Operational Excellence with Compliant Manufacturing Operations for Pharmaceuticals

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Trends and Key Metrics enabling Operations Performance Management

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Achieving Superior Performance with Compliant Manufacturing in Life Sciences

Summary
Evolving Global Manufacturing Environment – the Challenges

Time to Sense Changes in Customer Demand

- 1-2 weeks: 6%
- 2 weeks: 11%
- 3-4 weeks: 38%
- 4-5 weeks: 32%

Supply Network Operations – Average 22 Sites

- 1 manufacturing site: 2%
- 2-5 manufacturing sites: 17%
- 6-10 manufacturing sites: 17%
- 11-20 manufacturing sites: 19%
- 21-40 manufacturing sites: 19%
- 40+ manufacturing sites: 30%

Insight: complexity is increasing; need a new operating model

% of Responses. N=100
Evolving Global Manufacturing Environment – the Drivers

- More Product Variants
- Shorter New Product Development & Launch
- Regulatory Compliance
- Cost Reduction
- Better Short Term Demand Visibility
- More Dynamic Supply Networks

**Demand Driven Manufacturing:**
The synchronized execution of compliant manufacturing and logistics processes across a dynamically reconfigurable supply network, to profitably meet demand.

*Insight:* today’s business environment requires move to DDM model
## Demand-Driven Manufacturing

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**Insight:** think outside-in, execute inside-out

*Source: “Demand-Driven Manufacturing”, AMR Research, 2007*
Life Sciences Product Supply Strategies

Insight: focus is shifting from cost & compliance to velocity, agility, profitability

Current Focus

- Improve collaboration in your enterprise with internal partners across R&D/Man/Supply Chain/Sales & Mkt
- Manufacturing outsourcing as an opportunity to boost productivity and efficiency
- Improve efficiencies and lower costs across the enterprise
- Increased insight into downstream demand using near real-time data from distributors and other intermediaries
- Improve manufacturing performance visibility across manufacturing sites
- Replicating best practices across the enterprise using operational excellence programs
- Standardize manufacturing processes and systems
- Redesign of your supply chain networks
- Improve collaboration with your external partners such as Contract Manufacturers, 3rd Party Logistics
- Product authentication, track and trace, integrity of supply chain
- Improve compliance across financial, manufacturing and quality processes
- Detailed production scheduling, and adherence
- Identify and eliminate waste in manufacturing using lean manufacturing practices

Future Focus

- Improve collaboration in your enterprise with internal partners across R&D/Man/Supply Chain/Sales & Mkt
- Manufacturing outsourcing as an opportunity to boost productivity and efficiency
- Improve efficiencies and lower costs across the enterprise
- Increased insight into downstream demand using near real-time data from distributors and other intermediaries
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- Identify and eliminate waste in manufacturing using lean manufacturing practices
Leverage contract manufacturers for new product launch and agile response to demand

Ability to forecast demand

Achieving compliant, predictable product supply by manufacturing right-first-time

Managing the cost of compliance while achieving the desired levels of compliance

Ability to respond to changes in demand

A balanced S&OP processes which profitably matches demand and constrained supply

Aligning manufacturing, supply chain, sales & marketing, regulatory interaction for successful new product launches

Leveraging global opportunities in sourcing

Planning and implementing master data management processes across the organization

Reliable drug track and trace, authentication, reduce counterfeiting and fraud monitoring

Manage contract manufacturing relationships, compliance and product quality

Accessing existing unstructured information in manufacturing

Importance

Performance

Gap

-21%

-20%

-16%

-15%

-15%

-14%

-14%

-14%

-13%

-12%

-10%

-10%
Life Sciences Product Supply Strategies

Leverage contract manufacturers for new product launch and agile response to demand

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**Insight:** Gaps are in leveraging 3rd party capabilities, demand forecasting, right first time manufacturing
An Hierarchy of Manufacturing Metrics

**What it is**

- Production Contract Complexity
- Mfg Cycle Times
- Operational Excellence

**What it tells you**

- Demand Volatility
  - Right First Time
  - Mfg Cost
  - Supply Network Investment
  - Performance Constraints

- Cycle Times
  - Req. RM To Prod
  - RM Inspect
  - Stage Times
  - FG Inspect
  - Sched To Dispatch
  - Asset Performance (OEE+)
  - Schedule Adherence
  - First Pass Yield
  - Complexity (COs vs Mix)
  - Schedule Changes

- Right First Time Detail
  - Supplier On-Time
  - Supplier Quality
  - RM, WIP + FG Inventory
  - Schedule Cycle Variances
  - Mfg Cost Detail

**Insight:** becoming Demand Driven requires Right First Time manufacturing capabilities
AMR Research examined 100 manufacturing firms to prioritize, segment, and assess the importance/impact of manufacturing metrics.

