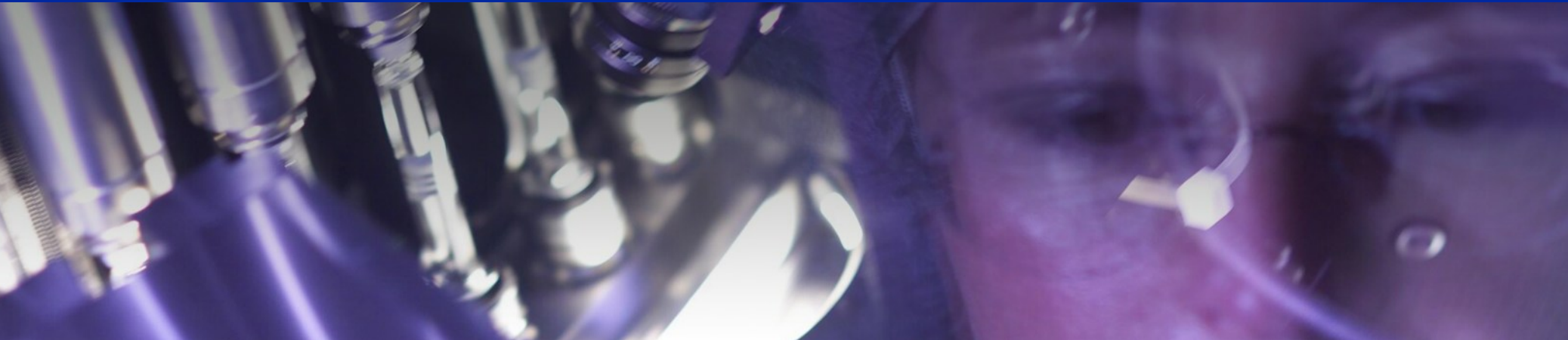

Enabling Superior Manufacturing Performance with SAP ERP and SAP xMII at Roche

Robert Fretz

Head of Process Automation & MES

Roche Pharmaceutical Division



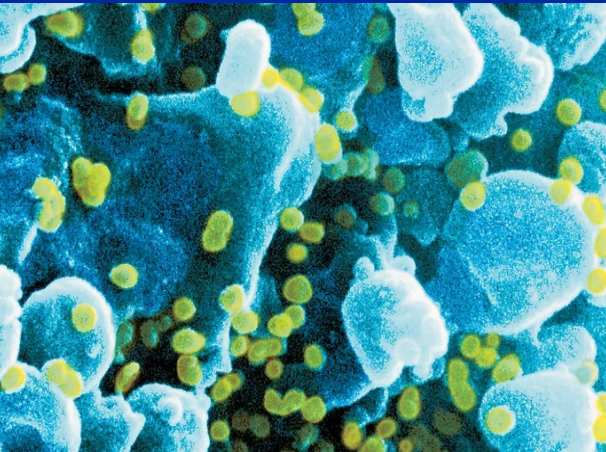
Company Background and Challenges

Business Considerations

Solution Implementation and Benefits

Lessons Learned and Next Steps

Roche - Basic facts at a glance



- Founded 1896 in Basel, Switzerland
- Employing around 74'000 people
- Currently active in 150 countries on all continents
- 2006 sales:
42.1 billion Swiss Francs
- Core businesses:
Pharmaceuticals and Diagnostics
- Number 1 in the global diagnostics market (in vitro), the leading supplier of medicines for cancer & transplantation and a market leader in virology

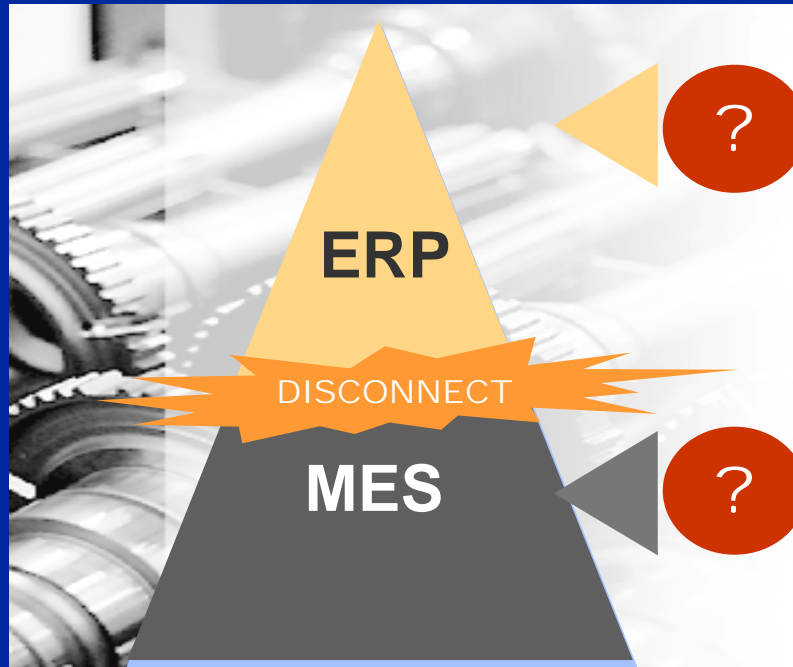
Manufacturing today has some key challenges...



- **Global Competitiveness** is placing tremendous pressure on **cost, quality and responsiveness**
 - Business and financial impact of **production exceptions cannot be monitored** or controlled at the enterprise level
 - Plants use **copies of master data** creating compliance and quality issues
 - Production personnel **lack the decision support** information to meet their targets

Connecting the Factory to the Enterprise and enabling Production Personnel are critical to cost-effectively deliver on customer expectations

Root Cause: Manufacturing and Enterprise business processes need to be synchronized



How are we hitting our targets?

- Total Cost of Production and Variance
- Labor and Resource Productivity
- Order Fill Rates and Cycle Times
- Fixed and Variable Asset Utilization

DISCONNECT

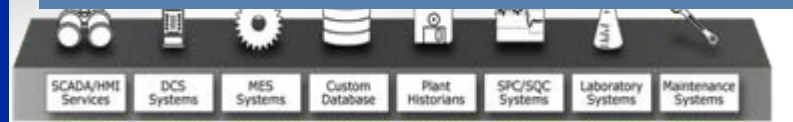
What's happening during every shift?

- Material availability and consumption
- Capacity availability and utilization
- Schedule changes
- Product Genealogy tracking and QM

“Less than 1% of respondents indicated that manufacturing data is automatically integrated with ERP with no manual intervention”

