MANUFACTURING EXECUTION SYSTEM (MES) : CHALLENGES

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TECHNOLOGY – THE GAME CHANGER

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AGENDA

- WHY MES ?
- WHAT IS MES ?
- IMPLEMENTATION CHALLENGES
- OTHER BENEFITS
- SOME MYTHS ABOUT MES

Why MES ?

Manufacturing records and SOPs for pharmaceutical products resemble flood of paper documents.. !!

WITH PAPER COME DATA INTEGRITY ISSUES : WHY MANUAL RECORDS AND PROCEDURAL CONTROLS ARE IN QUESTION?

- Approvals & Signatures are verified manually
- Reports are ‘Post Mortems’ in nature
- Calculations are re-verified manually for assurance
- Ancillary data is reviewed with four eye principle
- Issues occur, affect production and are investigated later
- Page-by-page review of Batch records for irregularities
- Compliance is entirely procedural

But Paper..

- Does not control what the operator writes
- Does not enforce procedural sequences
- Does not control what the operator omits
- Does not make calculations
- Does not raise alerts before incidents
- Does not identify exceptions
- Does not interact with other systems
- Does not qualify, unless checked manually by second person

DI COMPLIANCE IN PAPER WORLD

Compliance to paper based records depend on two factors:

1. Operator discipline and integrity
2. Constant checking and verification by other persons

- Both above must be achieved 24*7. There is finite possibility that there may slip once a while
- We may be lucky if audit which is always a sample check, does not pick up such defective records and result will be zero 483 on this count.
- At some other time you may not be so lucky.

DI COMPLIANCE IN PAPER WORLD

This explains why we come out clean in some audits only to have issues in subsequent audits

Any amount of training and retraining of operators and QA will not result is 100% assurance to DI but well designed electronic systems (MES) will !

MES ensures that this crucial compliance is not left to chance !!

DATA INTEGRITY ENABLER: ELECTRONIC SYSTEMS

ensures

A	Electronic signature and authorisation against permission authority and training. Initials with accurate identifier to a subject visit. Enforces GDP and change management.
L	Data is easier to read and recorded in a permanent medium, no transcription errors.
C	Automatically recorded, signed, and dated at the real time of entry.
O	Data is stored in its original source and available for usage such as reporting and analysis.
A	Checked instantly at the point of entry (Right First Time) against the actual expected result and specification.

SO MES IS ONE KEY ELECTRONIC SYSTEM TO ENSURE DI IN PHARMA MANUFACTURING DOMAIN

WHAT IS MES?