The research sample was split between process and discrete manufacturers to enable side-by-side comparisons.

The sample distribution also enabled comparisons by company size (under 10,000 employees vs. over 10,000 employees), and by job function/role (IT vs. Executive Management vs. Manufacturing Management).

- Process industries included: Pharma, CPG, Chem, Pulp and Paper, Oil and Gas, and Primary Metals
- Discrete industries included: Auto, High Tech, A&D, and Fabricated Metals
- Respondent titles included Corporate executives (36%), IT (23%), Ops/Production (27%)
- The average responding firm had over 22 manufacturing facilities
Manufacturing Metrics Tracked Today

Q: Which of the following manufacturing metrics do you track today in your manufacturing operations?

- Inventory levels: 74%
- Scrap and rework: 63%
- Finished goods quality: 59%
- Statistical Process Control: 45%
- First pass yield: 36%
- Raw material quality (supplier quality): 59%
- Supplier on-time delivery: 48%
- Fixed Manufacturing costs: 68%
- Variable manufacturing costs: 61%
- Profitability of products/mix across mfg sites: 60%
- Average cycle times: 67%
- KPIs,Performance of key production assets: 51%
- Asset availability/maintenance-related metrics: 31%
- Manufacturing Line Scheduling Visibility: 52%
- Manufacturing Line Capacity visibility: 54%
- Transportation/Logistics schedules and costs: 52%
- Variability of cycle times: 35%
- Demand/Demand variance: 55%
- Schedule Cycle variances: 30%

**Insight:** Metrics are driving performance toward quality, compliance and cost

AMR Research
Key Research Findings: Manufacturing Metrics

- The typical manufacturing organization only tracks 9 different performance metrics.

- Of the nearly 20 different manufacturing metrics examined, only 6 were used by more than 60% of the respondents. None were used by all.

- Most manufacturing firms rely on static metrics such as inventory levels, fixed cost measures, and average production or cycle time. Very few rely on predictive measures such as asset availability, variance analyses, or supplier-related metrics.

- Between 30% and 60% of responding firms believes their management ability and their agility is impacted by a lack of metrics.

Visibility into performance levels are moderately high in some areas, but the systems, tools, and optics provided tend not to focus on advanced/predictive metrics.
Manufacturing Metrics Gap Analysis: Importance vs. Perceived Performance

% of Responses indicating a 4 or 5 on a 5-point scale

- Manufacturing quality: Importance 94%, Performance 79%
- Supplier quality: Importance 87%, Performance 87%
- Manufacturing costs: Importance 87%, Performance 67%
- Manufacturing responsiveness: Importance 84%, Performance 59%
- Schedule adherence: Importance 81%, Performance 55%
- Manufacturing flexibility: Importance 76%, Performance 49%
- Measuring demand/demand visibility: Importance 73%, Performance 48%

**Insight:** measurement strategy must align with business & manufacturing
Key Research Takeaways: Metrics & Performance

- Among the vast array of metrics examined, quality-related issues ranked as the most important, followed by cost metrics, and agility/flexibility/responsiveness.

- Respondents stated that their lack of optics into supplier quality, demand measurement, and manufacturing costs were their most critical vulnerabilities.

- Visibility into performance metrics is impacted by inaccurate reporting/forecasting processes, disparate systems, lack of participation by key stakeholders, and inadequate staffing/tools.

The research clearly shows that respondents are both aware and deeply concerned about the lack of performance optics and metrics across their manufacturing lifecycle.
Capabilities Gap Analysis: Importance vs. Perceived Performance

% of Responses indicating a 4 or 5 on a 5-point scale

- Multi-site performance analysis: Importance 68%, Performance 44%
- Enterprise visibility of production financial performance: Importance 67%, Performance 49%
- Aggregation of data from multiple plant floor sources: Importance 63%, Performance 50%
- Multi-site aggregation of data from production assets: Importance 59%, Performance 45%
- Centralized repository for multi-site data: Importance 50%, Performance 41%
- Ability to compute a composite metric from multiple KPIs aggregated from multiple plant floor sources: Importance 58%, Performance 33%
- Acquisition of time series data from the plant floor: Importance 56%, Performance 38%
- Role-based visibility of real-time KPIs and exceptions and on-demand reports: Importance 55%, Performance 40%

Insight: end-to-end visibility is key
Key Research Findings: Supporting Capabilities

- A multi-site view of performance is perceived as important; respondents are beginning to connect core capabilities with that desired outcome.
- Composite metrics are desired, but remain elusive.
- Establishing relationships between key performance indicators and key performance drivers is the next challenge that manufacturers will focus on.

A multi-site, multi-environment, and multi-geography focus are increasingly important to major manufacturers.

