FactoryTalk® Pharma Suite

Overview
Life Sciences Industry Challenges

In the Industry’s Own Words:

• “Reduce spending per brand by 15 to 20% in the U.S.”
• “Reducing inventory by $400 million and saving $1.2 billion in procurement by 2008”
• “Redesigning all of our end-to-end processes”
• “Strengthened capabilities in vertical integration to secure future cost competitiveness”
• “Scale in manufacturing and infrastructure in low cost regions”
• “Integration of a global manufacturing network”
• “Creation of one Pharmaceutical Development “center of excellence” between R&D and Manufacturing”

Source: Various life sciences manufacturing’s investor relations presentations
Life Sciences Industry Challenges

• Economic pressures
  – Globalization
  – Pricing pressure
  – Litigation costs
  – Government pricing restrictions

• Changing regulatory environment
  – Risk-based manufacturing
  – Quality by Design

• Portfolio pressures
  – Move to Biotech
  – New delivery mechanisms
  – Targeted treatments
  – Shrinking pipeline
Challenges faced by the Life Sciences Industry

• **Time and cost for bringing new products to market**
  - 10-12 years to bring new drugs to market at a cost of $890M
  - 1 in 20 new drugs meet FDA approval with 8-10 years of patent life

• **Global production efficiency**
  - Quality checks and quarantine time account for 50% of manufacturing cycle times
  - Biotech manufacturing estimated to be significantly capacity restrained
  - Two-thirds of life sciences companies view boosting operating efficiency as their top business goal

• **Quality and compliance processes**
  - In 2003, FDA introduces new risk-based approach for regulatory compliance
  - Significant focus on quality-by-design and process optimization
  - Compliance and validation remain the most important categories of capital spending
To achieve Operational Excellence, tools, methods based on standards must be established to simultaneously meet the quality, regulatory and productivity requirements.
MES drives Operational Excellence

**Corporate Initiative**
- Process reliability, continuous improvement
- Business process re-engineering
- Real-Time enterprise

**Corporate Initiative**
- Regulatory compliance
- Lean manufacturing
- Quality by design

**Corporate Initiative**
- Asset optimization
- Demand driven manufacturing
- Design to manufacture
- Security

**VISIBILITY**
Exposing and synchronizing real time information

**TRACKING**
A product centric process view of order and status

**CONTROL**
Interactive business rules to manage process work flow

**Requirements**
- Data collection & warehousing
- Multiplatform visualization
- KPI reporting - dashboards
- Integration Frameworks

**Requirements**
- Track & trace
- Right first time
- Order & resource status

**Requirements**
- Equipment effectiveness
- Electronic batch recording
- Batch release
- Intelligent control system

MES realizes benefits for visibility, tracking and control
Production Management
• Manage Recipes
• Manage Master Data
• Manage Specification

Production Execution
• Collect data from shop floor
• Drive manual activities (EBR)
• Manage Deviations

Model Predictive Process Control & Optimization
• Apply process understanding to controls
• Advanced controls
• PAT

Manufacturing Business Intelligence
• Turn data into information
• Visibility into the shop floor

Energy Optimization
• Monitor usage
• Optimize

Serialization / Track&Trace
• Prevent counterfeiting
• ePedigree

Production Performance
• OEE
• KPIs
• Dashboards

Production, Quality & Maintenance Tracking
• Material tracking
• Equipment tracking
• Personal tracking

Real-time Environmental Management
• Qualified building automation
MES equation: Applied Capabilities = Value

- Manufacturing Business Intelligence
  - FactoryTalk Pharma Suite
    - Production Management

- Production Management
  - FactoryTalk Pharma Suite
    - Production Execution | Dispense | EBR

- Production Execution
  - FactoryTalk Pharma Suite
    - Production, Quality & Maintenance Tracking
  - Real-time Environmental Management

- Production Performance
  - FactoryTalk Pharma Suite
    - Production Analysis

- Third Party Systems
- Model Predictive Process Control & Optimization
- Data Historian (Timeseries)

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Applications of FT Pharma Suite

- FactoryTalk® Pharma Suite Production Management
- FactoryTalk® Pharma Suite Production Analysis
- FactoryTalk® Pharma Suite Quality Management
- FactoryTalk® Pharma Suite Production Execution
- FactoryTalk® Pharma Suite Dispense
- FactoryTalk® Pharma Suite EBR

