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Oracle Process Manufacturing Update and Roadmap

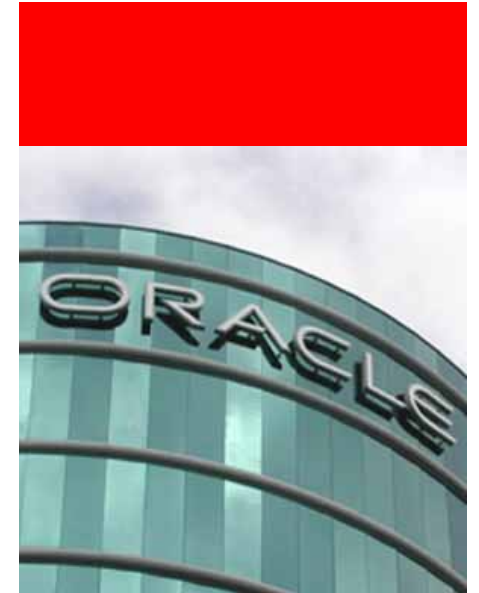
Karen Theel, Oracle



The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

Agenda

- Key Business Challenges in Process Manufacturing Industries
- Evolution to Information Driven Manufacturing
- Release 12: Business Benefits for Process Industries
- Introducing Two New Manufacturing Products
- Q&A



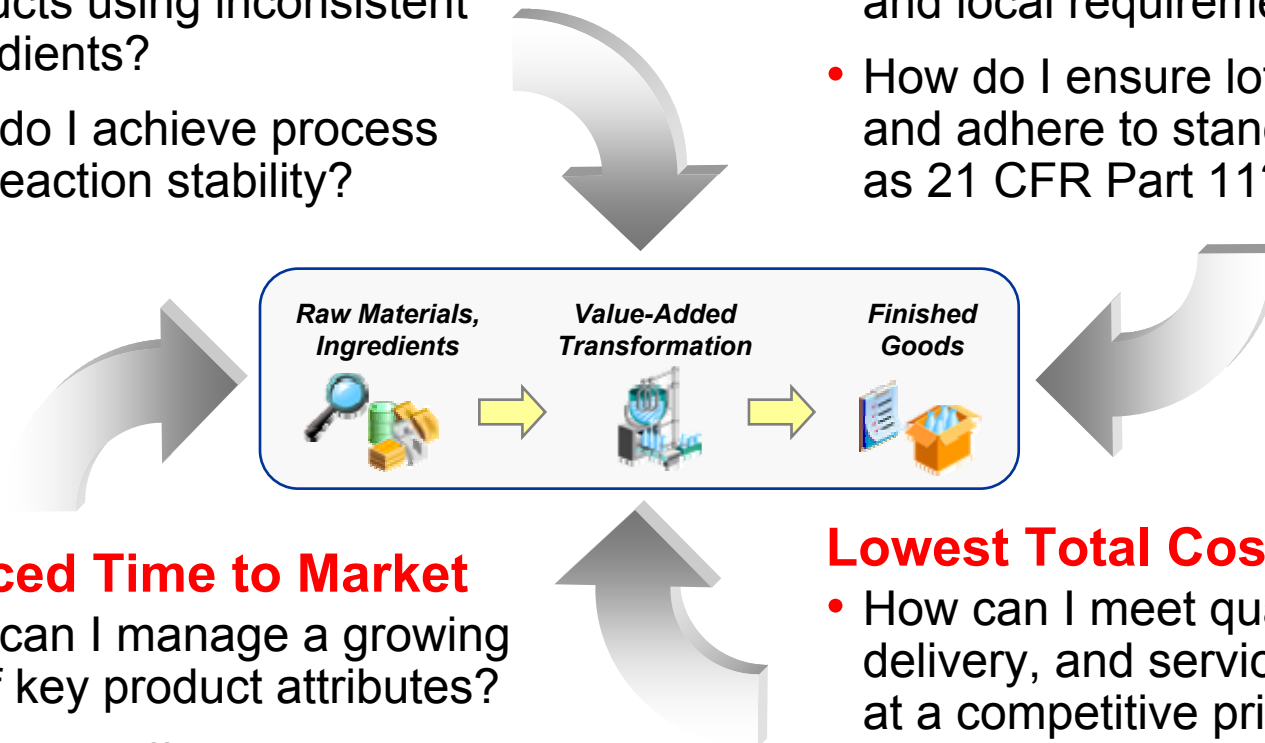
Process Industry Business Pressures

Variability

- How do I create consistent products using inconsistent ingredients?
- How do I achieve process and reaction stability?

Regulatory Compliance

- How do I comply with global and local requirements?
- How do I ensure lot traceability and adhere to standards such as 21 CFR Part 11?



Reduced Time to Market

- How can I manage a growing list of key product attributes?
- How can I efficiently mass customize my products?

Lowest Total Cost

- How can I meet quality, delivery, and service demands at a competitive price?
- How can I minimize waste and emissions?

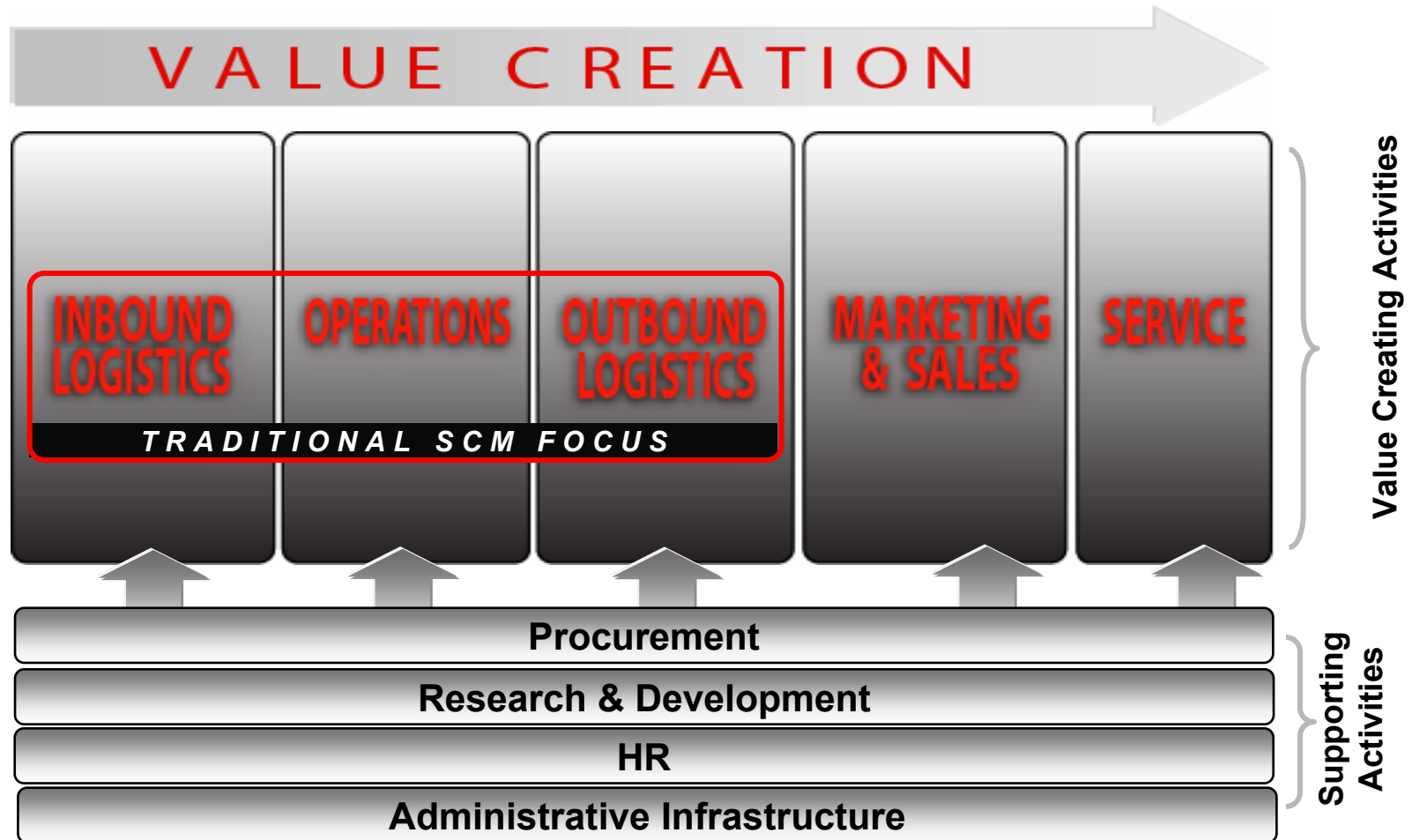
Evolution to Information Driven Manufacturing



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Legacy Value Chains Don't Work