AMR Research Customer Survey

September 2005

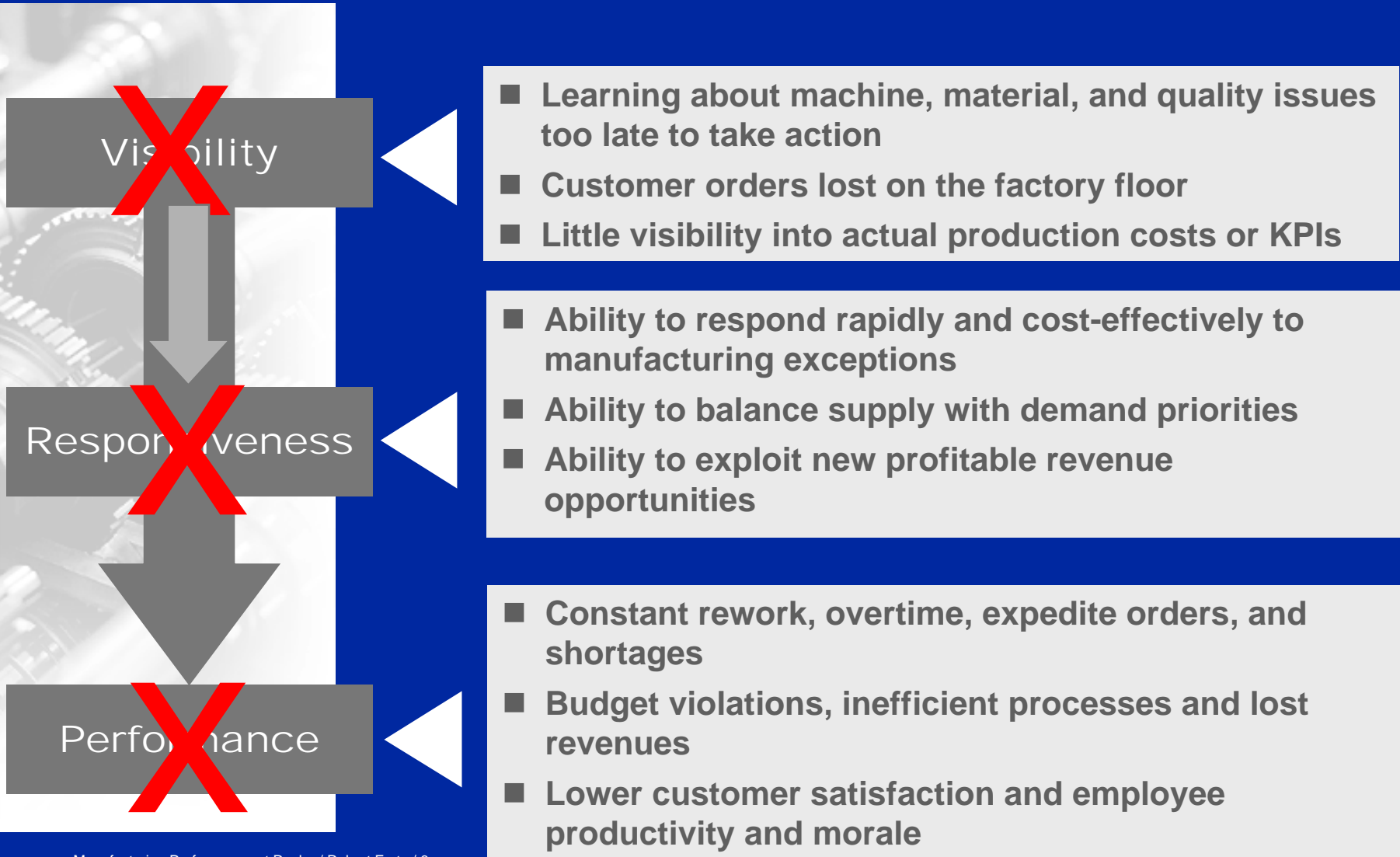


SFAC - Shop Floor Automation and Control Systems

MES – Manufacturing Execution Systems

DCS – Distributed Control Systems

Production Challenges and Their Business Implications



Company Background and Challenges

Business Considerations

Solution Implementation and Benefits

Lessons Learned and Next Steps

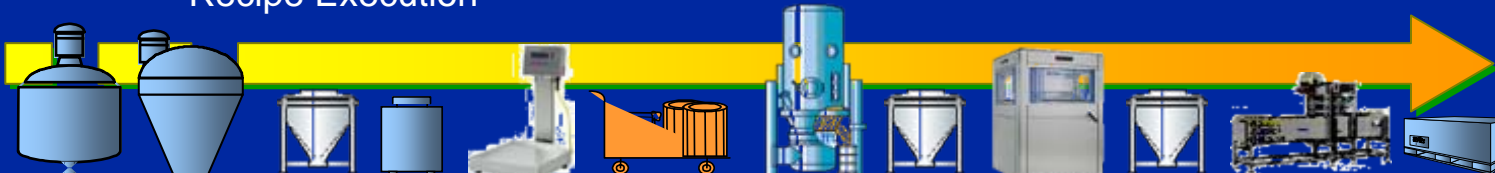
Business Goal 'Operational Excellence' - Top 5



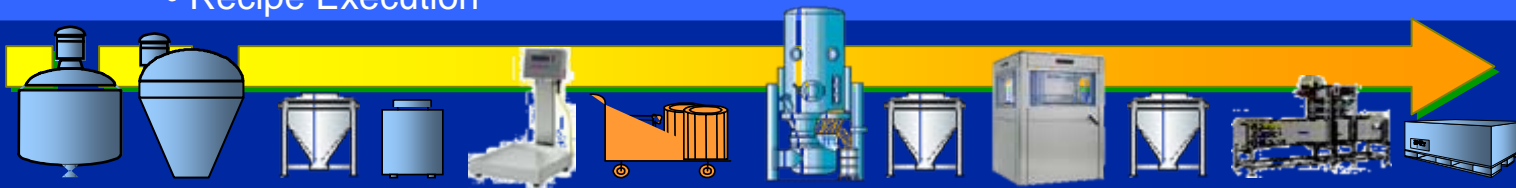
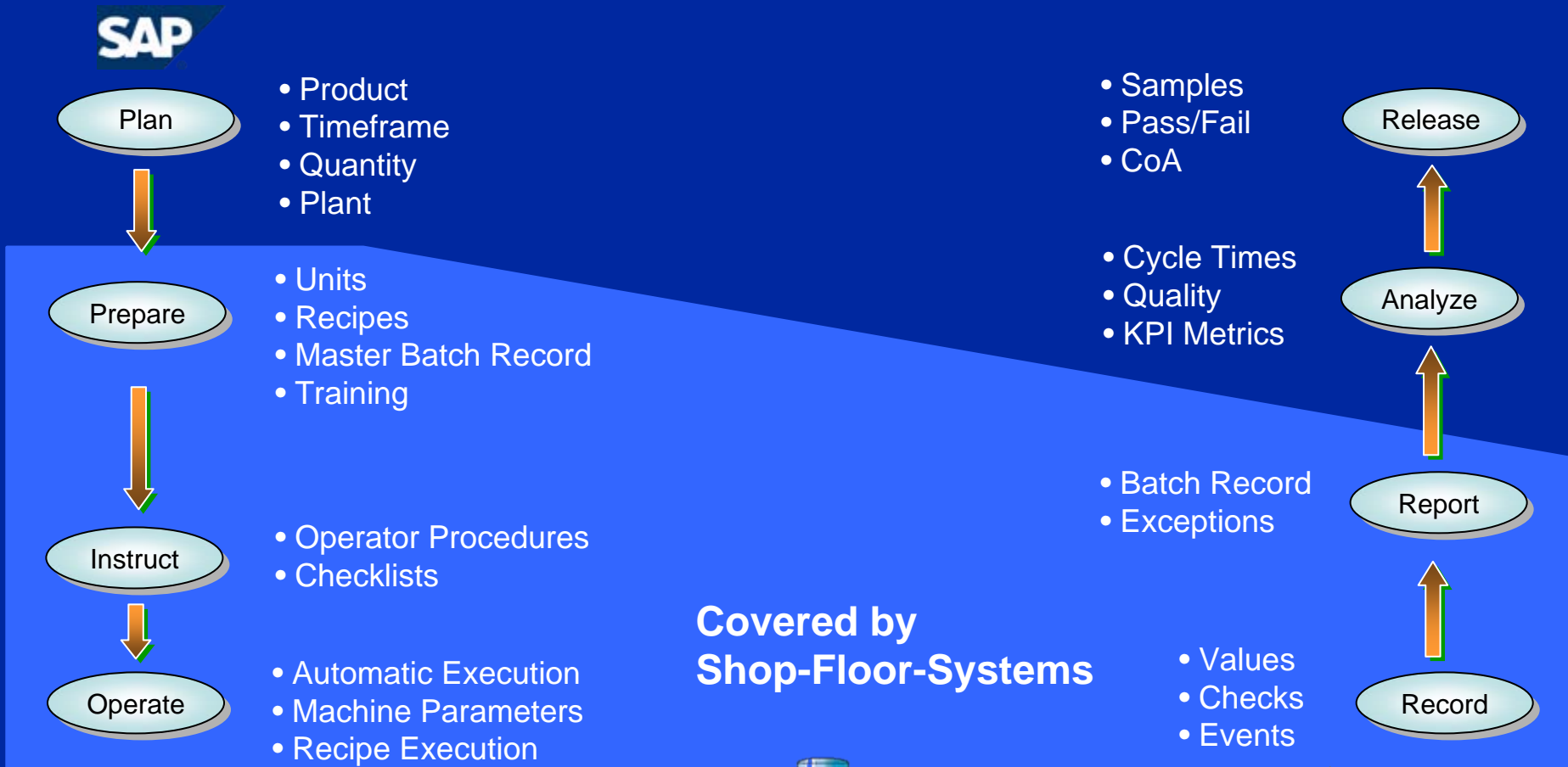
Excellence in Operations

<u>Goal 1</u>	<u>Goal 2</u>	<u>Goal 3</u>	<u>Goal 4</u>	<u>Goal 5</u>
Reduced manufacturing costs	Improved inventory situation	Better use of assets	Top quality and efficiency in all processes	Service level excellence
<u>Metric 1</u>	<u>Metric 2</u>	<u>Metric 3</u>	<u>Metric 4</u>	<u>Metric 5</u>
Revenue vs. manufacturing costs	Coverage days of inventory	Revenue vs. manufacturing fixed assets	Right first time	On time in full delivery

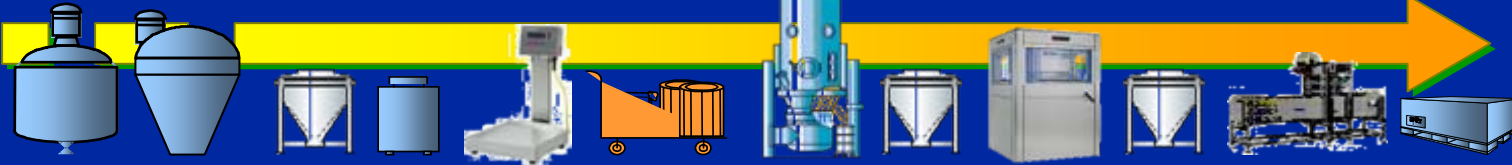
Manufacturing Challenge: How to 'automate' from Start to Finish ?



