Manufacturing Excellence thru MES & the PI System

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VALUE NOW, VALUE OVER TIME

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Agenda

▶ **Overview of BMS in Devens, MA**

▶ **Overview of Manufacturing Operational Philosophy (MOP)**
  – **Integrated recipe based on S95/S88 standards**
  – **MOP implementation**
  – **Reporting by exception**

▶ **Missing Links with MOP and using OSI Analysis Framework 2.0**
  – **Capturing event data and work instructions**

▶ **Extending the MOP**
  – **Lifecycle for Plant Equipment &Validation**
  – **Extending MOP/Integrated Recipe into Lab**

Bristol-Myers Squibb Company
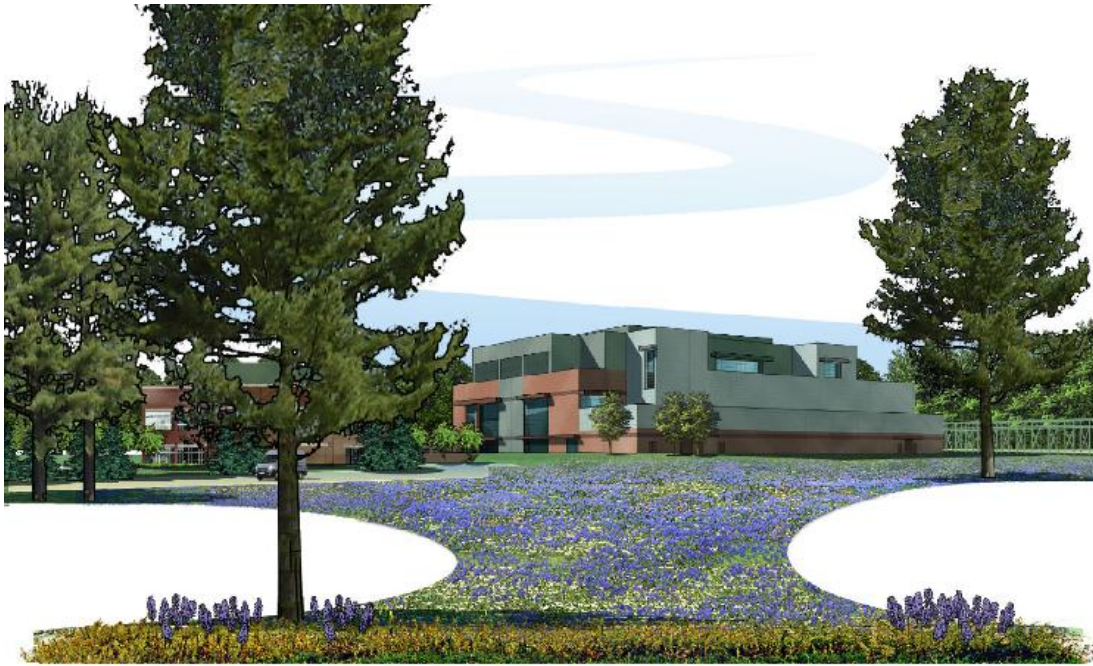
BMS in Devens

BMS is investing $750 million in the construction of a Large-Scale Cell Culture (LSCC) manufacturing facility for the commercial production of biopharmaceuticals in Devens, MA.

This facility will have 120,000 liters of bioreactor capacity.

The first product will be Orencia for rheumatoid arthritis.

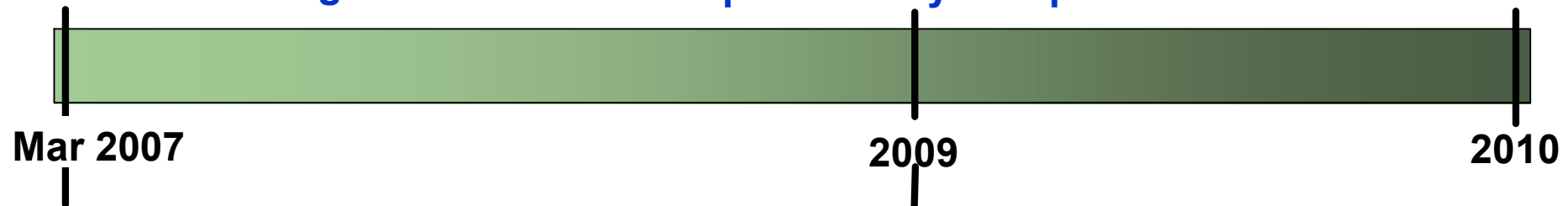ORENCIA™ (abatacept)

