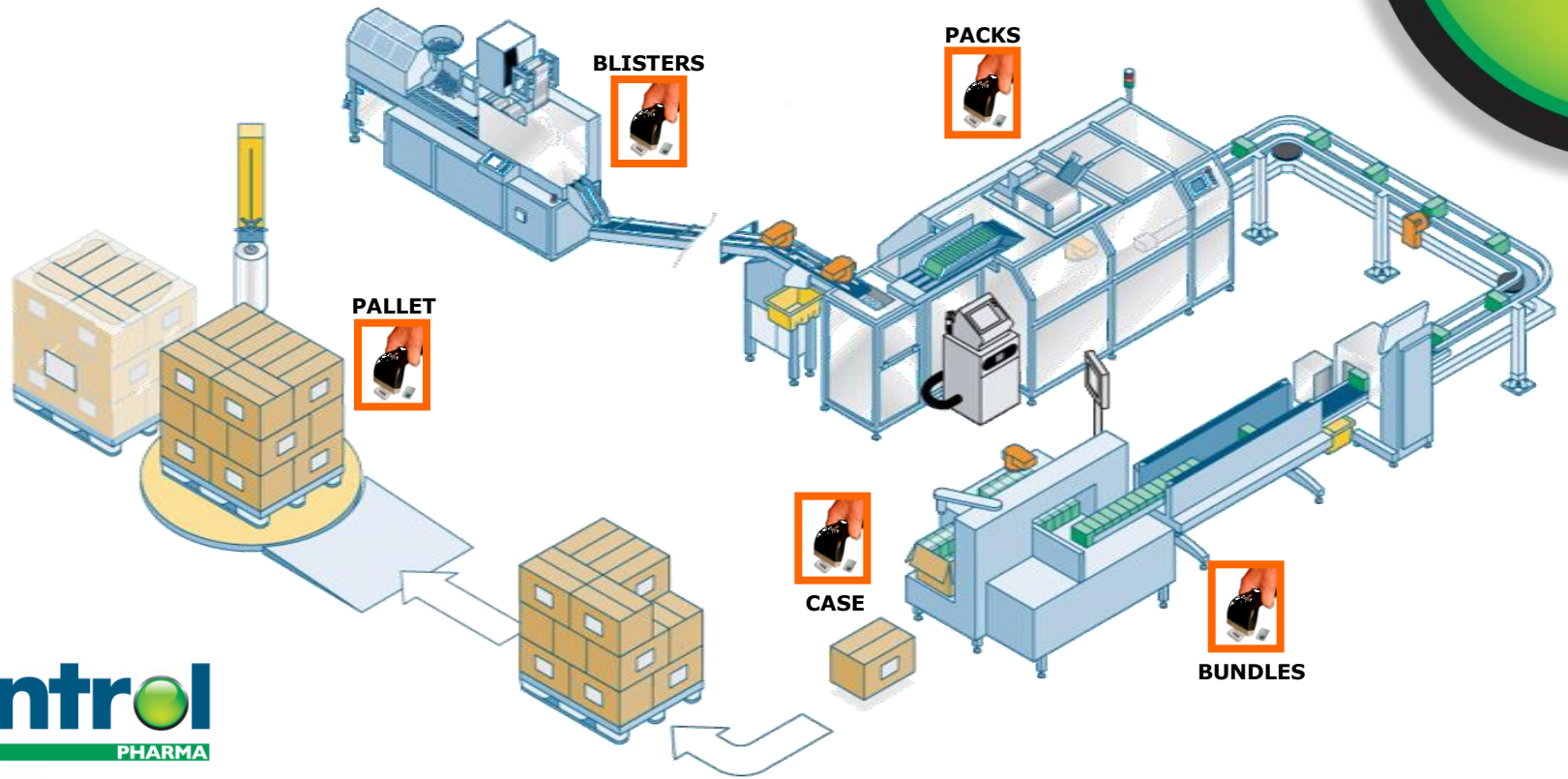
Building a fully integrated solution.

Presenter

Control PHARMA

DOMINO Group Company

Integrated Line



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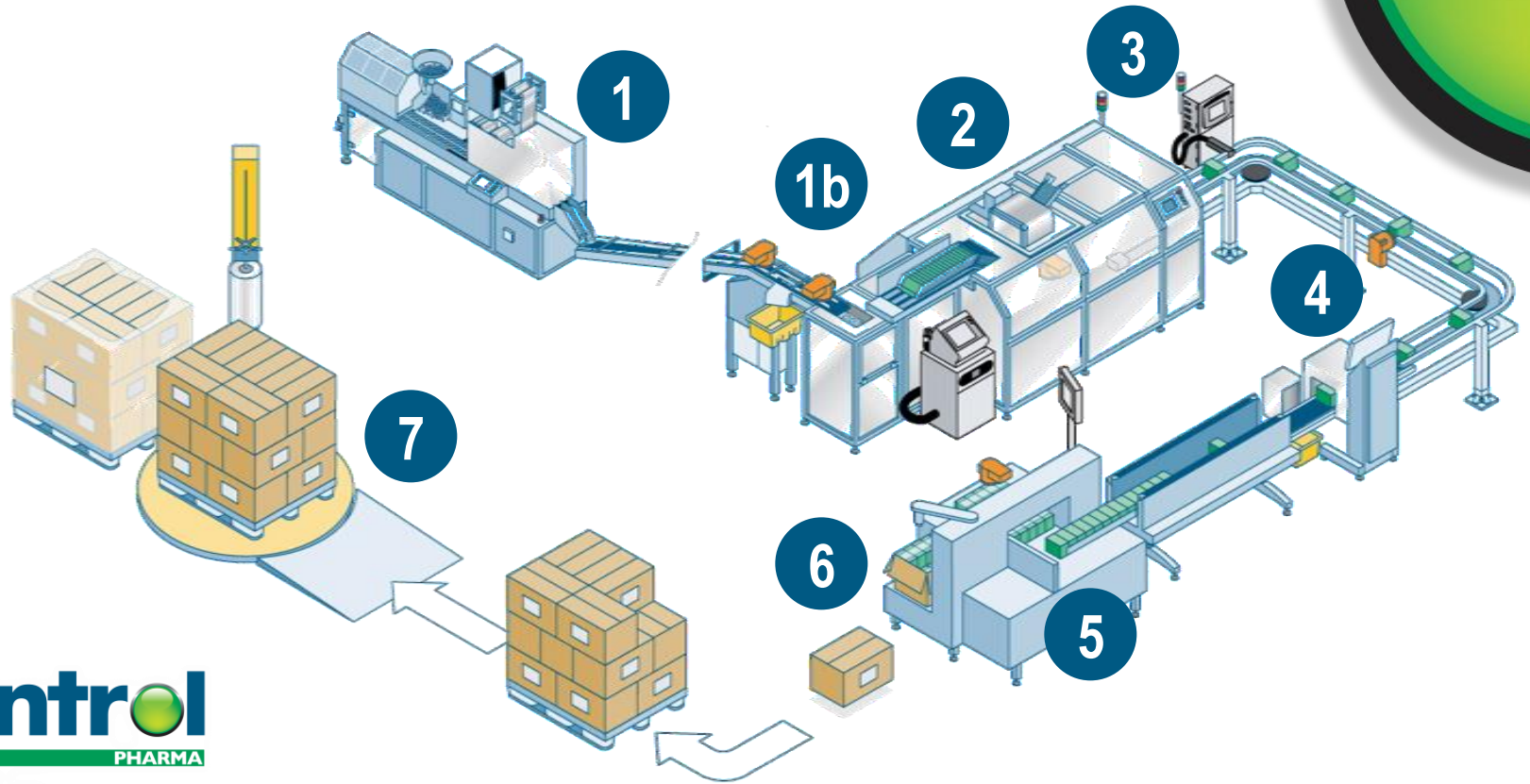
Identified Processes:



Control PHARMA

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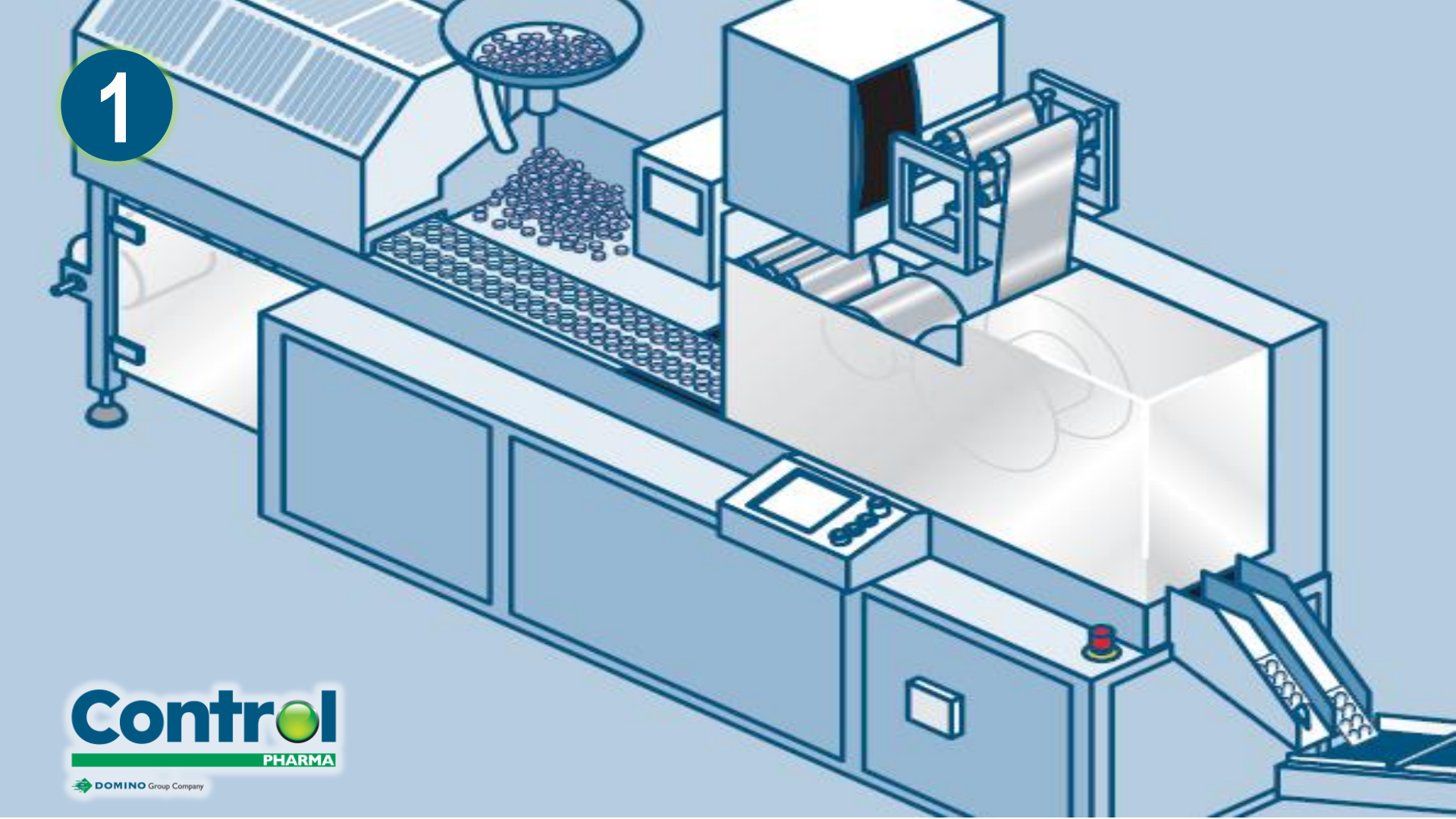

