

PHARMA*process*

Innovation Forum in Pharmaceutical Process

Full paperless operation in a distribution pharmaceutical plant

Case studies: Disalfarm, Cinfa

27/10/15

www.pharmaprocessforum.com

Full paperless operation in a distribution pharmaceutical plant

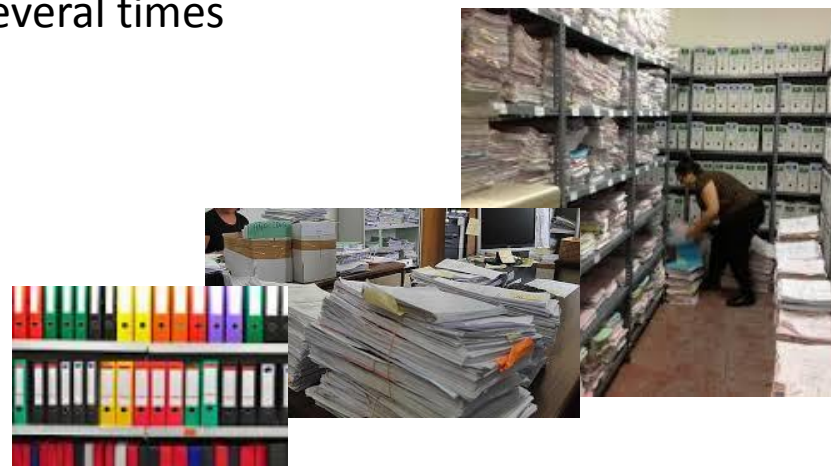
GDP Compliance

- Operations are based on validated procedures
- SOP that ensure that operators always do things the same way
- Batch records, full traceability information
- Information is stored during long periods according to regulation

Good distribution practice (GDP) ensures that the level of quality determined by GMP is maintained throughout the distribution network, so that authorized medicines are distributed to retail pharmacists and others selling medicines general public without any alteration of their properties.

Full paperless operation in a distribution pharmaceutical plant

- Materials management and manufacturing SOP are traditionally based on paper
 - For regulatory compliance inspections and audits needs
 - Certificate's and double checking's
 - Production order execution
- The same data is manually recorded several times
 - Productivity
 - Errors
 - Gaps in the time of update



Full paperless operation in a distribution pharmaceutical plant

Management tools

- Managed by a specialized software that allows:
 - Fully **guided** movements of the operators
 - **Data is entered just once**
 - **Real time** operation
- Information available:
 - Common **database**
 - Track and trace of all material **movements and operations**, Audits
 - Technical data to take advantage of reliable updated information (multi variable analysis, QbD etc...)
 - Global **Visibility**, from Suppliers to Customers

Full paperless operation in a distribution pharmaceutical plant

Key point Identification / automatic data capture

Accurate identification of materials with easy procedures

Barcode; Linear (1D)



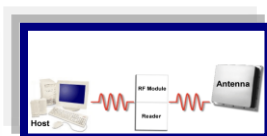
Datamatrix , (2D)



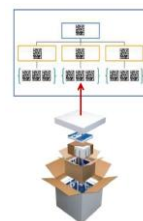
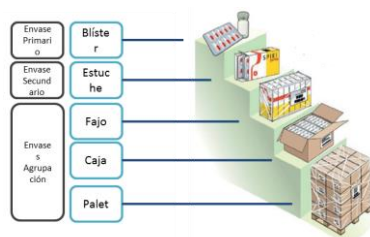
(01)07612345678900(17)100503
(10)AC3453G3



