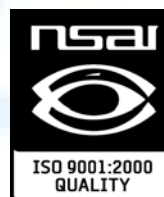

Electronic Paper / Batch Tracking: The Next Level.

Paul Murray
IT Team Leader



Electronic Paper- Why?

- Goal is greater control, efficiency, reliability and compliance of the process.
- Now have guidelines with 21 CFR Part 11 to implement electronic manufacturing and recording that is acceptable to the FDA.

Issues to Consider

- What is the current situation?
- What are the challenges?
- What do we need to do to achieve our goal of RFT /Six Sigma product manufacture?
- What is the future?

Manufacturing – Current Situation

- Isolated islands of information.
- Paper printouts from systems combined with paper batch record.
- No enforcement on paper batch record execution.
- How many manual entries in a batch record?
- Lengthy review process for paper batch record.
- Overall – very time consuming, does it add value to the process?
- What is the chance of achieving RFT/six sigma in this environment?

Opportunities

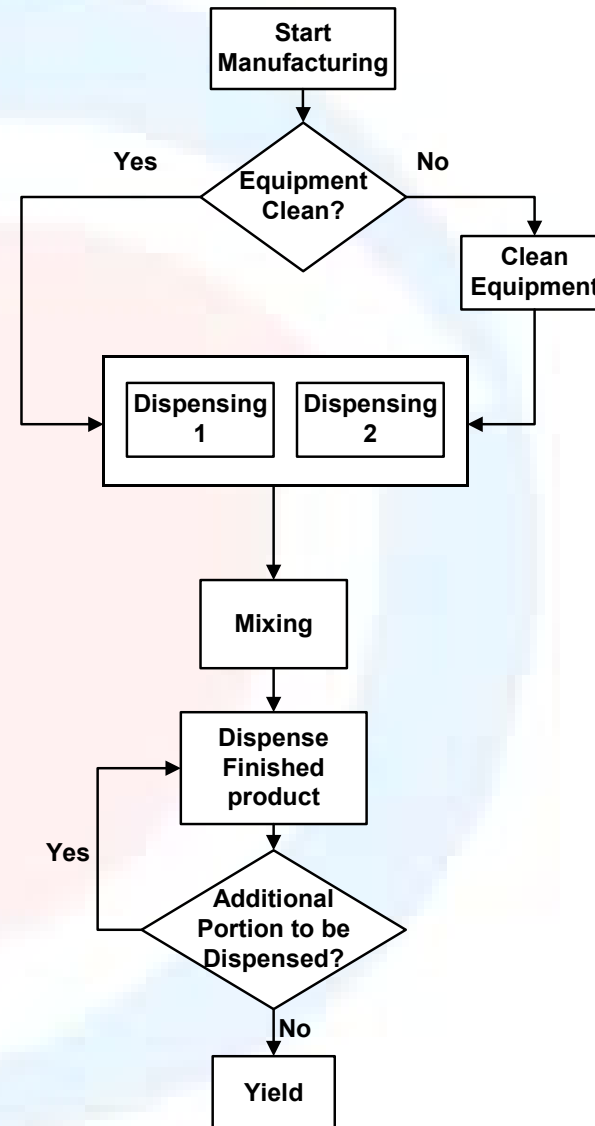
- Enhance compliance - providing electronic control and tracking of batch activities and records.
- Reduce manual data entry.
- Reduce paper - more efficient document management.
- Increased real-time reporting functionality to provide detailed and accurate information quickly.
- Release us from the time consuming tasks – focus on continuous improvement.

Electronic Paper/Batch Recording (EBR)

- Content – defined by predicate rules 21 CFR 210/211.
- Record all types of data, processing values, alarms & events, equipment status, IPC results, calculations, signatures etc.
- EBR should not just record actions during execution.
- EBR can drive correct execution of batch - sequencing.

EBR - Workflows

- Define Workflows.
- Procedures in EBR.
- Require flexibility.
- Loop and branch.
- Enforce workflow.



EBR - Limit Checking

- Enforce Limit checking on all data entry feilds?
- Warning limits. Max, Min values.
- Enforce comment if limit breached.
- Enforce correct signature to proceeed.

EBR – Data Entry

- In workflow procedure enforce all fields to be populated?
- User cannot sign/continue until all required data is entered.
- Calculations can be automatically calculated – eliminate ‘buddy’ check.
- Ensure any modifications are correctly audited.

Equipment/Container Management

- Electronic Log Books/Equipment Management.
- Electronic History.
- Take advantage of bar-coding where possible.
- Reduce human error.