Control
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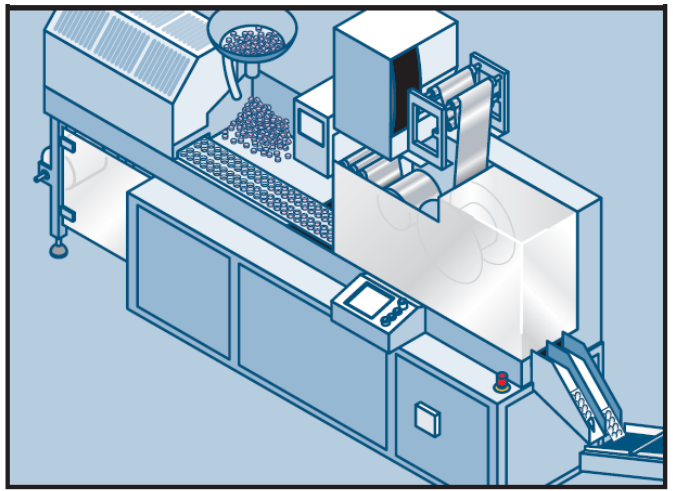
1 Unique Pouch Marking:

- Interface to retrofitted existing equipment
- User interface – batch & order set-up, production execution and visualisation
- Code generation and allocation managed by Control
- Data Matrix and human readable codes on each blister pouch or pocket



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1 Unique Pouch Marking:

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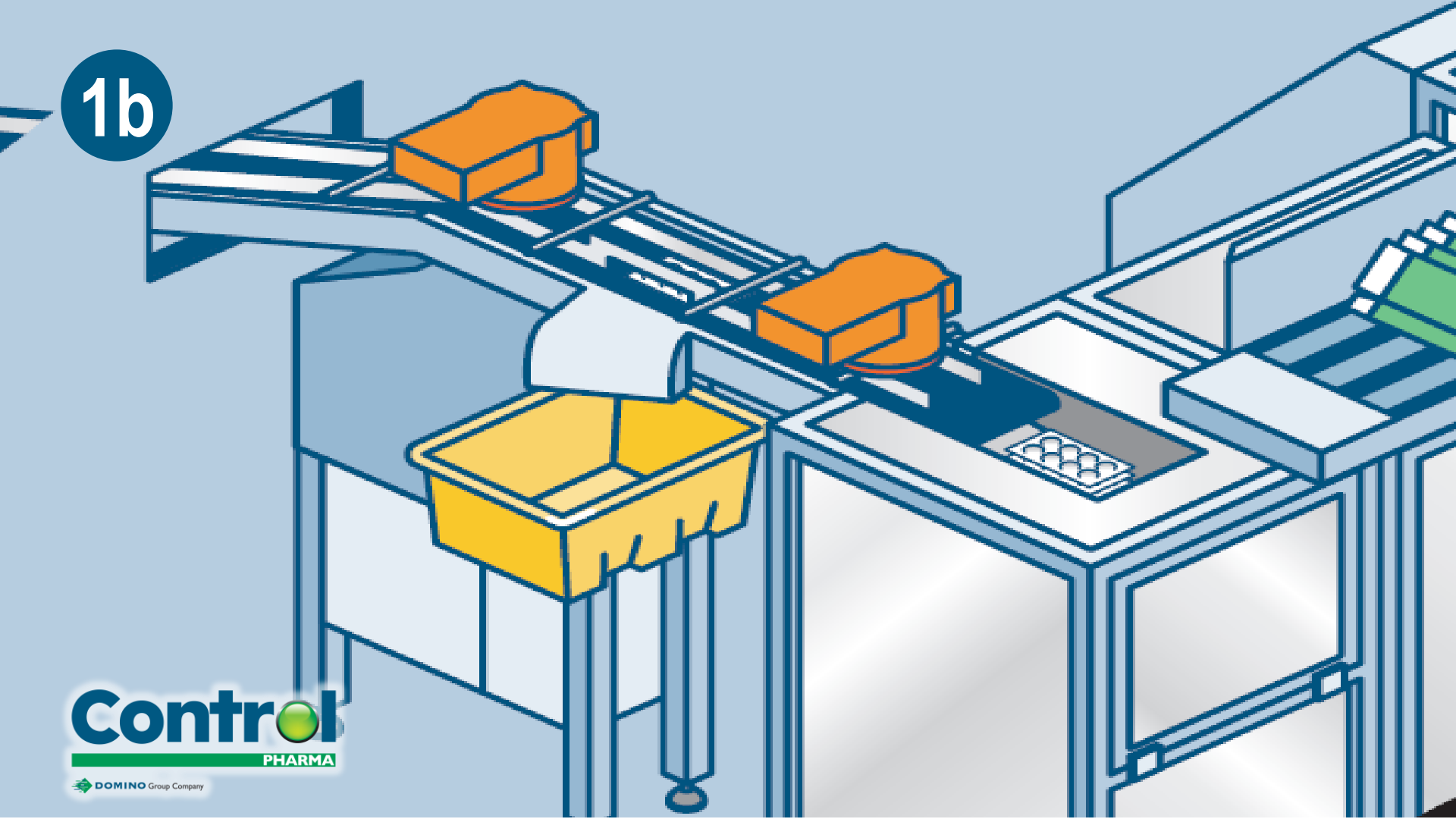
1b
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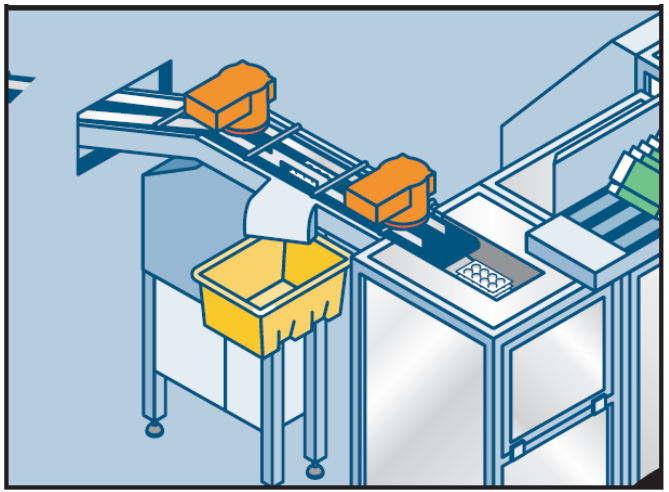
1b Blister Code Verification:

- Read and check content of each pouch code at variable production line speed
- Recording of blister and pouch code aggregation
- Rejection of blisters with faulty codes & reporting of ‘wasted’ codes
- Synchronisation process to detect any type of manual intervention to the system



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1b Blister Code Verification:

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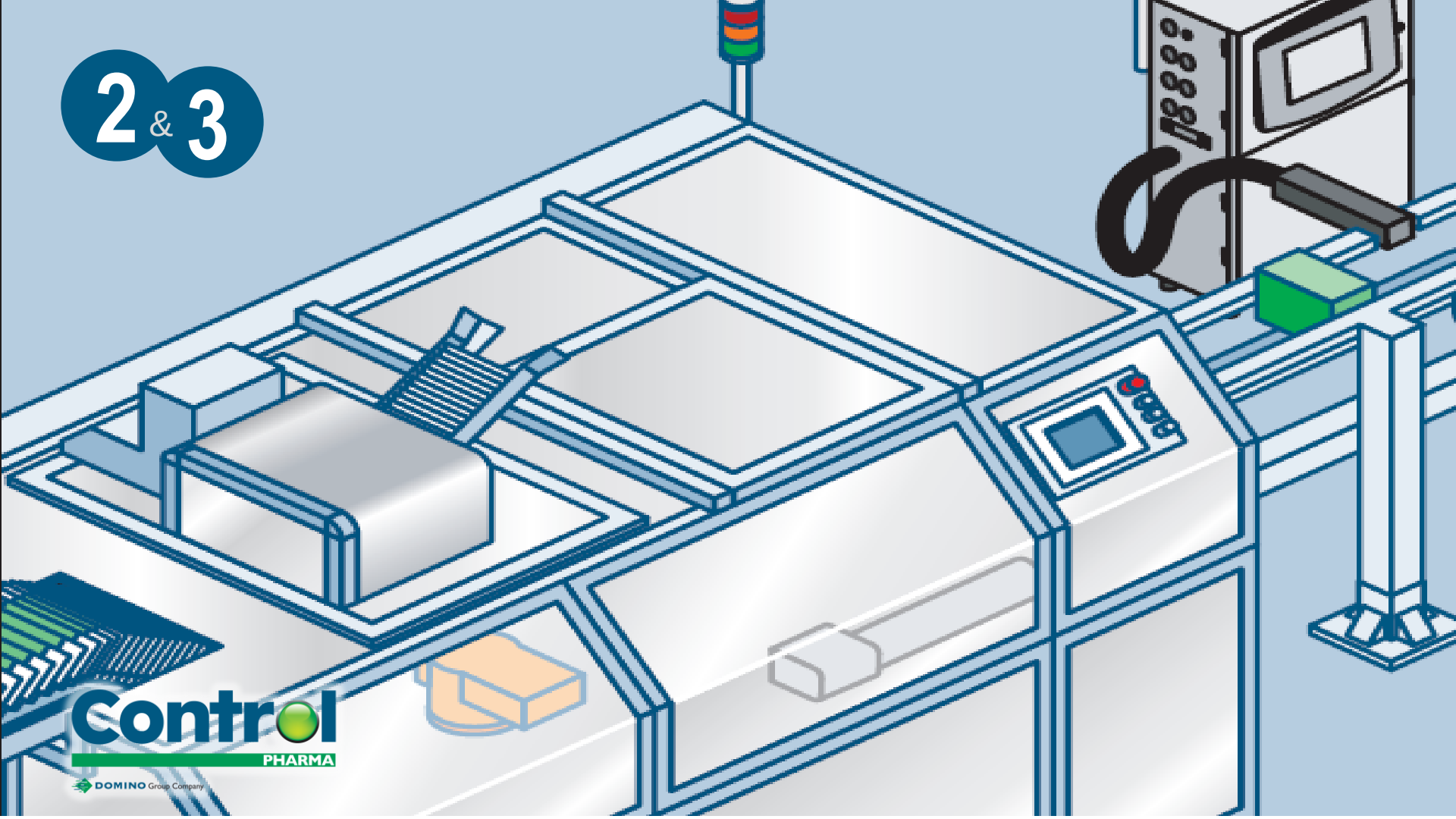
2 & 3
Control
PHARMA
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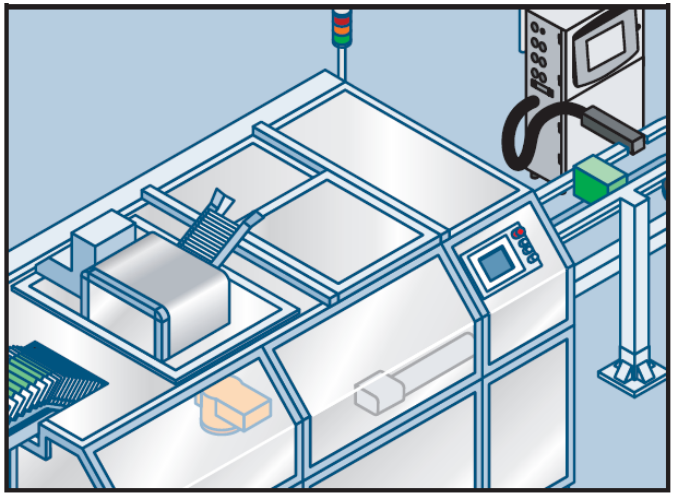
2 & 3 Carton identification:

- Monitor blister stack and verify prior to packaging process
- Supervision of the article specific pile scheme
- Carton code generation and allocation managed by Control
- Data Matrix codes and human readable text marked onto each carton
- Pack marking prior to packaging process
- Read and check content of each carton code
- Recording of carton and blister code aggregation
- Rejection of cartons with faulty codes & reporting of ‘wasted’ codes

- Optional continuous ink jet printing to mark additional human readable text



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2 & 3 Carton identification:

Control PHARMA

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2 & 3 Carton identification:

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2 & 3 Carton identification:

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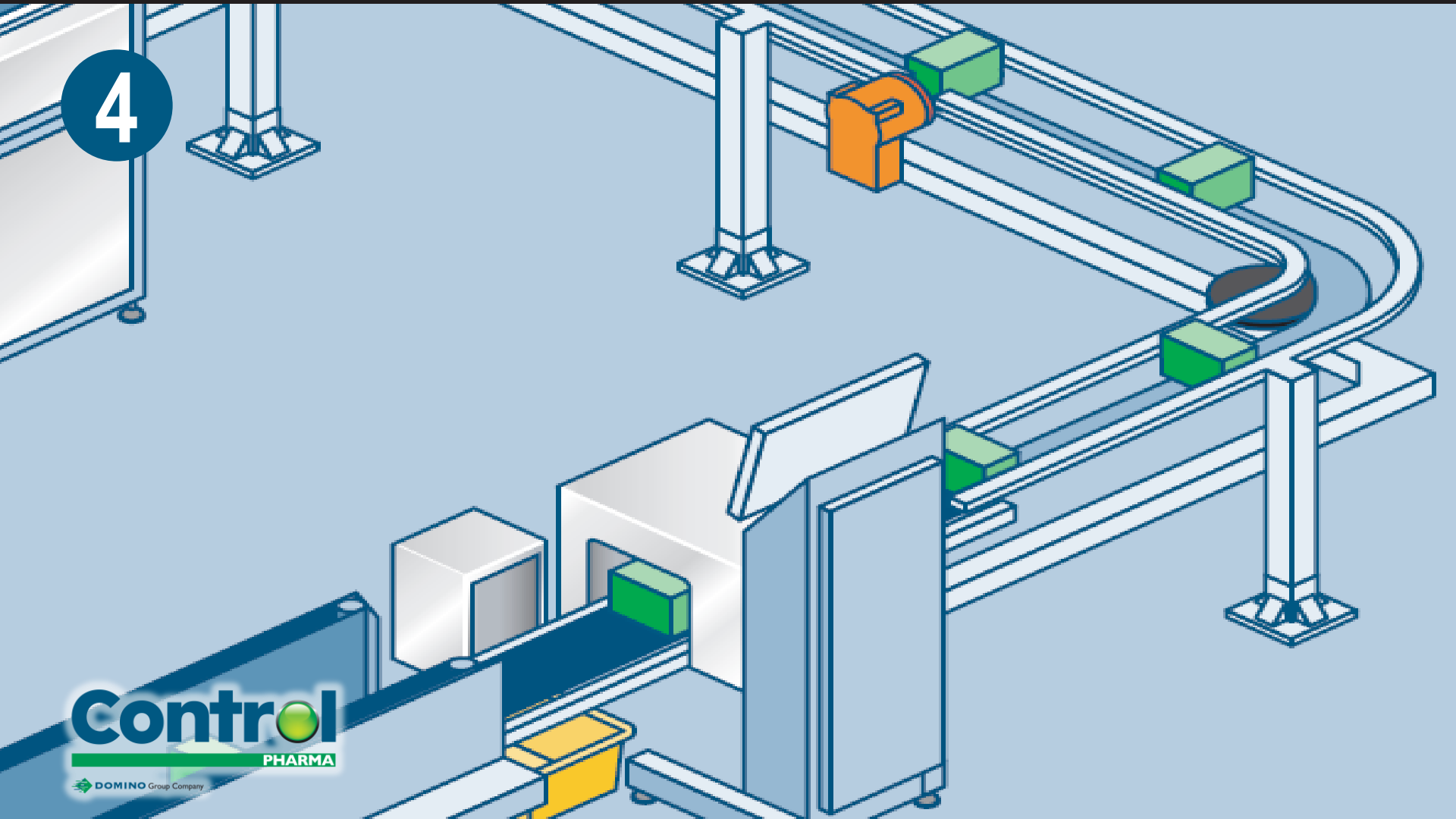
4
Control
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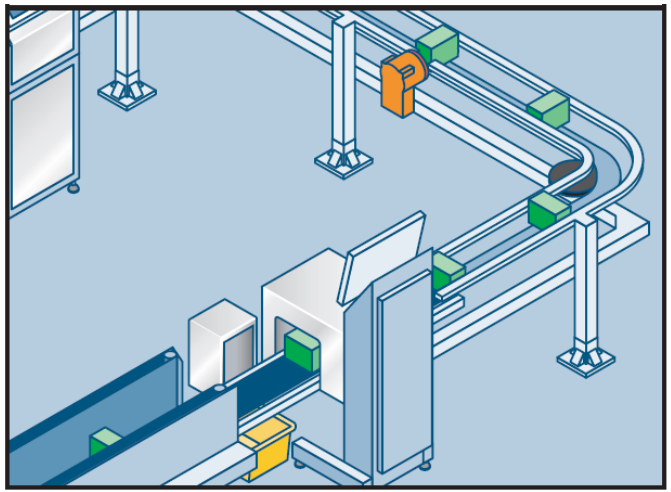
4 Carton Code Verification & Check Weighing:

- Read and check content of each carton code
- Recording of carton & blister code aggregation
- Rejection of cartons with faulty codes & reporting of ‘wasted’ codes

- optional Carton check weighing to register completeness of a carton & weight statistics on single carton level



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4 Carton Code Verification & Check Weighing:

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Control PHARMA
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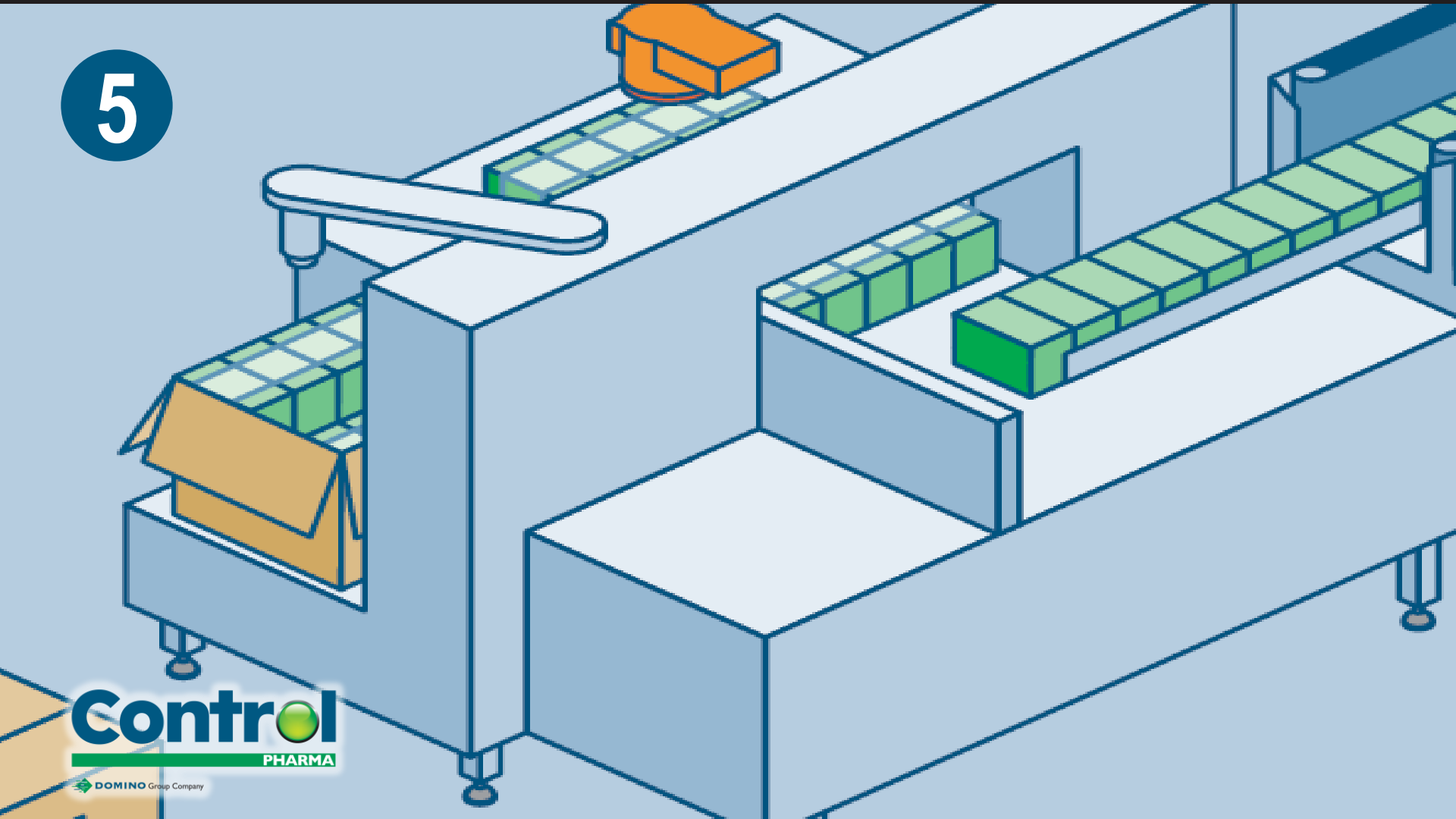
4
Carton Code Verification
& Check Weighing:
Control
PHARMA
DOMINO Group Company