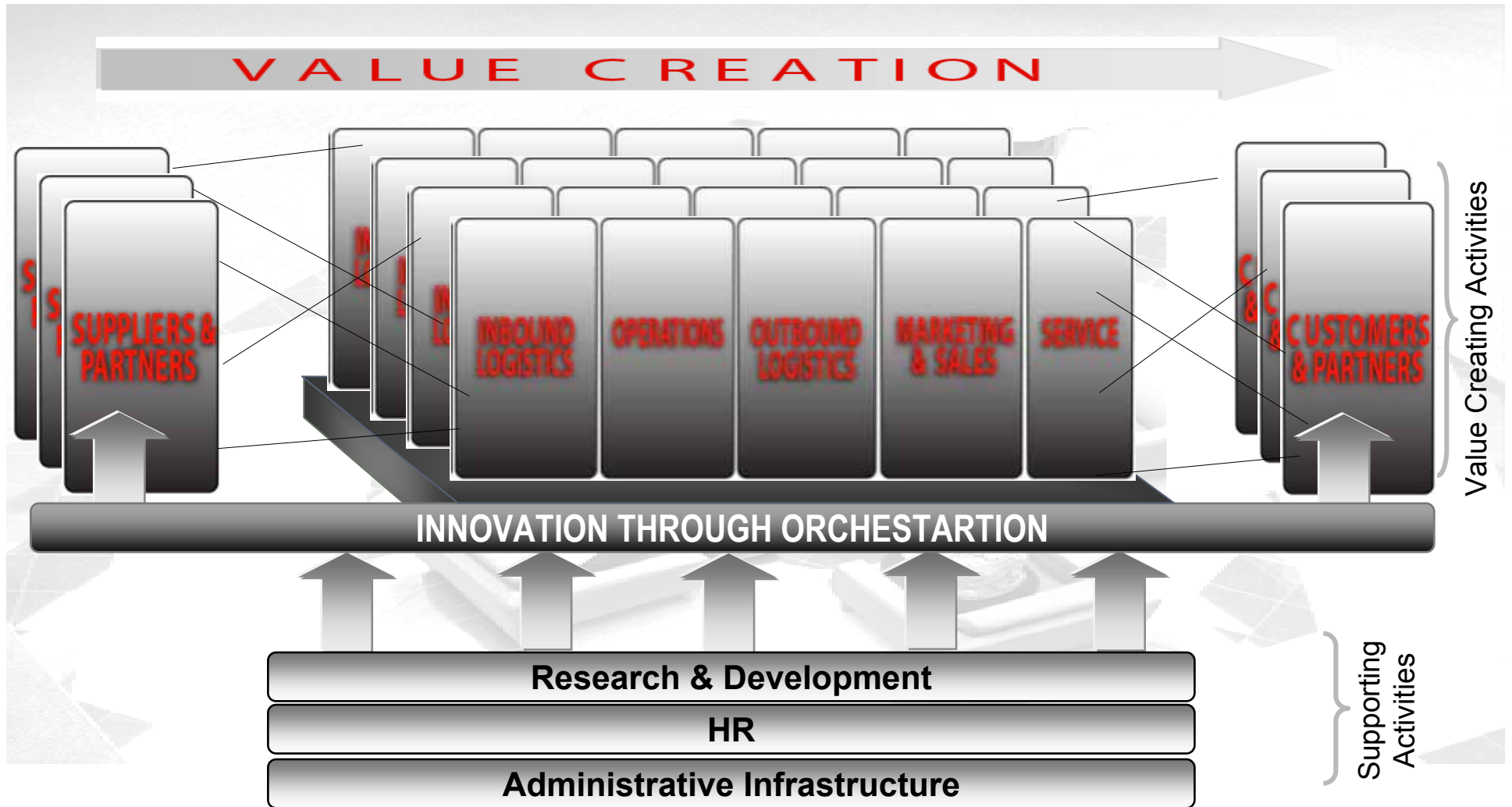
Dr. Michael Porter (Harvard, 1985)

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Value Chains In The 21st Century

Global, Complex, Virtual...

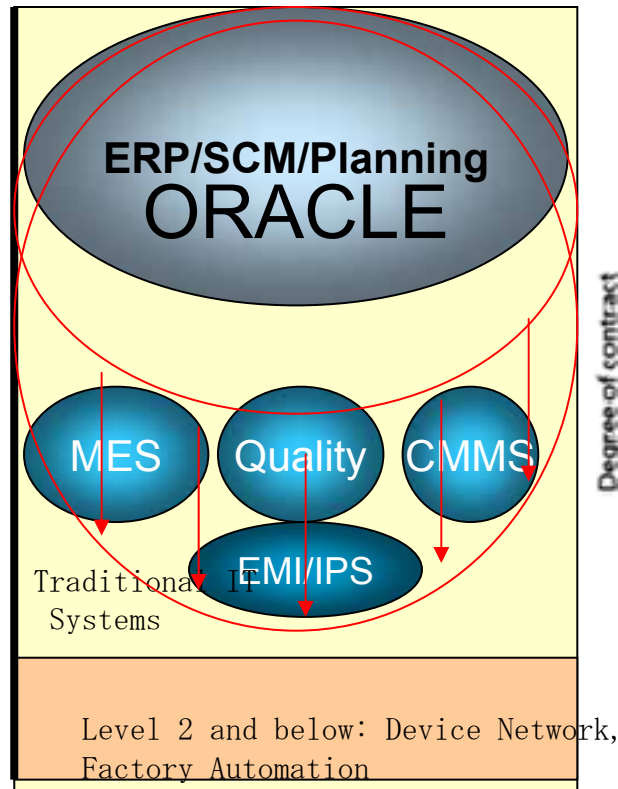


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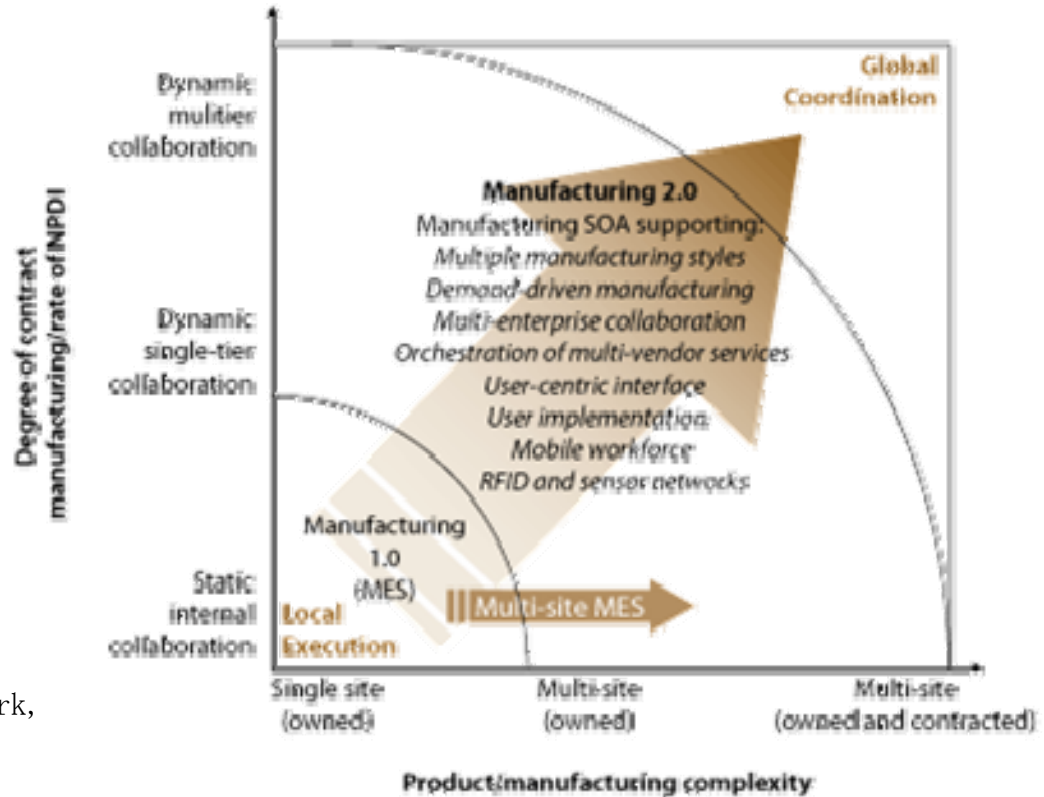
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Manufacturing Systems In The 21st Century

Global, Collaborative, Real Time...



