Enabling Operational Excellence to Optimize Plant Performance

PharmaTech
HYDERABAD 2008

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Agenda

- **Industry Challenges**
- Systems and Solutions
- Operational Excellence Program
- Future Direction
- Conclusion

Life Science Industry Past and Present

Increasing cost pressure

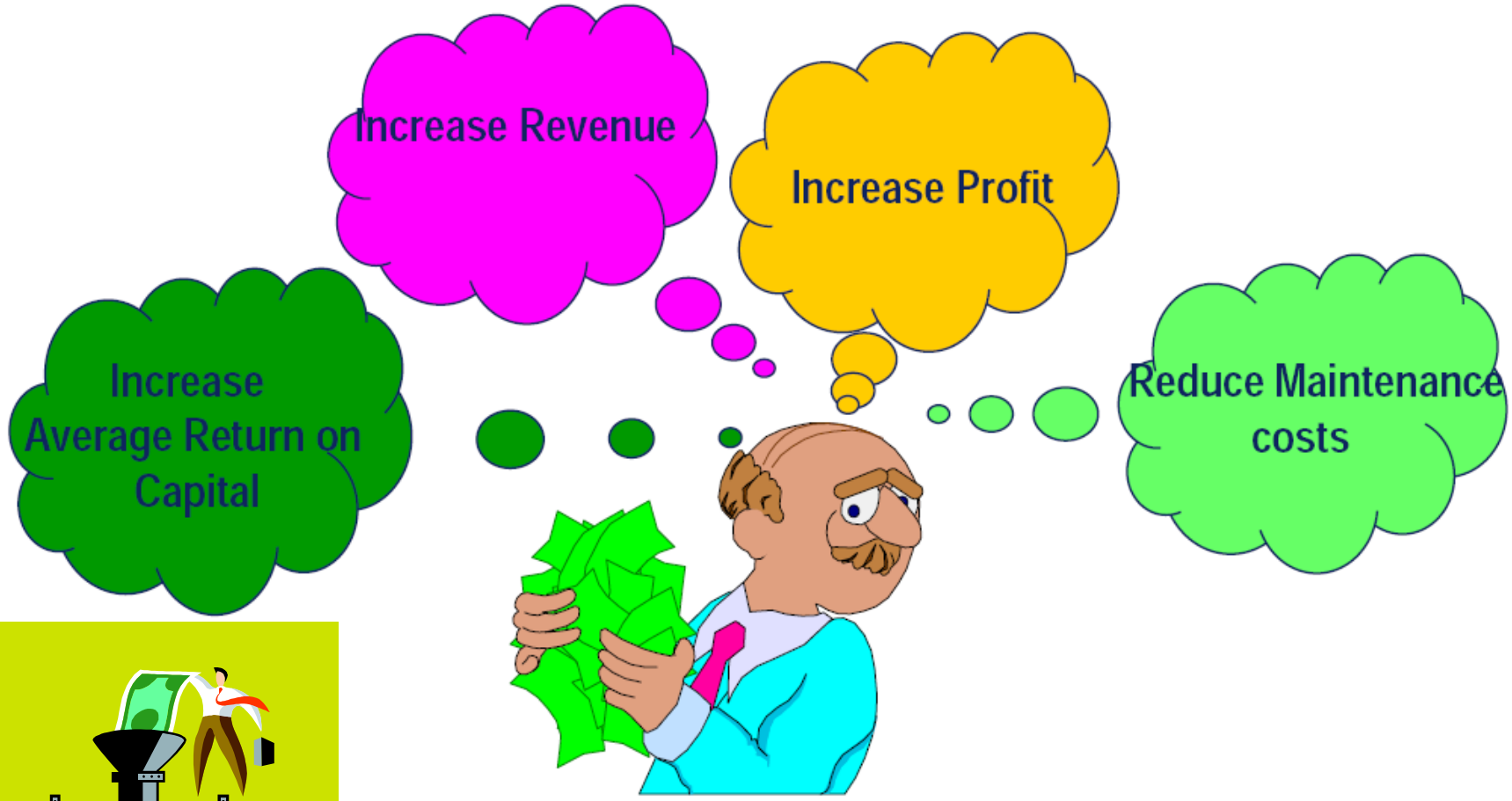
Situation in the past	Today's situation
• Growing market • High profit margins • Little market concentration • Stable product pipeline • High pricing flexibility due to limited buyer's bargaining power • API Blockbuster products based on "simple" organic chemistry	• Declining R&D productivity • High threat of substitute products • Increasing rivalry among established competitors • Increasing heterogeneity among customer preferences • "Complex" Biotech processes for narrow patient groups

University of St. Gallen. Institute of Technology Management. Operational Excellence in the Pharmaceutical Industry. 2004

