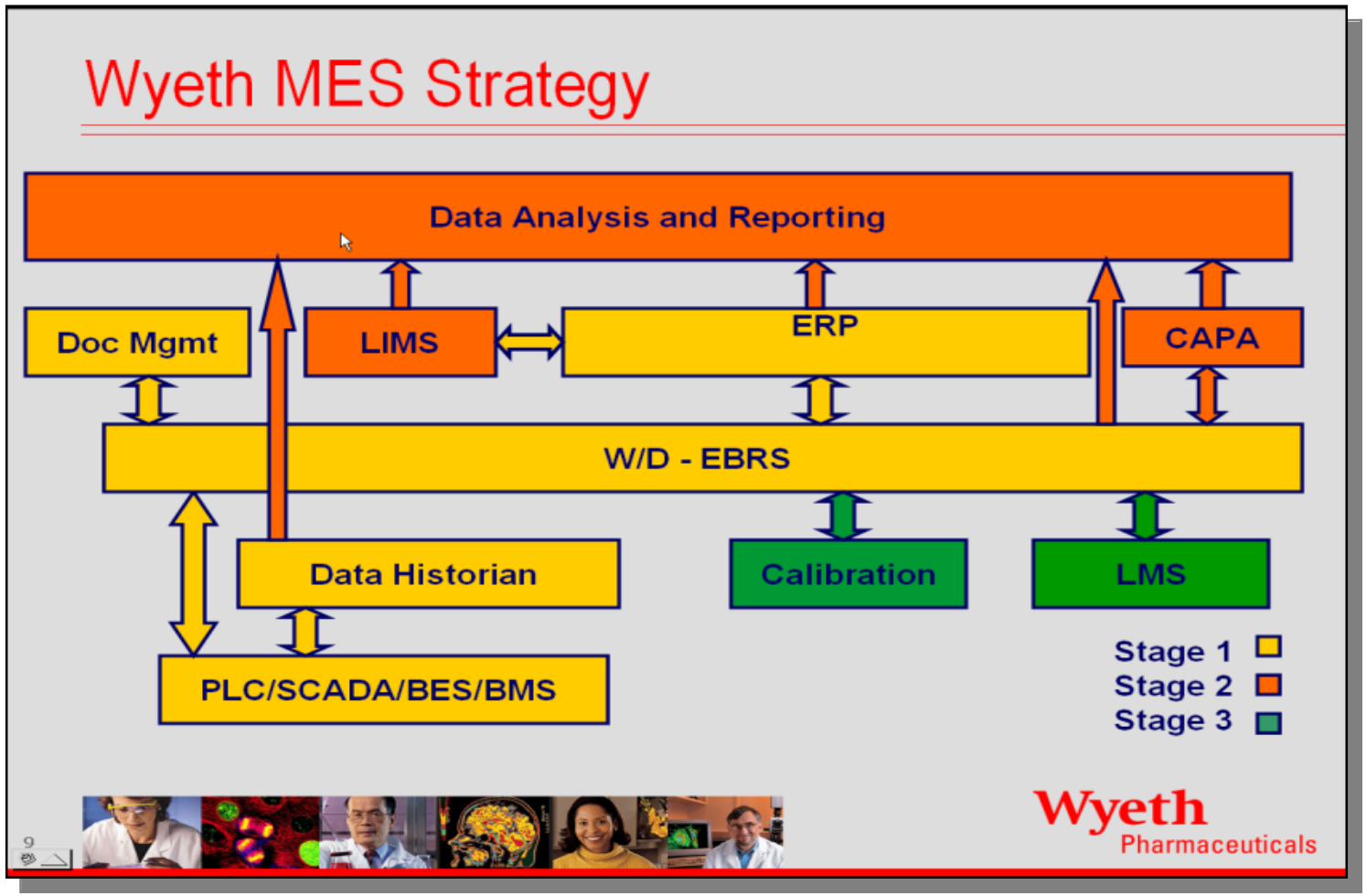
Proof of Concept

Proof Of Concept

Agenda

- Life Sciences Industry Concerns
- Business Process Improvement in Life Sciences
- Proof of the Concept
- **Examples**
- Summary of Results