RFID



Serialization



Materials flow

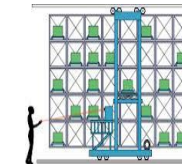
Operations



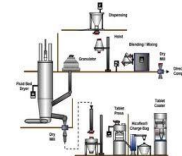
**Raw Materials
Reception**



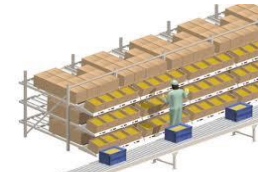
Quality Control
← ← → →



**Warehouse
Management**



**Recipe management
and manufacturing**



**Picking and
distribution**

Information



Monitoring

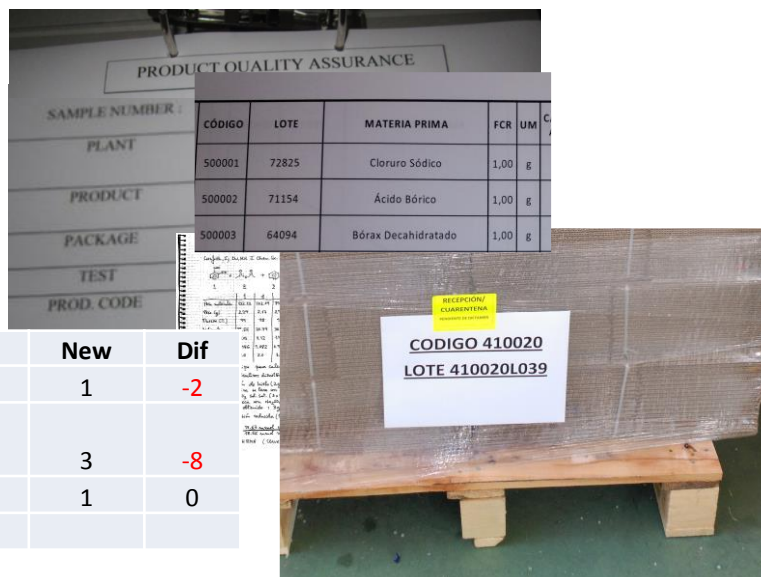


Managing materials in a facility

Paperless operation in a regulatory environment

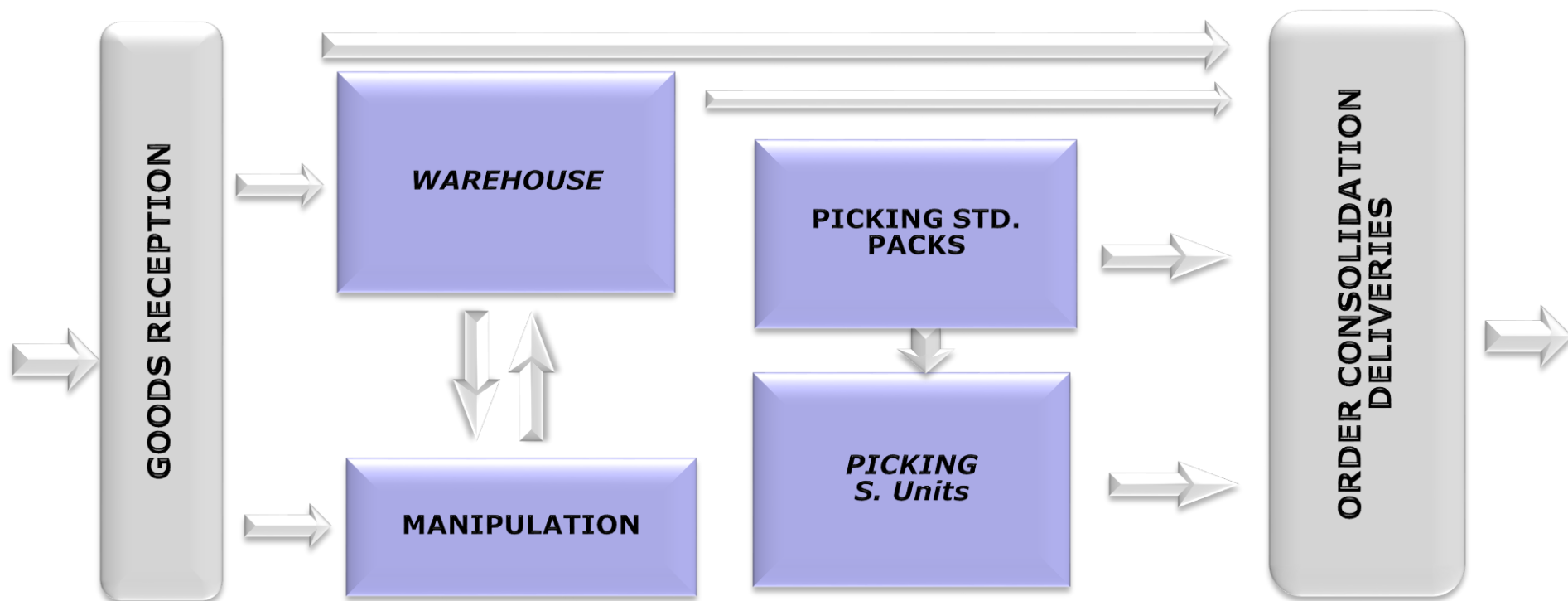
- SOP include several operations that can be suppressed