CONSIDER THE POSSIBILITY OF SAYING "I CAN"

BMS Devens Timeline

Ground Breaking   **Operationally Complete**   **FDA Submission**

Mar 2007   **2009**   **2010**

Drivers for Manufacturing Operational Philosophy Development

▶ **Emphasis on Plant Floor Performance and Standards**
- Make the operator's job easier
  - Allow focus more on the batch process
  - Behind the scenes: Seamless connectivity between appropriate systems
- Implement widely accepted S95/S88 standards for control of batch manufacturing process
  - Integrated recipe is *key*
  - Plant in a box
- Monitor *all* manufacturing activities
- Perform batch reporting by exception

Manufacturing Operational Philosophy

▶ **Approach..**
- – Internal gap analysis, external bench marking, industry consultants, industry conferences...

- – Develop and Execute a Manufacturing Operational Philosophy which is a set of best methods, practices, and performance objectives for all business functions involved in the manufacture of BMS products.
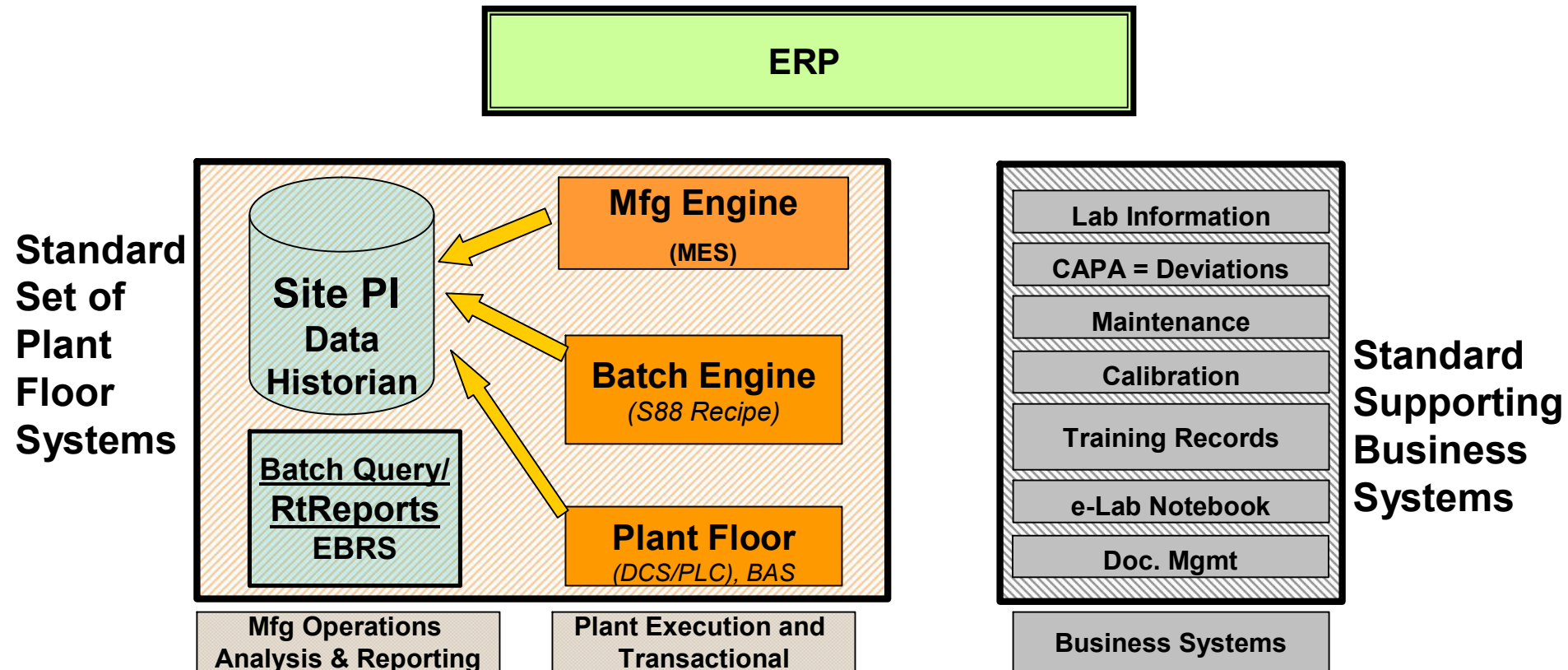
▶ **Solution..**
- – Fully automated based on S95 and S88 standards yielding a paperless solution that supports release by exception.