5
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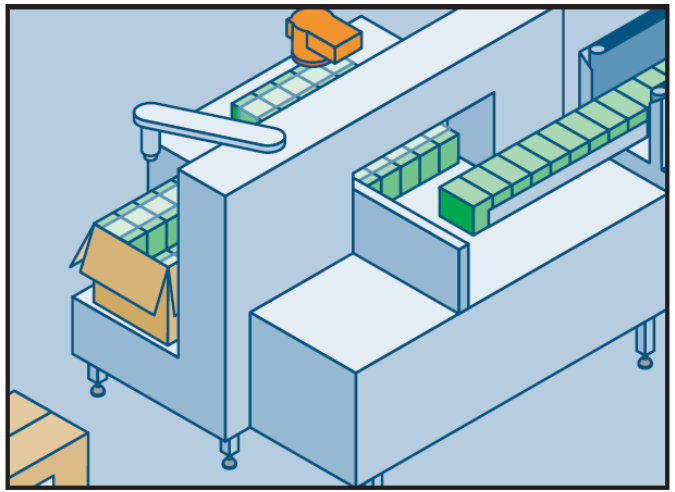
5 Bundling/Multi-packing:

- Cartons are packed into bundles
- Read and check content of all carton codes in the bundle simultaneously
- Read and check aggregation of bundles to cases



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5 Bundling/Multi-packing:

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5 Bundling/Multi-packing:

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5 Bundling/Multi-packing:

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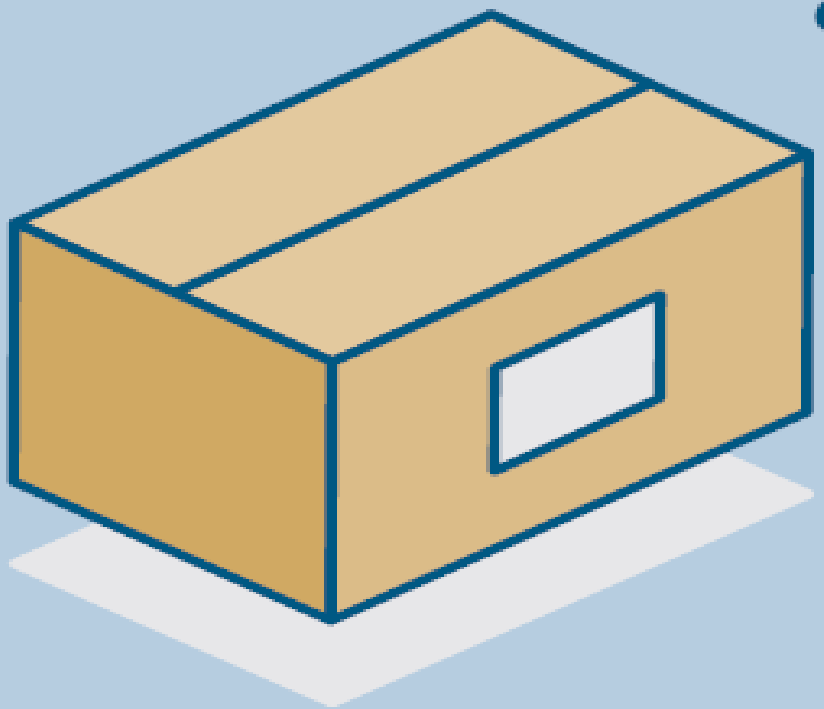
6



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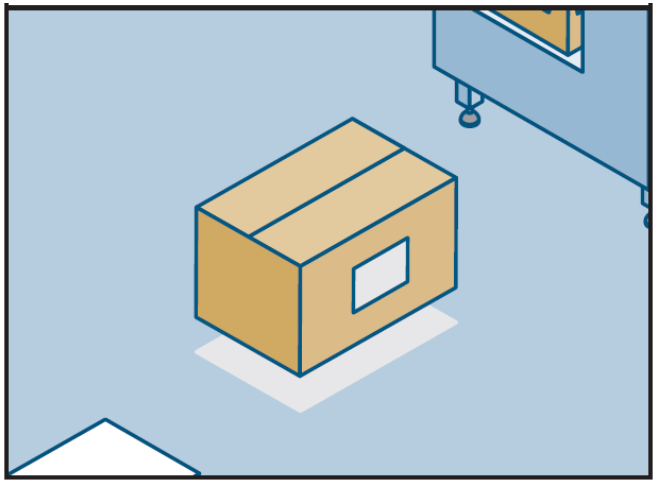
6 Case Identification:

- Code generation and allocation managed by Control
- Application of hybrid case labels
  RFID , EAN 128 barcode, and human readable text or optional Data Matrix
- Read and check content of all RFID & bar codes on case labels
- Continuous scanning of the case label during the packing process to detect any manual intervention
- Recording of case and pallet code aggregation
- Supervision of the article specific packaging scheme
- Management of semi finished cases



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6 Case Identification:

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7

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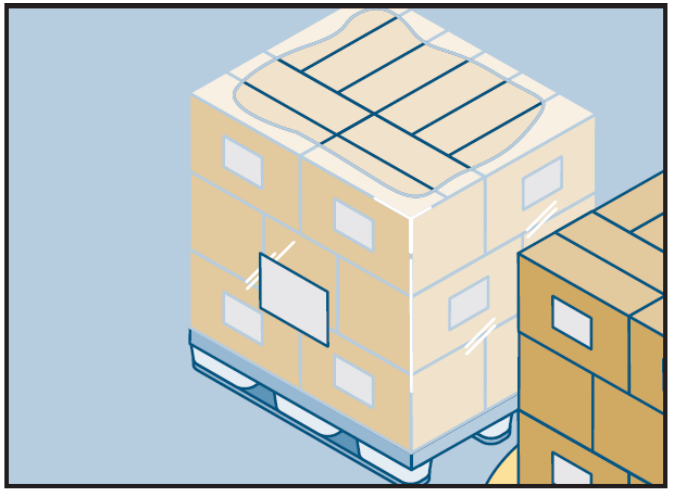
7 Pallet Identification:

- Read and check content of all RFID case labels during the stretch-wrapping process
- Cross check on consistency of pallet and case code aggregation via verification of all case and pallet RFID codes
- Pallet code generation and allocation managed by Control
- Print and application of hybrid pallet labels (RFID, EAN 128 barcode and human readable text)
- Management of semi finished pallets



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7 Pallet Identification:

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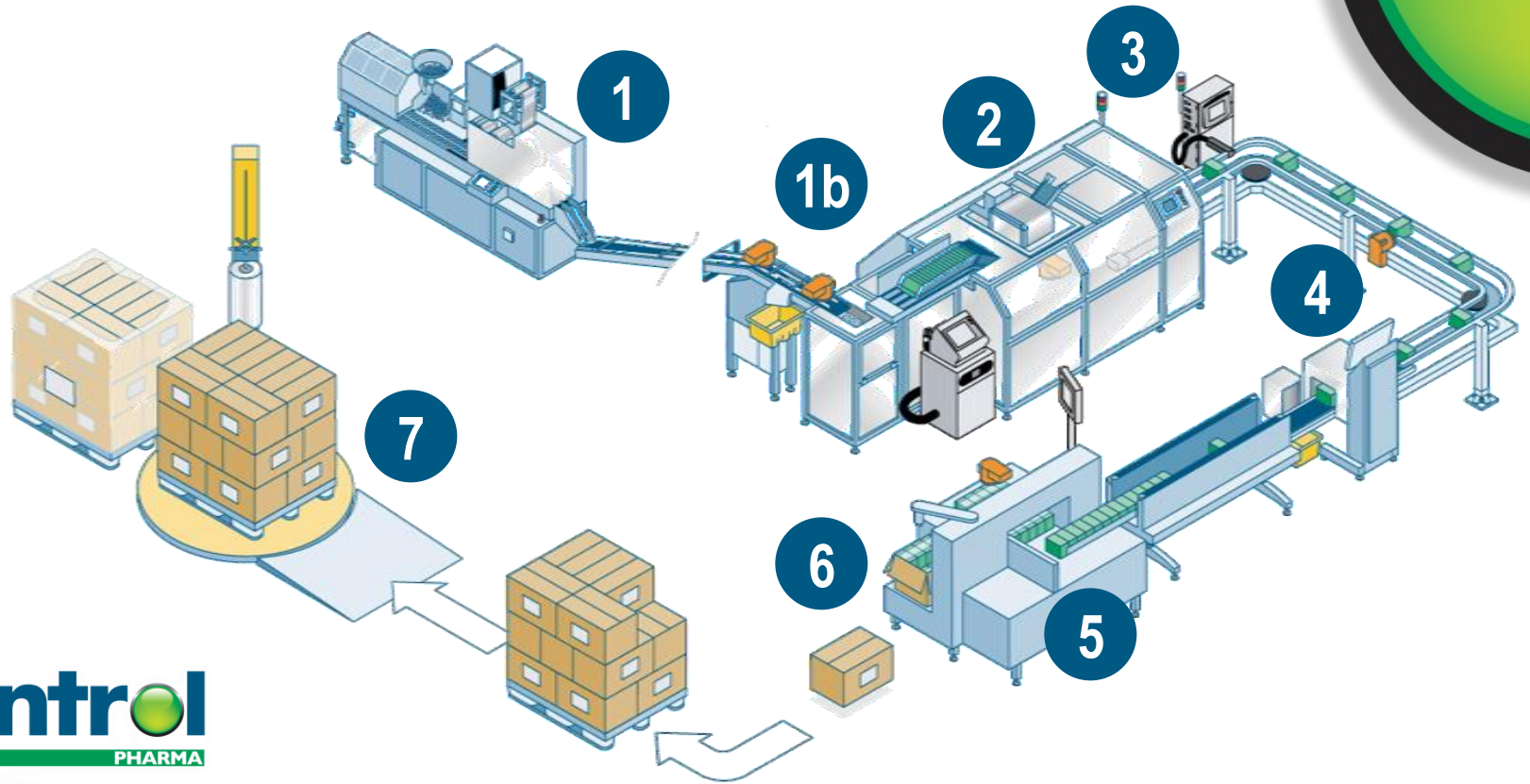
Identified Processes:



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The Trial Pack:

Control PHARMA

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The Trial Pack:

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Building a fully validated software solution.