Operations	Actual	New	Dif
Labels	3	1	-2
Manual data input /Writing/Printing/Labelling	11	3	-8
Physical Movements	1	1	0
Average time x pallet seg.			



Full paperless operation in a distribution pharmaceutical plant

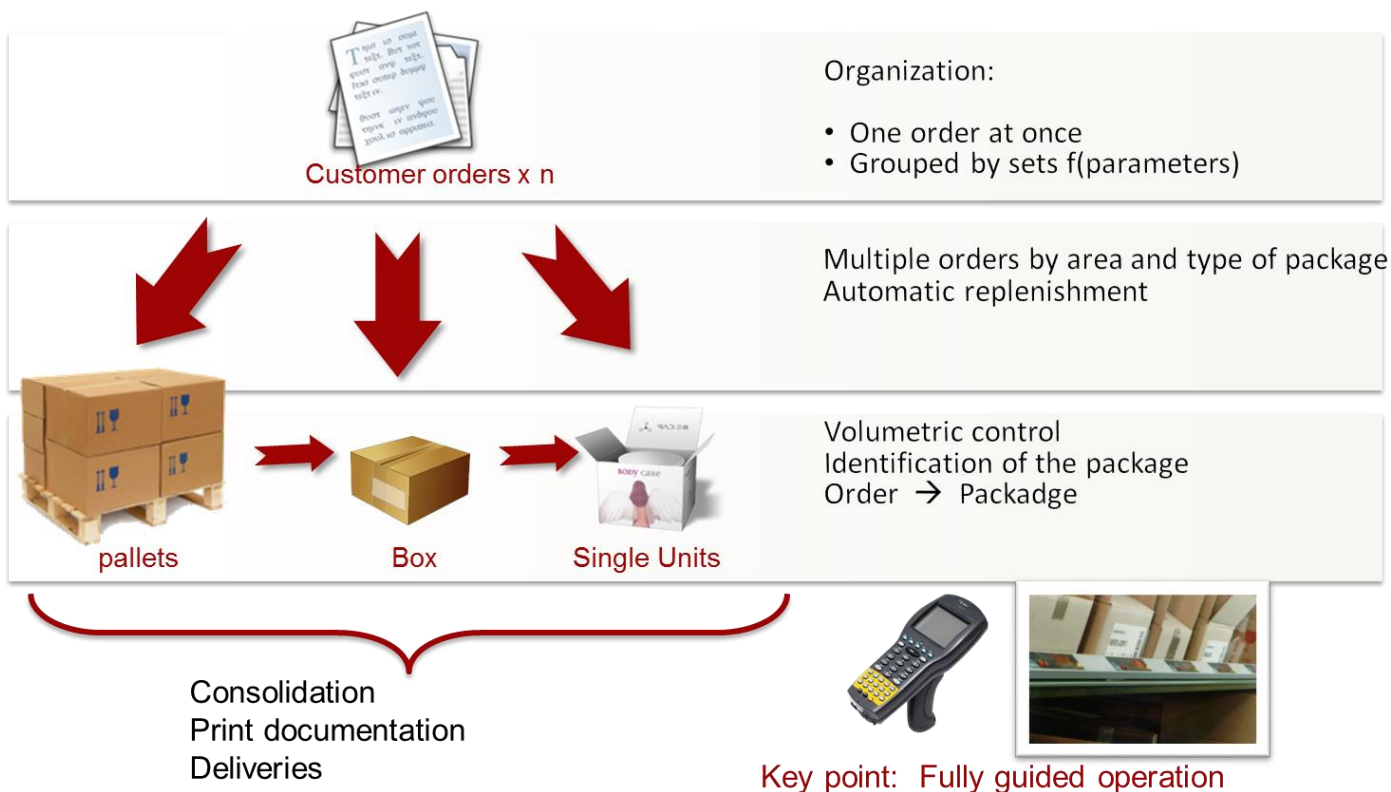
Working areas, Quality assurance



Areas, temperature 2-8°; 15-15° etc; psychotropic;