Demand-driven manufacturing 2.0

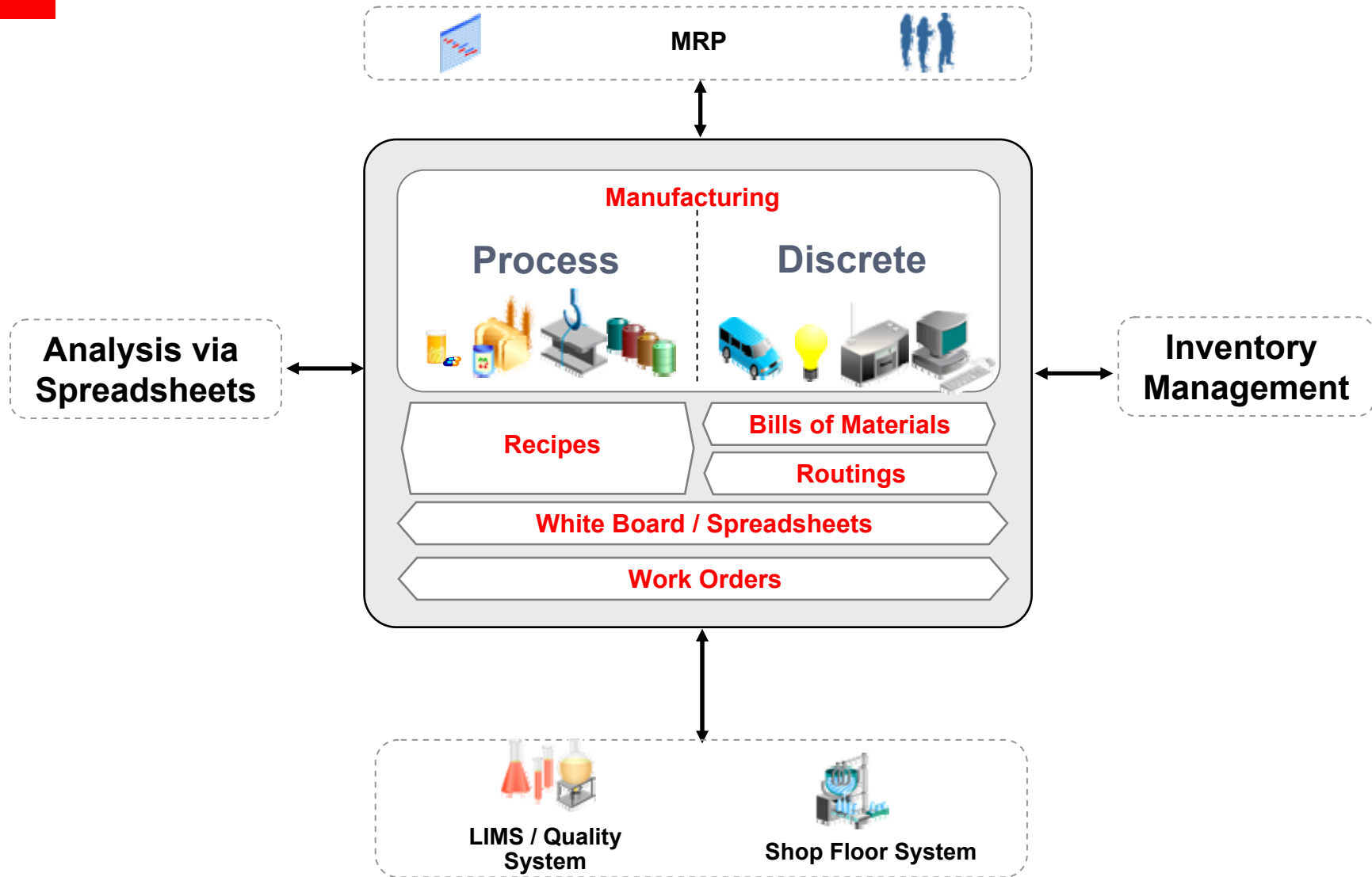


Source: AMR Research, 2007

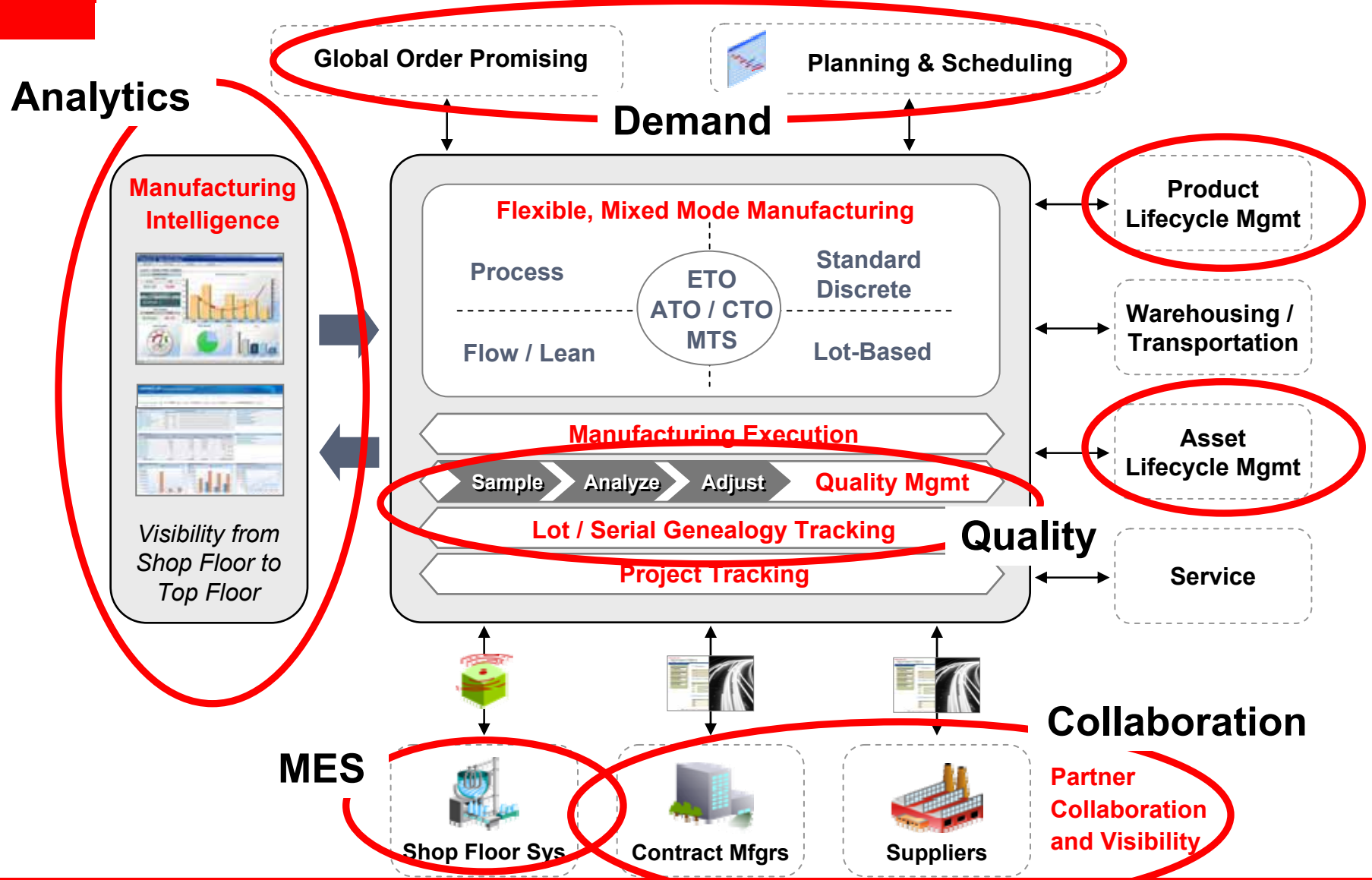
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Traditional ERP Manufacturing Solution



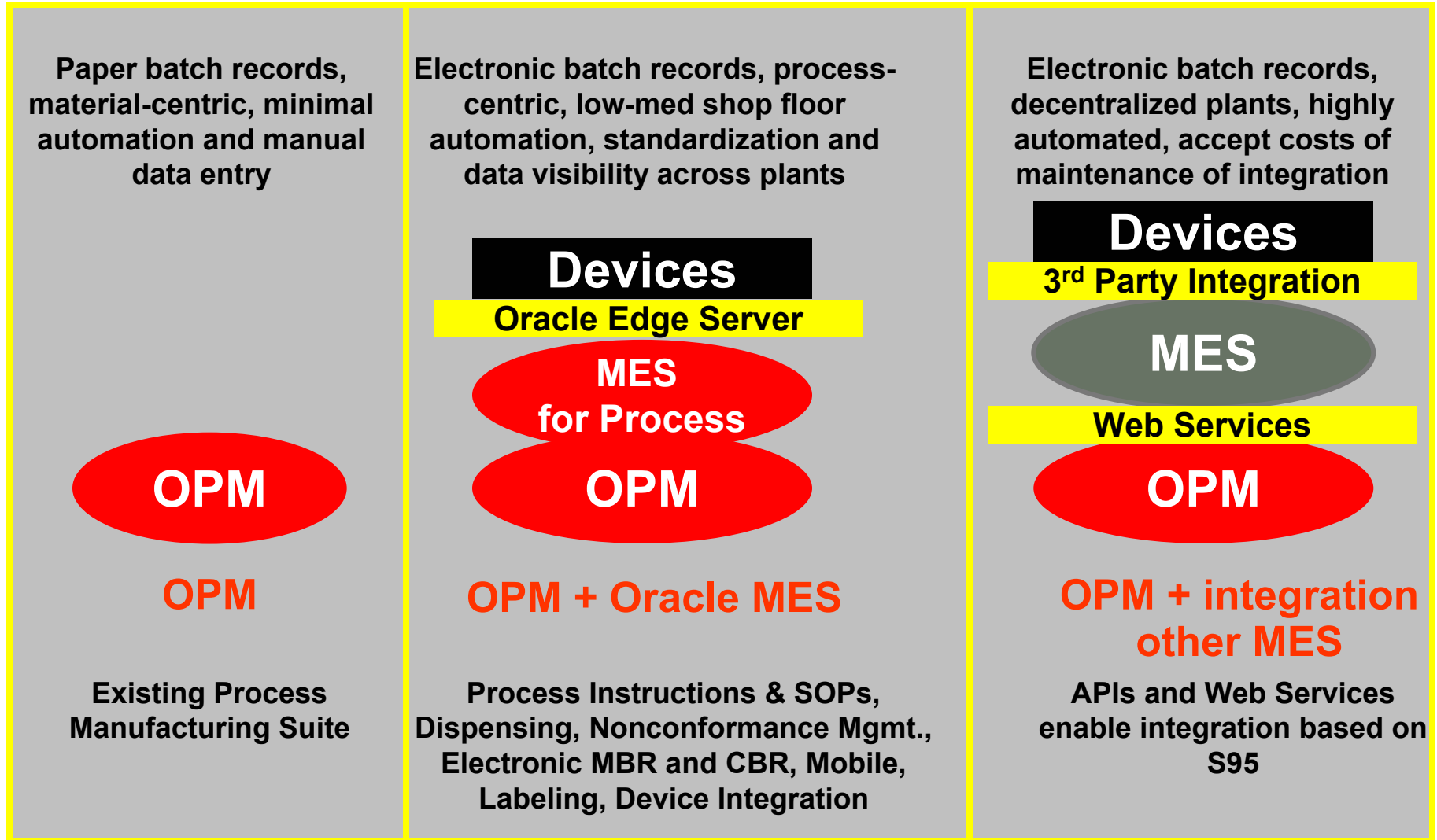
Oracle Information Driven Manufacturing Solution



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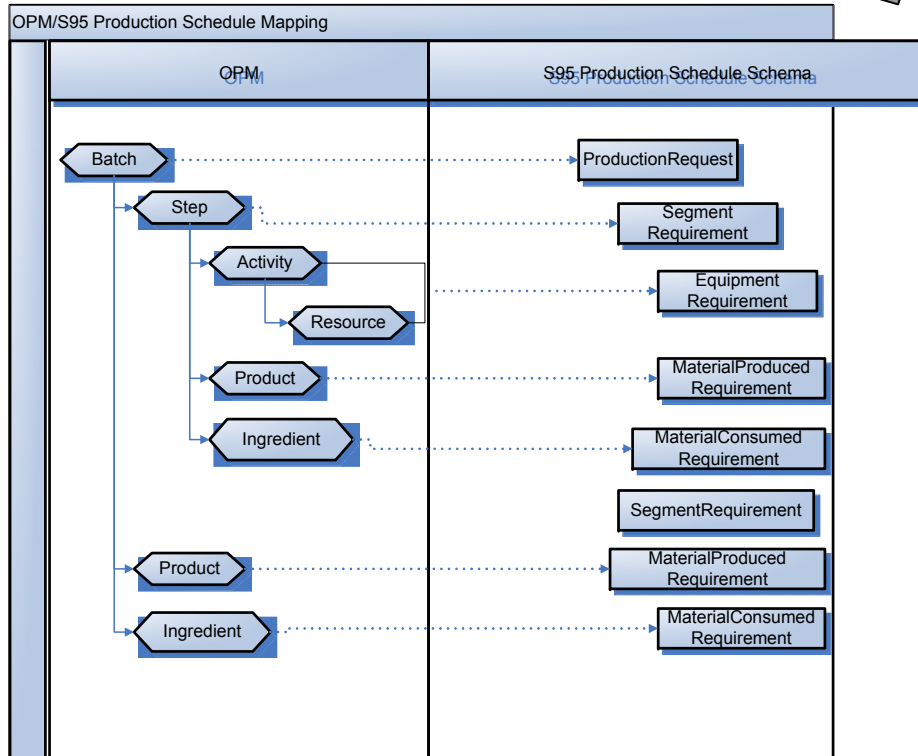
Manufacturing Execution Strategy