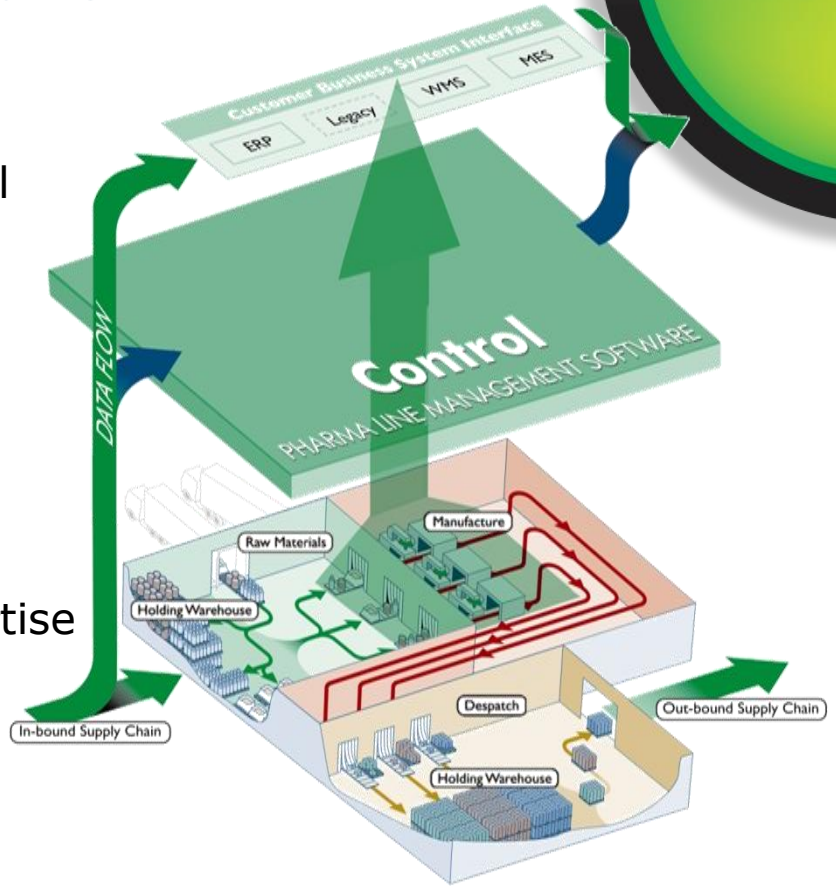
Presenter

Control PHARMA

DOMINO Group Company

Overview of Control Software

- High level architecture
- System configuration: Server/client model
- Product Philosophy
- Hardware: Line Controllers
- Machine and 3rd party interfaces
- Core functionality
- Quality assurance – Pharmaceutical expertise



Control PHARMA

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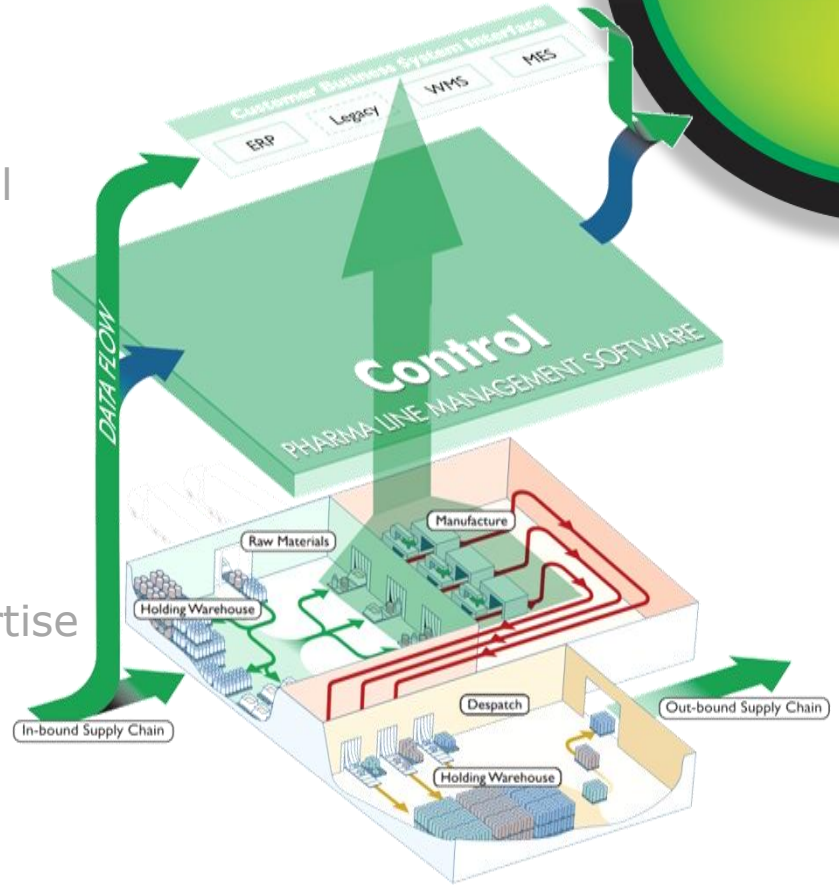

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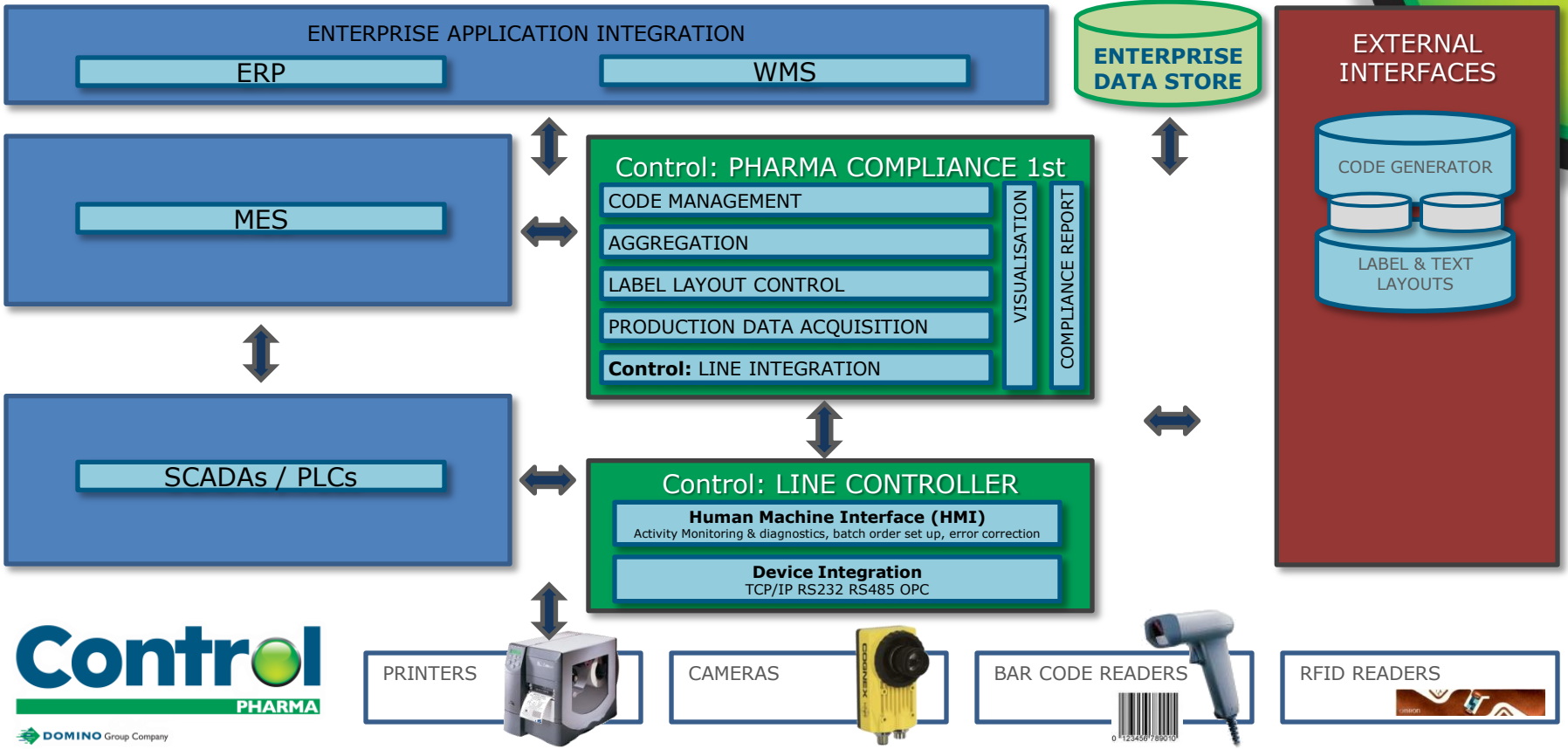
High level architecture