BMS Standard Manufacturing Architecture

ERP

Standard Set of Plant Floor Systems

Site PI Data Historian

Mfg Engine
(MES)

Batch Engine
(S88 Recipe)

Batch Query/ RtReports
EBRS

Plant Floor
(DCS/PLC), BAS

Mfg Operations Analysis & Reporting

Plant Execution and Transactional

Standard Supporting Business Systems

Lab Information

CAPA = Deviations

Maintenance

Calibration

Training Records

e-Lab Notebook

Doc. Mgmt

Business Systems

BMS MOP Implementation in Devens

Enterprise Resource Planning

Training

Documentation

CMMS

Master Data, Process Orders, Transfer Orders

Purch Req

Mat' Status

Operator Training Status

SOPs

GI/GR Confirm, Mat'l Status Check

Equipment & Instrument Status

Calibration Status

Calibration Event

CAPA

Trigger Quality Event

Quality Event Status

Calibration

Trigger Test Inbound Mat'l

LIMS

MES

Smart Device Master Data

Smart Device Calibration Status

Financials, BW Metrics

Recipe Authoring Order Management

Test Results

Facility Sample Plan

Trigger In Process Test

QC Sample Plan In Process Test Results

Control System

Building Status

Building Automation

QC Lab Methods

Building Data

Test Results

Test

Current QC Status, Test History

Instructions

Results

Batch History

Historian

Lab Instruments

Shop Floor Instruments

Batch History

Enterprise Management Information Portal

Bristol Myers Squibb Company

Hypothetical Batch Exception Report showing both Executed Work Instructions and Automated Sequences

Unit	TKXYZ21	Basel Medium 127-G Preparation 1000 L Tank		
Operation		Media Preparation		
		Start: 08 Feb 2007 13:25:00 End: 08 Feb 2007 14:00:10 Duration: 35 mins 10 secs		
Process Step		**Process Parameter**	**Acceptable Range**	**Actual**
Manual Addition Step 2A		Agitation	Off	No Exception
		Pressure	Atmospheric	No Exception
		Temperature	25 – 38 C	Exception
		CD-CHO 25x Acid Soluble	15200 – 15300 g	15193 g
Comments				
Fennt	Antony J Fenn	08 Feb 2007 13:27:15 This is a comment entered for testing purposes		
Signoff				
Fennt	Antony J Fenn	08 Feb 2007 13:56:45		

Exception Detail Table

Type	Parameter	Exception Value	Exception Limit	Exception Min/Max	Duration
Above High Limit	Temperature	39.2 C	38 C	45.3 C	24 mins 34 secs

BMS Manufacturing Operational Philosophy Architecture

Enterprise RtPortal for Manufacturing Intelligence:
(Enterprise PI Data Historian, SPC , Analysis Framework tools, Visualization)

ERP

Standard Set of Plant Floor Systems

Site PI Data Historian

Batch Query/ RtReports EBRS

Mfg Engine (MES)

Batch Engine *(S88 Recipe)*

Plant Floor *(DCS/PLC), BAS*

Query

Standard Supporting Business Systems

Lab Information

CAPA = Deviations

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Doc. Mgmt

Mfg Operations Analysis & Reporting

Plant Execution and Transactional

Business Systems

Bristol-Myers Squibb Company

BMS' plan to use OSIsoft AF 2.0

There are many non time-series data from Manufacturing Systems we need to examine