Full paperless operation in a distribution pharmaceutical plant

Order grouped to optimize performance



Full paperless operation in a distribution pharmaceutical plant PICK TO LIGHT

PICK TO LIGHT

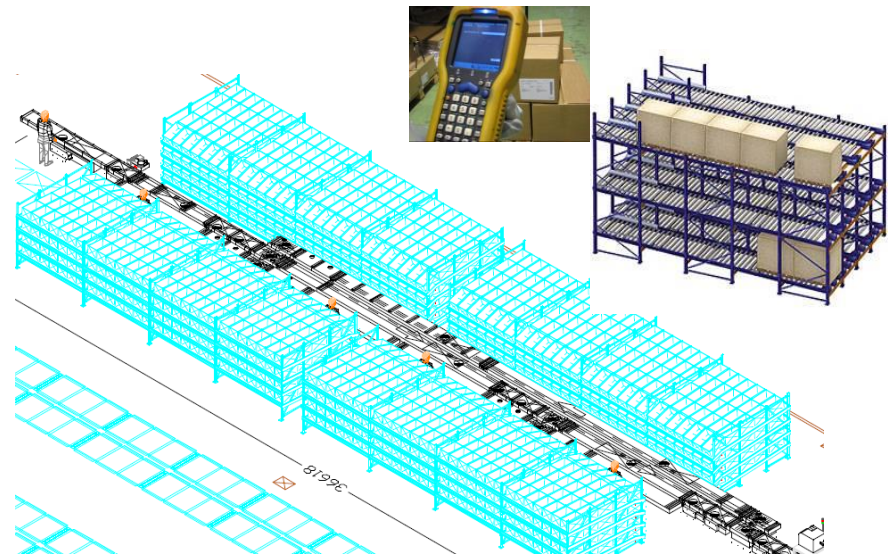
Products are assigned in each **zone** (operator)

Order boxes are automatically distributed to each picking zone

System “**man to product**”