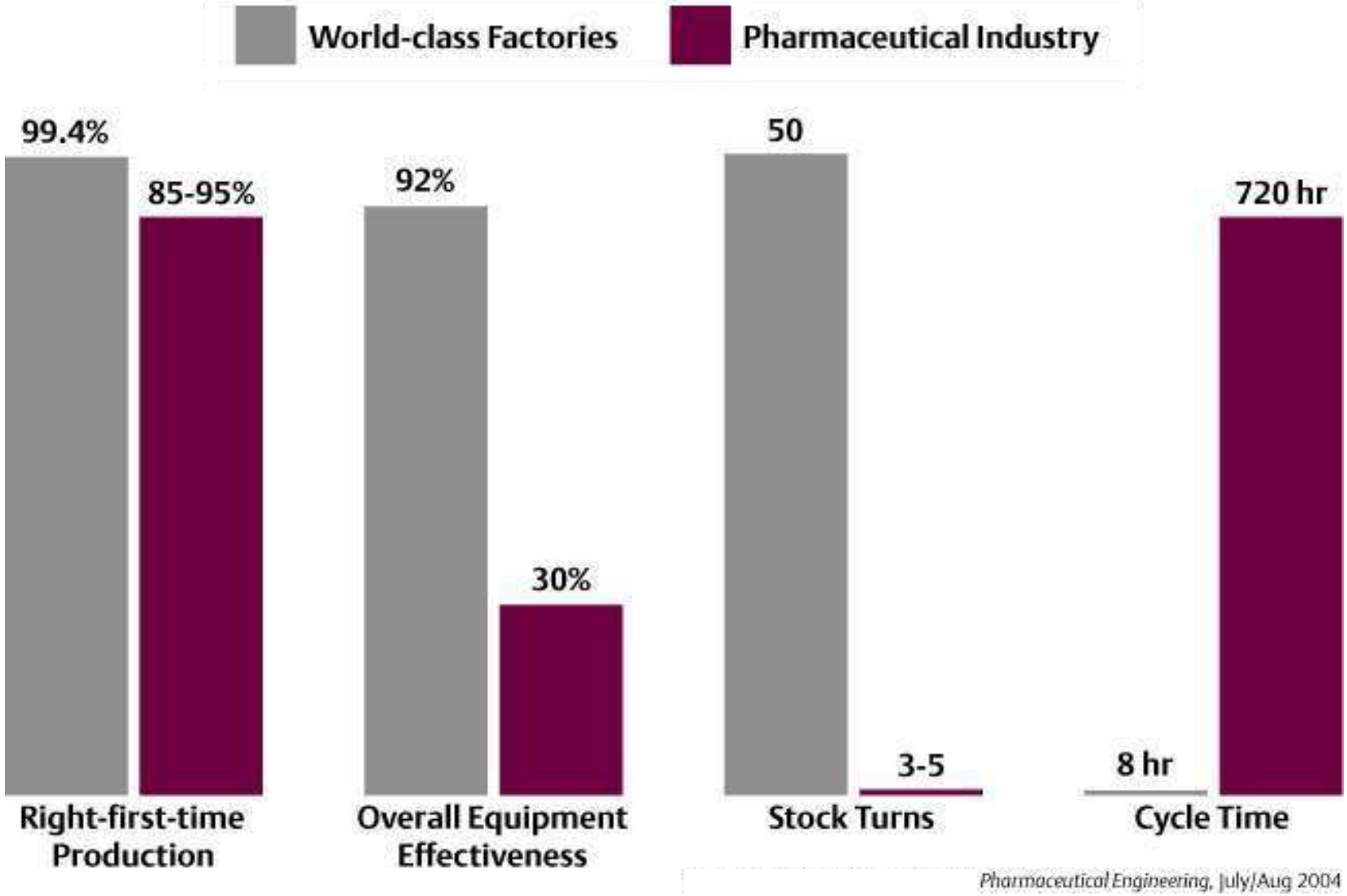
Industry Challenges.....

- Improve Time-to-Market
- Manufacture Cost-Effective Product for Delivery Worldwide
- Meet Global Regulatory Requirements
- Minimize Manufacturing and Automation Risks
- Improve Return on Assets

The Business Perspective



Poor Productivity is the Issue



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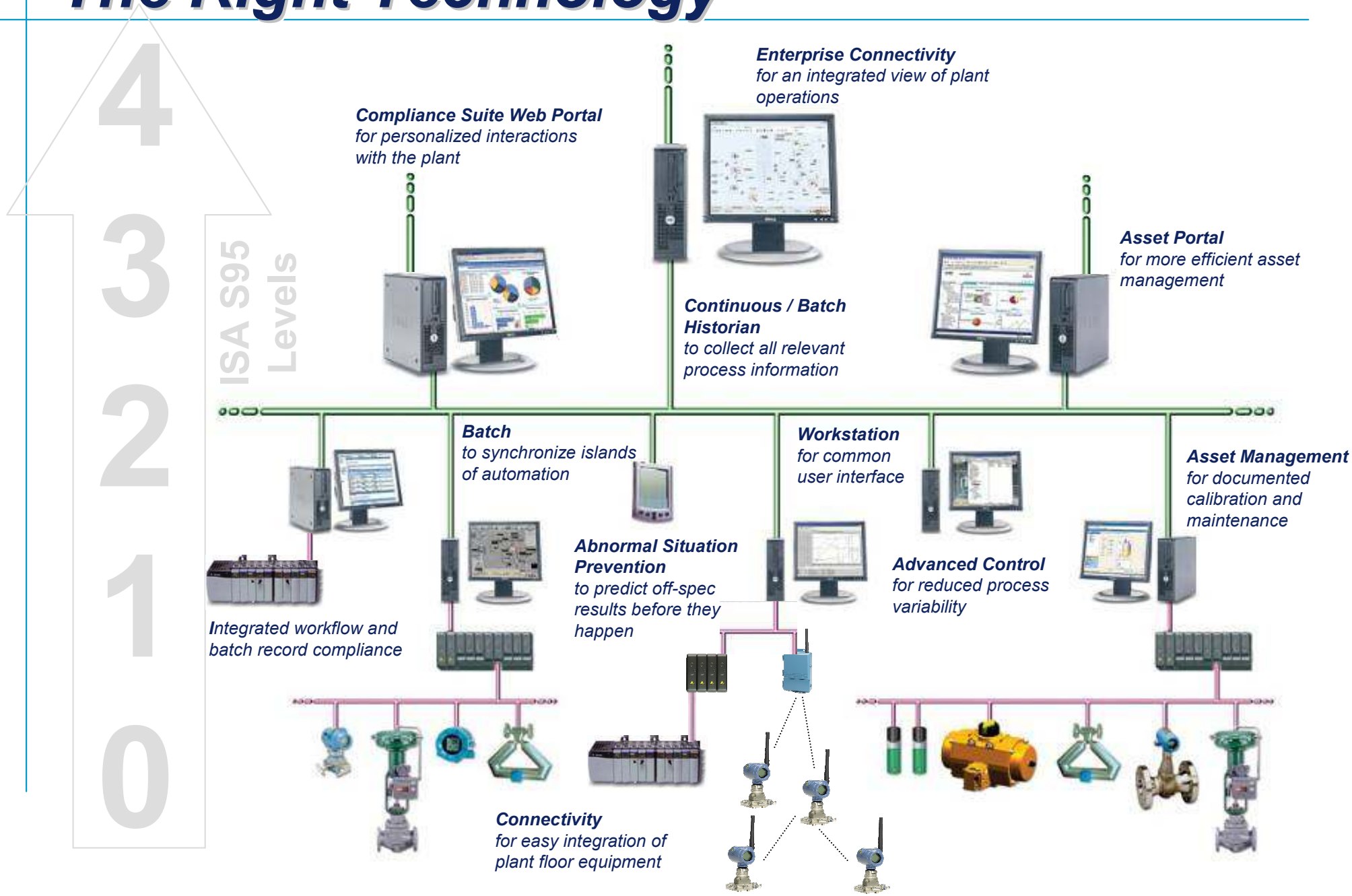
Key Thoughts to meet Challenges

- Make Technology **Easy and Cost** effective To use and enjoy
  - Think about an iPOD
  - Think about cell phones
- **Predict the Future** and we are all better off
  - Think about quality and throughput
  - Think about personal health
- How can I **Optimize my Efforts**?
  - Think about $$$
  - Think about work life balance
- Of course **Keep it Safe**