FactoryTalk® ProductionCentre Platform

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FactoryTalk Pharma Suite Overview

Comprehensive Production Management

- Supports multiple industry segments including Pharma, Biotech, Med Devices, Nutraceuticals
- Covers the whole drug life-cycle
  - R+D, Clinical, Primary and Secondary Production
- Feature-rich applications
- Compliant with regulations
  - FDA, EU, GxP,.. 
- Based on a proven platform
  - Modular, flexible, extensible and scalable
- Comprehensive integration with business and automation layer systems
- Alignment with standards (S88, S95, etc)

Key values

- Applications tailored to the needs of regulated industries ensure compliance at lower cost
- Support for the complete drug manufacturing life cycle helps to improve time to market
- State-of-the-art technology reduces TCO
- Implementation by customer, RA or partner
FactoryTalk Pharma Suite
Production Management Application

GxP-compliant recipe management

- Management of master data
  - Materials
  - Bill of materials
  - Routes
  - Master recipes

- Process order management
  - Order explosion
  - Dispatching

- Inventory management
  - Batch and sublot management
  - Visibility into inventory

- Equipment management
  - Scales, Rooms, Containers, etc

- Compliance
  - Versioning, Audit Trail, eSignatures

Key values

- Reduces risk of non-conformance by GxP-compliant data and recipe management
- Provides control on what happens and when on the shop floor
- Provides visibility into production status and shop-floor inventory
- Instant access to equipment status and history – without paper
Visibility and Tracking for the shop-floor

- Pre-defined workflows for Track&Trace
  - Material receive, Material issue
  - Material relocation, Material split
  - Material consumption, Material produce
  - Room & container cleaning

- Enforcement of processes / specifications
  - Correct material/batch
  - Calibrated, clean and correct equipment
  - Qualified personnel

- Tracking of material, equipment, personnel

- Compliant handling of exceptions

- Labeling, Label history, Re-print

Key values

- Enforces material and equipment is used according to specifications
- Ensures correct and complete documentation of material, equipment and personnel used throughout the process
- Eliminates manual bookings for order status, material consumed and produced in ERP
- Automatically tracks WIP
- Controls inventory on the shop-floor
**FactoryTalk Pharma Suite Dispense**

**Compliant weighing operations**

- Pre-defined weighing workflows / methods
  - Recipe weighing, Campaign weighing
  - Cost center weighing, Removal weighing
  - Scales test & calibration
  - Booth & container cleaning

- Real-time scales interface
  - Comprehensive list of supported scales
  - Scales identity check

- Potency correction / compensation

- Compliant handling of exceptions

- Weighing report

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**Key values**

- Guides operator through complex weighing processes and therefore prevents errors
- Ensures complete and correct documentation
- Eliminates manual calculations
- Scales interface makes 2nd operator redundant
- Review by exception reduces time and effort for review and investigations
**FactoryTalk Pharma Suite Electronic Batch Recording**

**Gapless electronic batch documentation**

- Graphical Recipe Workbench
  - User-friendly and intuitive modeling of process and material flow, equipment, etc
  - Rich set of pre-defined recipe building blocks
  - Freedom to define new recipe building blocks
  - Simulation and verification

- Integrated Recipe Execution
  - Focused on the needs of the shop-floor operators
  - Comprehensive Integration

- Configurable Review & Approval workflows

- Flexible and configurable Batch Reporting

- Aligned with standards

**Key values**

- Improves time-to-recipe and helps to simplify tech-transfer and scale-up
- Significantly reduces procedural and operator errors by guiding operators through complex processes
- Prevents documentation errors by capturing data from devices / automation layer
- Reduces batch review cycle-time and effort allowing „review by exception“
Include quality operations into your batch documentation

- Pre-defined workflows for quality operations in production, warehouse and lab
  - Sampling
  - In Process Control
  - SPC / SQC
- Comprehensive tracking of process activities
- Sampling plans, Supplier Management
- Interfaces to Automation Layer, Laboratory Equipment and LIMS
- Seamless integration with Dispense, EBR, Warehouse, etc