Oracle S95 Approach

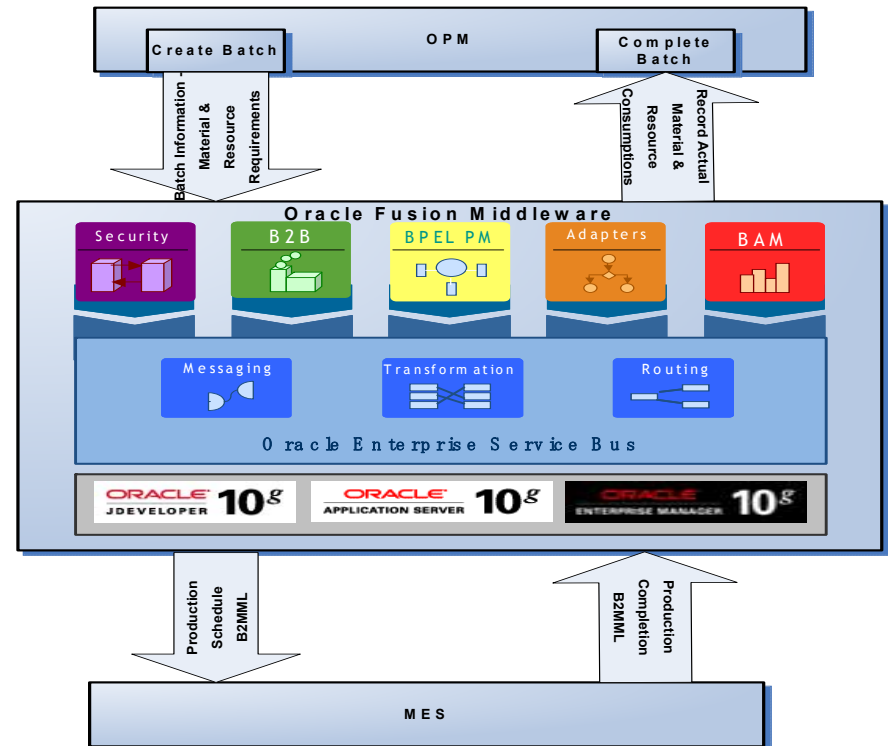
Use When Best of Breed MES is Needed

B2MML Standard Messaging



Mapping OPM Batch Objects to S95 Entities

Enabled with Fusion Middleware



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Release 12: **Business Benefits for Process Industries**



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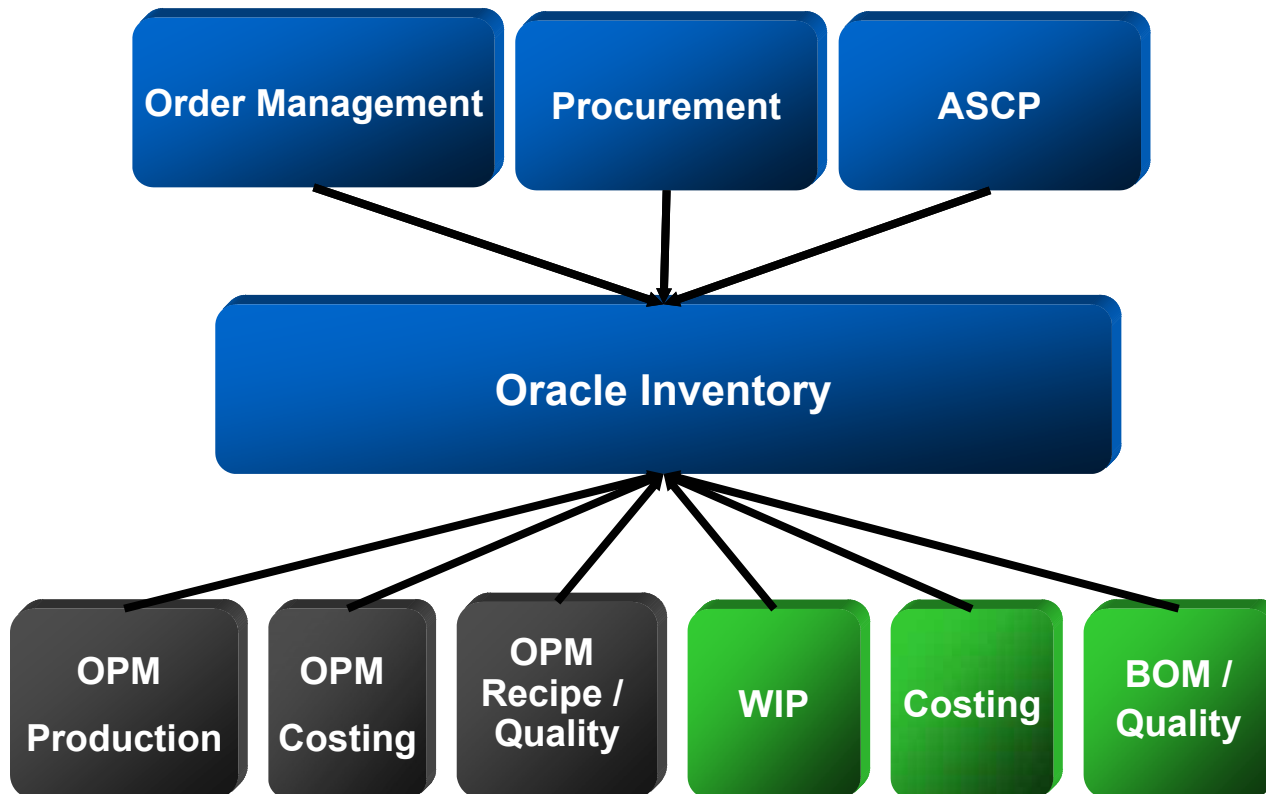
R12 for Process

The most important Oracle release for Process Industries ever

- R12 Subledger Accounting
- Enterprise Asset Management for Process
- Achieve global visibility with ability to manage plant specific variability
- Create and execute an optimal production plan
- Manage the production process to deliver profitable, regulatory-compliant, high-quality products

Single Source of Truth for Inventory Availability

Advanced Inventory Management for Process Industries



- Single Inventory Model
- Org specific attributes enabled at a Global or Local level
- Process features include:
 - Tracking in two units of measure
 - Grade
 - Expiration/ Maturation Dates
 - Material Status
 - Enhanced inventory allocation rules
 - Indivisible lots
 - Support for “child lots” (replace “sublots” in OPM)

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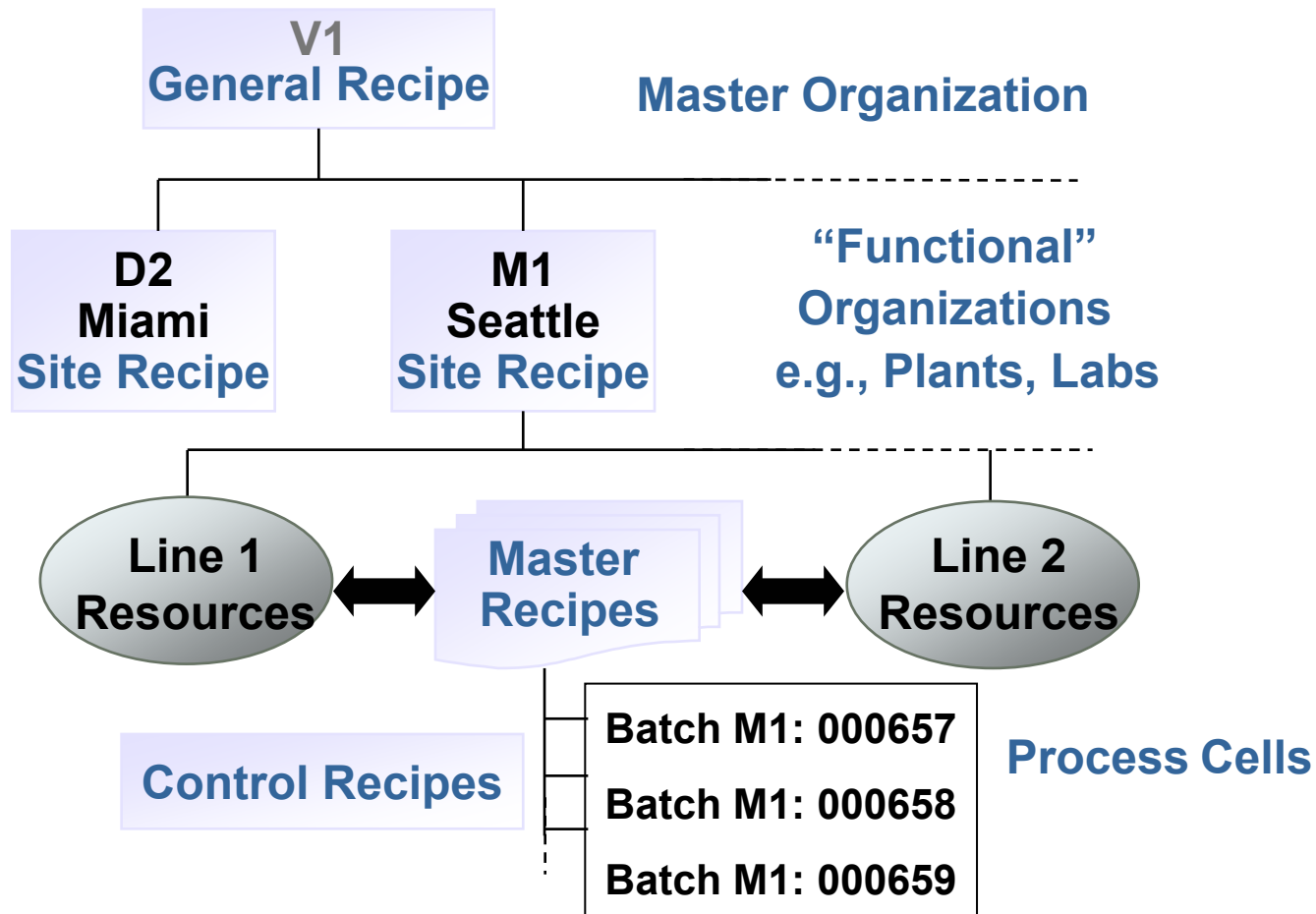
Single Source of Truth for Inventory Availability