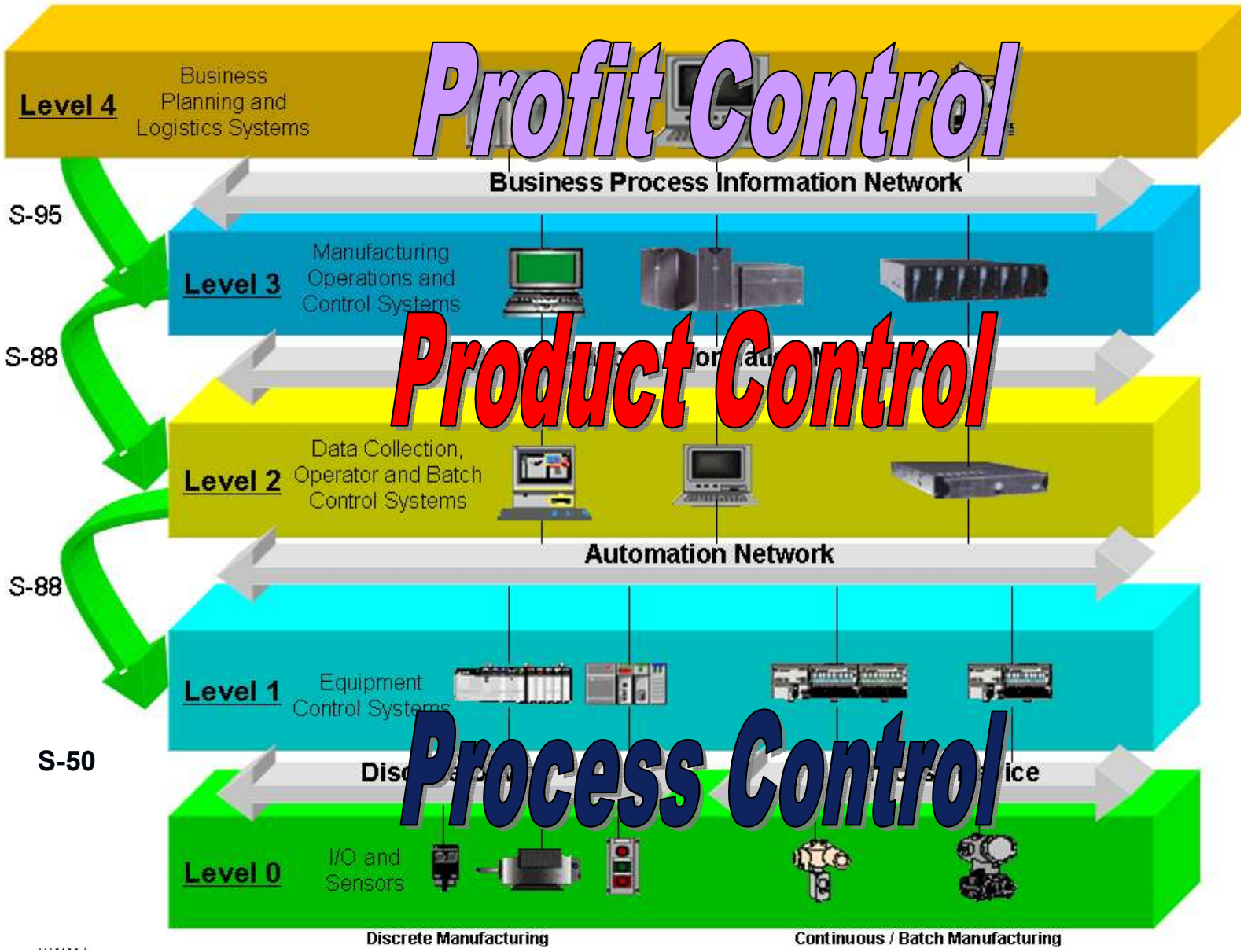
Right selection to meet Challenges

- Designed specifically to handle new wealth of information - imbeds and deploys **predictive intelligence** to the plant
- **Networked** rather than centralized
- Uses **standards** at every level of the architecture
  - Field: HART, Fieldbus, ASi, DP
  - Platforms: Commercial, off-the-shelf software and hardware
  - Network technologies: OPC, .NET
- Does more than process control - provides **asset management and ERP integration**

The Right Technology



Functional Layers Have Different Goals



ERP for:

- Financials
- Forecasting
- Production Planning
- Order Management
- Perpetual Inventory
- MRP/Purchasing

MES for:

- Production scheduling and control
- Line (plant) monitoring
- Weighing & dispensing
- Materials management and warehouse control
- Equipment tracking
- Container / asset management
- Electronic batch records and record management
- Operator qualification / training management

PAS for:

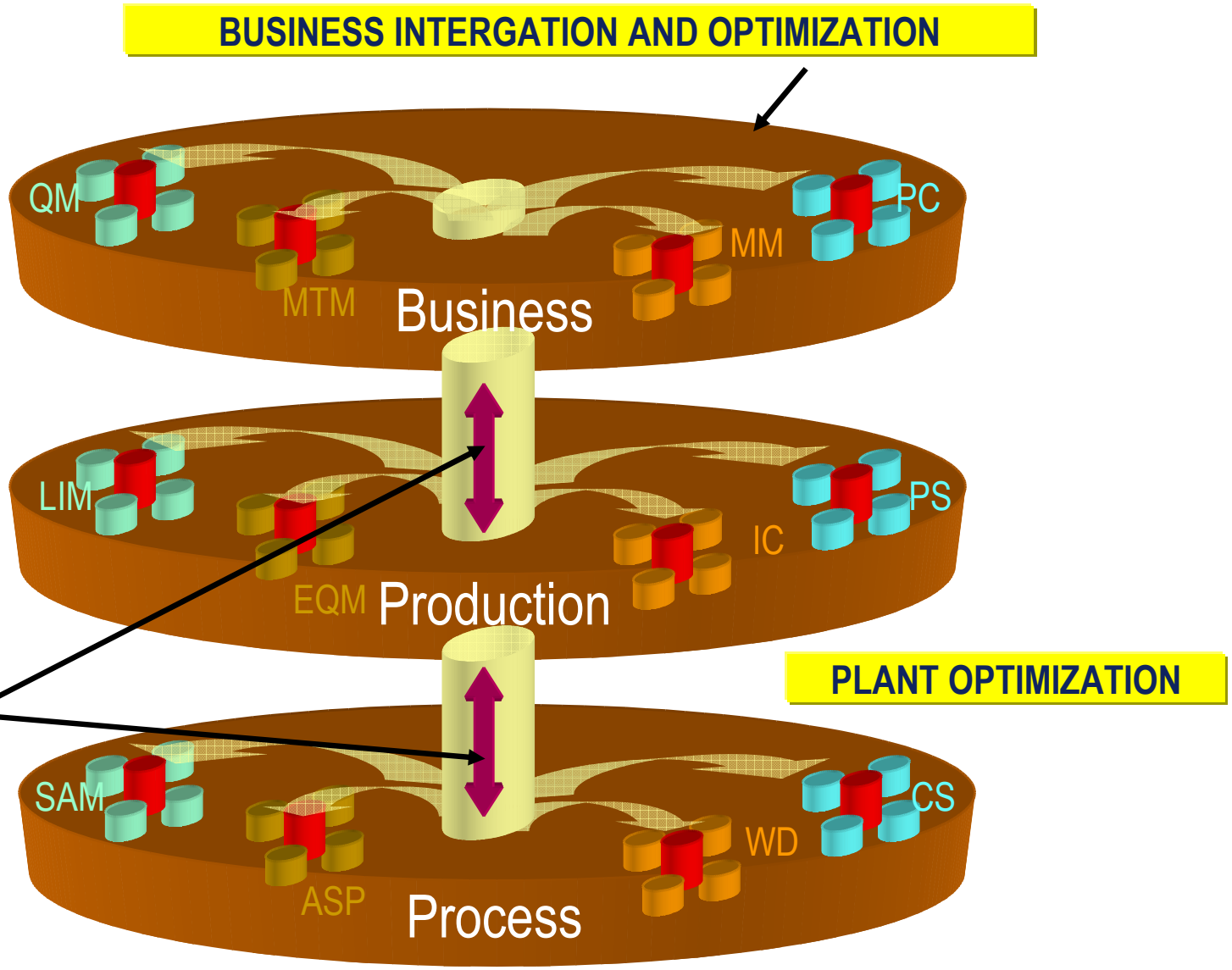
- Operator interface to plant floor
- Control modules and equipment modules
- Advanced control
- Asset monitoring
- Batch sequencing and recipe management
- Historical data collection/analysis

Smart Field Devices

View on Plant to Business Integration

Legends

PC: Production Control
MM: Materials Mgmt
MTM: Maintenance Mgmt
QM: Quality Mgmt
PS: Production Sch.
IC: Inventory Control
EQM: Equip. Mgmt
LIM: Lab Mgmt
CS: Control Sys
WD: Weigh & Disp.
ASP: Abnormal Sit. Prev.
SAM: Sample Mgmt