System	Example Asset
Training – HR	Personnel, Organizations, Personnel Capabilities
ERP – Inventory	Raw Materials, Suppliers, Inventory Items
Maintenance	Maintenance request, Technicians, Contracts, Companies, Equipment, Parts, Faults
MES	Dispensed Material, Equipment, Procedures, Work in Progress, Electronic Work Instructions
QC Lab and LIMS	Samples, Analytical Procedures, Technician, Test Results, COA
Document Management	Standard Operating Procedures, Material Safety Data Sheets
CAPA – Deviation Tracking	Batch Quality Exceptions, QC Lab Exceptions, Facility Exceptions

In the works from OSIsoft...

▶ New **DeltaV Batch Event** interface

▶ New **Compliance Suite** interface to capture electronic work instruction events for all recipes activities

▶ New interface to capture **Lab Event** data

▶ **Embedded PI** in all plant PLC/DCS systems

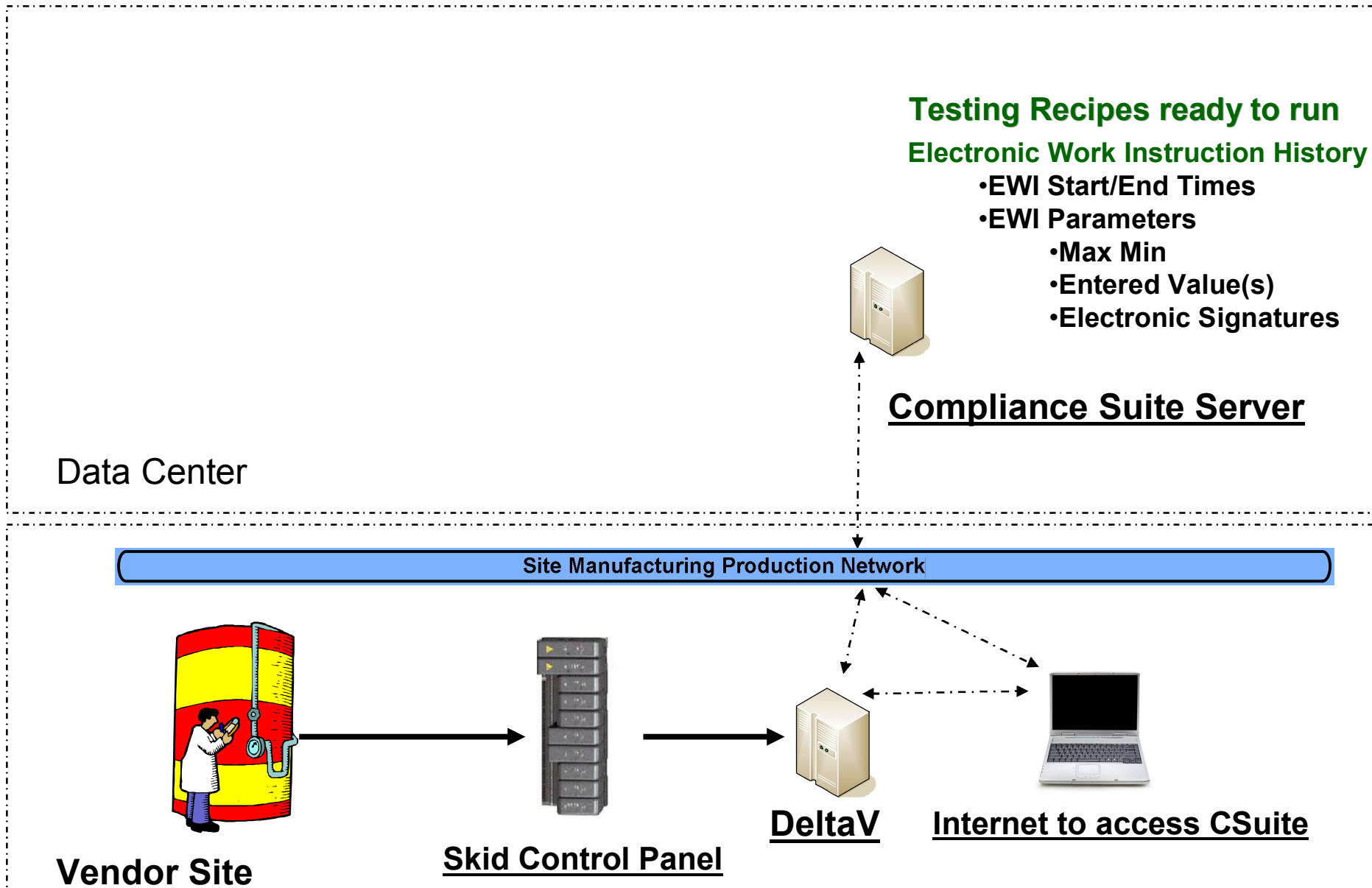▶ Visualization of all **Batch Execution/Analysis Data** and asset databases through **RtPortal**