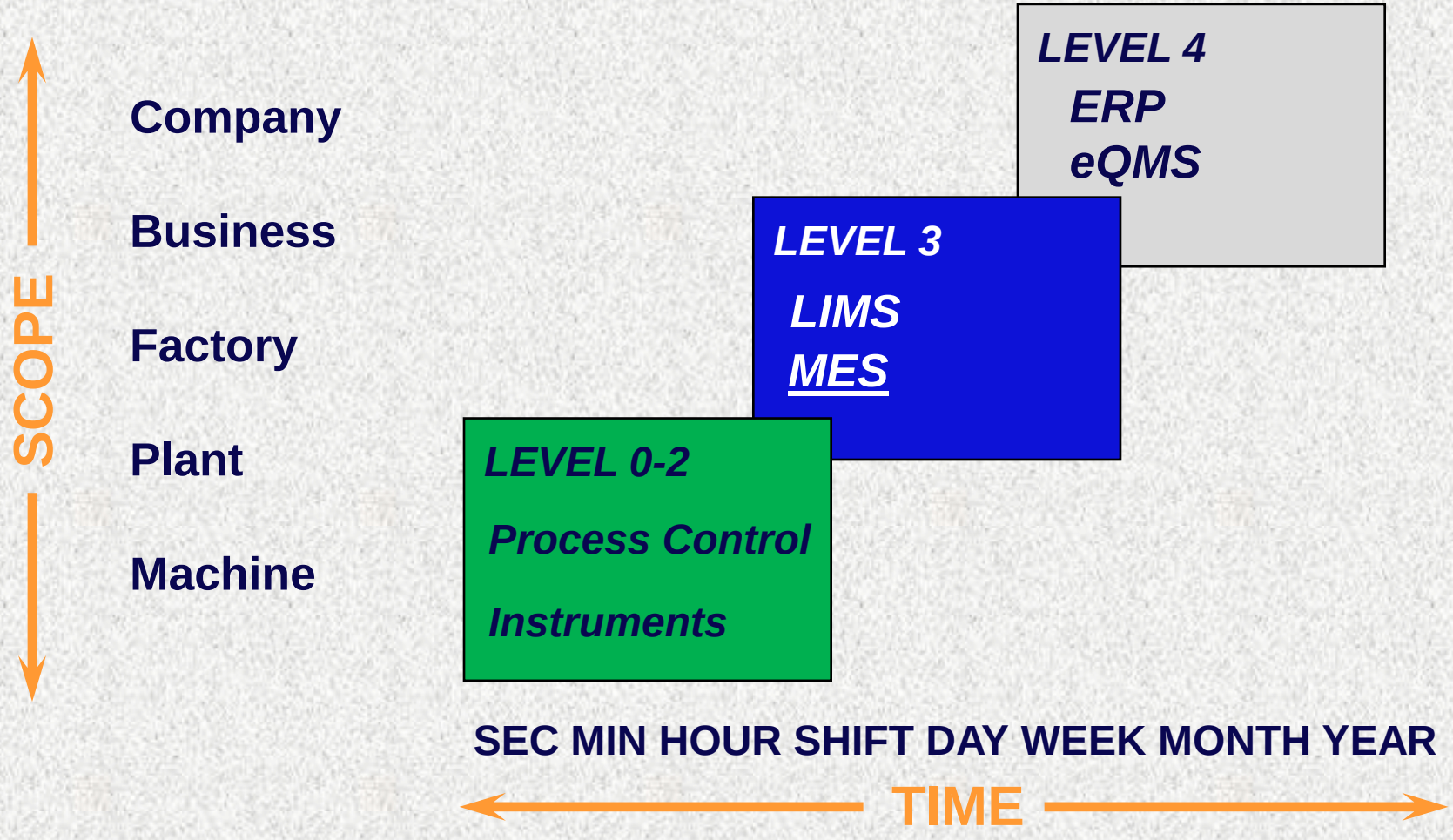
- Manufacturing Execution System (MES)
- A system comprised of hardware and software…
- That helps control (and record) the decisions made by operators and equipment at the point of manufacture
- A capability that removes errors, delays and waste from their processes
- In pharmaceutical manufacturing the key function is to manage the Batch Record *electronically* = EBR

WHAT IS ‘NOT’ MES :

MES IS NOT :

- ERP System
- Planning and scheduling system
- Direct individual machines control system
- SCADA
- LIMS
- QMS
- Document management system
- Historian / Data Storage system
- Plant maintenance system

WHERE MES SITS IN THE IT LANDSPACE



WHERE MES SITS IN THE PROCESS

Paperless production
Electronic workflows
Right first time
Compliance
Assured material flow