PROCESS STABILITY
OPERABILITY
MAINTAINABILITY
UPTIME
MAXIMIZE PRODUCT

Elements of the SMART Plant

Production Planning

Operations

Maintenance

Quality Management

Sales & Distribution

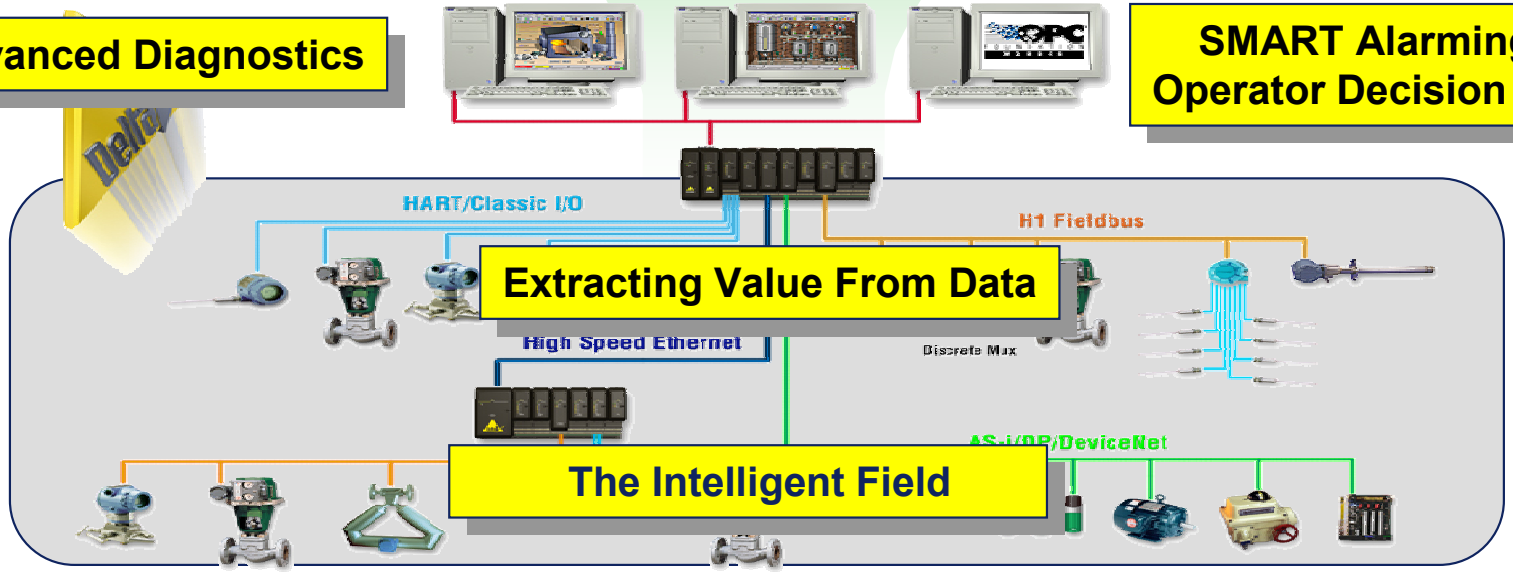
Accounting & Controlling

Real Time Performance Management

Connectivity to the User

Advanced Diagnostics

SMART Alarming and Operator Decision Support



Extracting Value From Data

The Intelligent Field

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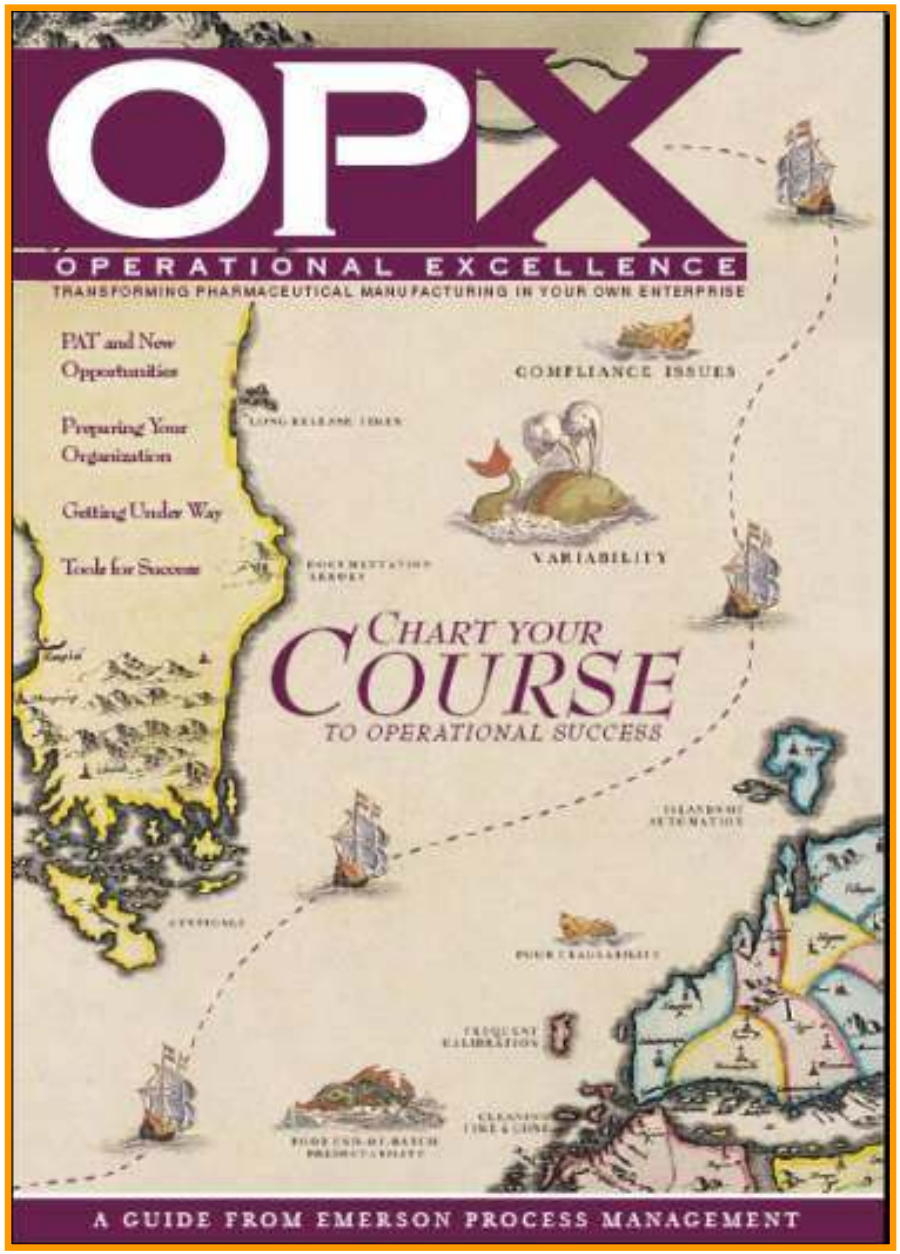
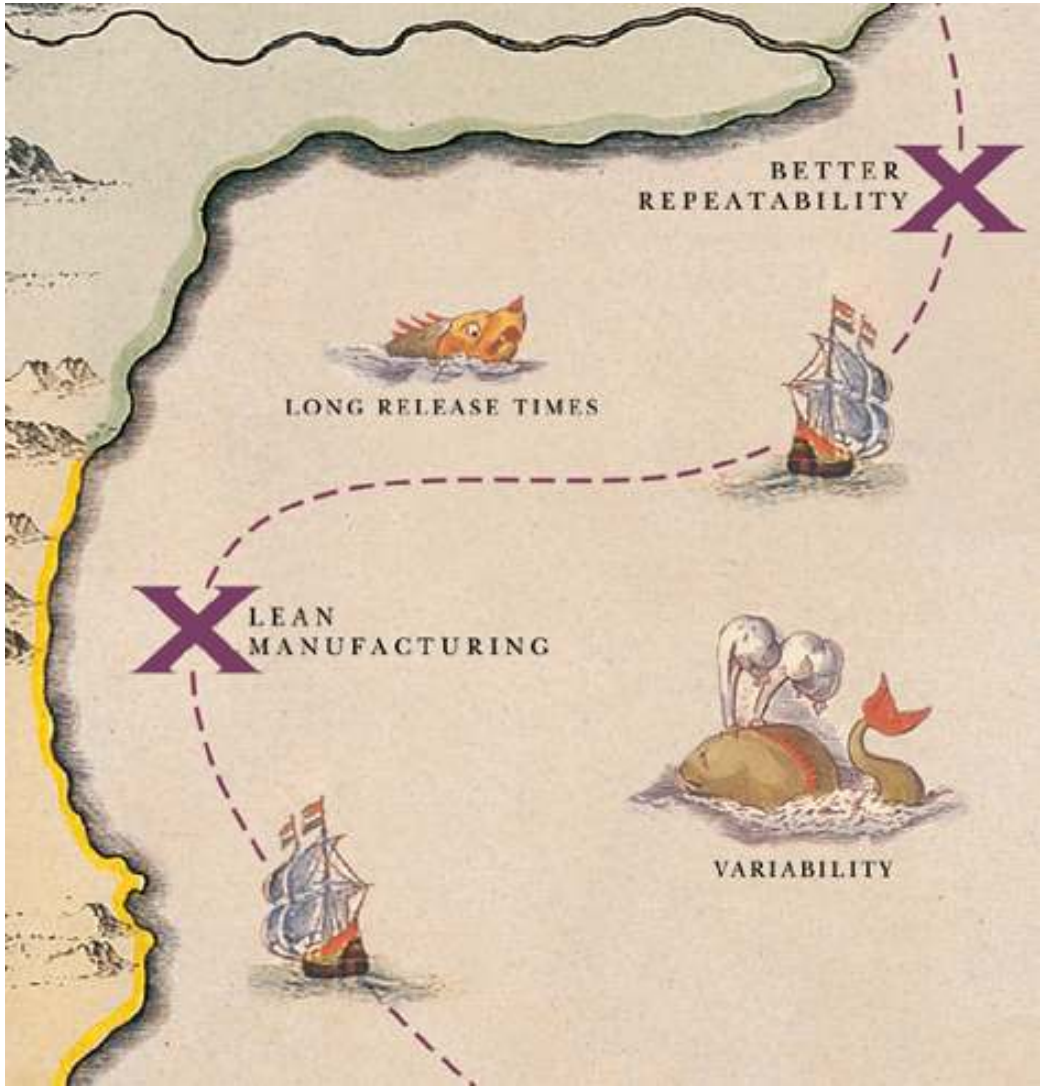
Operational Excellence



Are we missing the boat?