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▶ **Extending the MOP**
  – **Lifecycle for Plant Equipment &Validation**
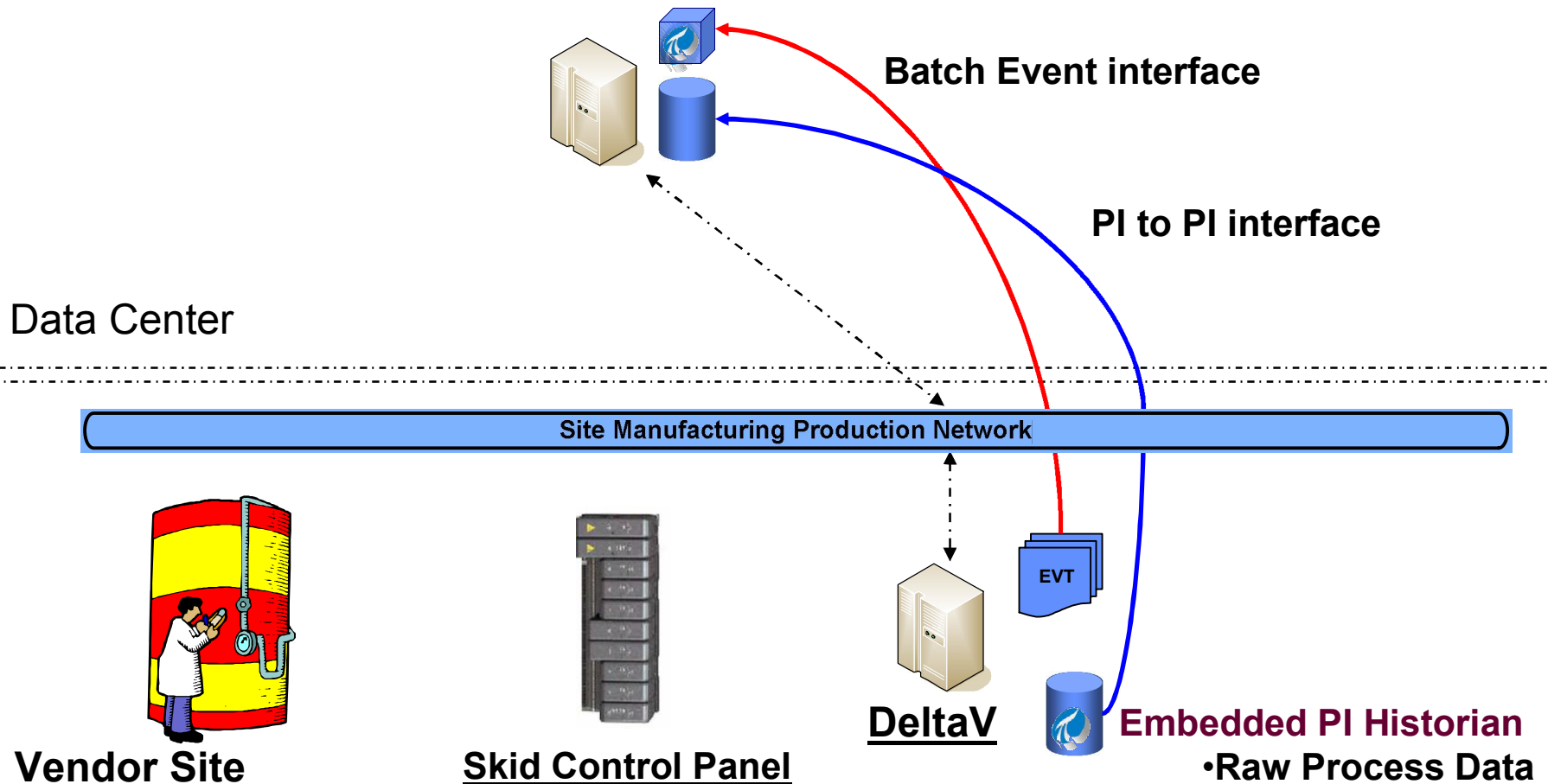 – **Extending MOP/Integrated Recipe into Lab**