Wyeth: MES – Automation Integration, Jeff Schaaf



Wyeth: MES – Automation Integration, Jeff Schaaf

Wyeth MES Basics

- MES is targeted for 12 strategic sites in North America and Europe by the end of 2008
- Formulations and processes cover the range from small molecule to biotech
  - Very diverse processes, equipment and control systems
- Functional design was approved in Feb 2004
- First W/D instance live in November 2004
- First EBR live in April 2005

Wyeth Pharmaceuticals

Wyeth: MES – Automation Integration, Jeff Schaaf

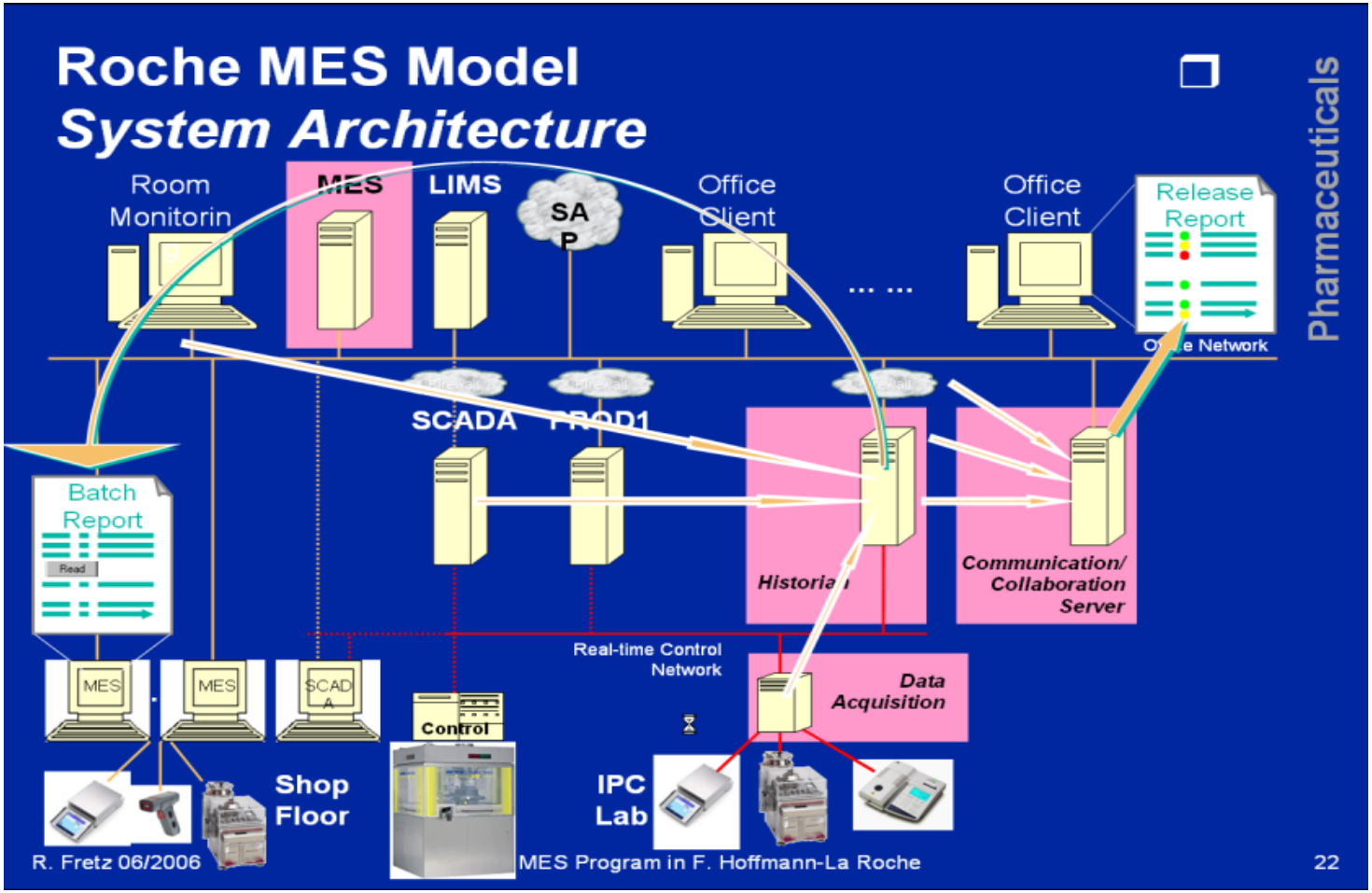
The Results – Wyeth MES Program

- 50 – 75% reduction in batch review resources through adoption of Review by Exception
- 50% reduction in processing cycle time for total MES solution
- 50% reduction in Batch Record review time
- 25 – 50% reduction in required staffing
- 98% reduction in Batch Deviations/investigations
- Design elements extended to integration with AGV systems and asset management incl. Wireless technology