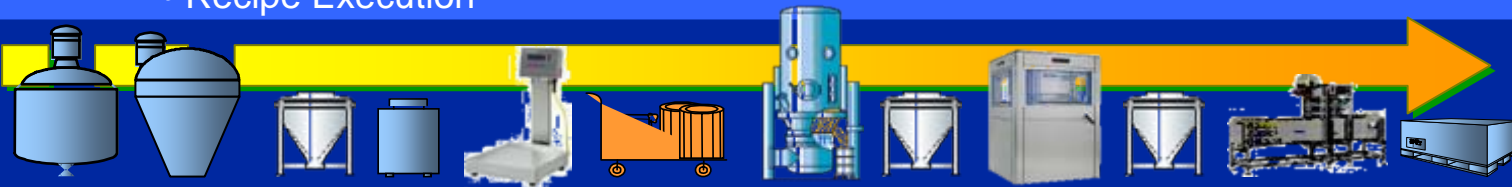
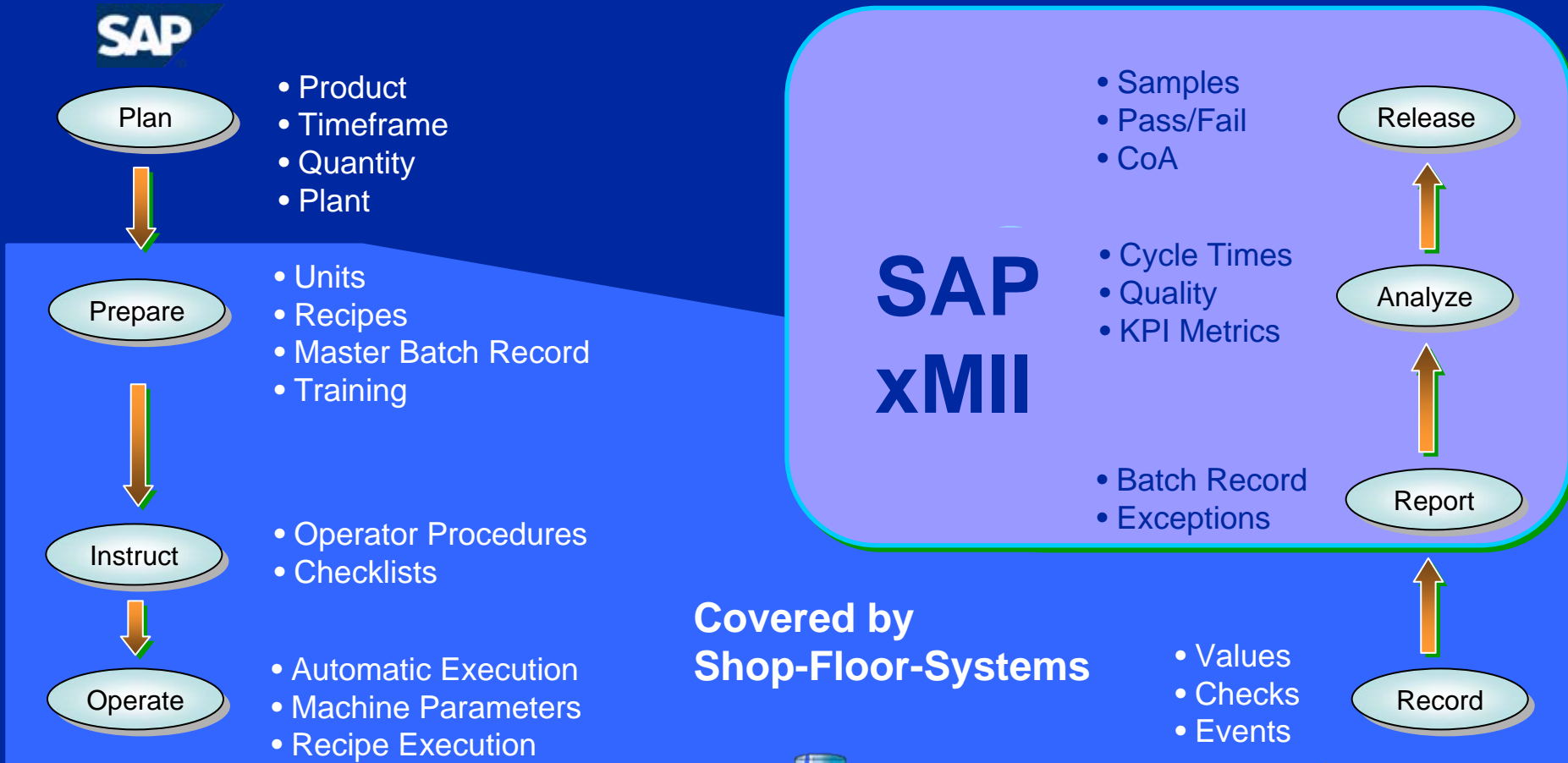
Manufacturing Challenge: How to 'automate' from Start to Finish ?



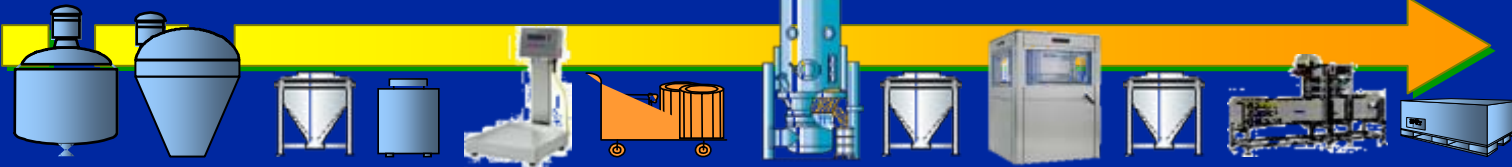
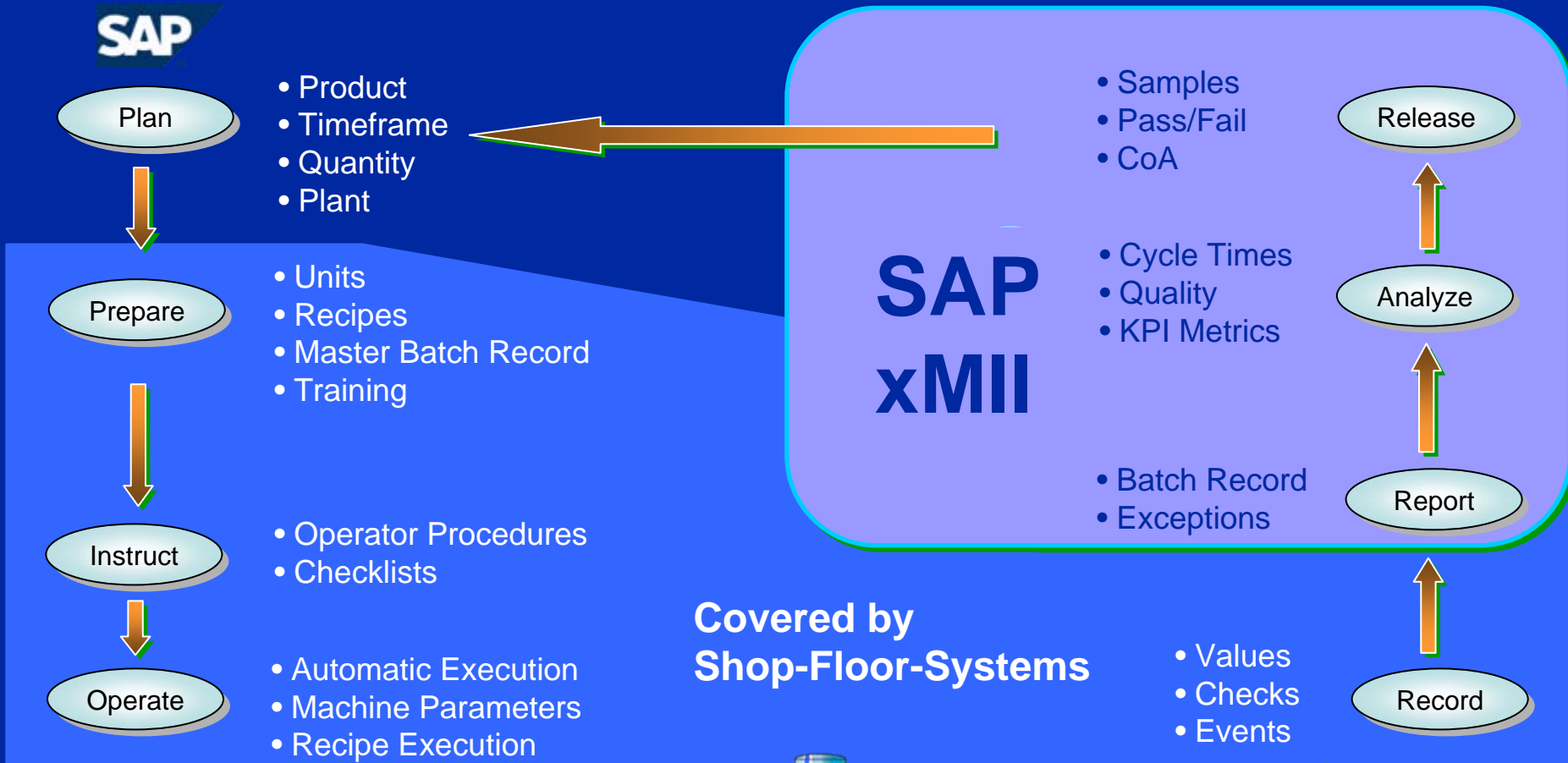
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Manufacturing Challenge: How to 'automate' from Start to Finish ?

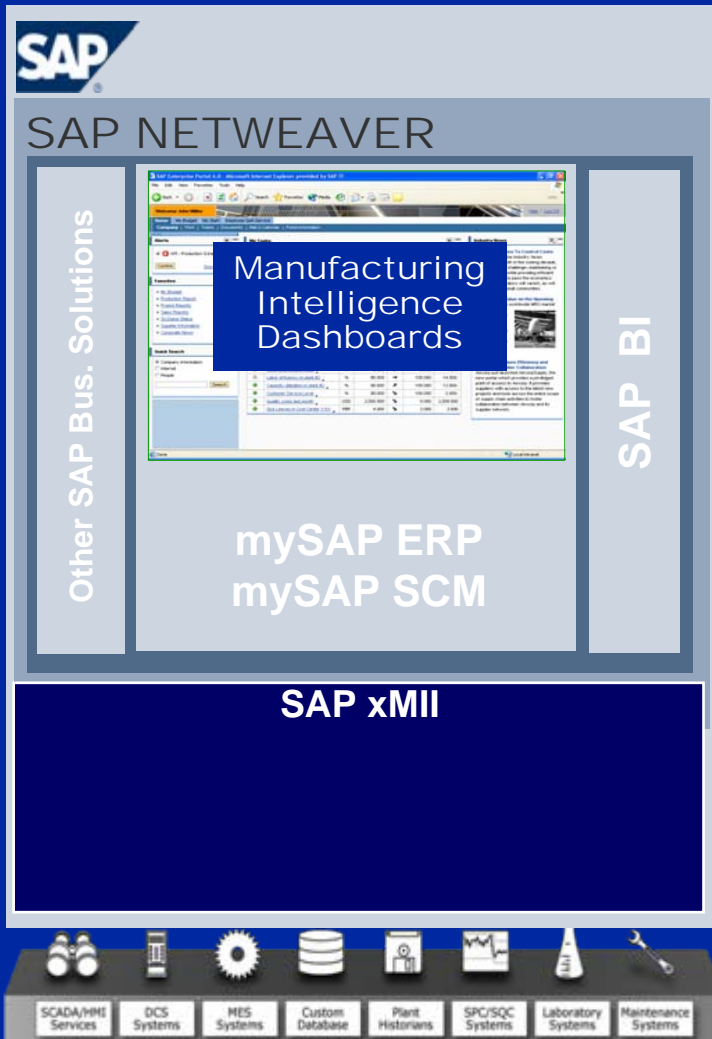


Manufacturing Challenge: How to 'automate' from Start to Finish ?