Key values
- Minimizes risk of non-conformance by enforcement of quality requirements
- Automatic capturing of quality data provides correct and comprehensive batch records
- Streamlines IPC activities at the line and in the IPC laboratory
FactoryTalk Pharma Suite

Production Analysis

Improve overall efficiency and analyze downtime issues

- Flexible definition of key performance indicators for equipment, quality and processes
- Line monitoring cockpit / downtime analysis
- Definition and monitoring of limits and notification of limit violations
- Role-based dashboards with standard KPIs
- Reporting and analytics
- Seemless integration with Dispense, EBR, Quality, Warehouse, etc
- Automated collection of real-time data

Key values

- On-demand visibility for decision support and continuous process improvement
- Process improvements based on objective, accurate and timely data
- Configurable and scalable to ensure that is measured and monitored what is important
FactoryTalk ProductionCentre Platform

**FactoryTalk SOA – Reliable and scalable Enterprise Architecture**

- J2EE – proven technology for mission-critical enterprise applications
  - Security and stability
  - Scalability without limits
- Service Oriented Architecture (SOA)
  - Feature rich business layer
  - Supports rich and thin (HTML) clients
- Variety of supported platforms
  - IBM WebSphere, JBoss, WebLogic
  - Windows, Linux, Solaris Enterprise
  - SQL Server, ORACLE
- Multi-tier data model
- Built-in application development framework
  - Comprehensive, flexible and extensible

**Key values**

- Security and stability
- Freedom of platform choice
- Ease of integration
- Configuration versus customization
- Easy to extend
- Deployment by IT organizations, partner, RA
FactoryTalk Pharma Suite
Business and Automation System Integration

Comprehensive integration with business and automation systems

- Business System Integration with FT Integrator
  - Standard adapters to various ERP systems like SAP, ORACLE, JDEdwards, etc
  - Pre-defined interface scenarios
  - Flexible and reliable middleware platform based on industry standards like S95 and B2MML

- Flexible integration with 3rd party middleware like IBM WebSphere or SAP NetWeaver XI using ProductionCentre JCA-Adapter

- Integration of process parameters, events and historical data using industry-standards
  - FT LiveData (OPC DA)
  - FT A+E (OPC Alarm+Events)
  - FT Historian, OPC HDA

Key values

- Flexible and cost-effective integration with business and automation systems
- Support for Rockwell and 3rd party systems
- Seamless integration in existing IT infrastructure
- Reliable and proven technology
- Service-oriented architecture (SOA) provides for open interfaces based on industry-standards
The Evolution of FactoryTalk Pharma Suite

- As RA continuously grow FactoryTalk to cover the complete information space, the current LS MES/IS offering will be merged into the FactoryTalk platform.
- FT Pharma Suite will be built on the strength of our existing offering RS PMX and FT ProductionCentre.
- No forced migration for PMX customers – convergence according to your business requirements.
- Ongoing, significant investment in the LS information solutions offering.
The Customer Advisory Board drives the direction of FactoryTalk Pharma Suite

- Functional enhancements
- Technology direction
- Yearly voting process determines major parts of the product scope
- Forum for customer interaction
- A platform to provide real-life experience to Rockwell Automation’s development group
- Rockwell Automation shares early product roadmap visions
- Regular meetings
  - Monthly (WebEx/PhoneConf)
  - Semiannual face-to-face
FactoryTalk ProductionCentre

FactoryTalk Pharma Suite is built on a platform that is proven in many installations!

- ProductionCentre hosts the biggest single MES serving over 3000 users at 28 sites with further 18 being deployed
- Installed at over 150 sites
- More than 100 customers world-wide with over 10,000 users
- Deployed in a variety of industries
  - Medical Devices
  - Electronics
  - Food / Beverage
  - Automotive
Summary

• Feature-rich MES applications tailored to the needs of Life Sciences industries help customers to ensure regulatory compliance at lower cost

• Leverages Rockwell’s long-time experience building Life Sciences MES applications

• Based on a state-of-the-art software platform proven in many installations

• Industry-standard technology allows for reduced cost of ownership (TCO)

• Works stand-alone as well as tightly integrated with ERP

• Minimum hardware requirements for small systems – yet scalable to 1000’s of users

• Can be deployed by customer, RA or partner
Thank You