Incoming Goods

Storage

Weighing

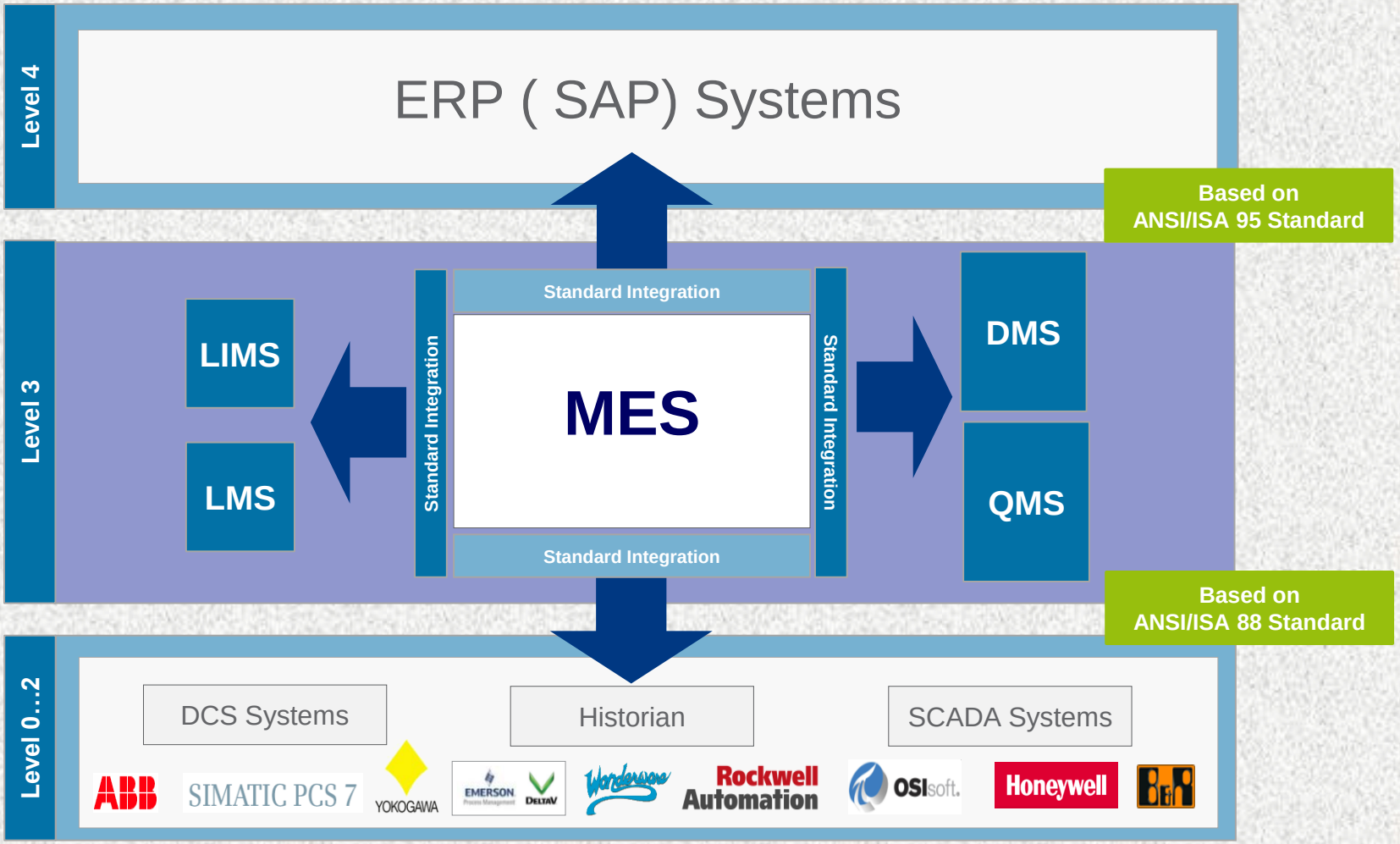
Manu-facturing

Packaging

Order Picking

Leaving Goods

TYPICAL INTERFACING SYSTEMS :