Fully paperless operation, automatic batch capture

Fully traceability compliance



Full paperless operation in a distribution pharmaceutical plant PICK TO LIGHT



Full paperless operation in a distribution pharmaceutical plant PUT TO LIGHT

PUT TO LIGHT

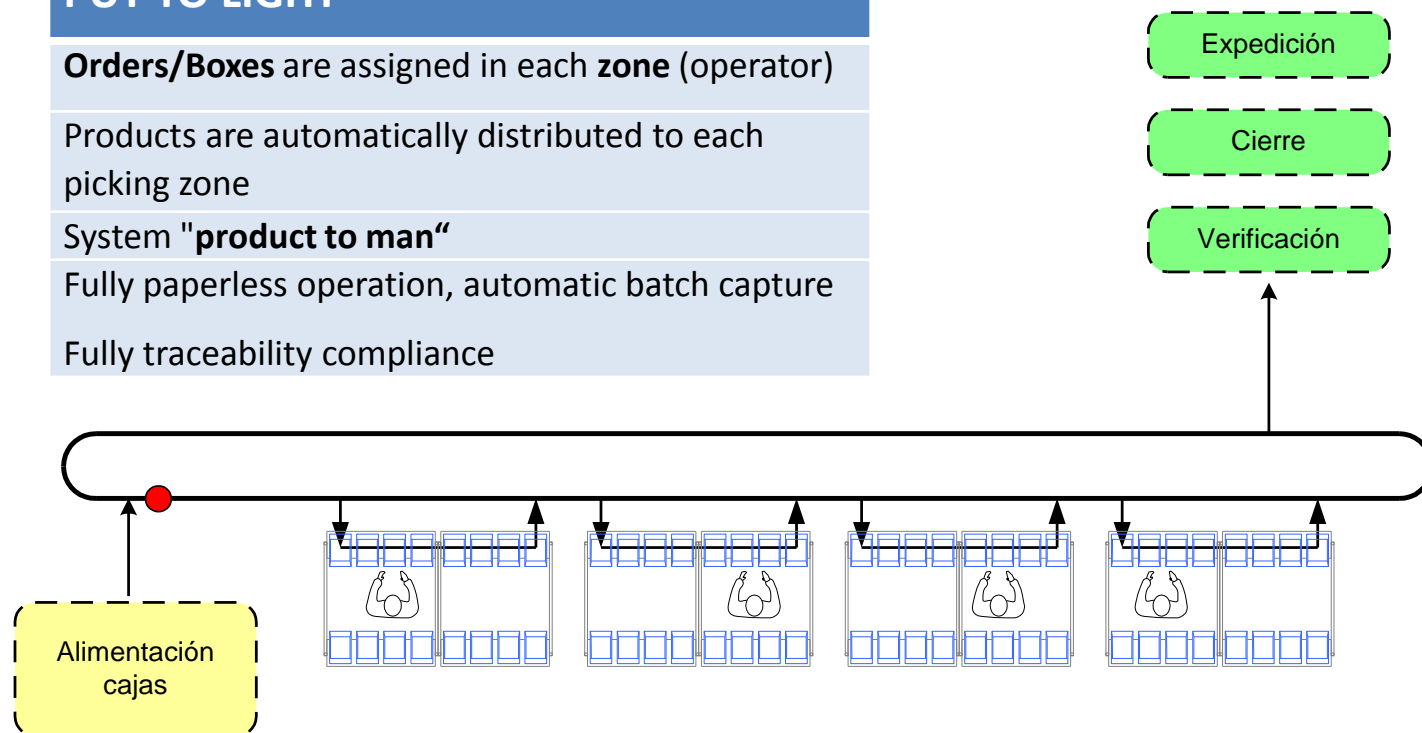
Orders/Boxes are assigned in each **zone** (operator)

Products are automatically distributed to each picking zone

System "**product to man**"

Fully paperless operation, automatic batch capture

Fully traceability compliance



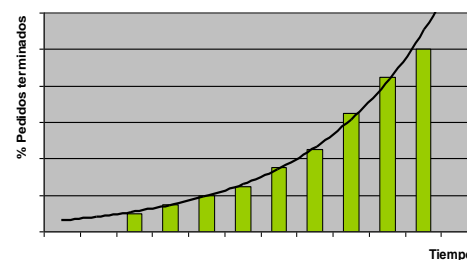
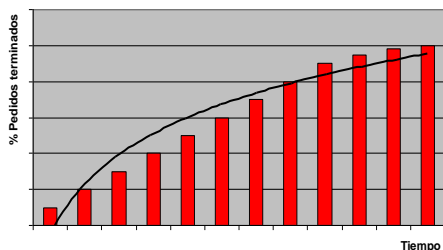
Full paperless operation in a distribution pharmaceutical plant PUT TO LIGHT



Full paperless operation in a distribution pharmaceutical plant

Single Units Picking

PICK TO LIGHT	PUT TO LIGHT
Products are assigned in each zone (operator)	Orders/Boxes are assigned in each zone (operator)
Order boxes are automatically distributed to each picking zone	Products are automatically distributed to each picking zone
System “ man to product ”	System “ product to man ”
Fully paperless operation, automatic batch capture	Fully paperless operation, automatic batch capture
Fully traceability compliance	Fully traceability compliance