Step 1 – Connect to Compliance Suite & Start Testing Recipe

Testing Recipes ready to run

Electronic Work Instruction History
- **EWI Start/End Times**
- **EWI Parameters**
  - **Max Min**
  - **Entered Value(s)**
  - **Electronic Signatures**

Compliance Suite Server

Data Center

Site Manufacturing Production Network

DeltaV

Internet to access CSuite

Vendor Site

Skid Control Panel

Step 2 – Synchronize Batch History and Raw data with Site PI Server

Site PI Server with PI to PI and Batch Event interface

Batch Event interface

PI to PI interface

Data Center

Site Manufacturing Production Network

Vendor Site

Skid Control Panel

EVT

DeltaV

Embedded PI Historian
•**Raw Process Data**

Step 3 – Produce FAT/Commissioning Data Reports with RtReports

Review Reports and Sign Off
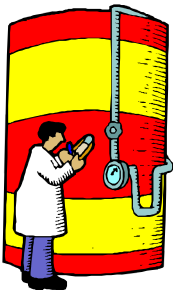**Testing instruction completion**

Can be saved as PDF
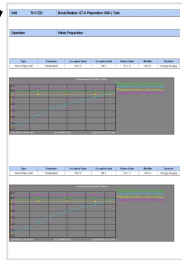
Executed Testing Recipes

Electronic Work Instruction History
- **EWI Start/End Times**
- **EWI Parameters**
    - **Max/Min**
    - **Entered Value(s)**
    - **Electronic Signatures**