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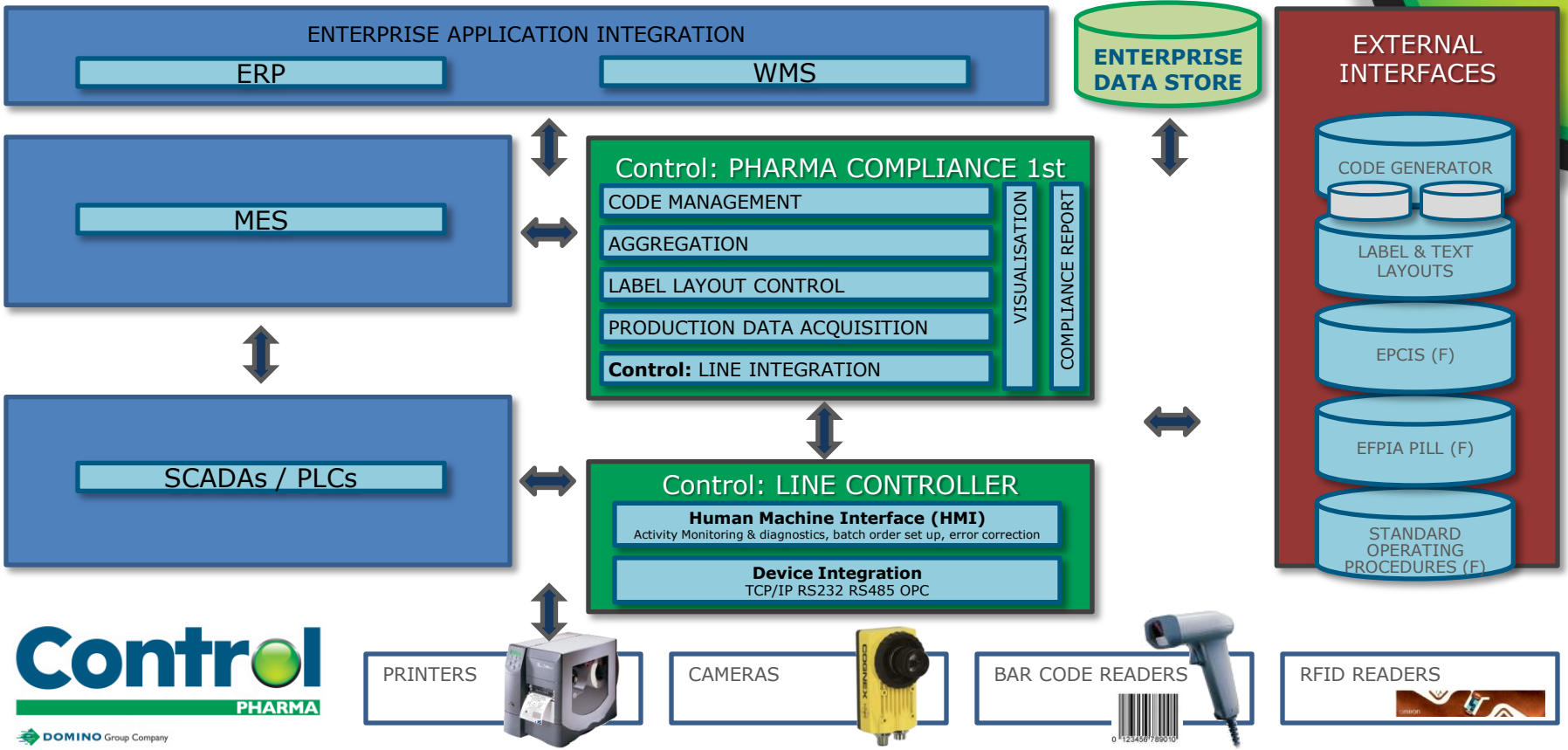
High level architecture



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System Configuration: Server/Client model

- At a local level

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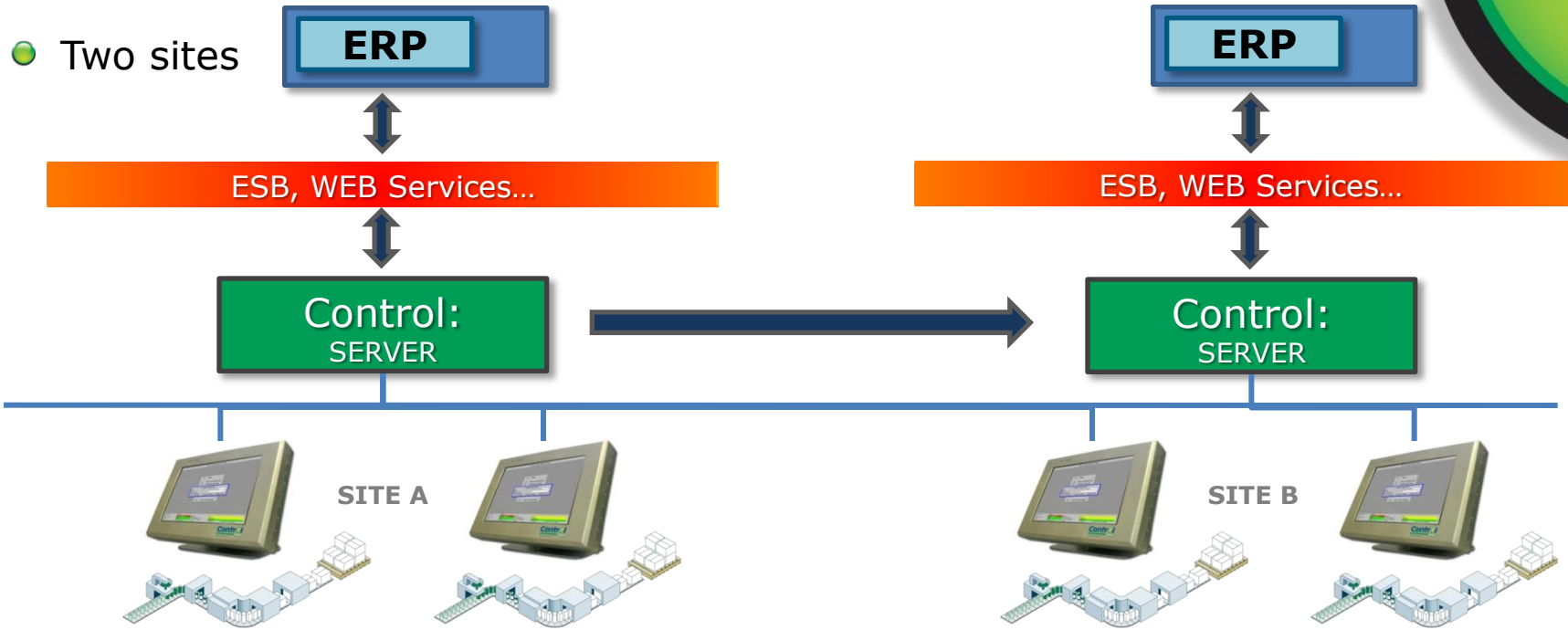
System Configuration: Server/Client model

- Two sites



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Advantages of Control System & Structure

- Flat model – with only two stages (clients and server)
- Core system functionality and critical processes centralised on the server
- Cascadable on server level
- Multiple (software) servers on a single hardware (server)
- Completely separated application and database server
- Optimised (re)-validation process
  - ie: test system, qualification system, production system
- No redundant data on the clients (line controllers)

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Advantages of Control System & Structure

- Line client failure management and maintenance
  (net/power loss failure etc.)

  - No hard drives. FLASH-based. No temporary files
  - OS is like the firmware of a PLC controller
  - Boots line application based on customisation via network from server system
  - Auto-reconnect on network failures
  - Power and network failure secure
    because no data is held on the line client
  - All application configuration is stored
    within the database
  - Easy, menu based client customisation tool

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Overview of Control Software

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Product Philosophy

- Solely global, open standards (HTML,TCP/IP, ...)
- Simple, secure operation
- Modular system design
- Customizable at customer level
- OS independent, runs on every OS that supports Java
- Manipulation secure
- 100% Acquisition of all production relevant Data
- 100% Coverage of all manufacturing stages

Overview of Control Software

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Two types of line controllers

- With and without User Interface (UI)
- Device integration (TCP/IP RS232 RS485 OPC)
- UI: Batch/order set-up, Device status monitoring, error/alarm messages

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Overview of Control Software

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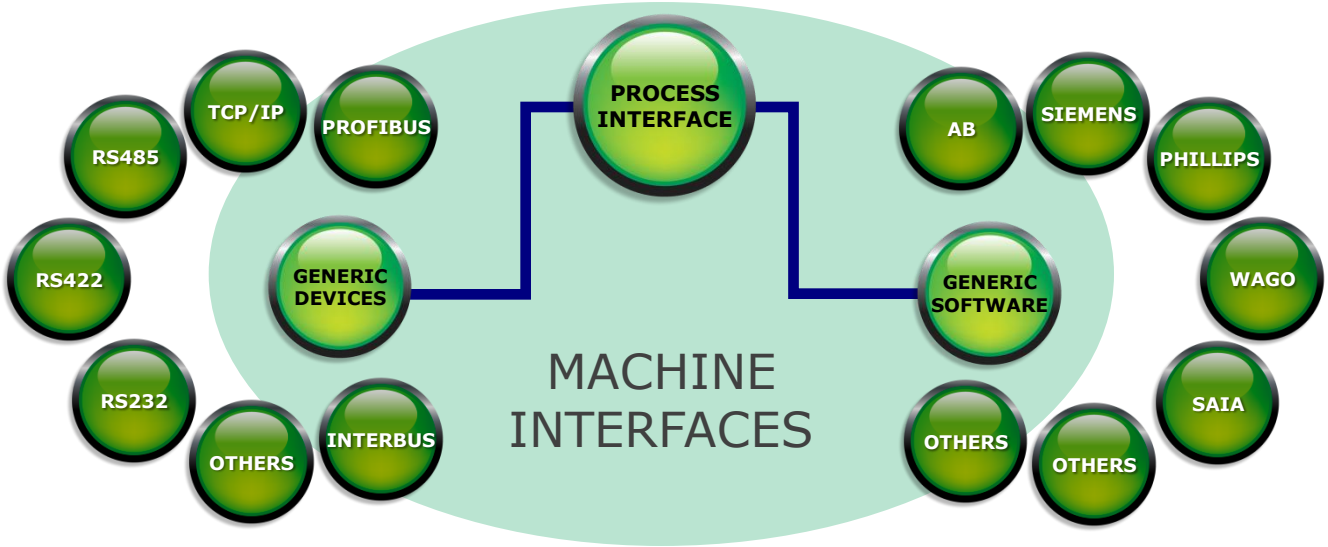
Device Management: Machine Interfaces

- Connection via standardized process interfaces
- Standard interfaces for devices and PLC s via direct connection or programmable controllers
- Single requirement: communicative device



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Machine Interfaces

- Integration with a wide range of equipment:
  - Inkjet and Laser Printers
  - Label print & apply
  - 1/2D scanners and RFID
  - PLCs and SCADAs
  - Vision systems, check weighers
  - Carton erectors
  - Line servers
  - Other
- Multiple vendors
  - e.g. Domino, Markem, Altec, Alien, Impinj, Siemens, Cognex, Laeutus, MicroScan, Sick