- Operational Excellence not new
- Other industries reaping rewards for years
  - Automotive
  - Semiconductor
  - Electronics
- Life Sciences lacked flexibility to leverage technology advancements and work practices…***until now***.

OpX is a long voyage…



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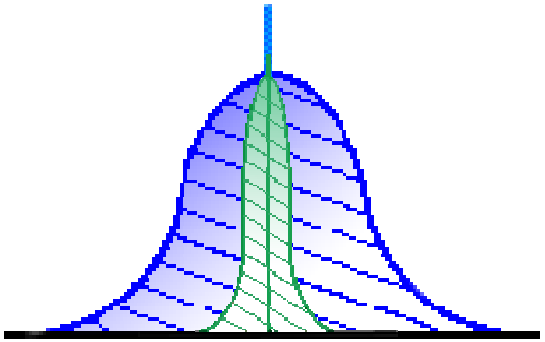

OpX Advantage Program

A proven, data driven methodology

1. **Initial Assessment**:
   What problem needs to be solved?
2. **Detailed Study**:
   What are the specifics of the problem and the capability of the processes?
3. **Report and Recommendation**:
   How will modifications to business processes and systems deliver benefit?
   How will changes impact the organization
4. **Project Implementation**:
   Define / execute realistic plan
5. **Results Analysis**:
   Compare results to initial baseline
6. **On-Going Control**:
   What work practices can be put in place to sustain and increase the gain?

Life Science Project Value

Lowest risk for schedule and budget
Predictable and consistent global project delivery
Extensive scope single supplier of automation solutions (MAC)
Best Total Installed and Commission Cost

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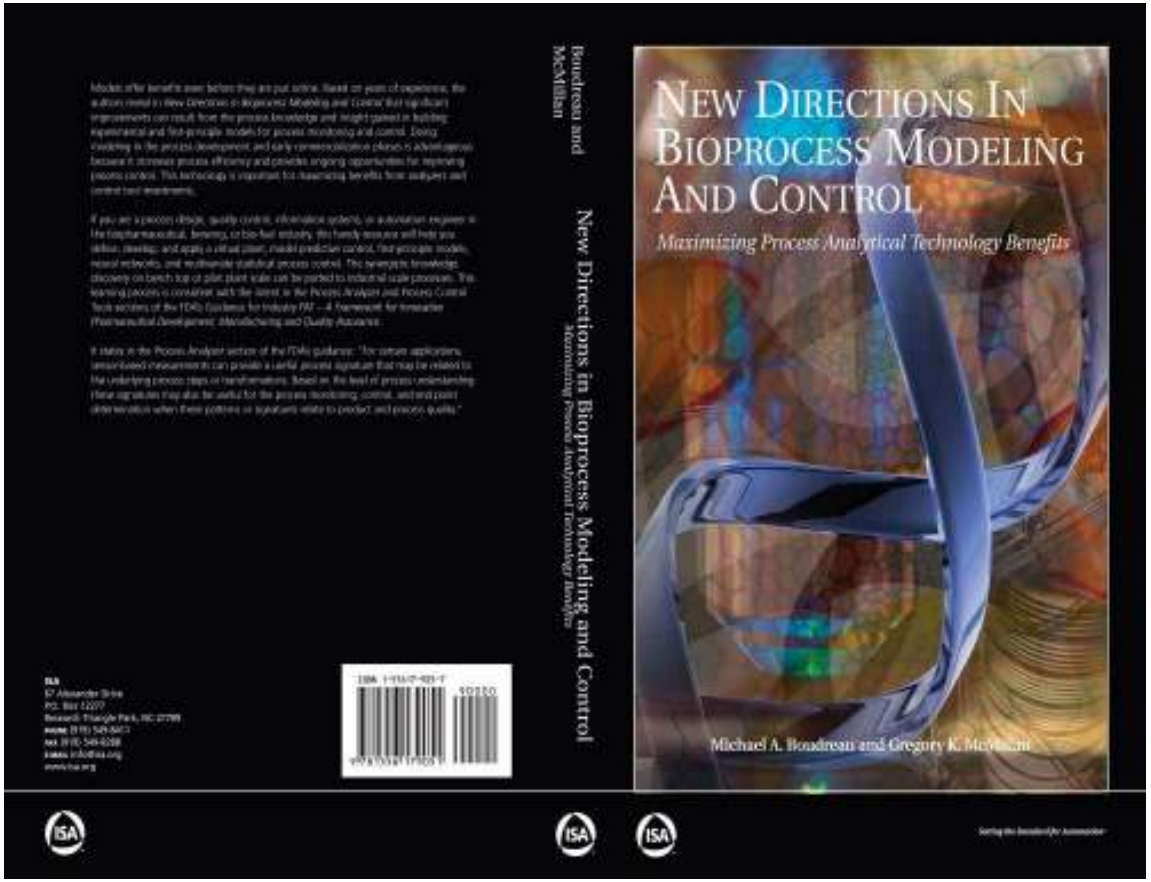
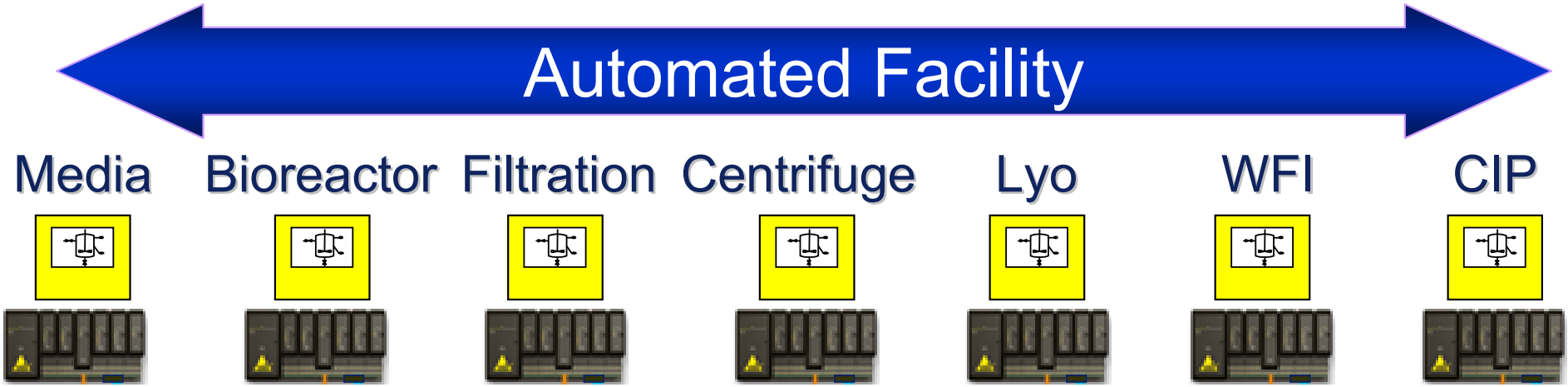
Bioprocess Modeling & Control



