Agenda

1. Define “What?”
   - Discuss ISA95 standard and its modeling of business/manufacturing systems
   - Examine Manufacturing Operations Management
2. Answer “Why?”
   - Discuss the importance of properly utilizing data and the technologies to do so
3. Unveil “Who?”
   - Discuss the characteristics of the ideal manufacturing technologist
   - Examine the opportunities presented for the future

ISA95 Model

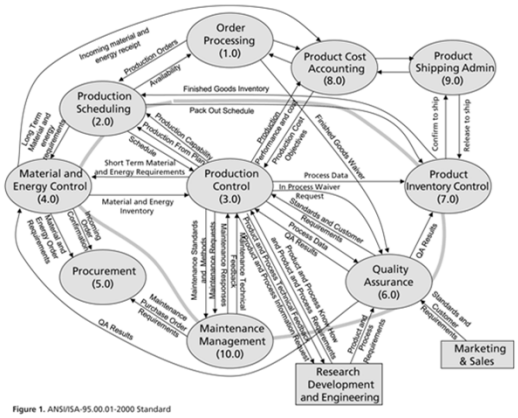


Figure 1. ANSI/ISA-95.00.01-2000 Standard

ISA95 Model

LEVEL 4 — Enterprise Resource Planning
- Supply Chain/Production Planning
- Electronic Business System(s)
- Materials Management Systems

LEVEL 3 — Manufacturing Operations Management
- Manufacturing Execution Systems
- Plant Historian
- Batch Reporting System

LEVEL 2 — Production Control
- Distributed Control System
- SCADA
- PLC

LEVEL 1 — Device Control
- Distributed Control System/Process Control System/PLCs
- On-board Control Systems
- Instrumentation

Note: Level 0 – the Production Process not depicted

Levels 1 and 2 – System Examples

Distributed Control System (DCS)/Process Control System (PCS)

– Used for controlling the Manufacturing Process through any combination of discrete, continuous, and batch control. Spans Levels 1 and 2.

On-board Control Systems

– Used for controlling a standalone piece of equipment such as parts washer or autoclave. May be Manufacturer proprietary control system.

Plant Historian

– Used for logging and archival of data from process and manufacturing support systems. Can be Level 3 system if not part of DCS.

Level 3 – System Examples

Manufacturing Execution System (MES)

– Used to enable the control of multiple elements of the production process.

Warehouse Management System (WMS)

– Used for performing inventory activities, tracking lot history, and managing materials inventory.

Computerized Maintenance Management System (CMMS)

– Used for performing maintenance activities, tracking equipment history, and managing parts inventory.

Laboratory Information Management System (LIMS)

– Used for tracking QC samples and results.

Alarm Management System

– Used for logging alarms and alarm responses and routing and escalating alarm notifications. Can be a function of DCS/PCS (Level 2), Plant Historian, (Level 2/3) or standalone system (Level 3).

Level 4 – System Examples

Enterprise Resource Planning (ERP) System

– Used to manage and facilitate information flow between all business functions inside the organization such as accounting, finance, and supply chain.

Product Lifecycle Management System

– Used to manage the entire lifecycle of a product. Often part of the ERP system.

Customer Relationship Management System

– Used for organizing and managing marketing, customer service, and technical support. Often part of the ERP system.

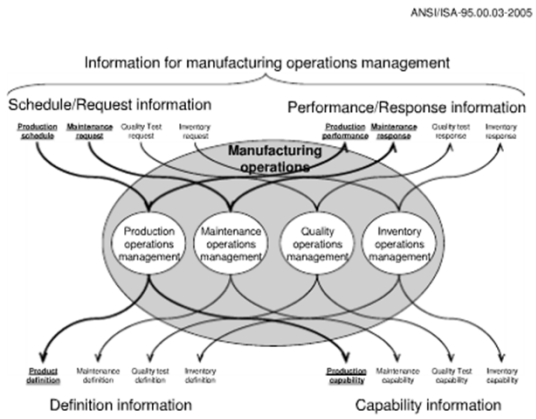
Master Data Management System

– Used to standardize data, prevent duplicate data eliminate incorrect data in order to create an authoritative source of master data. Master data are the products, accounts and parties for which the business transactions are completed.