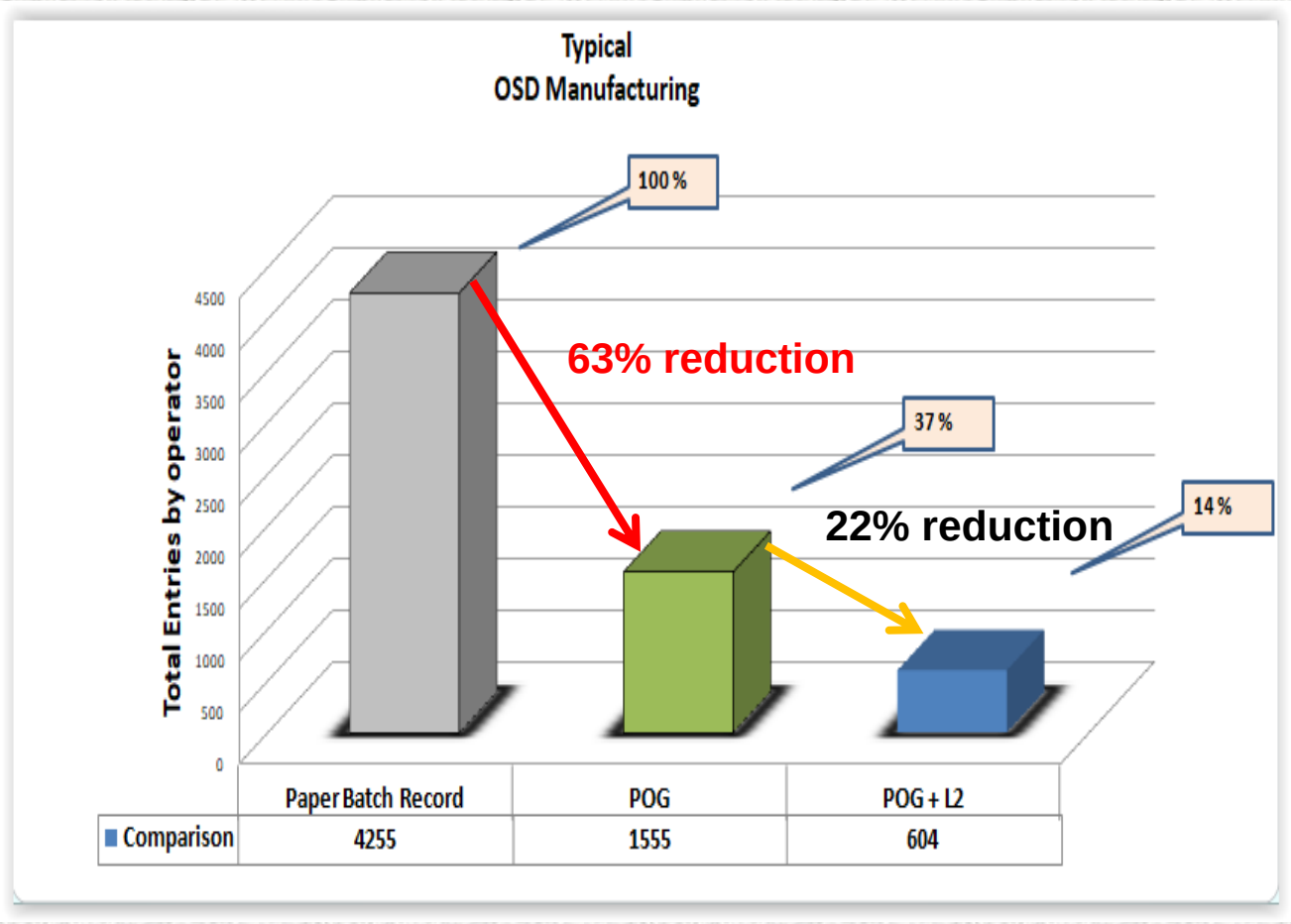


OTHER BENIFTS

EBR WITH MACHINE INTEGRATION: QUANTIFIED BENEFITS

Reduction of defects (product quality) by	25%
Reduction of batch deviations by	80%
Reduction of WIP “Work In Process” by	25%
Reduction of paperwork between shifts by	60%
Elimination of lost paperwork by	80%
Reduction of manufacturing cycle time by	35%
Reduction of data entry time by	80%

Case Study from Indian pharma: MES Impact on Batch Recording efforts by operator



- Study conducted from several Indian Pharma companies shows consistent reduction in the range of 60 – 65% in batch record entries after MES implementation.
- An additional reductions in the range of 20 – 25% is observed after Level 2 automation integration

IMPLEMENTATION CHALLENGES

MES JOURNEY IS NOT EASY !

MES PROJECT CHALLENGES

- Bandwidth
- Ownership
- Redefining roles / Change management
- Managing Expectations
- Cost
- Scalability
- Project Time
- Decision Making
- Launch Strategy
- Centre Of Excellence and training

MYTHS ABOUT MES

- **After MES implementation we can reduce workforce in manufacturing**
- **MES will control machines by connecting to each machine**
- **MES can connect to machines which are not upgraded for connectivity**
- **MES EBR will look exactly like paper batch record**
- **Regulatory Audits with MES take place on paper printout of EBR**
- **MES implementation to drive data integrity is achieved only when we integrate machines (L2) and POG (paper on Glass) option does not add value**
- **MES projects should be given lower priority over automation projects (L2)**

- **We have unique processes and that will require highly customised MES software**
- **There will be hurdles in implementing MES since customers and regulators will raise doubts and my not approve the change**
- **we need different versions or modules of MES to manage different dosage forms or API or even biotech.**
- **It is better to integrate from day zero MES to QMS (Track wise) -CAPA system, LIMS , LMS , L2)**
- **We will need to upgrade MES software more frequently since vendor brings out new versions**
- **We need not change any SOPs and documentation even after MES**

Thanks

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