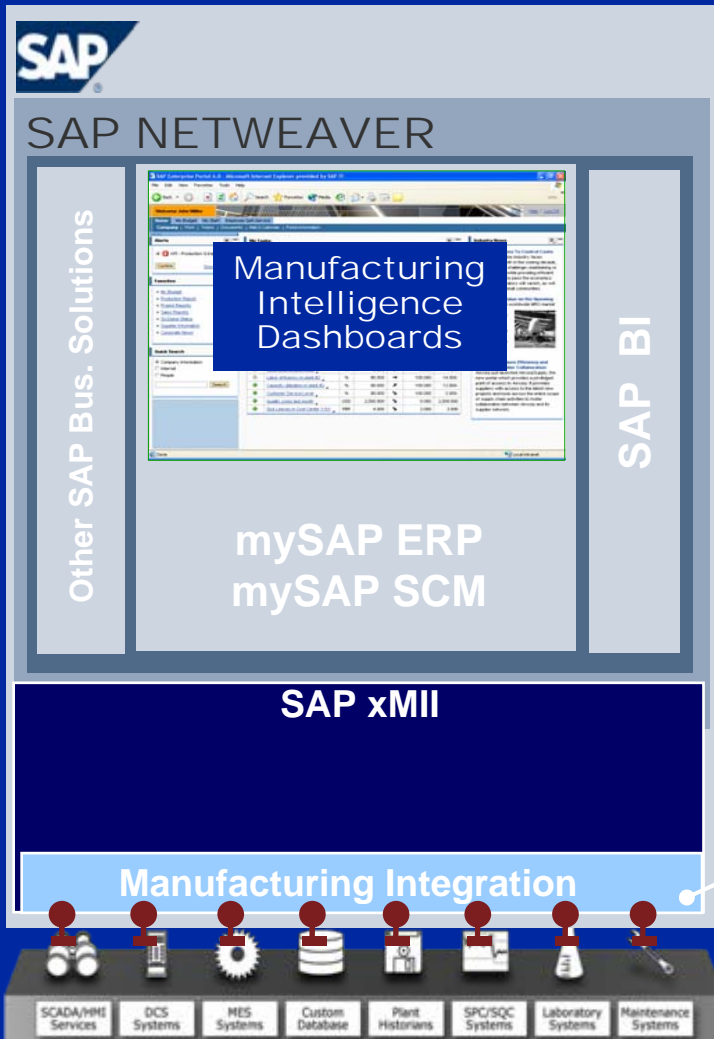
What is the SAP xApp Manufacturing Integration and Intelligence (xMII)?

The SAP xApp Manufacturing Integration and Intelligence (xMII) is a packaged composite application that delivers:



MES – Manufacturing Execution Systems, EMI – Enterprise Manufacturing Intelligence, BW – Business Warehouse (from SAP)
 SFAC – Shop Floor Automation & Control,

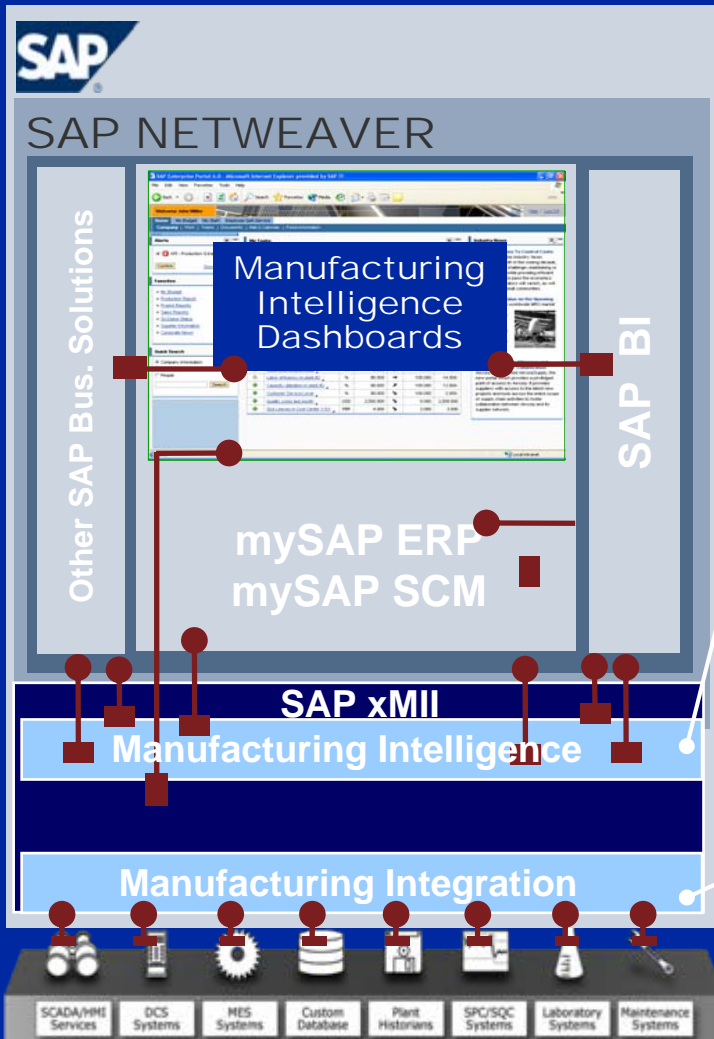
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Manufacturing Integration: A single ISA-95 compliant layer enabling SAP ERP connectivity into real-time plant floor apps. (MES, SFA, legacy apps.) to drive plant-to-enterprise business process interoperability

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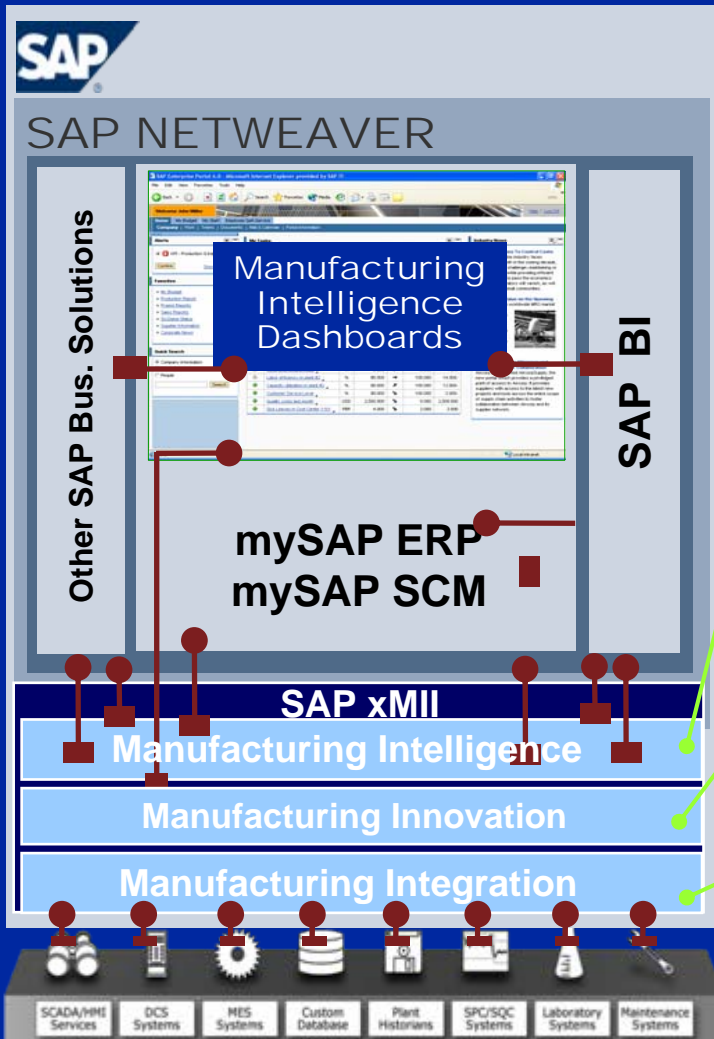


The SAP xApp Manufacturing Integration and Intelligence (xMII) is a packaged composite application that delivers:

Manufacturing Intelligence: Real-time analytics engine that aggregates and delivers unified visualization of events, alerts, KPIs and decision support to production personnel thru role-based dashboards

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What is the SAP xApp Manufacturing Integration and Intelligence (xMII)?