- Key to delivering a virtual plant environment.
- First principal bacterial model presented in New Directions in Bioprocess Modeling and Control
- Model is being modified to address mammalian cell process
- Using a virtual plant environment, it is possible to evaluate input step techniques and control strategies in the product development (PD) stage.

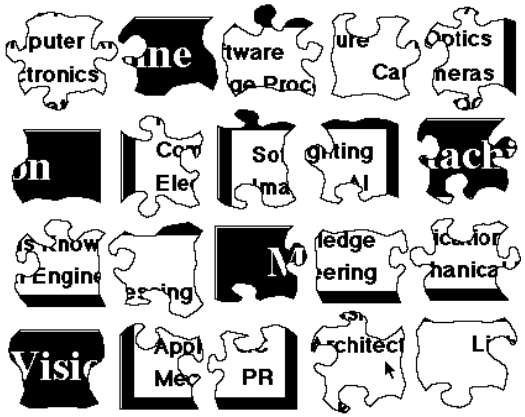
What's Needed: Integrated Eng. and Real-Time Manufacturing

- Comprehensive Plant Floor Scope
  - Materials, Equipment, Process, Order Management, Asset Management, Quality Assurance
  - Common Operator Interface
  - Integrated Execution
- Integrated Engineering
  - Common Objects
  - Common Standards
  - Single Recipe Format & S88 structures
  - Integrated Change Control
- Common Data Management and Reporting



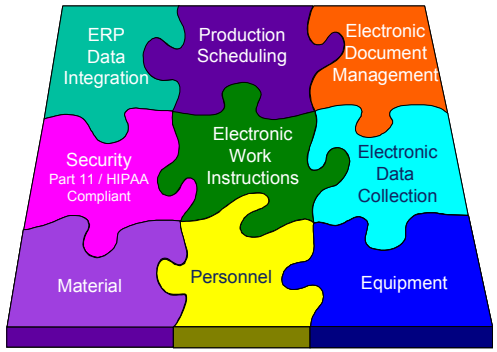
Comprehensive Plant Floor Scope

Today



- Islands of Automation across S95 Levels 2 and 3
- Whatever came with OEM is used
- Separate User Interfaces
- High Integration Costs
- Configuration / installation / commissioning times are long

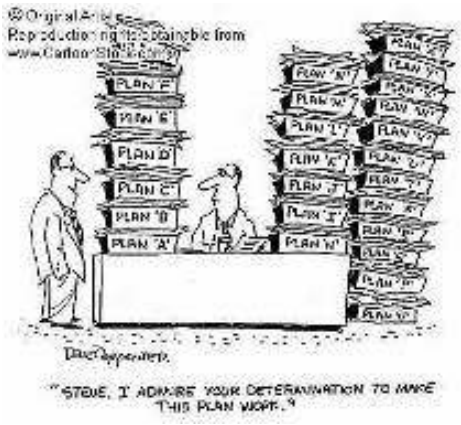
Future



- Integrated Applications across S95 Levels 0,1, 2 and 3
- Common User Interface
- Re-Usable Standard Objects
- Easy Updates
- Modular Expansion
- Ensures valid data at point source every time

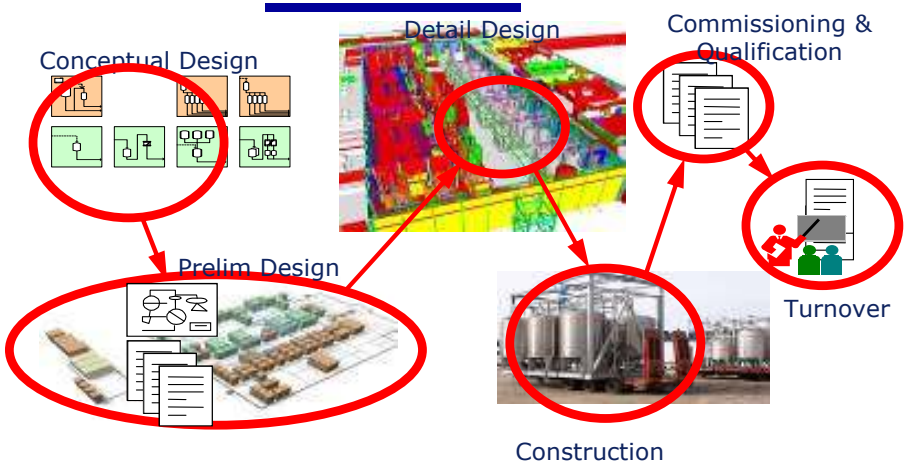
Integrated Engineering

Today



- Disconnected Recipes / Orders
- Multiple Applications to Set Up
- Multiple Users Accounts / Security to Manage
- Changes Done Manually to Multiple Systems
- Updates / Revisions Challenging

Future



- Integrated S95 Data/Information Connectivity
- Common S88 Recipe Engineering
- Common, Re-Usable Standard Objects
- Leverage of Work Done in Earlier Design Stages
- Integrated Commissioning / Qualification