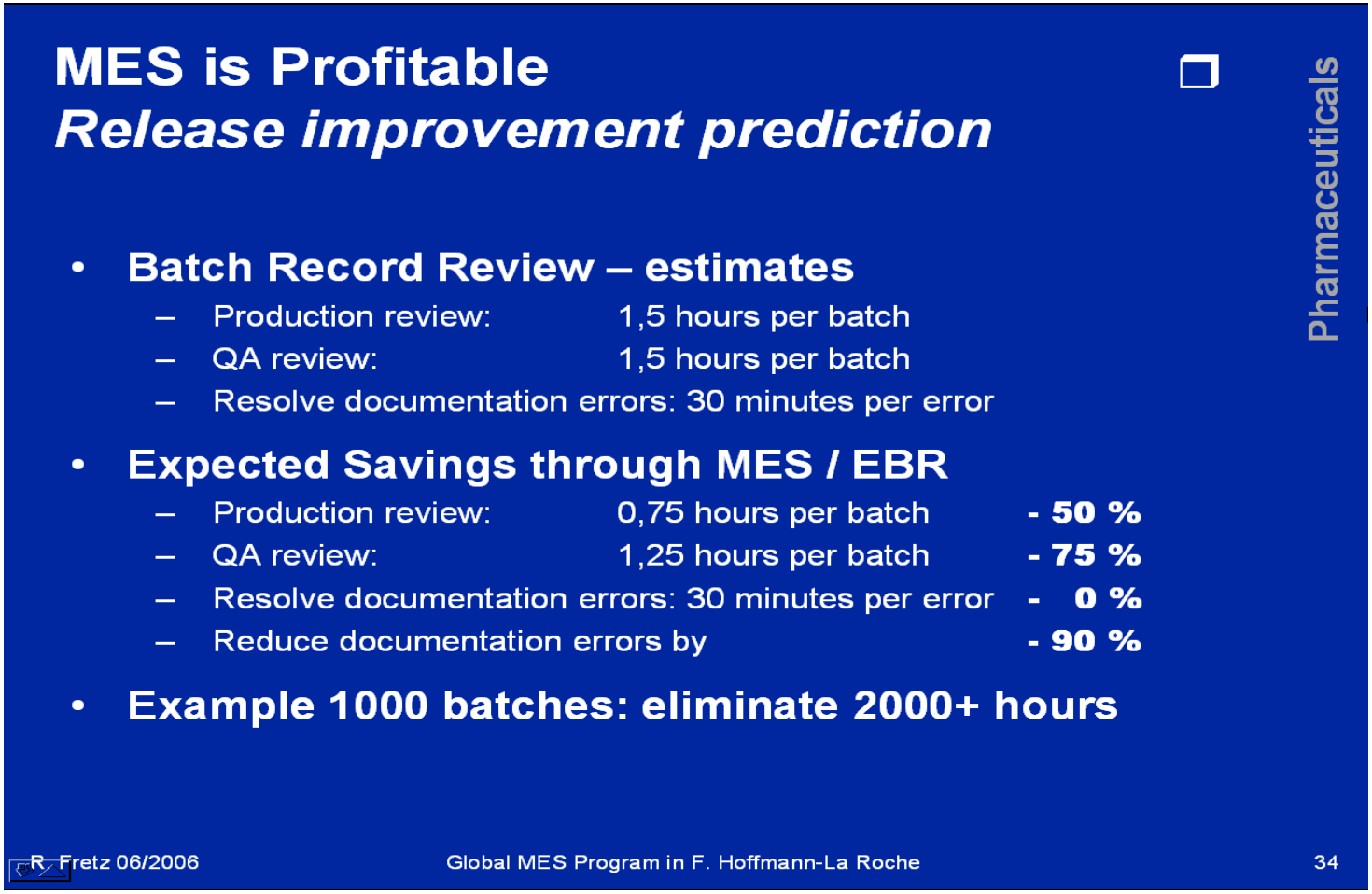
24

Wyeth Pharmaceuticals

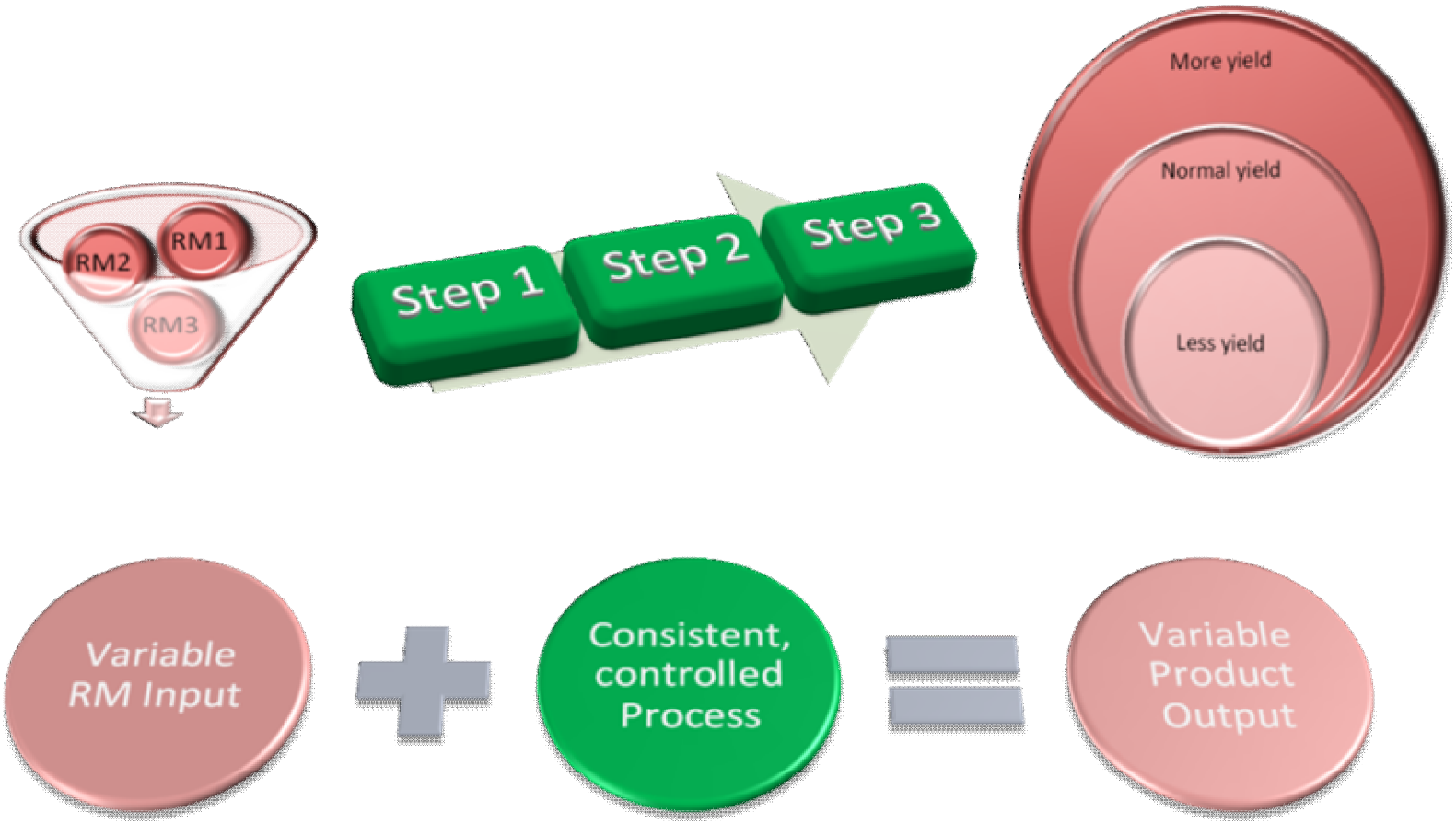
Roche: Implementing a Global MES-Program, Robert Fretz, June 2006