ISA95 Model

Note: Level 0 – the Production Process not depicted

Manufacturing Operations Management (MOM)



Level 3 – MOM

Product Definition Information
– what must be defined to make a product

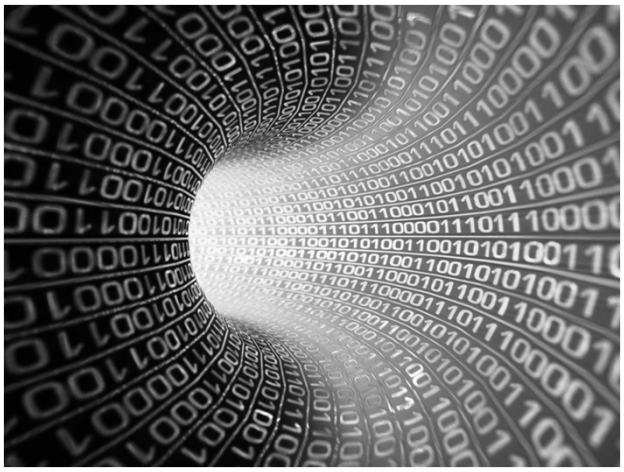
Production Capability Information
– what resources are available

Production Schedule Information
– what actual production will be executed

Production Performance Information
– what actual production was achieved

Note: Production information structure is also applicable to Maintenance, Quality, and Inventory information which is only in scope of this presentation as it relates to Manufacturing information.

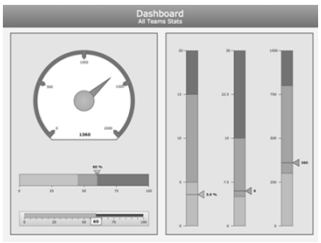
Transforming Data into Information



Transforming Data into Information

- Companies are collecting more and more data in every area of the organization
  - Business and Logistics Data
  - Manufacturing Operations Data
  - Customer/Commercial Data
  - One leading software/device manufacturer collects 450GB of data daily
- Data must be processed and made available
  - Business Intelligence
  - Enterprise Manufacturing Intelligence

Data Utilization



- EMI/BI dashboards
  - Effective tool if properly designed
  - Care must be taken in presented only relevant information
- Systems integration
  - Link two or more systems for exchange of information
  - Should replace a process which would have previously been done manually
  - Should simplify process and remove unnecessary steps rather than simply connecting systems

    Substitution → Extension → Breakthrough

  - Could, in many cases, eliminate the need for an existing system

Systems Integration

- Must provide clear benefit to the organization
  - Simple **substitutions** rarely do so
- Must not be implemented for the sake of new technology
- Can be very costly depending on organization required
- Integration should be an **extension** the capabilities of the business
- In the special case, the integration is a **transformation** of process

MOM and the Electronic Batch Record

Primary focus of Manufacturing and MFG Automation has been utilizing manufacturing data collected to achieve the ultimate goal of the **electronic batch record**

- Streamlines and eliminates manufacturing work practices to increase productivity
- Provides cost savings from reduced paper handling, reviews, and long-term storage
- Allows for release of batch by exception for expedited product release
- Supports centralized, comprehensive data aggregation for easy and distributed batch review
- Provides a full audit trail history of production data collected for 21CFR Part 11

Other Integration Possibilities

MES – CMMS

- Equipment tracking
  - Automated Equipment Logbook record generation for work orders executed against equipment in GMP space
  - Upon completion of work logbook entry automatically generated
- Automatically generate work orders for events in MES
  - Room needs cleaning
  - Device needs calibrating

CMMS – ERP EBS

- Automated procurement of spare parts and services

CMMS – EQMS

- Remedial Action Report generation
  - Device out of tolerance detected
  - Generate exception in EQMS

Integration Case Studies

Case Study 1 – Predictive Maintenance
(CMMS/Asset Analytics)

Case Study 2 – Automated Exceptions
(CMMS/MES/EQMS)

Case Study 3 – Real-time Production Planning
(MES/ERP(SCM)/CMMS)

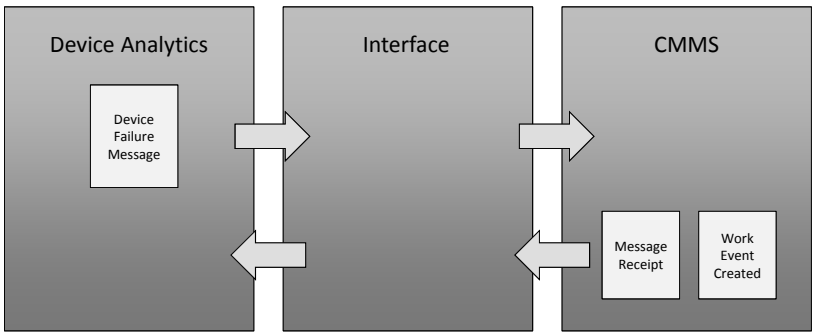
Case Study 1
Predictive Maintenance

Provides functionality to help determine the condition of in-service equipment in order to predict when maintenance should be performed, allowing tasks to be performed only when warranted.