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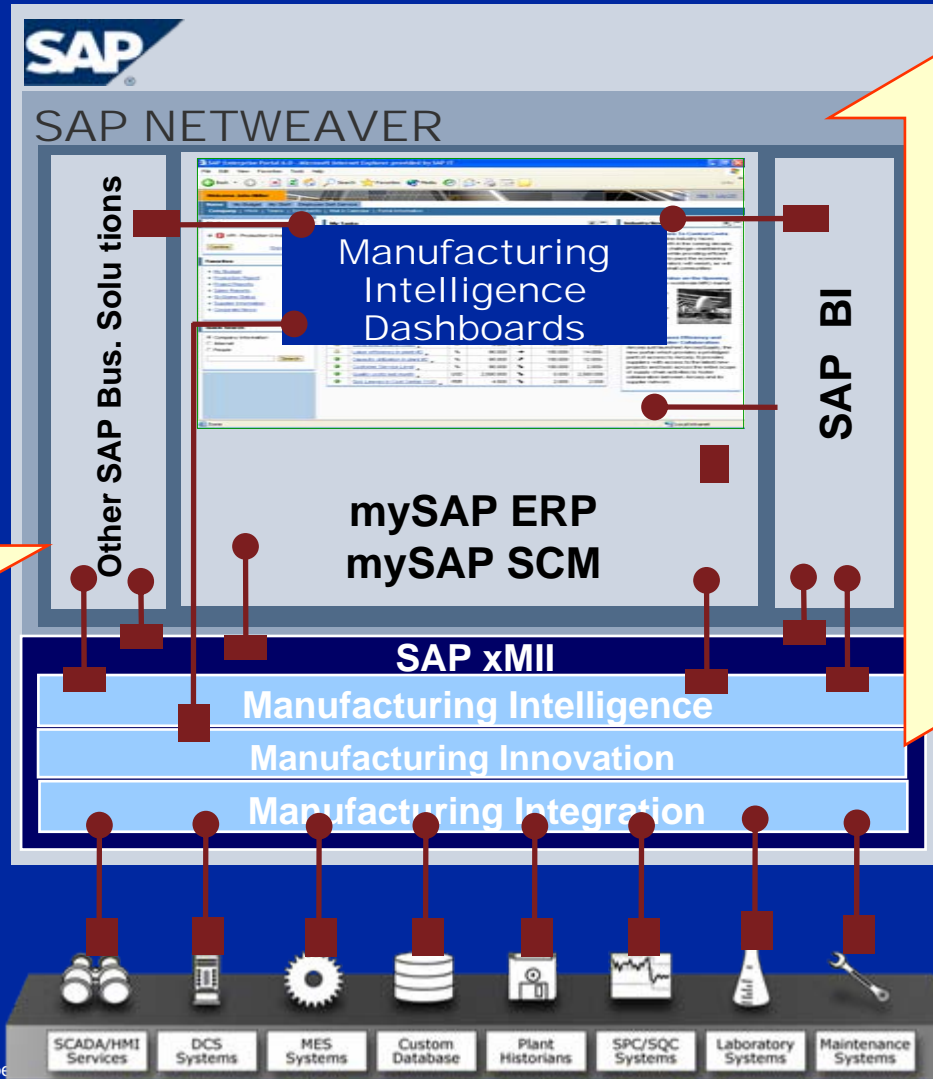
Manufacturing Intelligence: Real-time analytics engine that aggregates and delivers unified visualization of events, alerts, KPIs and decision support to production personnel thru role-based dashboards

Manufacturing Innovation: Web-services and content to rapidly design and deploy Composite Business Processes, Applications and Metrics

Manufacturing Integration: A single ISA-95 compliant layer enabling SAP ERP connectivity into real-time plant floor apps. (MES, SFA, legacy apps.) to drive plant-to-enterprise business process interoperability

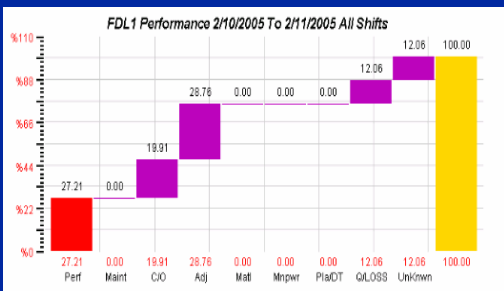
SAP xMII integrates manufacturing operations with the enterprise, and delivers actionable visibility...

- Plan work orders
- Check resources
- Create mfg plan
- Scheduling
- Release work order
- Close order
- Shipping and logistics

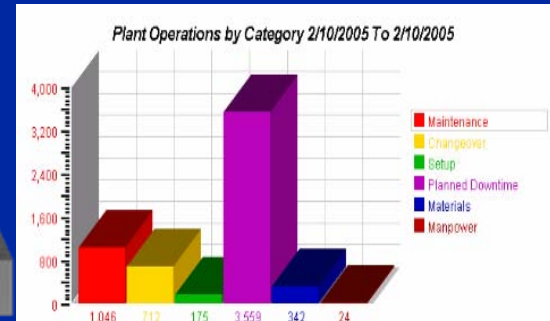


- Real-time events/alerts
- Order status
- Charge rates
- Life of inventory
- Yields
- Completions and usage
- Start and stop times
- Quality and lab data
- Process history
- Best practice deviations
- Efficiency
- Downtime tracking
- Rework scrap rates