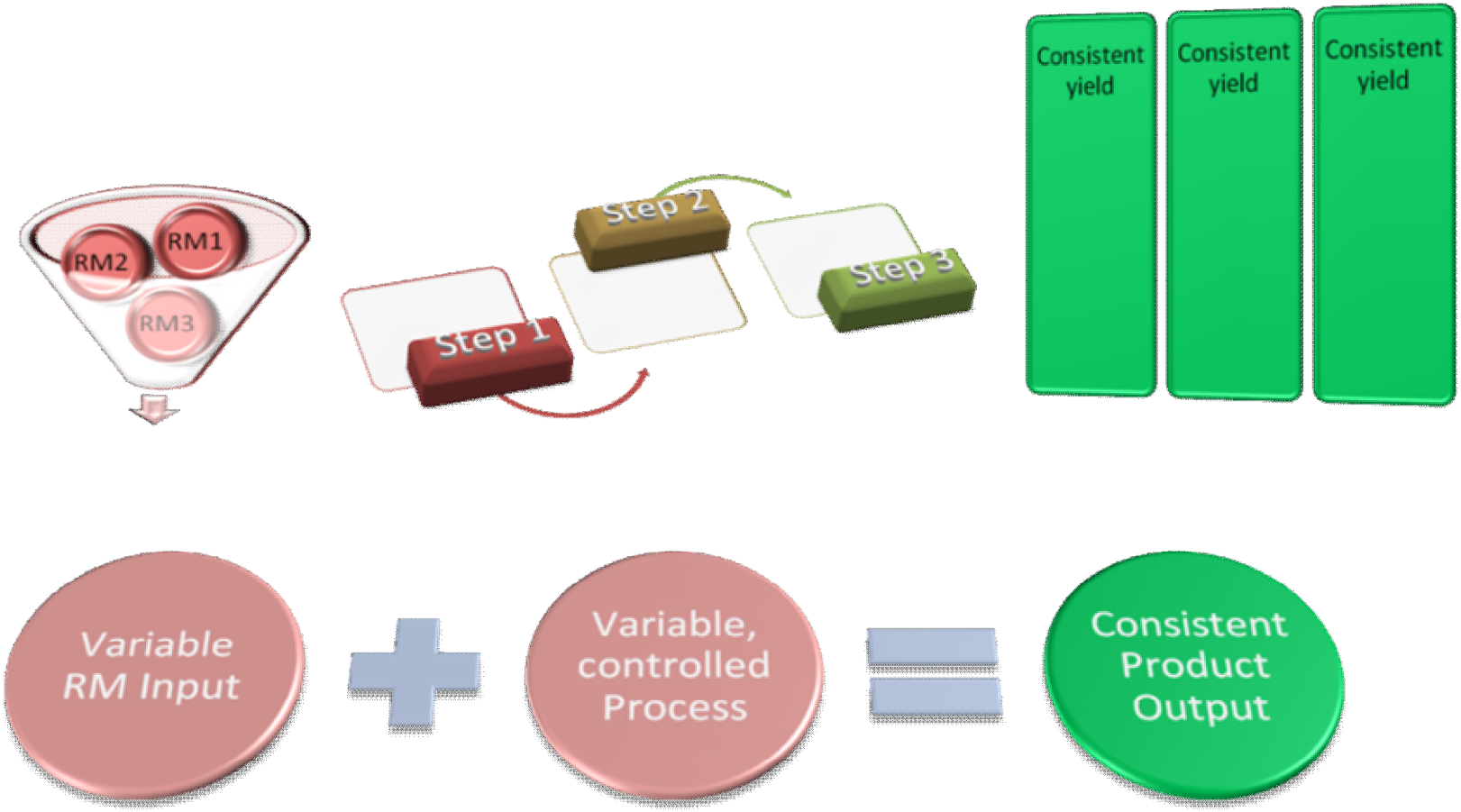
Roche: Implementing a Global MES-Program, Robert Fretz, June 2006



Current Manufacturing Model



Baseline Regulatory Opportunity



Agenda

- Life Sciences Industry Concerns
- Business Process Improvement in Life Sciences
- Proof of the Concept
- Examples
- **Summary of Results**

Unlocking The Potential of...Proven Results

- A large pharma company improved clinical trial management by **20%** and achieving a **shorter time-to-market**
- A global pharma player **reduced throughput from 48 to 12 hours**
- One of the biggest pharma companies in the world **reduced shop floor setup times by 50%**
- **35% reduction in WIP materials & 20% cycle time reduction**
- **30% productivity increase & 10% reduction in maintenance costs**
- **Increased yields 10-15%** by decreasing production deviations and out-of-spec product