Mature manufacturers are focused on aligning capabilities that will support performance visibility on this scale.
Enterprise Manufacturing Intelligence (EMI) is a key area of investment in Life Sciences...

Q41. Which of the following PRODUCT SUPPLY software components does your company currently use?

Q42. What PRODUCT SUPPLY software components does your company plan to continue to use or use for the first time in 2012, 5 years from now?

- Enterprise Manufacturing Intelligence (EMI)
- Supply chain planning
- Specification/Formula/Recipe Management
- Lean Planning
- Manufacturing Execution Systems (MES)
- Supplier and customer portals
- EH&S Waste/Emissions Management
- Lean Execution
- Continuous Improvement Tools (e.g. 6 Sigma)
- Enterprise Asset Management (EAM)

% of Responses, N=98
Perceptions of Technology on the Plant Floor – Enterprise Players Wanted

Perceptions of Plant Floor & Manufacturing Applications/Technology

- I would prefer to have a single, integrated solution for managing our manufacturing capabilities
  - Agree: 77%
  - Neutral: 17%
  - Disagree: 5%

- It would be valuable to allow shop floor and manufacturing personnel to access a broader range of operational information
  - Agree: 71%
  - Neutral: 22%
  - Disagree: 7%

- I would prefer to source my manufacturing solution from a large stable software provider
  - Agree: 67%
  - Neutral: 24%
  - Disagree: 9%

- My organization can effectively collaborate and share information between headquarters and shop floor systems
  - Agree: 64%
  - Neutral: 26%
  - Disagree: 11%

- I would prefer to source my manufacturing application from my ERP provider
  - Agree: 61%
  - Neutral: 27%
  - Disagree: 12%

- My organization can effectively collaborate and share information between our operations and my contract manufacturer’s systems
  - Agree: 54%
  - Neutral: 31%
  - Disagree: 14%

- My organization can effectively collaborate and share information between our operations and my supplier’s systems
  - Agree: 53%
  - Neutral: 30%
  - Disagree: 17%
Who will deliver Composite Applications?

Who will deliver Composite Applications?

Enterprise Resource Planning, Supply Chain Management, Enterprise Asset Management, Advanced Planning and Scheduling

Pure Business Intelligence Applications / Data Mining

Advanced Analytics and Modeling Tools

EMI Frameworks

Interfaces to ERP/EAM

MES Operational Data Store

Historians

Real-time Process Control, SCADA, HMI/MMI

Operational Excellence with Compliant Manufacturing Operations in Pharmaceuticals - 11

TIME GRANULARITY OF ANALYTICAL INFORMATION
Who will deliver Composite Applications?

SAP MII as the EMI framework

Ecosystem partners
In Closing

- Life Sciences now recognizes the strategic nature of manufacturing operations and are prepared to make investments

- Visibility into predictable and profitable product supply performance is a key driver for prioritizing manufacturing investments

- Performance metrics on this scale will require architectures that provide federation of data from multiple disparate applications and data stores – financial and operational

- Composite applications – including EMI or Operations Intelligence - offer a mechanism that coordinates the architectural elements that comprise emerging manufacturing operations management architectures

- Life Sciences Buyers would prefer applications from a single, stable, provider – ERP is the logical point of contact
Achieving Superior Performance with Compliant Manufacturing in Pharmaceuticals

Andy Dé
SAP for Life Sciences
SAP Labs LLC
Trends and Key Metrics enabling Operations Performance Management

Achieving Superior Performance with Compliant Manufacturing in Life Sciences

Summary
Key Customer Challenges
Global Competitiveness is *HERE* placing tremendous pressure on cost, quality and responsiveness

- Lack of Visibility and Control into Manufacturing Exceptions in Real-Time and inability to profitably fulfill new orders
- LOB Managers and Production Personnel cannot monitor, measure, analyze and control performance deviations in real-time across people, processes, asset and plants
- Inability to rapidly design and deliver innovative plant-to-enterprise composite business processes and metrics for operational excellence
- High TCO (total-cost-of-ownership) of integrating and extending Manufacturing Processes from ERP into the Plant Floor

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 integrated...

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

What’s happening during every shift?
- Material availability and consumption
- Capacity availability and utilization
- Schedule changes
- Product Genealogy tracking and QM

What’s happening at each line?
- Cycle Times / Operating Efficiencies
- Machine Breakdowns / Unplanned Downtime
- Quality Index
- Predictive Maintenance requirements

SFAC - Shop Floor Automation and Control Systems
MES – Manufacturing Execution Systems
DCS – Distributed Control Systems
Integrating the real-time Plant Floor with the Enterprise poses formidable challenges.