Equipment Tracking and Performance



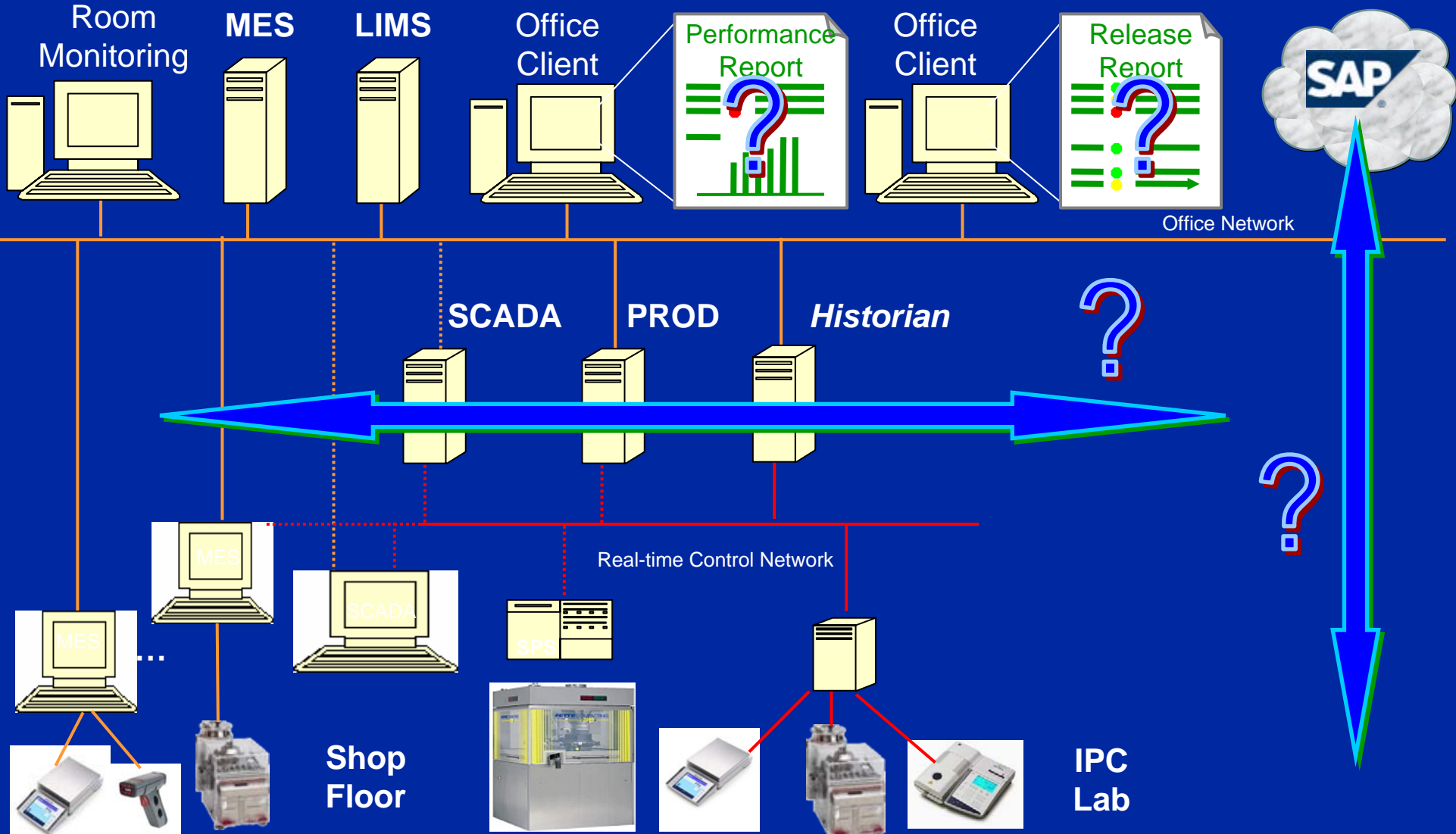
Downtime and OEE Reporting



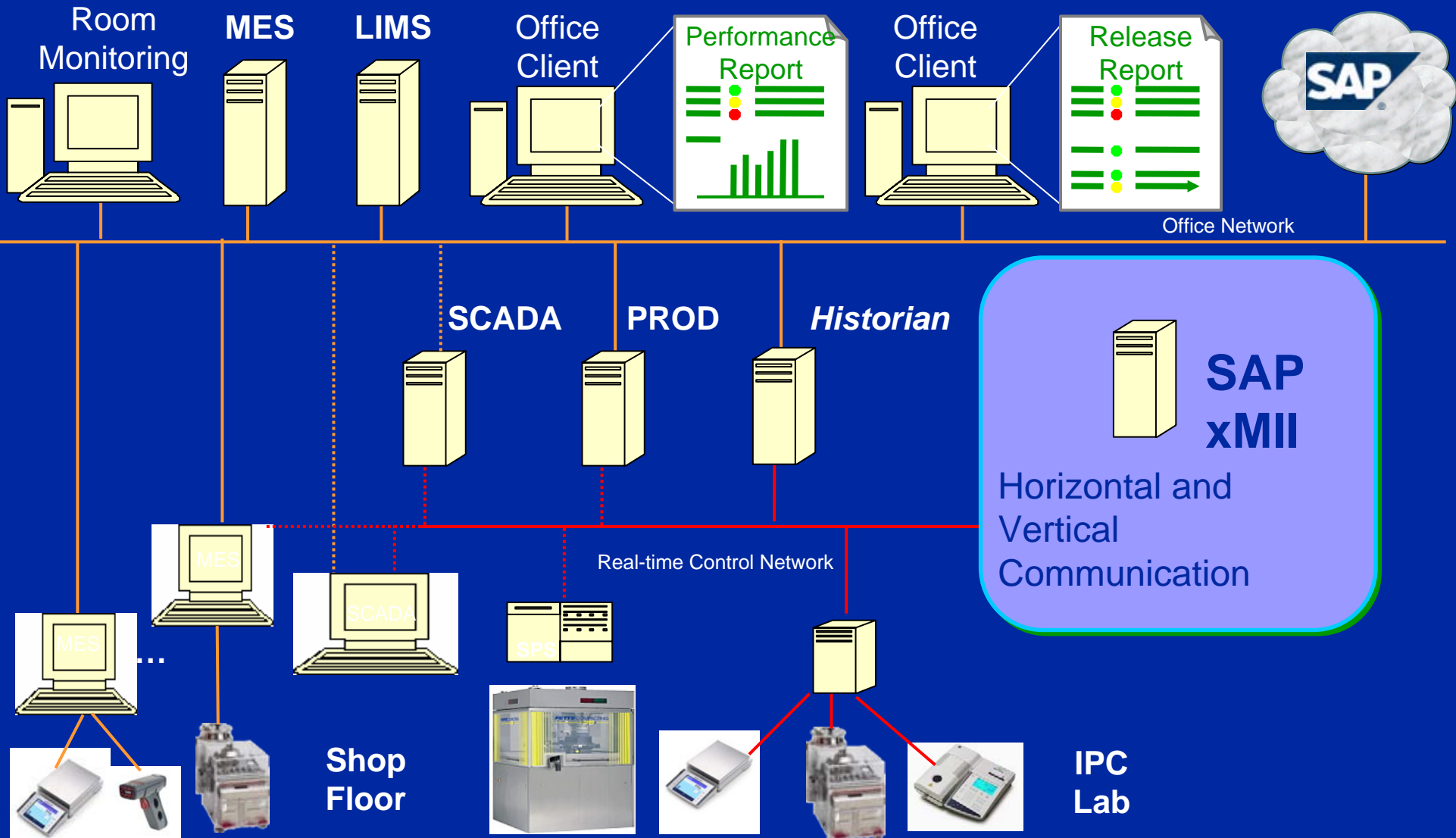
Challenge: Company-wide production communication



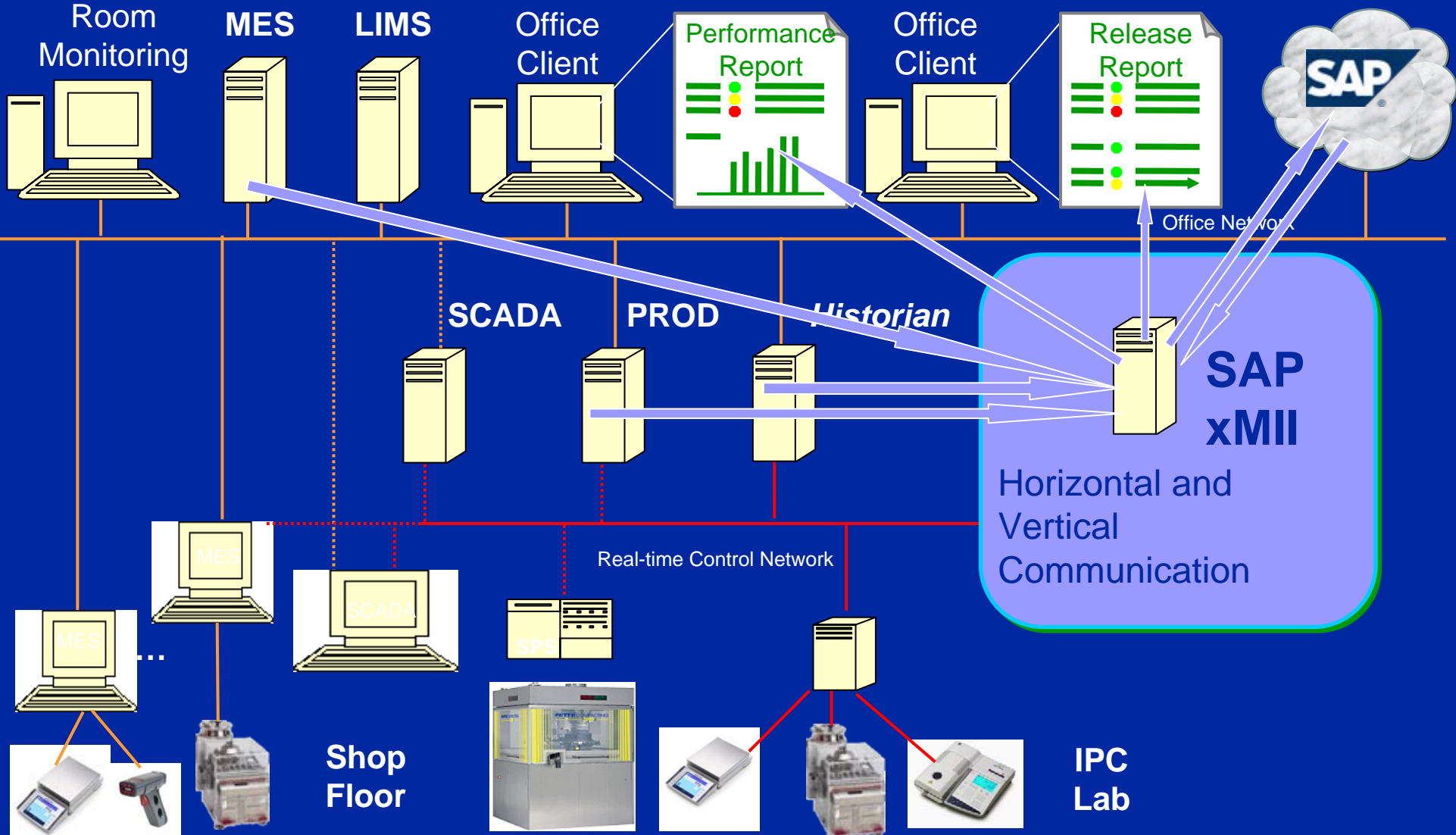
Pharmaceuticals



Challenge: Company-wide production communication



Challenge: Company-wide production communication



Real-Time Integration Platform Selection Process

– Product Categories and Alternatives



- **Enterprise Application Tools**
lack of connectivity to manufacturing systems
no 'portal', no 'dashboard', no visualization features
- **Integration only based on standards (e.g. OPC)**
no workflow, transaction capabilities
- Selected product:
SAP xMII (Manufacturing Integration Intelligence)
 - Workflow – Transaction Services
 - Manufacturing, Database and SAP Connectivity
 - Visualization Services

Real-Time Integration Platform Pilot Project Objectives



- 1. Implementation of **workflows and transactions in reaction to events**
- 2. Integration to **enhance communication between systems**
- 3. Real-time **process integration for time-optimized, structured visualization** of production data from various systems
- 4. Better **process understanding**

Real-Time Integration Platform Selection Process Proof of Concept (PoC)



- Generic use cases, typical for API (chem/biotech) and **galenical production**
- If the product can cover all requirements in PoC, it is suitable for all other manufacturing issues
- Less focus on visualization and dashboard in PoC, because no technical risk
- Focus on technical risk :
 - **Connectivity – (Visibility) – Reactivity**
 - **Product features:**
 - **Integration – Dashboard – Transaction**

Company Background and Challenges

Business Considerations

Solution Implementation and Benefits

Lessons Learned and Next Steps

Proof of Concept with generic Use Cases

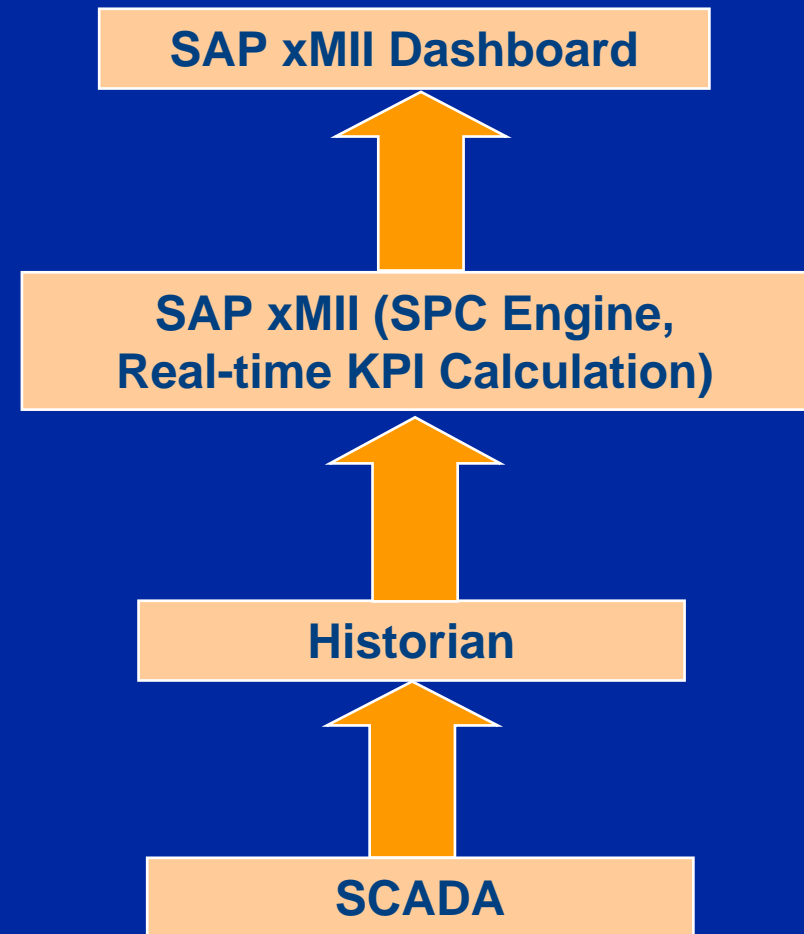
Use Case (1) - Continuous Batch Cycle Monitoring