Summary of Business Gains for Process Users

- Vendor-Managed and Consigned Inventory to reduce on-hand inventory
- Improve picking and putaway process with Warehouse Management
- Leverage Mobile Supply Chain Applications to improve productivity
- Flexible account mapping with Subledger Architecture
- Real-time Lot Management Transactions
 - Lot Merge
 - Lot Split
 - Lot Translate
 - Flexible Attribute Definition
 - Attribute Inheritance
- Advanced Unconstrained Advanced Supply Chain Planning replaces Oracle Process Manufacturing MRP

ANSI/ISA-S88.01 Standard Based Recipes

Global standards with provisions for local plant variations

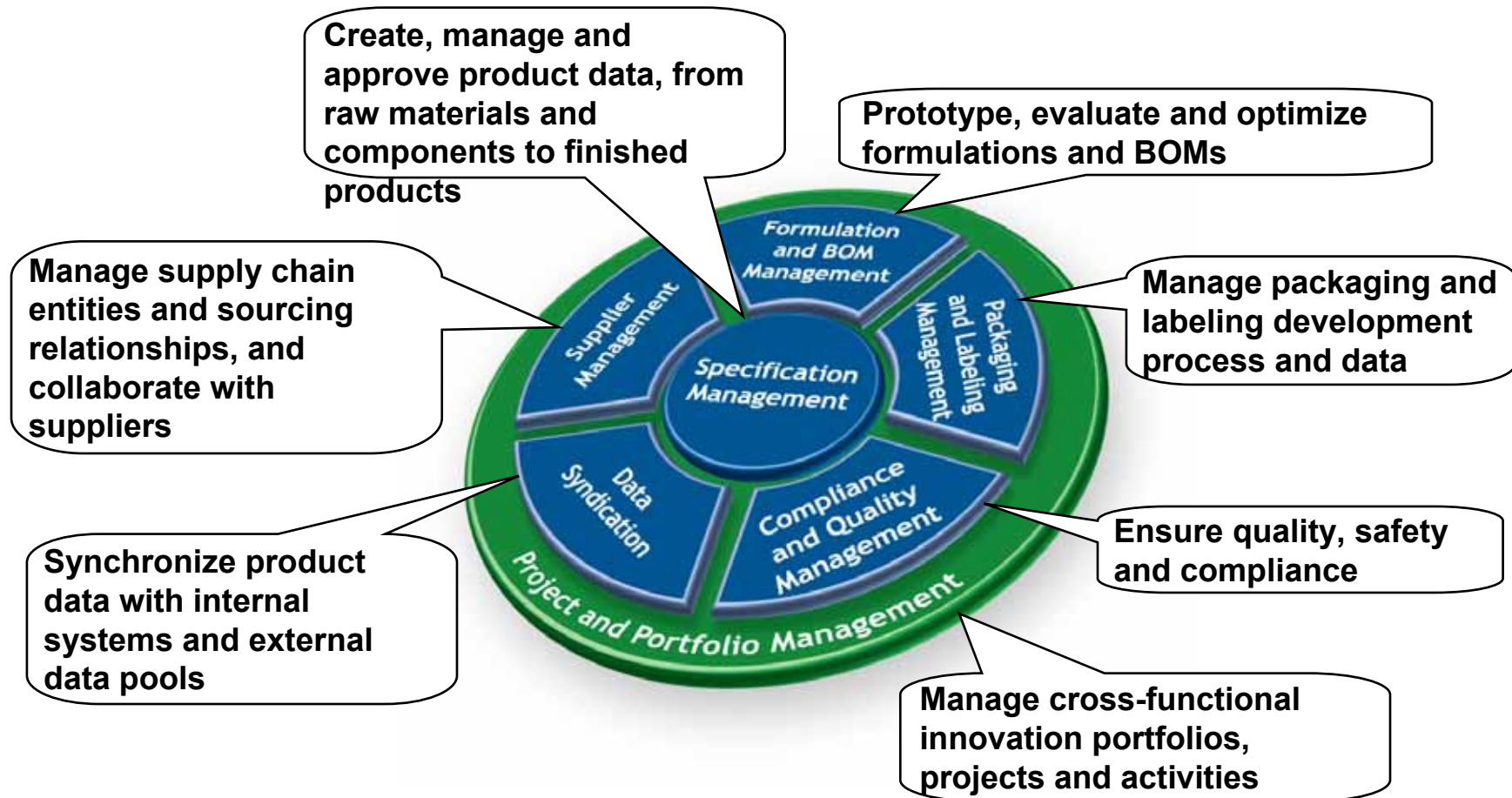


- Facilitate integration to MES systems
- Models and terminology for structuring the production process and for developing the control of equipment
- Document and communicate standard manufacturing science information

Innovation in Process Industries

The Solution: Product Lifecycle Management

One Single “Version of the Truth” for Innovation



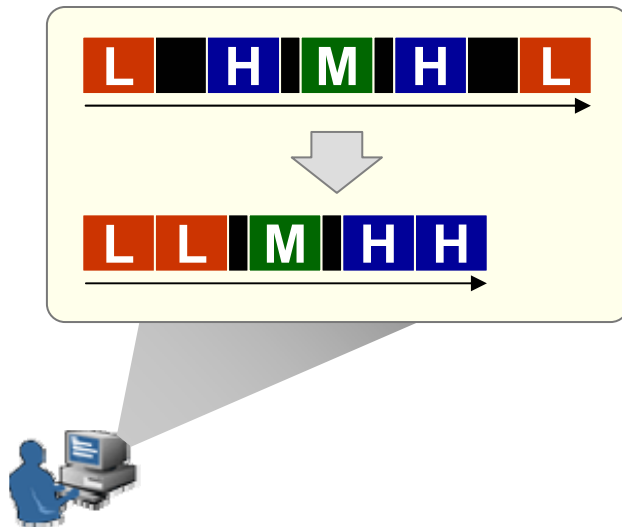
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Sequence Dependent Setups in ASCP

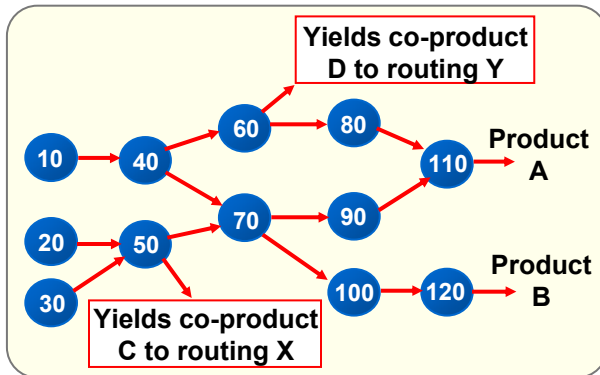
Reduce changeover times

- Model SDS directly and schedule activities to reduce changeover time
- No need to reduce resource efficiency or utilization as a surrogate for changeover time



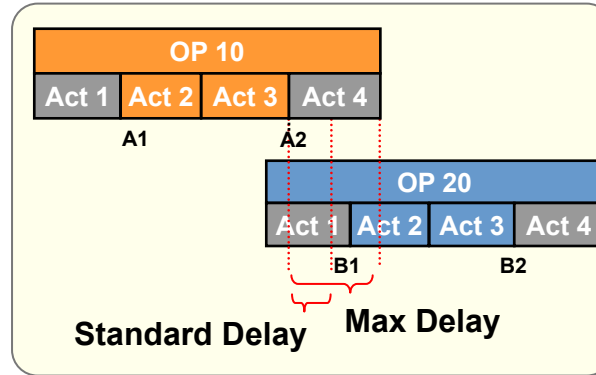
Scheduling in Process Industries

Operational Efficiency and Optimization



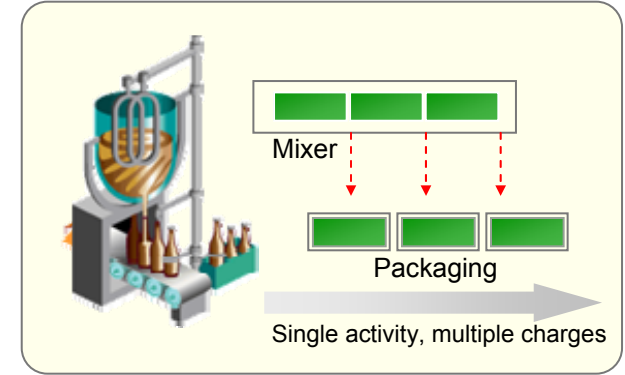
Schedule Complex Routings

- Enable operations to run simultaneously, feed one or more operations, or be fed by one or more operations
- Specify multiple starting operations and multiple terminal operations for routings
- Yield products at other operations in addition to the last one



Schedule Operations with Hard Links

- Support minimum and maximum time offsets between operations
- Apply minimum and maximum offsets to charges
- Respect shelf life of items purchased from suppliers
- Respect lot expiration date when planning the use of the lot to meet demands