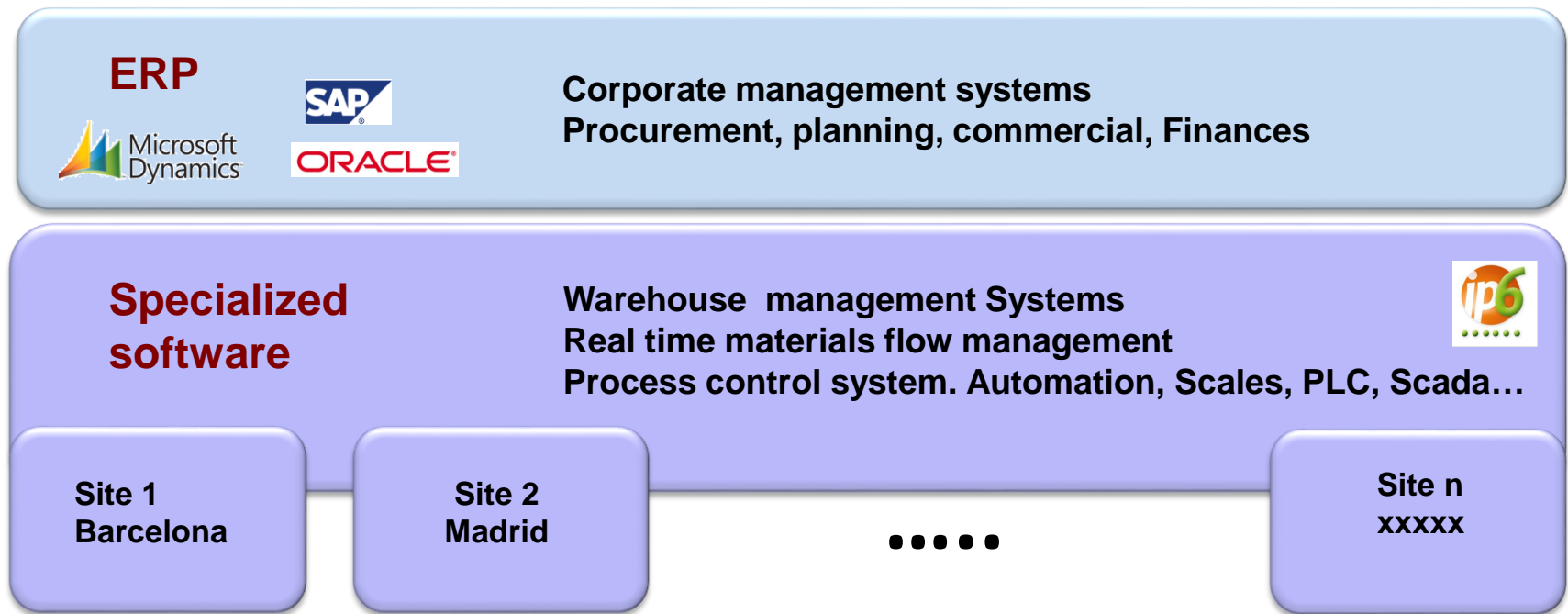


Full paperless operation in a distribution pharmaceutical plant

Standard packs



Full paperless operation in a distribution pharmaceutical plant Information levels



Paperless SC and manufacturing tools are based on specialized software that uses electronic records and electronic signatures.

Full paperless operation in a distribution pharmaceutical plant

Competitiveness tools of Food and Automation sectors

The world is changing, and sectors that lead operation management use sophisticated software tools



'Design Thinking' driving
Global Supply Chain
networks from
complexity to
simplicity



Full paperless operation in a distribution pharmaceutical plant

Materials **identification**

Flow management, **real time** guided operations

Flexibility

Change controls

Global **visibility**

Reducing:

Validation times

Training cost and resources

Improving:

Productivity

Reliability

ERP



ORACLE

**Corporate
management
systems**

**Specialized
software
tools**

**Warehouse
Automation
Process control
MES, LIMS, eBR**

Managing materials in a facility

Paperless operation in a regulatory environment

Fully Auditable



Paperless data



Highly Efficient



ROI



Guided Operations



100% Compliant





Thanks for your attention



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