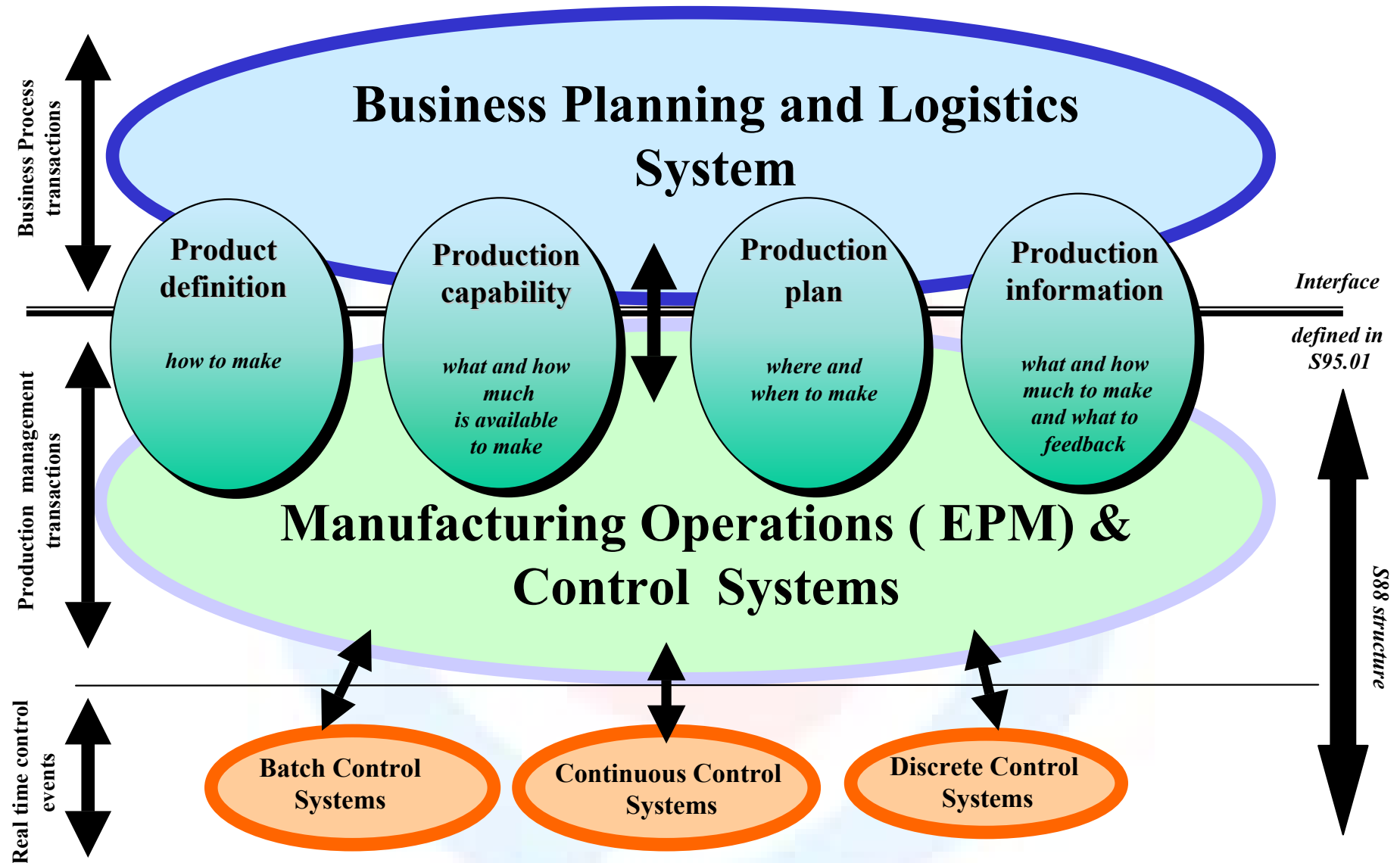
Batch Tracking - Sequencing

- Able to see status of batches, defined, in progress, what stage of manufacturing, in review, completed.
- Automatically route batches within manufacturing operations and for review to QA.

Integration to Automation/Enterprise

- Integrate EBR to Control Systems and ERP systems.
- Order information from ERP to facilitate scheduling of batches.
- Electronically verify status of materials.
- Automatically populate data entry from manufacturing systems – reduce transcription errors.
- Use S88 & S95 model.

Industry Standards S95 & S88



Source: ISA SP95 Committee and AMR Research

Training Issues

- Can electronically enforce training regulations.
- Only users who have been trained assigned to system.
- Interface to training records.

Review By Exception

- Validated system.
- EBR enforces correct execution.
- Any deviations, out of spec results, changed data should be captured in deviation log.
- QA review deviation log, not entire batch record.
- No longer chasing missing entries, signatures, or other deviations on batch record.

Information Management

- Real Time Data
- Comprehensive reporting to the desktop
- Metrics required to assess performance – cycle times, golden batches.
- Single point overview of all aspects of manufacturing.

The Future

- Increasing competition in pharmaceutical industry.
- Increasing pressure to reduce costs.
- Manufacturing efficiency will be critical.
- Electronic manufacturing used in other industries.

The Future

Electronic manufacturing to play a key role in future pharmaceutical manufacturing and will enable

- Fewer Deviations.
- Review by Exception.
- Increased Compliance.
- Increased Efficiency.
- Access to real time information for key decision making.

The End



Thank you!