Use Case:

Real-time acquisition of batch KPI directly at the end of batch and presentation of measured and calculated values (quality, duration of phases)

Goals:

- Better process understanding (SPC)
- Faster pro-active deviation management
- Demonstrates the integration of shop floor data
- Demonstrates reaction to events in the process



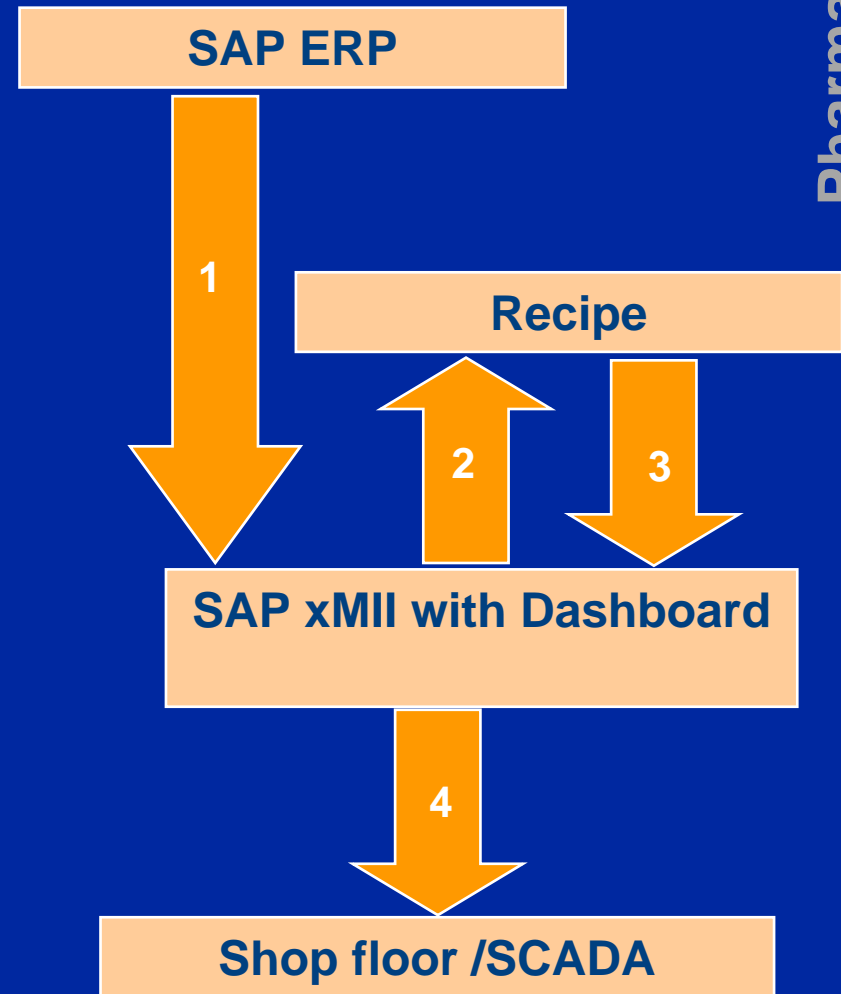
Use Case (2) – Download Order-Dependent Setpoints

Use Case:

Linking SAP order and product information with the corresponding recipe setpoints and sending them to the shop floor

Goals:

- Increase speed of bringing data together
- Avoid failures from manual data entry
- Demonstrates transfer of SAP ERP orders
- Demonstrates download to shop floor



Screenshot Use Case 2



http://rbamints1/servlet/Illuminator?Service=Personalization - Microsoft Internet Explorer

Address http://rbamints1/servlet/Illuminator?Service=Personalization

Pharma Technical Operations

Collaboration Manufacturing Suite Portal - fretz

- Administrator
- Workshop Examples
- Prototype Use Cases
 - Use Case 1
 - Use Case 2
 - Logfile
 - Use Case 3
- Trials
- My Illuminator

Download Setpoints

Orders*

Order:	1000096835	1000096836	1000096837	1000096838
Product:	10018789	10018789	10018789	10018789

Order depending Setpoint*

UnitName	ModuleName	PhaseName	Tag1	Value1	Tag2	Value2	Tag3	Value3	Tag4	Value4	Tag5
Dosing	Weighing	Off	pu1m1p1	0.00	pu1m1p2	0.00	---	0.00	---	0.00	---
Dosing	Weighing	Prepare Scale	pu1m1p1	1.00	pu1m1p2	0.00	---	0.00	---	0.00	---
Dosing	Weighing	Weigh RM	pu1m1p1	0.00	pu1m1p2	300.00	---	0.00	---	0.00	---
MixingGranulation	Granulation	Granulate	pu1m3p1	100.00	---	0.00	---	0.00	---	0.00	---
MixingGranulation	Granulation	Mix	pu1m3p1	0.00	---	0.00	---	0.00	---	0.00	---
MixingGranulation	Mixing	Add RM	pu1m2p1	300.00	pu1m2p2	0.00	pu1m2p3	0.00	pu1m2p4	0.00	---
MixingGranulation	Mixing	Granulate	pu1m2p1	100.00	pu1m2p2	0.00	pu1m2p3	0.00	pu1m2p4	0.00	---
MixingGranulation	Mixing	Mix	pu1m2p1	500.00	pu1m2p2	0.00	pu1m2p3	0.00	pu1m2p4	0.00	---
MixingGranulation	Mixing	Off	pu1m2p1	0.00	pu1m2p2	0.00	pu1m2p3	0.00	pu1m2p4	0.00	---
MixingGranulation	Mixing	Prepare M/G	pu1m2p1	0.00	pu1m2p2	0.00	pu1m2p3	0.00	pu1m2p4	0.00	---

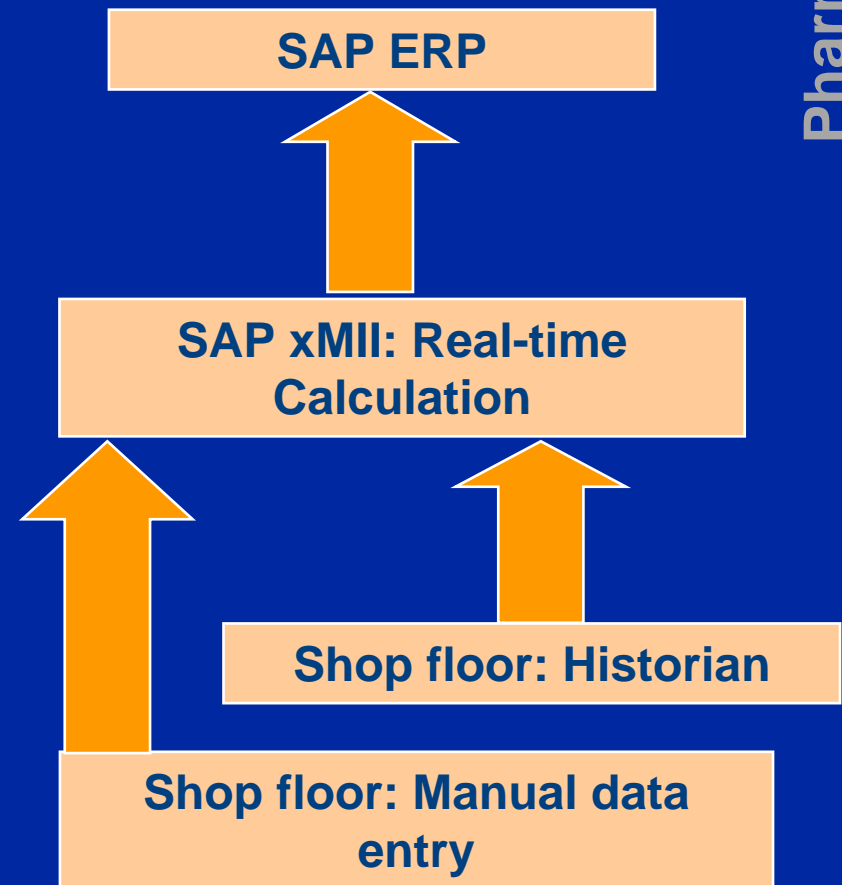
Use Cases (3) – Material Consumption / Goods Movement

Use Case:

Automatic update of all material consumptions in SAP directly after finishing batch

Goals:

- Acquisition / calculation of material consumption of a batch over all process units / batch phases
- Reducing manual effort
- Demonstrates automatic feedback to SAP ERP



Screenshot Use Case 3



Microsoft Internet Explorer window showing the Pharma Technical Operations portal.