Test Data Report

PI Server

RtReports

Compliance Suite Server

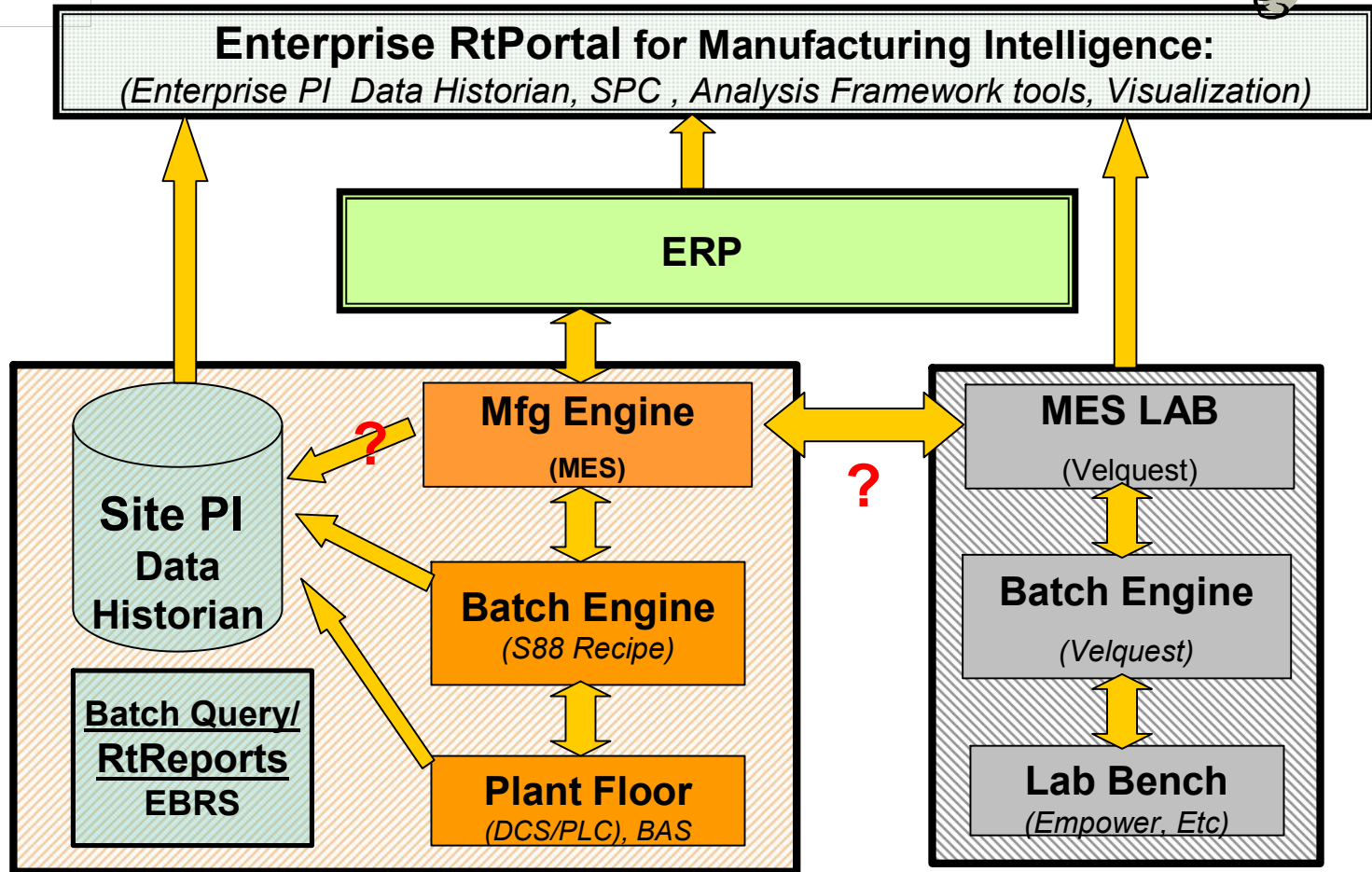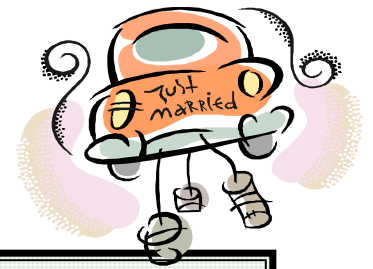Data Center

Vendor Site

Skid Control Panel

DeltaV

Marriage of MOP and Lab Systems

▶ Express analytical space in S95/S88 structure
  – Structuring lab automation steps into procedures, unit procedures and work instructions/phases
▶ Opportunity to reduce overall cycle time
▶ Better coordination and information flow between batch and analytical activities
  – Direct communication between MES and lab system

Marriage MOP and Lab Systems

Enterprise RtPortal for Manufacturing Intelligence:
(Enterprise PI Data Historian, SPC , Analysis Framework tools, Visualization)

ERP

Mfg Engine
(MES)

MES LAB
(Velquest)

Site PI Data Historian

Batch Engine
(S88 Recipe)

Batch Engine
(Velquest)

Batch Query/ RtReports
EBRS

Plant Floor
(DCS/PLC), BAS

Lab Bench
(Empower, Etc)

? ?

Extending the MOP/Integrated Recipe into the Lab

▶ **Creating an S95/S88 integrated recipe to include analytical data.**

- – Batch recipe that represents the "**Full Story**"

- – Store the "**Full Story**" in PI
  - *New interface to capture **Lab Event** data*

- – Report by exception on the "**Full Story**"

In Summary…

▶ **Implementing the MOP will enable BMS to achieve its strategic objectives**

- Highly integrated S95/S88 recipe including the "**Full Story**" of a batch
  - Lots of data and process knowledge gained
  - Having data in context of a batch
- RtPortal view across all plant systems
  - Easy to use and access batch information for all purposes
- FDA compliance
  - Reliable and repeatable batch execution

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Thank You

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