Disparate Plant System Landscape

- A Typical manufacturing plant will have between 10 and 50 shop floor automation systems (SFA)
- A multi-site manufacturer will have between 40 and 700 SFA systems across its enterprise
Current State

Enterprise

Manufacturing integration

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

Managing Automation and AMR Research
September 2005, Customer Survey

Plant

Manufacturing intelligence

“There are gaps in providing adequate visibility into manufacturing KPIs, Financial performance and multi-site performance analysis”

Managing Automation and AMR Research
September 2005, Customer Survey
Lack of integrated Manufacturing, Quality and Compliance in a single solution impacts ability to consistently deliver quality products, compliant with GxP**....

** GxP = Good Manufacturing/ Clinical/ Lab Practices
Lack of integrated Manufacturing, Quality and Compliance in a single solution impacts ability to consistently deliver quality products, compliant with GxP**.

** GxP = Good Manufacturing/ Clinical/ Lab Practices

The World Without SAP ...

Pain: Disconnect between and across the Plant Floor and the Enterprise

Implications:
- Very high TCO - less than 2% of Pharma Manufacturers have integrated plant-to-enterprise business processes

Pain: Inability to document, validate and comply with GxP requirements, at the lowest cost

Implications:
- Warning letters from the FDA, high penalties, fines and unplanned shutdowns - very high cost of compliance (10-30%)

Pain: Production Personnel cannot deliver quality products consistently to customers, and meet performance targets

Implications:
- Low order fill rates and missed shipments (5-25%)
- Excessive fire-fighting and expedites
- Higher rejects, re-work etc. and higher cost of Quality (5-15%)

Operational Excellence with Compliant Manufacturing Operations in Pharmaceuticals -11
Lack of integrated Manufacturing, Quality and Compliance in a single solution impacts ability to consistently deliver quality products, compliant with GxP** ....

The World Without SAP ...

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- Very high TCO - less than 2% of Pharma Manufacturers have integrated plant-to-enterprise business processes

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** GxP = Good Manufacturing/ Clinical/ Lab Practices

The VP of Manufacturing is challenged with consistently delivering high quality products to customers while complying with GxP** requirements, at the lowest cost of operations, compliance and ownership (TCO)
Operational Excellence in a Compliant Manufacturing Environment with SAP
Compliant Manufacturing in Life Sciences Industry

Customers

Packaging & Filling

Bulk Production & API and Formulations

Suppliers

Compliant Manufacturing

Business Operations drive selection of type of Manufacturing Capabilities in the regulated environment

Process Manufacturing
(In-house Mfg)

Lean Manufacturing = Flow + Repetitive
(with Six Sigma)

Contract Manufacturing
(Outsource Mfg)

SAP Capabilities:
Master Recipe,
Process Order,
Operator Sheet,
EBR

SAP Capabilities:
Rhythm Wheel-APO,
Line Design-Balance,
Kanban Orders

SAP Capabilities:
Inter-company Stock
transfer orders,
Subcontracting
Purchase orders

Planning / Procurement
(by Parent)

Manufacturing
(at Contractor)
Compliant Manufacturing Operations can help you deliver quality products to customers consistently with GxP compliance at the lowest possible cost.

**Key Stakeholders & Objectives**

- **Chief Operating Officer**
- **VP of Manufacturing**
- **Plant Manager**
- **Production Supervisor**

**Enterprise Planning and Control**

- How can we deliver quality products while ensuring compliance with GxP**?
  - Profit Margin
  - Customer Satisfaction
  - Quality and EH&S Compliance

- How do we bridge the disconnect between the plant and the enterprise?
  - On-Time Delivery
  - Manufacturing budget attainment
  - Throughput

**Plant-Level Operations**

- How do I deliver high quality products to customers consistently, at the lowest cost of operations?
  - OEE
  - Quality Conformance (Right First Time)
  - Operating and Inventory Costs

**Manufacturing Execution**

- How do I ensure compliance with quality and safety standards like GxP**?
  - Scheduling Execution / Adherence and Attainment
  - EH&S and Traceability Compliance
  - Unplanned Downtime
  - Fines and penalties

* GxP = Good Manufacturing/ Clinical/ Lab Practices
Compliant Manufacturing Operations connects Enterprise Planning and Control, Plant-Level Operations and Manufacturing Execution to bridge the chasm between the shop floor and the enterprise.
How does SAP MII fit within SAP’s Compliant Manufacturing Architecture (based on S95 standards)

**Level 4:**
- **Enterprise Business Process**
  - SAP MDM: Master Data

**Level 3:**
- **Shop floor level Manufacturing Operations**
  - SAP EP: Manufacturing Dashboard
  - SAP BI: SCOR
  - SAP MII: Manufacturing Integration & Intelligence
  - SAP BI: Manufacturing Performance Analysis
  - SAP BI: Shop-floor Communication