Common Data Management and Reporting

Today

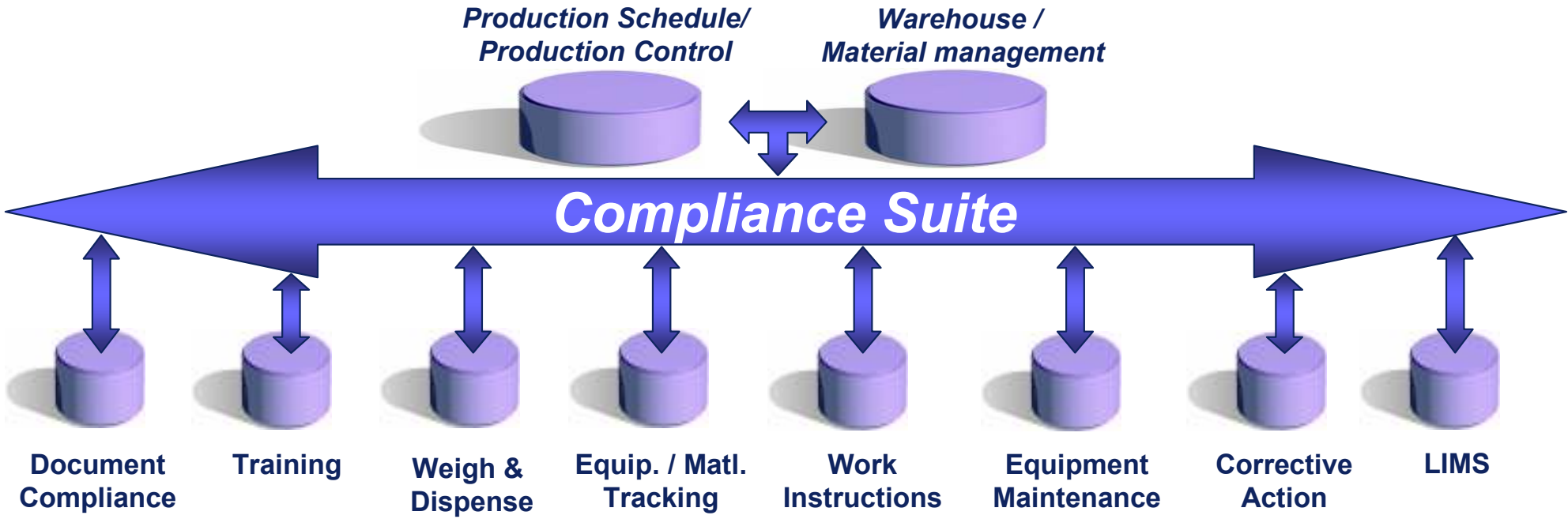
- Most information is still on paper
- Multiple Spreadsheets / Databases for what is electronic
- Custom Reports to get to information
- Not Real-time

Future

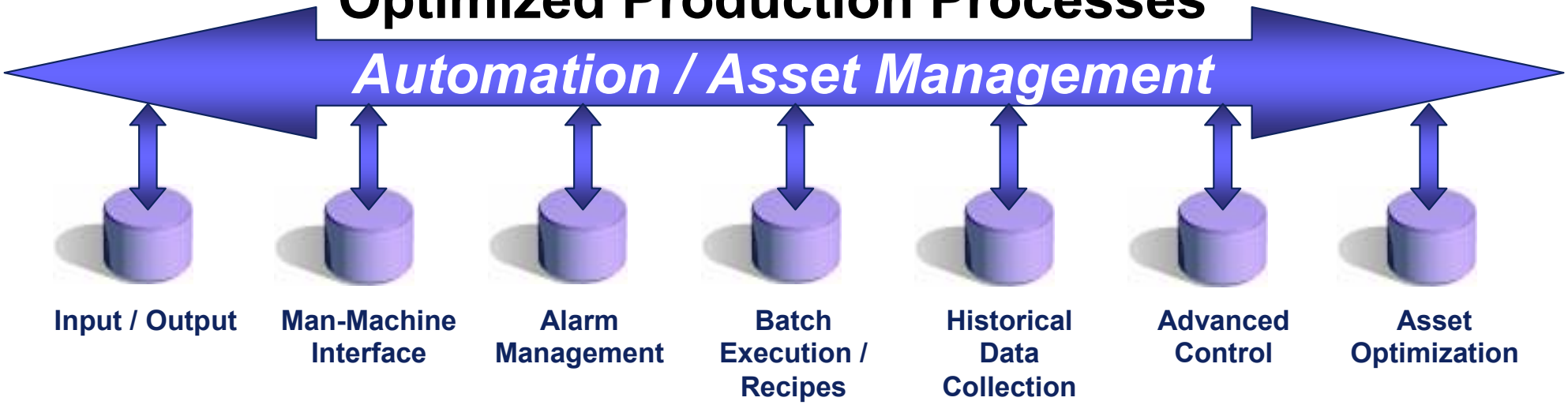
- Integrated Database of Required Data
- XML Access to Data
- No Data Silos
- Real-time Updates
- Includes recipe, batch, alarm, event, history, material, equipment, lab, etc. data

PRODUCTION

Optimized Manufacturing & Quality Processes



Optimized Production Processes



MES Functionalities to Consider for Future State

- **Electronic Master Batch Records** – Batch records created, routed and approved in the MES system.
- **Electronic Work Instructions** – Electronic instructions to lead the operator through the manufacturing process, collecting information and data throughout process.
- **Electronic Batch Records –** Electronically compile and report information related to the manufacturing process for review, approval, and batch release.
- **Electronic Materials Update** – Electronically update and track the material production and consumption through the manufacturing process.
- **Manufacturing Function Integration** – Integration of the above functions and other strategic systems such as LIMS, ERP, Deviation tracking, CMMS, etc.

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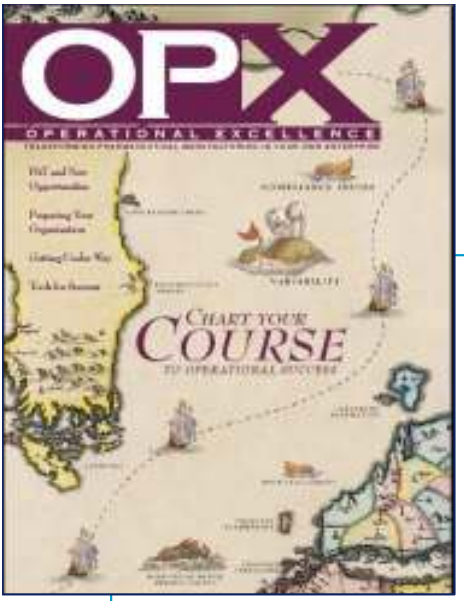
Conclusion

- There are ***Compelling Business Opportunities*** in Life Science Operations
  - Must Evaluate Complete Scope
- Automation Supplier should have ***Proven Experience and Approaches*** to Identify and Capture the Business Opportunity
- Automation Supplier should have ***Differentiated Solutions*** to Deliver the Business Opportunity
- Automation Supplier should be ***Ready to Deploy*** this Approach to Improve Life Science Business Operations
- Automation Supplier should deliver greater System Availability using tools like **Predictive Intelligence, Asset Optimization** etc.
- Automation Supplier should **invest in latest technology like wireless**.



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Thank You

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