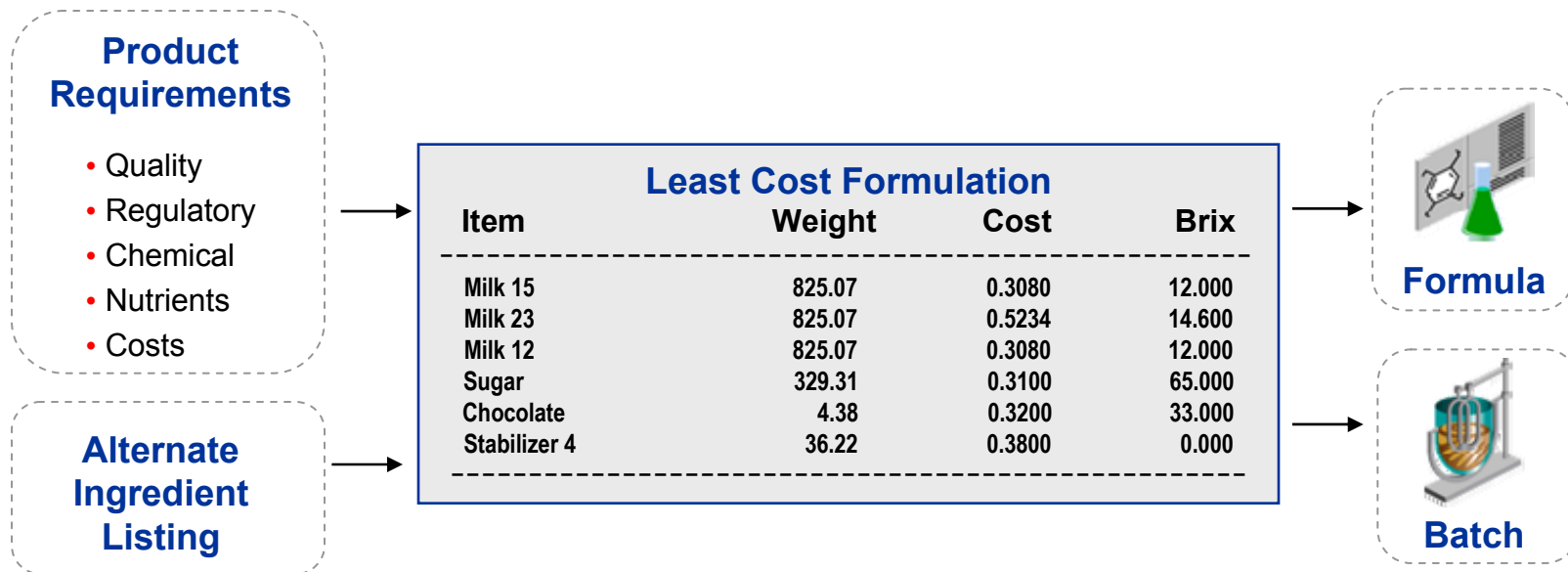
Schedule Charges

- Schedule a charge as a continuous process
- Apply operation dependencies to charges
- Overlap operations by incremental feeding to and from chargeable resources

Least Cost Formulation

Optimize Costs while Complying with Product Requirements

- Generate formulations based on material, compositional, and technical requirements
- Analyze formulations using Product Requirements
- Load cost from any source
- Create formulas or production batches directly



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Focus on Product Targets

Assure customer satisfaction at target cost

Typical Formulation Process – Start with Ingredients



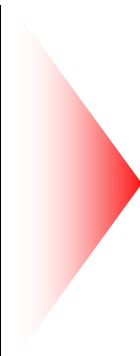
•Ingredients	•Qty
•Apricot Juice	•5
•Grapefruit Juice	•25
•Water	•55



Fruit Juice Product

Least Cost Formulation Process – Start with Product

•Product: Fruit Juice
•COST
•BRIX
•%MOISTURE
•SWEETNESS



•Ingredients	•COST	•BRIX	•%MOIST	•SWEET
•Apricot Juice	•10.00	•28	•70	•30
•Grapefruit Juice	•8.00	•27	•70	•29.5
•Water	•.75	•0	•100	•0

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Manufacturing Execution System for Process Industries

R12 MES for Process



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Outstanding Issue...

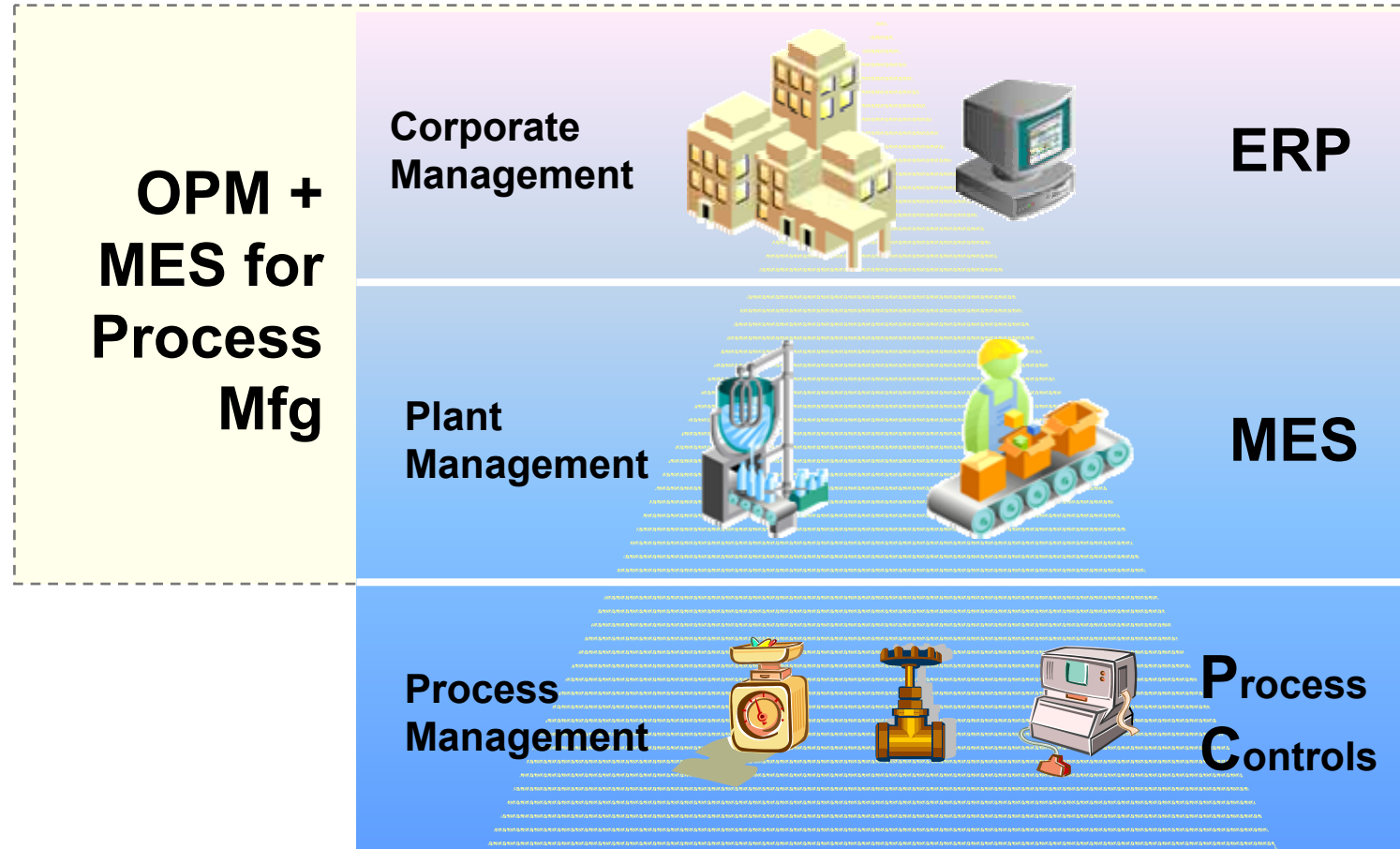


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Enforce Manufacturing Best Practices

New MES Product Guides Operator through Operations

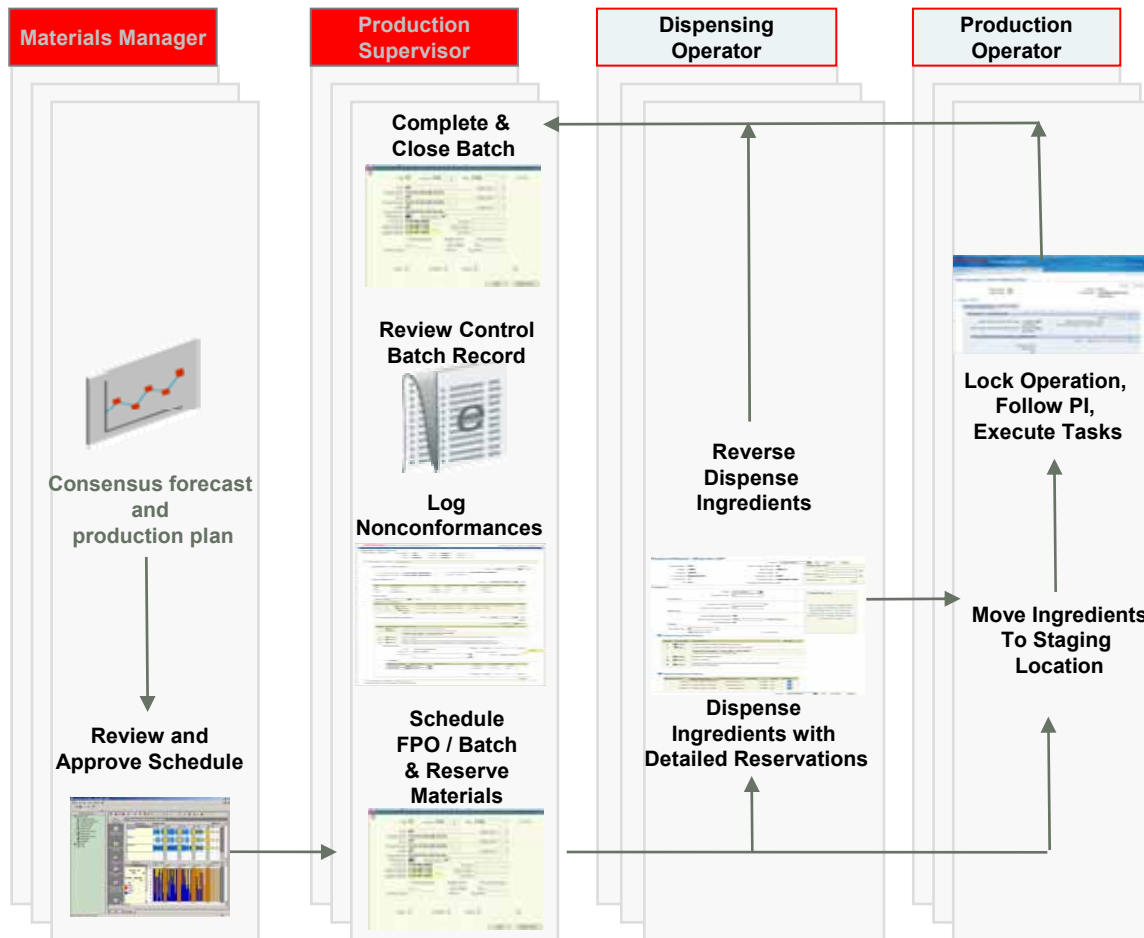


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Model Actual Scenario of Shop Floor

Improve inventory visibility at each stage of the Supply Chain



- Reservation supply to assure inventory meets customer needs
 - High level
 - Detail Level
- Model plant areas so that stock is readily available
 - Dispensing Locations
 - Staging Locations

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Dispensing Workbench

Improve Accuracy & Compliance While Reducing Risk

The screenshot displays the Dispensing Workbench interface for Material Dispense: 8801. It includes sections for Dispense, Containers, Measures, and Labels. Red callout boxes highlight key features: 'Multiple methods supported' points to the Mode dropdown; 'Read Values Direct from Devices' points to the Read Measure buttons; and 'Generate Labels' points to the Security Tag field and label checkboxes.