**Level 2:**
- **Automation & Connectivity**
  - Adaptive Device Integration
  - Data Historian

**Level 1:**
- **Shop floor Process Control**
  - RFID Sensors
  - Inspection Equip/Testers
  - Environmental Bldg Mgmt Sys
  - PLC/DCS/SCADA
  - Weigh Scales

**Manufacturing Platform**
- Operator Interface
- EBR Checklist
- Lot Genealogy
- Real time QM
- Labour, WIP
- Process Step Enforcement
- Scrap Analysis
- Electronic Logbook
- Weigh & Dispense
- Production Trend Analysis
- Shopfloor Data (OPC)
- Shop-floor Communication
- Sample Mgmt
- Incidence Reporting
- Document Mgmt System
- Recipe/Spec Management
- S95 (B2MML): Prod Plan, Performance, Maintenance & Quality
- Adapters for Collaborative Manufacturing

**Manufacturing solution space (SAP focus)**

- SAP ERP
- SAP MII
- SAP NetWeaver
PAS-X (Weigh-Dispense, MBR & EBR) by Werum

PAS-X extends the compliant manufacturing capabilities of SAP ERP. With the help of PAS-X solution integrated with ERP leveraging MII, offices can be connected to the factories, weigh-dispense can be managed with better visibility to SAP Manufacturing for global sites.

Solution

- End-to-End Solution:
  - Integrated solution to reduce integration challenges
  - Provides complete functional coverage
- Open architecture:
  - Supports industry standards
  - Adheres to compliance and validation

Business Benefits

- Better manage the business growth by gaining control and visibility over global mfg to optimize performance.
- Reduce overall manufacturing cost by lowering cost of ownership and improve product quality.
- Ensure Compliance by adhering to regulations.
Today’s burning issue:
Built into the Manufacturing Process

Enforce Compliance within Manufacturing

Operational Excellence with SAP MII

Tremendous cost and competitive opportunities

ERP for Business Infrastructure Support

SAP ERP 6.0

Value Realization

Manufacturing Process and Technology Maturity
**Benefits of Contract Manufacturing Solution**

How to provide visibility and control in a flat world ...

### Improved visibility into supply chain
- Leverage accurate information on inventory & purchase orders
- Get visibility into production progress thru work order
- Complete visibility also for multi-tiered supply chain
- Identify material events for SOX

### Increased collaboration with partners
- Collaborate on quantity confirmations (instead of dictating)
- Minimize disruptions through proactive alerting
- Improve collaboration on Engineering Changes
- Improve supplier relationship by providing more accurate data

### Enhanced Control and Orchestration
- Quickly react on shifts in supply situation, reduce liabilities
- React to demand changes (by knowing your supply options)
- Increase customer service by more accurate ATP dates
- Control costs of outsourced manufacturing in your backend
What do Pharma Manufacturers need for Operational Excellence with Compliant Manufacturing?

Pharma Companies need capabilities for:

- **Manufacturing operations**: A comprehensive ERP solution for managing Manufacturing Operations compliant with CFR Part 11
- **Manufacturing integration**: A manufacturing integration platform to connect manufacturing processes with enterprise processes
- **Manufacturing intelligence**: real-time actionable analytics and decision support to production personnel so they can deliver on their performance goals
- **Manufacturing innovation**: a web-services based rapid design and development framework for composite business processes, application and metrics
What do Pharma Manufacturers need for Manufacturing Excellence with Compliant Manufacturing Operations?

Pharma Companies need capabilities for:

- **Manufacturing operations**: A comprehensive ERP solution for managing Manufacturing Operations compliant with CFR Part 11.

- **Manufacturing integration**: A manufacturing integration platform to connect manufacturing processes with enterprise processes.

- **Manufacturing intelligence**: Real-time actionable analytics and decision support to enable compliance, so they can achieve their performance goals.

- **Manufacturing innovation**: A web-services based rapid design and deployment framework to enable business processes and applications, metrics.
How does SAP MII enable Compliant Manufacturing thru Manufacturing Integration, Intelligence and Innovation?

**Compliant Manufacturing**

**Manufacturing Operations**

- **SAP ERP**
  - **Manufacturing Integration**
    - "A Single Version of the Truth" across the Plant and the Enterprise
  - **Manufacturing Intelligence**
    - Reliably produce to target with year-to-year process and cost improvement
  - **Manufacturing Innovation**
    - Deploy plant-to-enterprise composite business processes, applications and metrics
How does SAP MII enable Compliant Manufacturing thru Manufacturing Integration, Intelligence and Innovation?