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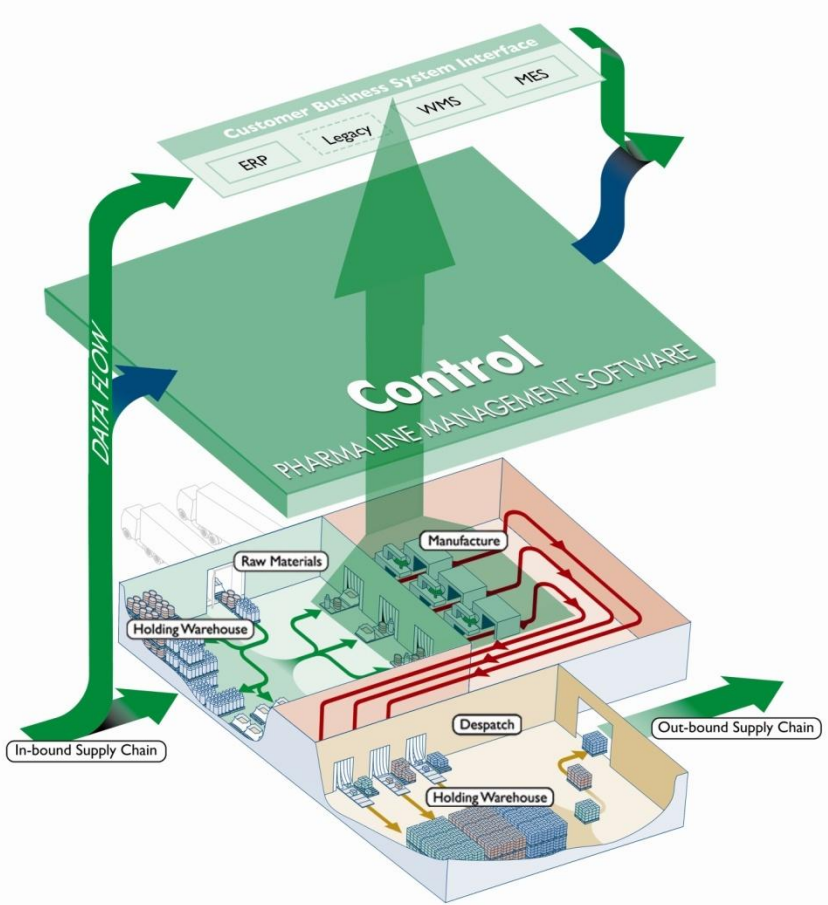
3rd Party Interfaces

- Standard interfaces to all major proprietorial ERP,MES and WMS Systems.
- Import and export of production relevant master data for production and serial/random numbers for serialisation.
- Currently developing interfaces to EPCIS and SAP AII.



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Control Software: Main Functionalities

- Code/ Number Generation, Allocation & Management
- Aggregation of parent-child relationships
- Image/Label/Marking creation
- Management of partially filled containers
- Electronic Batch Report
- Exception management
- Reporting engine
- Audit trail
- Production data acquisition
- System administration

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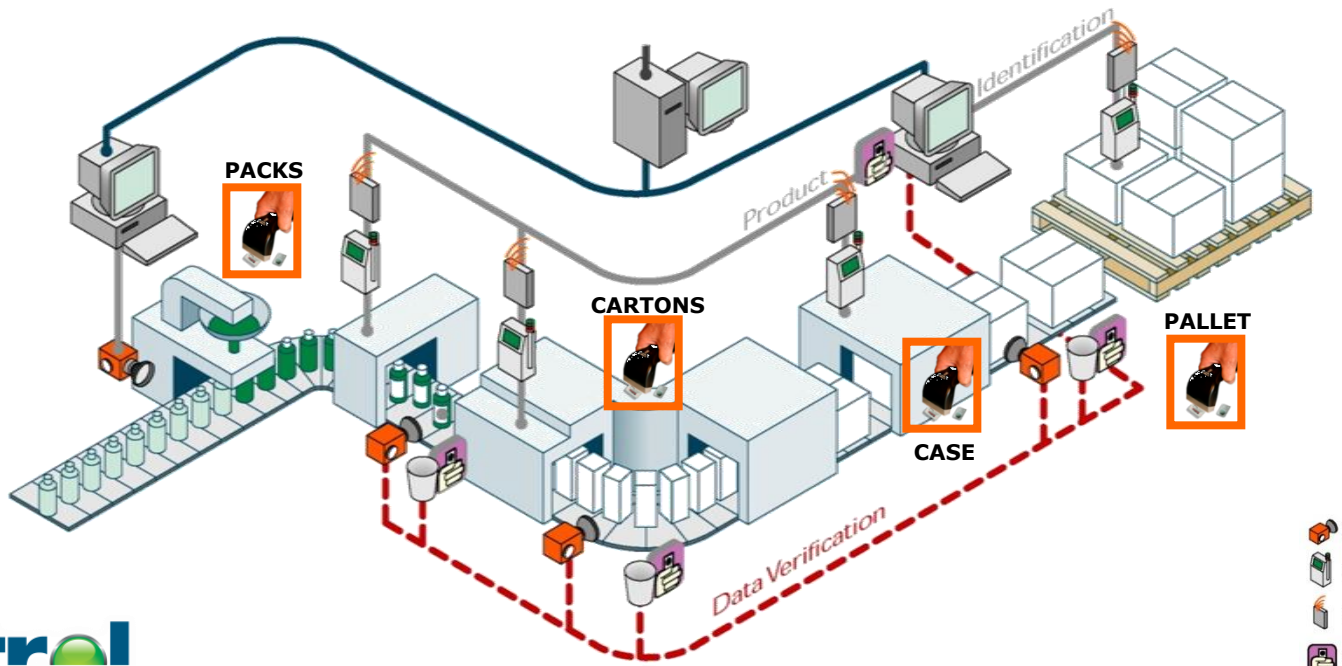
Integrated Line



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Quality Assurance

- Pharmaceutical Expertise
  - GAMP 4
  - 21CFR-Part 11
  - ISO9001:2000 by Lloyds Registered and UKAS
  - 13 year of experience in pharmaceutical industry
  - Several validated systems
  - “Think tank” for BIP

UKAS QUALITY MANAGEMENT 001

LLOYD'S REGISTER QUALITY ASSURANCE · ISO9001

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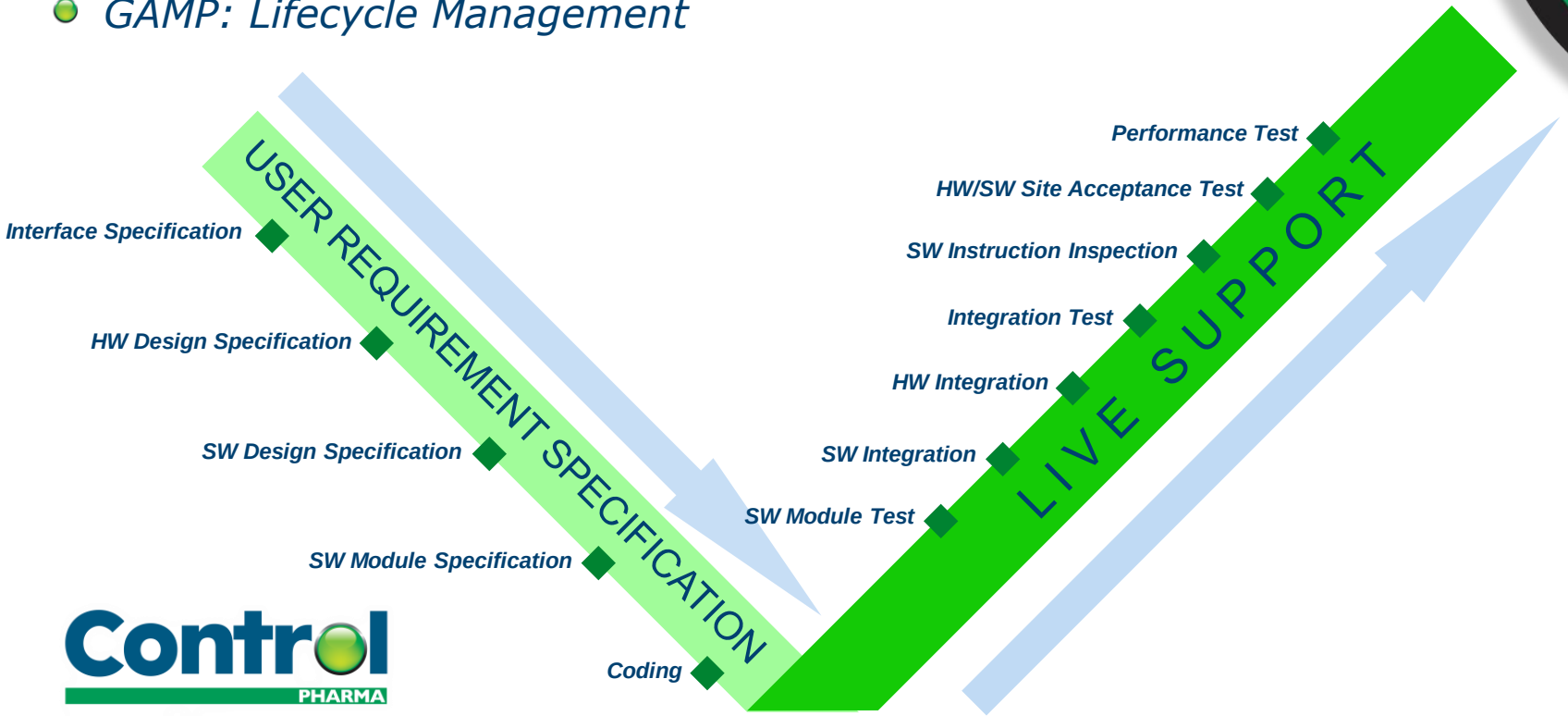
Quality Assurance