Organization	PR1	Ingredient Description	Ibuprofen USP
Organization Name	PR1	Dispense UOM	KGM
Dispense Area	PRO	Lot	RCT LOT R FDR 8801

Dispense

* Indicates required field

Pending Dispense Quantity: 50

Mode: Source Container

Source Device: SCALE10

Target Device: SCALE10

Containers

* Source Container: JEDCONT1

Source Container Tare: 0.5

* Target Container: JEDCONT1

Target Container Tare: 0.5

Measures

* Measure Source Container: 55.5 [Read Measure]

Gross Measure Required: 5.5

* Measure Target Container: 5.5 [Read Measure]

* Re-measure Source Container: 50.5 [Read Measure]

Quantity Dispensed: 50

Labels

Security Tag: 123-ABC

Dispense Label

Material Label

Pallet Label

- Improve accuracy by removing human interaction
- Enforce compliance
 - Configurable level of control on process instructions enforce best practices and regulatory compliance
- Reduce complexity & risk
 - Simplified task-based operator interface
 - Consolidate systems

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Operator Workbench Provides Next Task

Forces Compliance with mandatory acknowledgment rules

The screenshot displays the Oracle Process Operations Operator Workbench interface. At the top, it shows the Oracle logo and 'Process Operations' title. Below this, there are navigation tabs for 'Workbench' and 'Setup'. The main area shows 'Process Instructions: Operation 10-1-PHARMACY' with a 'Batch 134983' and 'Operation-Version 1-1-PHARMACY-0'. A task 'Consume 8801' is highlighted, with an instruction text: 'Verify labels on dispensed ingredients 8801 Then add to granulation hopper.' A red callout box points to the 'Instruction Completed' checkbox, stating 'Configurable acknowledgement: • Optional • Required Acknowledgement • E-Signature(s)'. Another red callout box points to the 'Task' field, stating 'One-Click Access to Transactional Forms'. At the bottom, a table lists instructions with columns for 'Details', 'Status', 'Instruction Num', 'Type', and 'Instruction Text'. The table shows three instructions: 10 (Mandatory, Status: checkmark), 20 (Mandatory, Status: warning), and 30 (Mandatory, Status: error).

Details	Status	Instruction Num	Type	Instruction Text
Show	✓	10	Mandatory	Wear respirator
Show	⚠	20	Mandatory	Verify labels on dispensed ingredients 8801 Then add to granulation hopper.
Show	✖	30	Mandatory	Verify labels on dispensed ingredients 8805 Then add to granulation hopper.

Touch Screen Operator Workbench

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Links to SOPs

Logged In As 25921

Process Instructions: Oper... HEAT

Batch: 41
Batch Step: 10-RG-HEAT
Product: R12-A-GMOPROD

Actual Start Date: 04-Oct-2006 22:54:30
Planned Completion Date: 04-Oct-2006 22:42:55
Product Description: dual non default

SOP	Instruction	Comments	Response
	Eye protection in the form of safety glasses must be worn at all times when handling flammable liquids. Ordinary (street) prescription glasses do not provide adequate protection.	Comments	Completed
	Anticipate spills by having the appropriate clean up equipment on hand, the appropriate clean up supplies can be determined by consulting the material safety data sheet.	Comments	Completed
	Add a resource	Comments	Resource transaction
	Add Material	Comments	Material transactions
	Read Process Parameter Values	Comments	Process Parameter

1 - 5 of 0 Records

Privacy Statement

Online Process Instructions

Focus on the Operator

- Process guides move operators through work instruction view, progress reporting, and material consumption tracking
- Configurable level of acknowledgement
- All responses logged in Electronic Batch Record

Complete Process Support for Work Instruction Display, Batch Progress Tracking, and Ingredient Consumption Reporting

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Touch Screen Dispensing

ORACLE Process Operations

Logged In As KIOSK1

Material Dispense

Dispense Context

Organization: PR1 Batch: 1995
Dispense Area: PR0 Lot: L3
Item: 6804 Hazard Class: Radioactive
Hazardous: Yes

Dispense: Measuring from Model T-5195 Mode: Source

Measurement: 3.75 KGM

Source Scale: 3 5 10.0

Quantity: 1.25 KGM

Target Scale: Model T-5195

Container: 3 L Jar

Tare: 1.75 KGM

Quantity: KGM

Reweigh Source: Model N-4157

Quantity: KGM Security Tag

Cancel Continue

Supporting Deep Manufacturing Operations Management

- Process guides move operators through work instruction view, progress reporting, and material consumption tracking
- Quality data collection and lot data capture for genealogy
- Integration to process equipment

Complete Process Support for Work Instruction Display, Dispensing, Batch Progress Tracking, and Ingredient Consumption Reporting

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Supervisor Workbench (Dispense Planning) Graphical Mode

Display Bucket (Daily / weekly)

From Date: (example: 16-May-2007) To Date:
Display Bucket: Dispense Area Utilization:

Dispense Planning details at Area/booth, Resource, Storage Area

Dispense Focus Area/Operator	16-May-2007 Wednesday	17-May-2007 Thursday	18-May-2007 Friday	19-May-2007 Saturday	20-May-2007 Sunday	21-May-2007 Monday	22-May-2007 Tuesday
Root Node							
Loading Dock	Red bar		White bar	Red bar			
Light Sensitive Bulk Material	Green bar						
API	Green bar						
APIDISP	Green bar						

Dispense Capacity Plan Vs Actual

Done Local intranet 100%

Operator Certification

ORACLE[®] MES for Process Manufacturing

Home Logout Preferences Diagnostics

Workbench Dispensing Inquiry Setup Dispense Task Planning

Document Numbering | Dispensing Setup | **Operator Certification** | Dispense Area

Operator Certification - Update Object

Apply Cancel

Certification Setup for Organization, Transaction
 Organization SUN
 Object Type Transaction
 Transaction Material Transaction
 Description Material Transaction
 Override

Override Status

Competence Criteria

Transaction Go

Competencies

*Type	*Certificate	*Competence	Description	Proficiency	*From Date	To Date	Delete
Certification	Operator Certification	<input type="text"/>		<input type="text"/>	28-May-2007	<input type="text"/>	<input type="text"/>
Competency	<input type="text"/>	Hazardous Material Hand		3-Semi proficient	28-May-2007	<input type="text"/>	<input type="text"/>

Add Another Row

Apply Cancel

Workbench Dispensing Inquiry **Criteria for Enabling Operator Certification** Home Logout Preferences Diagnostics

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Nonconformance Management


Capture and Record Deviations in-line for greater compliance

The screenshot displays the Oracle Inventory Management System interface. The top window, 'Batch Details (PR1)', shows a 'Log Nonconformance' option highlighted in the 'Main' menu. Below this, a table lists ingredients with columns for Line, Item, Item Description, Revision, Original Qty, Planned Qty, Reserved Qty, UOM, and Consumption Type. The bottom window, 'Enter Quality Results', shows a 'Collection Plan' of 'GMO R12 TRAINING' and a table of results with columns for Nonconformance Number, Description, Detailed Description, and Nonconform Severity. The first row in the results table is highlighted, showing 'Automatic' for the number, 'Power Irregularity' for the description, 'Electrical power irregularity caused shop floor' for the detailed description, and 'MEDIUM' for the severity.

Line	Item	Item Description	Revision	Original Qty	Planned Qty	Reserved Qty	UOM	Consumption Type
1	8801	Suprofen USP		50.00000	50.00000	.00000	KGM	Automatic
2	8802	Coin Stamp (LB)		660.00000	660.00000	.00000	LB	Automatic
3	0004	Stearic Acid		330.00000	330.00000	.00000	LB	Automatic
4	8806	DNC Res #40 Aluminum Lak		7.50000	7.50000	.00000	LB	Automatic
5	8805	Amel 101		660.00000	660.00000	.00000	LB	Automatic
6	8803	Magnesium Stearate (LB)		440.00000	440.00000	.00000	LB	Automatic

Nonconformance Number	Description	Detailed Description	Nonconform Severity
Automatic	Power Irregularity	Electrical power irregularity caused shop floor	MEDIUM

- Access directly from batch
- Capture and document nonconformances / deviations
- Configurable criticality
 - Informational
 - Resolution required prior to completing batch or step
 - Configurable e-signatures
- Included in control batch record
 - Critical nonconformances must be reviewed and signed prior to close of the batch
 - Leverages Oracle Quality

 "Any deviation from the written procedures shall be recorded and justified." -- 21 CFR Part 211.100, Written procedures for deviations

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Eliminate Massive Amounts of Paper

Completely replace paper batch records with Electronic Batch Records

- Master Batch Record is comprised of all Recipe info
- Control Batch Record is the record of each batch
 - Documents all events & data generated during a batch's life cycle
 - Materials, resources, steps, deviations, QC samples, labels, process instructions, e-signatures, etc.
 - As events occur, they are appended to the CBR
- PDF format, securely stored in the E-Records Evidence Store

Electronic Batch Record

ORACLE MES for Process Manufacturing Control Batch Record

Date: 2006-11-13T19:04:40.756+0
Page: 4 of 12
Batch Number: 134980
Formula: 8401

Organization Code: PR1
Recipe: 8401

Step	Item	Lot	Dispensed Date	Dispensing Mode	Required Quantity	Dispensed Quantity	UOM	Event	User Name	Date
10	8810	L1	2006-11-09 06:49:14.0	Target Container	4.06	4.06	KGM	GMO ERES Material		

Step	Status	Operation (Version)	Step Quantity	UOM	Dates
Nonconformance Details					

Collection Plan: MES NONCONFORMANCE					
Collection Plan Type: Nonconformances					

(MES NONCONFORMANCE) - Result Row 1/1					

Specification Used: None					
Nonconformance Number: NC145 ()					
Nonconformance Source: INPROCESS ()					
Detailed Description: Tetst of nonconformance. Testing TEsting Testing ()					
Nonconform Severity: MEDIUM ()					
Nonconformance Type: PROCESS_ERROR ()					
Nonconformance Status: NEW ()					
Owner: Copeland, Mrs. Susan ()					
Email Address: scopelan@visionhr.com ()					
Send Email?: NO ()					
Entered By User: Simms, Mr. Phil ()					
Date Opened: 09-NOV-2006 08:26:01 ()					
Process Batch Number: 134980 ()					
Process Batch Step Num: 10 ()					
Process Operation: 1-PHARMACY-0 ()					

Nonconformances



The above reflects Oracle's current development plans which are subject to change at any time

Improve Accuracy

Capture data instead of typing it in

- Device Integration
 - Provide standard integration points
 - Weigh scales - Direct input during dispensing process
 - Process equipment - Capture readings, such as temp, pressure, speed
- Mobile Support
 - Ingredient Issue
 - Return Ingredient
 - Return Product
 - Create Product Lot
 - Update Product Lot
 - Backflush
 - Update Resource
 - LPN Transactions





Oracle MES for Process Mfg.