Compliant Manufacturing

Manufacturing Operations
SAP ERP

Manufacturing Integration
“A Single Version of the Truth” across the Plant and the Enterprise

Manufacturing Intelligence
Reliably produce to target with year-to-year process and cost improvement

Manufacturing Innovation
Deploy plant-to-enterprise composite business processes, applications and metrics

Only SAP MII delivers Manufacturing Integration (with the Enterprise), Intelligence and Innovation, in weeks per Plant, to enable Superior Manufacturing Performance at the lowest TCO
What is the SAP Manufacturing Integration and Intelligence (MII)?

SAP Manufacturing Integration and Intelligence (MII) 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.

**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.

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

MES – Manufacturing Execution Systems, EMI – Enterprise Manufacturing Intelligence, BW – Business Warehouse (from SAP)
SFAC – Shop Floor Automation & Control,
How does SAP MII Integrate Manufacturing Operations with the Enterprise?

SAP MII enables real-time transactional integration between plant floor and enterprise (SAP ERP) systems out-of-the-box thru:

- **Universal Connectivity** to the data, functionality and processes of existing plant floor systems
- **Business Logic** for creating automated events, KPIs and alerts
- **Workflow** to synchronize plant and Enterprise business processes
- **Built in S95 and B2MML messages and schema** to make legacy systems interoperable

**Key Customer Benefits:**

- Automated synchronization of orders, materials, maintenance and quality between plant and SAP ERP – a “single version of the truth”
- Real-time detection and automated resolution of manufacturing exceptions
- ERP integrated to Plant Systems in 2-16 weeks per plant

**Bottom Line:** Faster time-to-value and lower TCO
SAP MII 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

Operational Excellence with Compliant Manufacturing Operations
How does SAP MII deliver Manufacturing Intelligence?

SAP MII enables **production personnel** to deliver superior performance thru:

- a real-time analytics engine that aggregates data from the plant floor

- delivery of **right-time actionable intelligence** from multiple systems - unified real-time analytics (KPIs, reports etc.) into role-based dashboards, at a low cost of information delivery

- monitoring, drill-downs, analysis, control and improvement of Six-Sigma metrics

- asset-to-asset, plant-to-plant comparisons for sharing best business practices
How does SAP MII deliver Manufacturing Intelligence?

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- delivery of right-time actionable intelligence from multiple systems - unified real-time analytics (KPIs, reports etc.) into role-based dashboards, at a low cost of information delivery
- monitoring, drill-downs, analysis, control and improvement of Six-Sigma metrics

**Key Customer Benefits:**

- Real-time performance management – provides actionable measurements of asset performance to speed goal attainment
- Continuous Improvement – links production metrics to improvement and causal analysis to accelerate process improvement

**Bottom Line:** Production Personnel can monitor, measure, analyze and control KPIs and variances thereof, to improve their performance, productivity and quality of work life
How does SAP MII enable Manufacturing Intelligence?

Analytics: Long Execution Time of Manufacturing orders

- Long Execution Time of Manufacturing orders
- Variance in Execution Time
- Upper Limit
- Workcenter Chart View of the selected order (SAP)
- Workcenter View of the selected order (SAP)
- Percentage Variance of Execution Time (SAP)
- ProcessConditions for Selected Order (Lighthammer)
- Order Alarm(s) & Event(s) (Lighthammer)
How does SAP MII enable Manufacturing Intelligence?

Analytics: Long Execution Time of Manufacturing orders

SAP ERP

Process Historian via SAP MII

Control system via SAP MII
How does SAP MII enable Manufacturing Intelligence?

Analytics: WIP Orders – Analytics with Work center KPIs
How does SAP MII enable Manufacturing Intelligence?

Analytics: WIP Orders – Analytics with Work center KPIs
How does SAP MII enable Manufacturing Innovation?

SAP MII enables design and deployment of innovative plant-to-enterprise business processes, applications and metrics by providing:

- **Data and Event Services**
  - provide unified and secure access of data and events to all of the other platform services and functions

- **Analytic Services**
  - Metrics/KPIs
  - SPC
  - Data transformation

- **Manufacturing Process Management**
  - Service-enablement of plant applications
  - Composite service-composition
  - Manufacturing process orchestration

N.B. This is not a complete listing of SAP xMII web-services available today
How does SAP MII enable Manufacturing Innovation?