Address: <http://rbamints1/servlet/Illuminator?Service=Personalization>

Pharma Technical Operations

Admin Menu CMS Menu Operate Report Analyse Release

Collaboration Manufacturing Suite Portal - fretzr

Material Consumption

Logfile

Timestamp	Material	Plant	SLOC	Quantity	Unit	ProcessOrder	PostingDate	ReservationNr	Res
02/24/2005 14:20:37	110003	1110	BLS	13.434247970581	KG	1000085504	24.01.2005 15:16:20	0006062582	0010
02/24/2005 14:22:52	110002	1110	BLS	27.96515083313	KG	1000085504	24.01.2005 15:21:47	0006062582	0010
08/08/2005 15:53:58	110003	1110	BLS	12.438950538635	KG	1000085531	08.08.2005 15:53:54	0006063565	0013
08/08/2005 16:21:12	110003	1110	BLS	12.450589179993	KG	1000085531	08.08.2005 15:51:23	0006063565	0013
08/08/2005 17:52:32	110000	1110	BLS	12.450589179993	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
08/08/2005 18:08:39	110000	1110	285D	12.450589179993	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
01/01/1970 00:59:59	110000	1110	285D	12.450589179993	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
08/08/2005 18:17:46	110000	1110	285D	12.450589179993	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
08/08/2005 18:32:11	110000	1110	285D	12.450589179993	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
08/08/2005 18:32:57	110000	1110	285D	12.450589179993	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
08/08/2005 18:34:15	110000	1110	BLS	12.450589179993	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
08/08/2005 18:36:04	110000	1110	BLS	12.450589179993	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
08/09/2005 10:47:11	110000	1110	BLS	12.450981140137	KG		08.08.2005 15:51:23		
08/09/2005 10:51:03	110000	1110	BLS	12.450981140137	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
08/09/2005 11:14:15	110000	1110	BLS	12.450981140137	KG	1000096832	08.08.2005 15:51:23	0006437105	0003
08/09/2005 12:45:15	110000	1110	BLS	13.434066772461	KG	1000096833	09.08.2005 12:43:44	0006437106	0003
08/09/2005 16:17:25	110000	1110	BLS	12.936509132385	KG	1000096834	09.08.2005 16:15:31	0006437107	0003

Proof of Concept with generic Use Cases Results Achieved



- All 3 Use Cases have been accomplished successfully
 - SAP xMII has the required functionality
 - SAP xMII can be easily controlled by the user
 - Trebing & Himstedt implemented the solution within time and budget
- SAP xMII offers a powerful, but easy to handle tool for Performance Monitoring and Plant-to-Business Integration.

Results Achieved



- Better process understanding enabling **significant process improvements**
- **Real-time information flow** through usage of a flexible IT-System
- **Protection of investment for existing system environment** – just connecting, not replacing
- Shift to **workflow-oriented organisation** and ‘**Review and Decision by Exception**’
- **Prevention of false entries** by avoiding multiple entries/transfers in validated/quality-critical processes

The Roche Pharmaceuticals Division already realized significant process improvements by Performance Monitoring and Plant-to-Business Integration with SAP xMII.

Further considerable gains and benefits are anticipated when the full potential of the solution is exploited.

Company Background and Challenges

Business Considerations

Solution Implementation and Benefits

Lessons Learned and Next Steps

Lessons Learned...



- **SAP xMII** is easy to install
is powerful
easy to handle
- **Connections to your own systems are easy to establish - once you get across the security barriers**
Know your own systems, get support from the network security organisation
- **Transactions offer a wealth of functionality – many ways to achieve a result**
Start with a proper design – as every software project

Future Direction and Further Implementations of SAP xMII

Use in 3 galenical sites



- **Roche uses SAP xMII in 3 sites** with galenical production
- **Further Deployment** already in productive use beyond the 'Use case':
 - **Display and interactive handling of hygiene status** of assets and rooms
 - Flexible, recipe and database controlled interactive checklists for **manually operated and automatic cleaning operations**
 - Flexible, recipe and database controlled interactive lists for **checking of batch reports regarding completeness and status for batch release**

Further Implementations

Interactive handling of hygiene status

<http://rm4msebr01/Lighthammer/Illuminator?service=Personalization&ticket=ST-5-k17J3a92QU95eMcYb> - Microsoft Internet Explorer p

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media

Address <http://rm4msebr01/Lighthammer/Illuminator?service=Personalization&ticket=ST-5-k17J3a92QU95eMcYb&sniffer=Microsoft%20Internet%20Explorer,6,617,1024,en> Go Links

Roche

Main menu CMS Menu

Lighthammer CMS Portal - Brian Gray Change Password Refresh Help Docs

- Administrator
- ReleaseDoc
- Equipment Status
 - Equipment outside cell
 - Cell status
 - Unit Status
 - Equipment Inside Cell
- Produzione
- Segnalazioni
- Log book
- Documentazione
- TestPerProva
- My Illuminator
- Main Menu
- Check Lists
 - CELLA
 - SPA
 - LOADER
 - PMA
 - SETACCIATRICE
 - TSG
 - ARREDI
 - 30FR15
 - 30RR15

```

    graph TD
        riutilizzabile((riutilizzabile)) -- Firma --> InManutenzione((In Manutenzione))
        InManutenzione -- Firma --> inprocesso((in processo))
        inprocesso -- Firma --> pulito((pulito))
        pulito -- Firma --> riutilizzabile
        pulito -- Firma --> NonUtilizzabile((Non utilizzabile))
        NonUtilizzabile -- Firma --> Sporco((Sporco))
        Sporco -- Firma --> InPulizia((In Pulizia))
        InPulizia -- Firma --> Sporco
        InPulizia -- Firma --> DaDichiararePulito((Da dichiarare pulito))
        DaDichiararePulito -- Firma --> pulito
        Sporco -.-> riutilizzabile
        Sporco -.-> NonUtilizzabile
        NonUtilizzabile -.-> Sporco
        InManutenzione -.-> riutilizzabile
        inprocesso -.-> riutilizzabile
        inprocesso -.-> InPulizia
        DaDichiararePulito -.-> riutilizzabile
    
```

Transizione Automatica (dashed arrow)
 Transizione con Firma (solid arrow)

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Done Local intranet

Start L:\EBR\Validacion\Plan http://rm4msebr01/... Inbox - Microsoft Outlook 14:35

Further Implementations

Interactive checklist for cleaning operations



Microsoft Internet Explorer

Delle seguenti operazioni ne viene firmata l'esecuzione:
 x - Collegare spinotto GS0106 (in caso di pulizia dopo gran in PMA)

OK Cancel

User Authentication

Command Audit Role 1 is required to authenticate.

Username: fretzr
 Password: *****

OK Cancel

Lighthammer CMS Portal - Brian Gray

Autore: ... Data Inizio: ... Data Fine: ...

Intestazione verificata da Brian Gray on 15/12/2005 16:39

Change Password | Refresh | Help Docs

Conferma Intestazione
 Chiusura Check List

PREPARAZIONE ATTIVITA' DI LAVAGGIO

Operazione	Operatore	Verificatore
PMA :Togliere i filtri da PMA	Brian Gray (07/12/2005 17:34)	N/A
PMA :Inserire il tubo flessibile	Brian Gray (08/12/2005 18:03)	Gen. Supervisor (16/12/2005 14:16)
PMA :Collegamento tubo di s...	Brian Gray (08/12/2005 18:12)	N/A
SP :Controllo posizione mani...	Brian Gray (08/12/2005 17:38)	Gen. Supervisor (16/12/2005 14:16)
TSG girare le protezioni su antideflagranti lavaggio	Brian Gray (07/12/2005 17:34)	---
- TSG spostare braccio spruzzatura dentro (in caso di pulizia dopo spray_gran) togliere	Brian Gray (13/12/2005 18:09)	---
- Collegare spinotto GS0106 (in caso di pulizia dopo gran in PMA)	x	N/A

Firma Operatore: Eseguito N/A Firma Verificatore: Verificato N/A

- PREPARAZIONE SOLUZIONE GRANULANTE (7 / 8) (2 / 6)
- SISTEMI DI CARICAMENTO (4 / 4) (1 / 4)
- IMPASTATRICE PMA (9 / 10) (2 / 10)
- SETACCIATRICE AD UMIDO CO MILL (4 / 4) (0 / 4)
- LETTO FLUIDO TSG (0 / 0) (0 / 0)
- PAVIMENTI E ARREDI (0 / 0) (0 / 0)

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Further Implementations

Interactive list for checking of batch reports

http://rm4msebr01/Lighthammer/Illuminator?service=Personalization&ticket=ST-5-k17J3a92QU95eMcYb - Microsoft Internet Explorer p

File Edit View Favorites Tools Help

Address http://rm4msebr01/Lighthammer/Illuminator?service=Personalization&ticket=ST-5-k17J3a92QU95eMcYb&sniffer=Microsoft%20Internet%20Explorer,6,617,1024,en

Main menu **CMS Menu**

Lighthammer CMS Portal - Brian Gray [Change Password](#) [Refresh](#) [Help Docs](#)

Show available Documents for Batch: Note: Only batches with documents are shown

Product	[Product name]	Product Code	[Product Code]	Lot	[Lot]
Product	[Product name]	Product Code	[Product Code]	Lot	[Lot]

Nome Documento	Pag.	Tipo	Stato	Ultimo commento
Dispensing Cleaning Protocol	0		approved with errors	ghhhjhjhkjk
Granulation Cleaning Protocol	0		reviewed internal	documento disponibile
Solid Production Yield	0		not available	
Tabletting Production Protocol	0		not available	
Zanchetta Report	0		not available	

Information for the selected document:

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Summary



- **Once we had installed SAP xMII we immediately found – and are still finding - many additional uses**
- **SAP xMII will allow Roche to grow new applications incrementally, step-by-step**
- **SAP xMII will be an evolutionary system - very much in line with our drive for continuous improvement - and will support Roche to achieve ‘Operational Excellence’**

Enabling Superior Manufacturing Performance with SAP ERP and SAP xMII at Roche

Robert Fretz

*Head of Process Automation & MES
Roche Pharmaceutical Division*





We Innovate Healthcare



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Αγ. Αθανασίου 17 Τ.Θ. 76
19002 Παιανία
marketing@theodorou.gr

Τηλ: 210 6690900
Fax: 210 6640200
www.theodorou.gr