Required Functionality:

- CMMS – equipment master data, ability to generate work events for equipment
- Plant Historian – log runtime data, usage statistics (e.g. motor run-time, valves strokes)
- Device Analytics – fault/failure analysis, ability to detect and categorize degradation of performance

Case Study 1
Predictive Maintenance



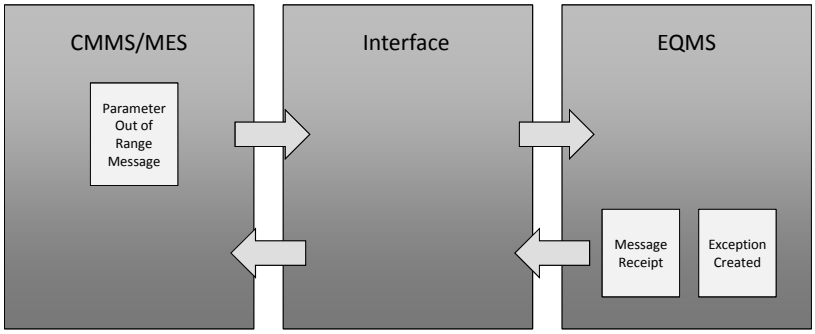
Case Study 2
Automated Exceptions

Provides functionality to help determine the condition of in-service equipment in order to predict when maintenance should be performed, allowing tasks to be performed only when warranted.

Required Functionality:

- CMMS – equipment master data, ability to generate out of tolerance events for calibrations
- MES – ability to generate events for batch exceptions (critical parameters out of range)
- EQMS – able to generate exceptions

Case Study 2
Automated Exceptions



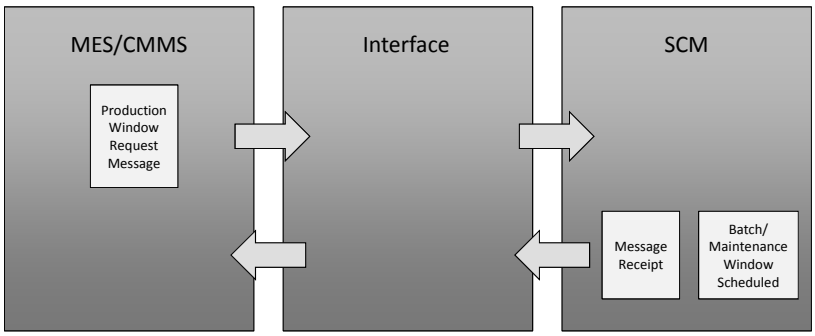
Case Study 3
Real-time Production Planning

Provides functionality to help determine the condition of in-service equipment in order to predict when maintenance should be performed, allowing tasks to be performed only when warranted.

Required Functionality:

- MES – ability to calculate rolling average batch time
- SCM – ability to modify schedules based on up to date information
- CMMS – ability to request maintenance window in production

Case Study 3
Real-time Production Planning



New Technology Keys to Success

- Strong relationship between Operations and IT
  - Fully-invested IT business analyst
- Clear communication paths
  - Operations goals – current business practices, advantage to be gained
  - IT capabilities – new technologies, technologies used in other organizations
- Prioritization – clear methods for evaluating project cost/benefit for both organizations
- Accountability – create transparency and ownership of decisions to build trust

Role of an IT Business Analyst

- Analyze the existing organization
- Analyze the design of systems, including businesses, departments, and procedures.
- Assess business models and their integration with technology.
- Design solutions to create ideal, lean business processes

Automation – the Ultimate BA

- Close relationship with Manufacturing and Facilities
- Firsthand knowledge of business processes
  - Change control/CAPA/Exceptions
  - Use of Standard Operating Procedures
  - Maintenance practices
  - Calibration management
  - Production scheduling
  - Procurement

- Understanding of system capabilities and best practices
- Experience working with IT organizations
  - Work with IT infrastructure in configuring MFG control networks
  - Work with IT DBAs on systems with SQL backbone
- Agility

Automation – Historical role

- Work with MFG and Process Engineering to automate MFG Process
- Troubleshoot and maintain control systems and instrumentation
- Control loop tuning
- Device control

Automation – New roles

- Work with MFG and Facilities to create EMI dashboards
- Work with IT to advance and **transform** technology in Manufacturing
  - Create a fully connected, optimized manufacturing suite
- Drive OEX initiative through advanced knowledge of capabilities
- Streamline existing systems (eliminate systems no longer necessary)
- Prepare for what's next in MFG technology

Go Bruins!