SAP MII enables design and deployment of innovative plant-to-enterprise business processes, applications and metrics by providing:

- **Data and Event Services**
  - provide unified and secure access of data and events to all of the other platform services and functions

- **Analytic Services**
  - Metrics/KPIs
  - SPC
  - Data transformation

**Key Customer Benefits:**

- Rapid and cost-effective design of plant-to-enterprise business processes and applications not delivered by packaged apps., in days and weeks
- Deploy composite metrics like OEE, Right First Time etc. to sustain your Lean and Six-Sigma initiatives
- Applications and KPIs can be delivered by Plant IT without external support

**Bottom Line:** Innovation and Superior Performance, at a far lower cost of development
### Illustrative example of a Composite Metric developed using SAP MII: OEE Availability

#### OEE - Availability

<table>
<thead>
<tr>
<th>Plant Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plant</td>
</tr>
<tr>
<td>Werk Hamburg</td>
</tr>
</tbody>
</table>

#### Workcenter View

<table>
<thead>
<tr>
<th>Workcenter</th>
<th>Availability</th>
<th>Actual Exec Time</th>
<th>Target Exec Time</th>
<th>T/A Exec Time Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drill press I CAP</td>
<td>82.29</td>
<td>18,223.91</td>
<td>64,964.30</td>
<td>118.45</td>
</tr>
<tr>
<td>Balancing machine</td>
<td>76.08</td>
<td>4,453.00</td>
<td>3,388.00</td>
<td>131.43</td>
</tr>
<tr>
<td>Steel saw</td>
<td>88.66</td>
<td>15,244.32</td>
<td>13,516.00</td>
<td>112.79</td>
</tr>
<tr>
<td>Annealing furnace</td>
<td>83.69</td>
<td>19,406.78</td>
<td>16,275.00</td>
<td>119.49</td>
</tr>
<tr>
<td>Universal Lathe</td>
<td>85.73</td>
<td>5,356.40</td>
<td>4,592.00</td>
<td>116.65</td>
</tr>
<tr>
<td>Universal lathe sna</td>
<td>94.71</td>
<td>4,646.64</td>
<td>3,996.00</td>
<td>110.05</td>
</tr>
<tr>
<td>Drill press</td>
<td>84.44</td>
<td>5,593.25</td>
<td>4,723.20</td>
<td>118.42</td>
</tr>
</tbody>
</table>

#### Time View for Workcenter: Drill press I CAP

**From Date:** 1 Jul 2004  
**To Date:** 14 Apr 2005

#### Detailed View for Month: MAR 2005

- **Casing**
- **Material**
- **Bearing case**

---

Operational Excellence with Compliant Manufacturing Operations in Pharmaceuticals - 11
Key Customer Benefits
Consistently deliver high quality products to customers while complying with GxP** requirements, at the lowest cost...

** GxP = Good Manufacturing/ Clinical/ Lab Practices
Consistently deliver high quality products to customers while complying with GxP** requirements, at the lowest cost...

Solution: Deploy a comprehensive solution for manufacturing, quality and compliance, globally, across multiple plants

Benefit
- Consistently deliver high quality products to customers at the lowest cost of quality and operations (increase efficiency 5 - 25%)

Solution: Integrate SAP ERP to real-time plant floor systems, in 2-16 weeks per plant

Benefit
- Lower TCO 2-5 X on plant- to- enterprise integration; minimize fire fighting thru real-time visibility

Solution: Deploy Electronic Batch Records (EBRs) for GxP compliance across people, equipment and processes

Benefit
- Manage GxP compliance by exception – lower cost of compliance (and risks) 10-30%

** GxP = Good Manufacturing/ Clinical/ Lab Practices
Operational Excellence with Compliant Manufacturing Operations in Pharmaceuticals

Consistently deliver high quality products to customers while complying with GxP** requirements, at the lowest cost of operations, compliance and ownership (TCO).

The World With SAP...

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SAP enables the VP of Manufacturing to consistently deliver quality products to customers, while complying with GxP** requirements, at the lowest cost of operations, compliance and ownership (TCO).
Invitation to the Perfect Plant Center of Excellence (COE) from SAP and Tata Consultancy Services (TCS)

- Jointly developed by SAP and TCS
- Capture a true day-in-the-life of Manufacturing Operations
- Model various best practices within Process Manufacturing
- Profile end-to-end cross-functional business processes
- Showcase an integrated manufacturing solution for Life Sciences, including those from SAP’s partners
- Mitigate risk of adoption for SAP’s customers

Customers and Prospects are invited to visit the Perfect Plant Center of Excellence (COE) at the SAP facilities in Newtown Square, PA, USA and Walldorf, Germany

White Paper on the Perfect Plant COE for Life Sciences available on demand
## Partial Listing of SAP ERP and SAP MII Lighthouse Customers in Life-Sciences