Benefits

- Board Room to Shop Floor Visibility
- Process Repeatability
- Enforce Best Practice SOPs
- Reduce Labor - Remove a Level of Approvals
- Eliminate Massive Amounts of Paper
- Advanced Search Capability
- Eliminate Errors
- Lower Training Costs
- Lower Cost of Compliance

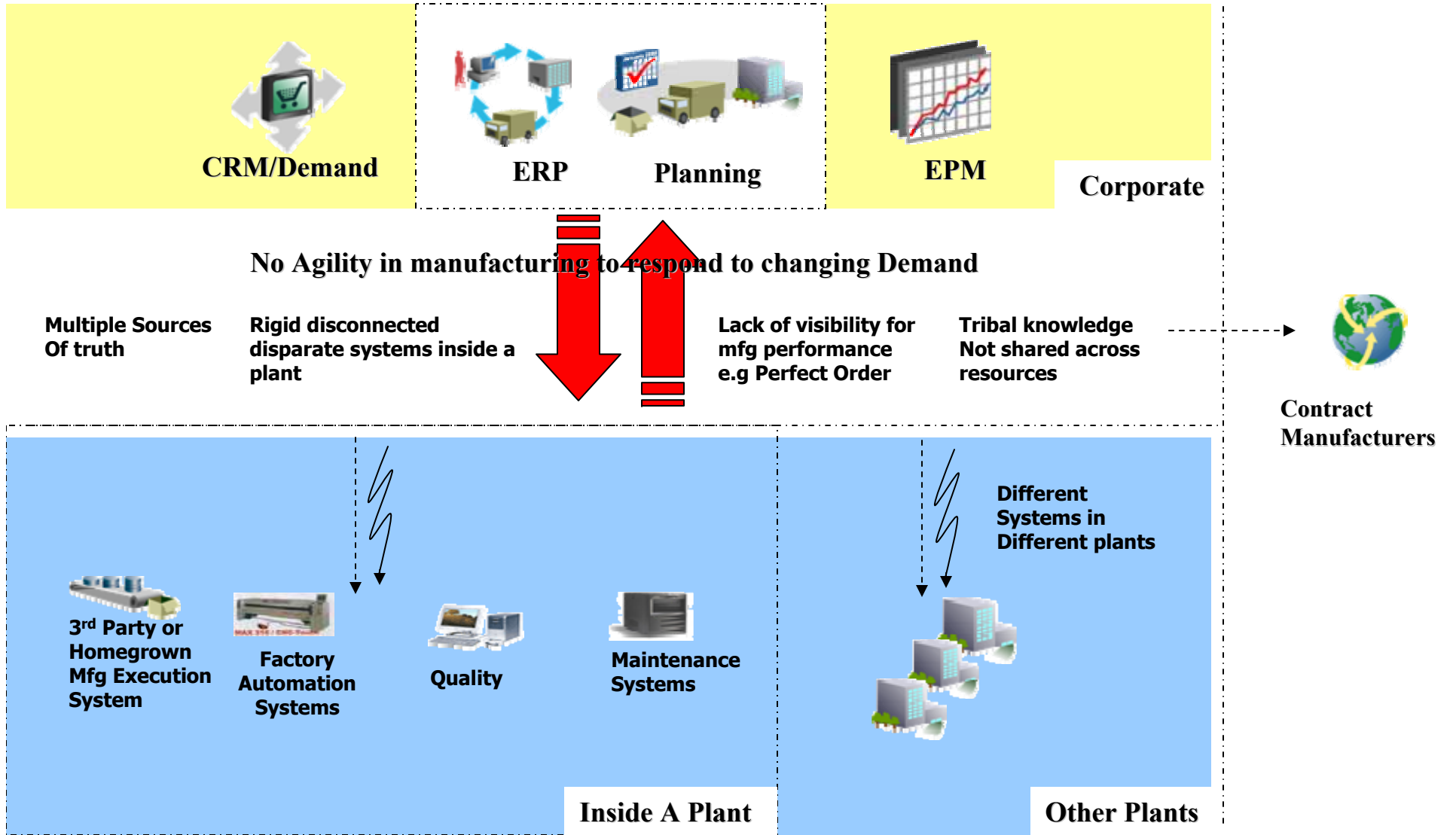
Introducing Manufacturing Data Hub



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Current State: Disconnected Systems

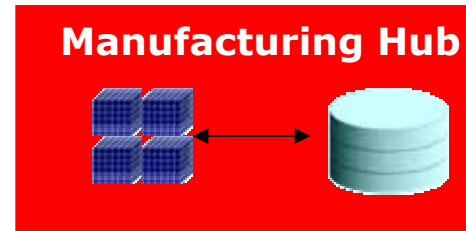


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Introducing Manufacturing Hub

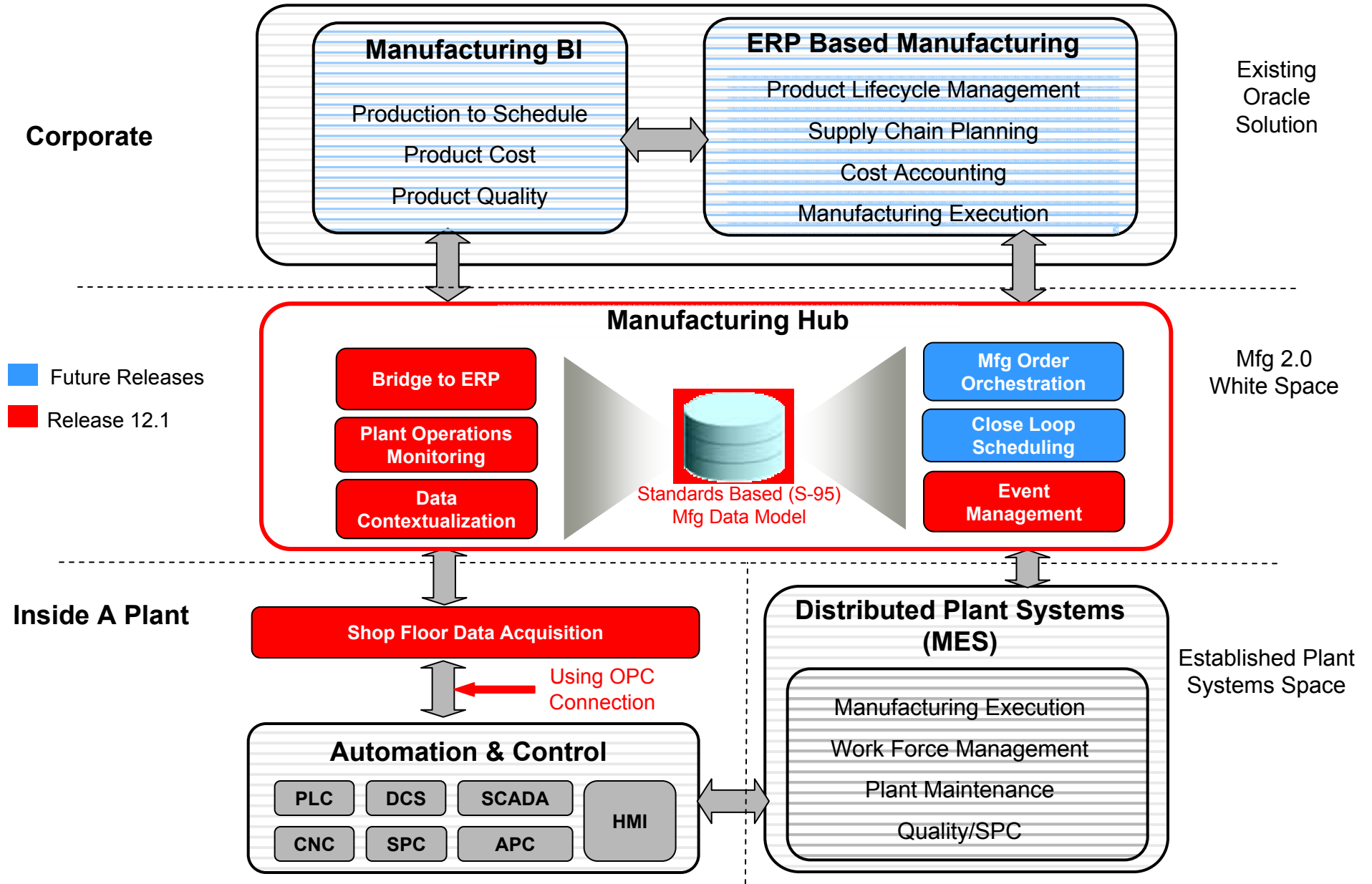
- Bridge between ERP and Plant floor systems
 - Connect to variety of plant floor systems
 - Orchestrate data flow between ERP and plant floor systems
- Monitor Production performance in real-time, irrespective of the source
 - Gather information in real-time
 - Provide alerts and notify key personnel
 - Contextualize the information for full drill down for investigation and root-cause analysis
- Foundation for running Lean, Six Sigma and Compliance Initiatives
 - Identify improvement / waste elimination
 - Monitor trends
 - Compare plants, production lines etc
- Enabler for Virtual Manufacturing
 - Orchestrate production data flow
 - Provide visibility into contract manufacturers' facilities



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Manufacturing Hub Overview





For More Information

<http://search.oracle.com>

Process Manufacturing



Process Manufacturing R12 Migration

- See Metalink Note 376683.1

Release Content Documents for E-Business Suite R12

- See Metalink Note 404152.1

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