<table>
<thead>
<tr>
<th>Core Manufacturing Customers (SAP ERP)</th>
<th>SAP MII Customers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson and Johnson</td>
<td>Wyeth Pharma – <em>Manufacturing Performance Management</em></td>
</tr>
<tr>
<td>Allergan</td>
<td>Roche Pharma – <em>connecting SAP ERP to the plant floor</em></td>
</tr>
<tr>
<td>Bristol Myers Squibb</td>
<td>Novartis Pharma – <em>operational excellence (SCM and manufacturing)</em></td>
</tr>
<tr>
<td>Glaxo Smithkline</td>
<td>Merck - <em>facilities management, performance management / reporting</em></td>
</tr>
<tr>
<td>Daiichi</td>
<td>Eli Lilly - <em>production management – batch reporting</em></td>
</tr>
<tr>
<td>Purdue Pharma</td>
<td>Amgen – <em>manufacturing analytics</em></td>
</tr>
<tr>
<td>Helvoet Pharma</td>
<td>Genentech – <em>KPI management</em></td>
</tr>
<tr>
<td>St. Jude Medical</td>
<td></td>
</tr>
<tr>
<td>Respirationics</td>
<td></td>
</tr>
</tbody>
</table>
## Why SAP Solution (SAP MII) and TCS Was Selected

- Transactional integration between SAP ERP, MES, LIMS and Document Management Systems enabled in Weeks per Plant, at lower TCO.
- Rich, unified visualization of manufacturing data, metrics, exceptions and performance delivered in real-time via role based dashboards using DART (Data Analysis and Reporting Tool) delivered by TCS.

## Key Benefits

- Real-time data retrieval (metrics, exceptions, reports and performance), analysis and visualization, and fact-based GMP decision making capabilities enabled thru role based dashboards for managers and production personnel.
- Measurable ROI from labor reduction, exception based management of electronic batch records (EBR), quality improvements and significantly reduced cycle times and compliance exceptions.

## Project Objective

- Institutionalize Operational Excellence across the enterprise.
- Ensure consistent and sustainable compliance.
- Standard KPIs for ROI measurement — “a single version of the truth.”
- Improve quality, reduce costs and increase utilization of assets.

**Wyeth Pharma** is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines. Major divisions are Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

- 2007 Sales – $22.4 billion
- 50,000 employees worldwide

- Realized ROI - $1.3 – 7.4 MM per plant from their DART initiative using SAP MI.
- 12 manufacturing locations in scope for deployment.

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### Customer Success: Lean Manufacturing at Novartis

**Novartis** is one of the top 5 Pharma manufacturers globally, headquartered in Basel, Switzerland, with over 90,000 employees in 140 countries, with 2005 revenues of US $ 32.2 Bn. Novartis is well on its way to becoming the “Toyota of the Pharma Industry” using Lean processes enabled by SAP’s solutions.

### Project Objective
- Achieve vision of becoming the “Toyota of the Pharma Industry” while maintaining high compliance
- Extend Lean from the Supply Chain to the Plant Floor using SAP
- Manage Lean Manufacturing by Exception

### Why SAP Solution wasSelected
- Transactional integration between SAP ERP and Plant Floor systems (incl. Werum) enabled in Weeks per Plant, at lower TCO
- Rich, unified visualization of manufacturing data, metrics, exceptions and performance delivered in real-time via role based dashboards
- Ability to extend manufacturing processes beyond the plant floor (e.g. Supply Chain) and vice-versa

### Key Benefits Projected
- Real-time data, metrics, exceptions, reports and performance delivered to Managers and Production Personnel
- KPI driven exception based management of Lean Manufacturing across the Plants
- Protection and leverage of investments in current Plant IT infrastructure and integration with SAP ERP at lower TCO
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PROJECT OBJECTIVE
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KEY BENEFITS PROJECTED
- Real-time data, metrics, exceptions, reports and performance delivered to Managers and Production Personnel

SAP MII offers Novartis real-time process status visualization and communication capabilities as well as the ability to integrate SAP ERP to our legacy and non-SAP plant systems, rapidly, at a lower total-cost-of-ownership.

Ralph Haefeli
Head of Global TechOps IT Systems, Novartis Pharma AG
Summary

Trends and Key Metrics enabling Operations Performance Management

Achieving Superior Performance with Compliant Manufacturing in Life Sciences
Summary of Key Customer Benefits:

- Consistently deliver high quality products to customers at the lowest cost of operations
- Manage GxP compliance requirements, by exception, at the lowest cost of compliance
- Bridge the disconnect between the Plant Floor and the Enterprise, with SAP MII, to enable Operational Excellence:
  - Integrate and extend your ERP Manufacturing Processes into your Plant Floor at the Lowest TCO
  - Empower Production Personnel with Actionable Intelligence for Superior Performance
  - Design and deliver innovative Composite Processes, Applications and Metrics for Competitive Advantage

SAP delivers a comprehensive solution for manufacturing quality products, compliant with GxP, at the lowest cost of operations, compliance and ownership
Operational Excellence with Compliant Manufacturing Operations for Pharmaceuticals

Hussain Mooraj and Wayne McDonnell
AMR Research

Andy Dé, Senior Director Industry Solutions
SAP for Life Sciences