- *GAMP: Lifecycle Management*



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The Future …

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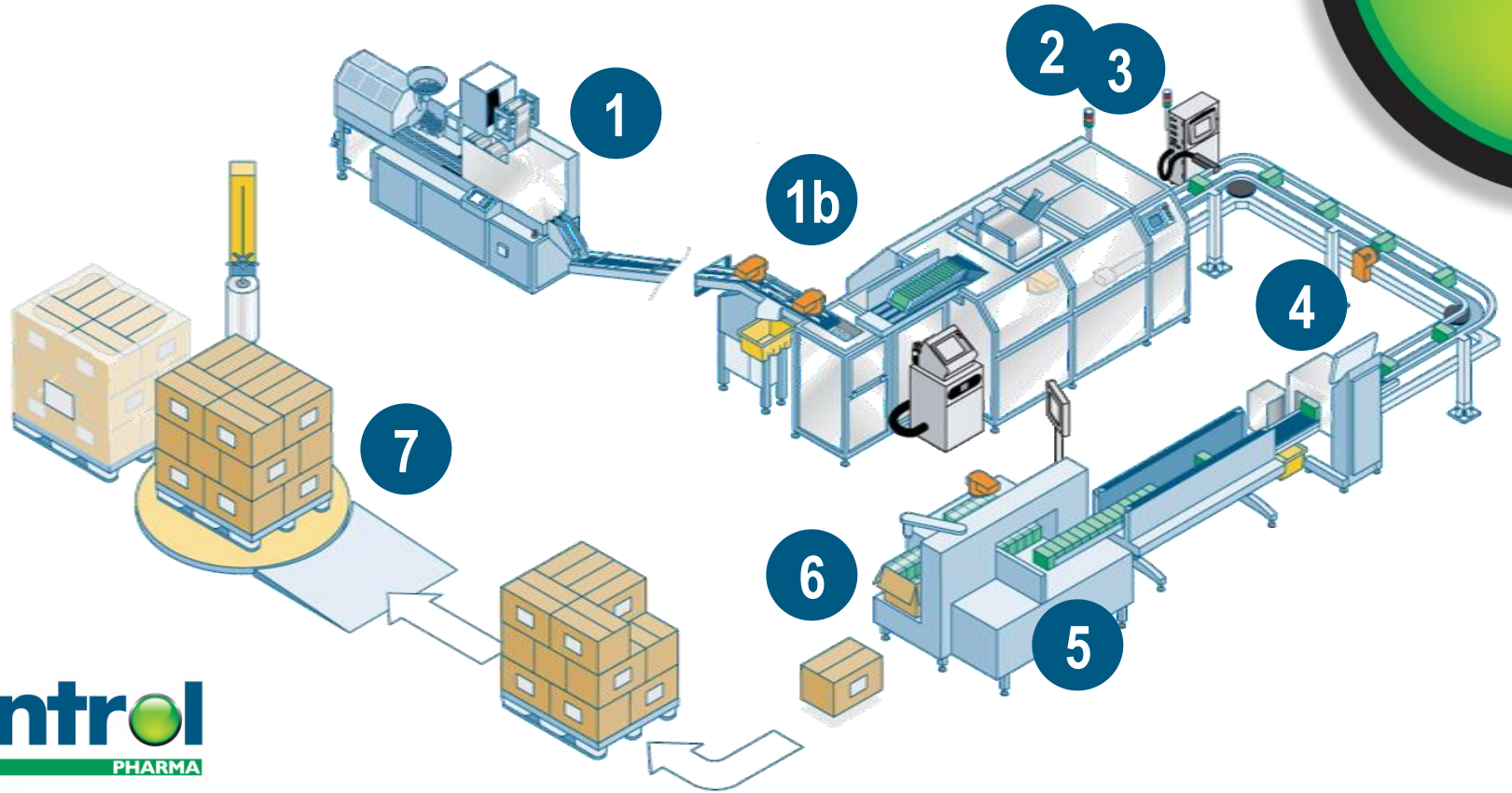
Identified Processes:



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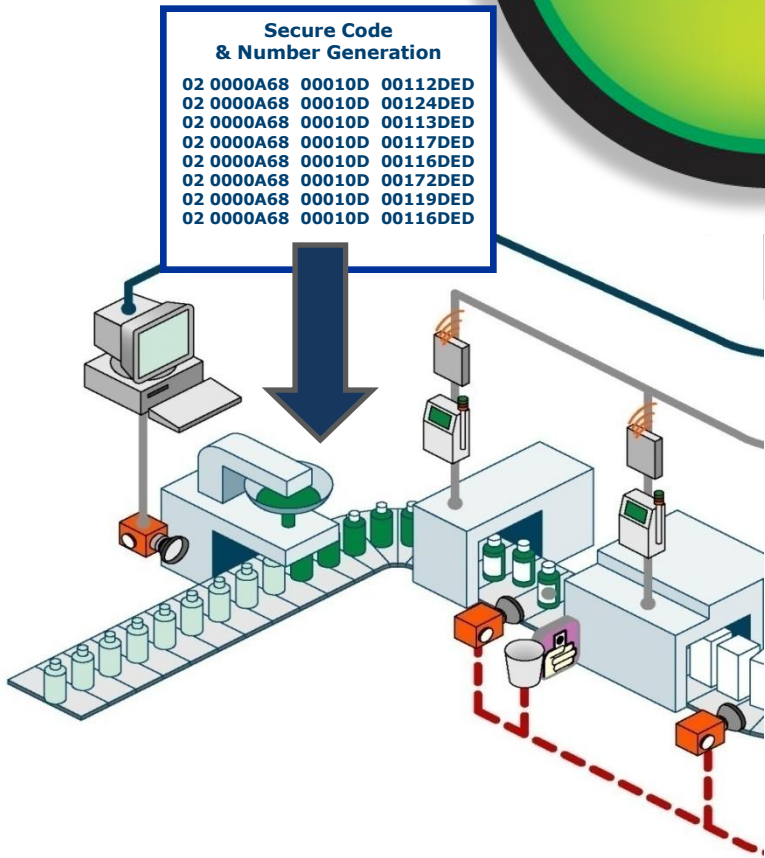
Code/Number Generation, Allocation & Management

- **Code data generation**
  - Stand-alone solution (internal generation)
  - ERP integration (external generation)
- **Coding structure and numbering system**
  - Serialised random or sequential numbers
  - Internal numbering system
    or a Global Supply Chain System
- **Code data allocation**
- **Code aggregation and verification**
- **100% code traceability**



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Code generation:
Stand-alone solution vs. ERP integration

A. Stand-alone solution:

- Custom numbers can be provided (uploaded) manually via import tool, in the same way as reports and layouts.
- They can also be generated by the internal number generation module which provides specific or custom algorithms to generate unique numbers in customizable formats.

B. ERP integration:

- ERP generated serial number can be transferred either online or in a bulk mode in advance to the site server.
- For both options the serial numbers can also be provided to the DOMINO:Control database or to an external database.

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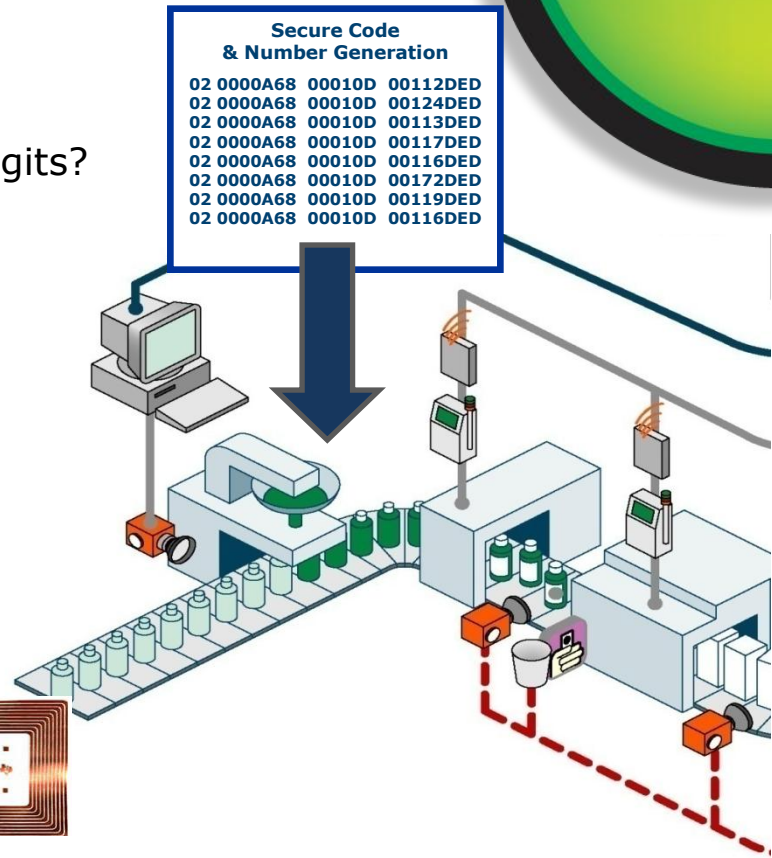
Once code is allocated printing can begin

- You will need to decide on code format.
  i.e. alpha-numeric, linear, 2-D bar code or RFID tag
- Will you need to add human readable characters or digits?
- Will this be a single code, a hybrid
  or a multiple code structure?



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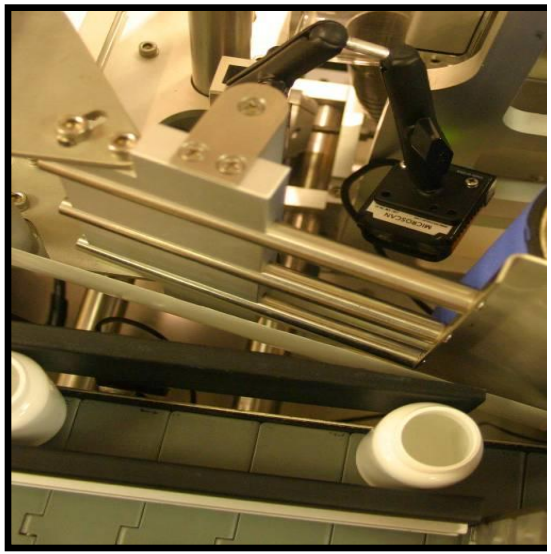
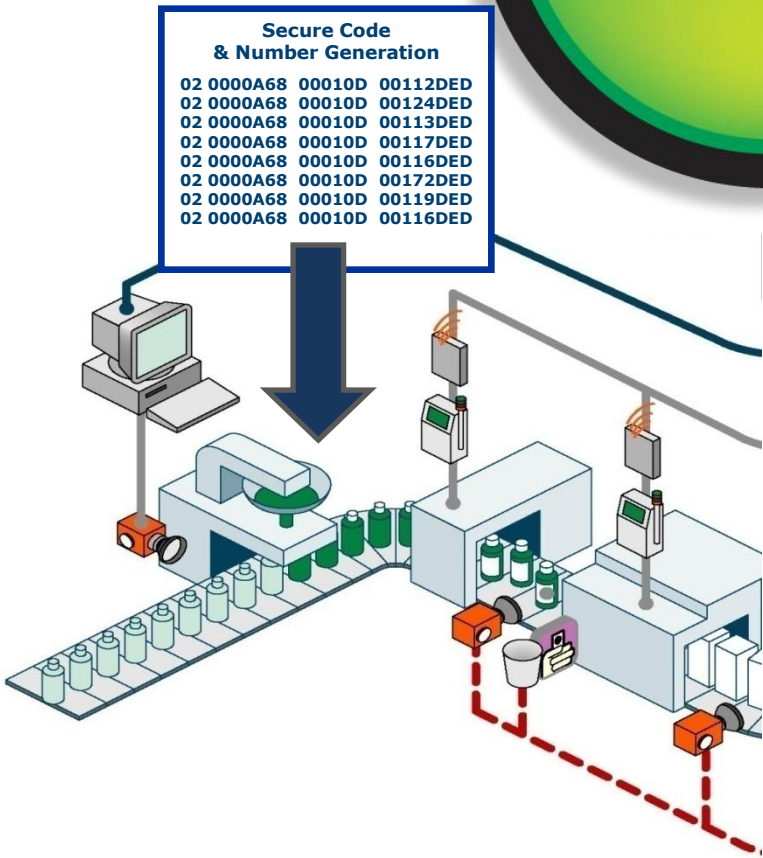
Once code is printing it can be checked and verified

- The number/code is printed and read and the encoded data checked.
- This is achieved in a number of ways – vision system, RF reader, scanning system





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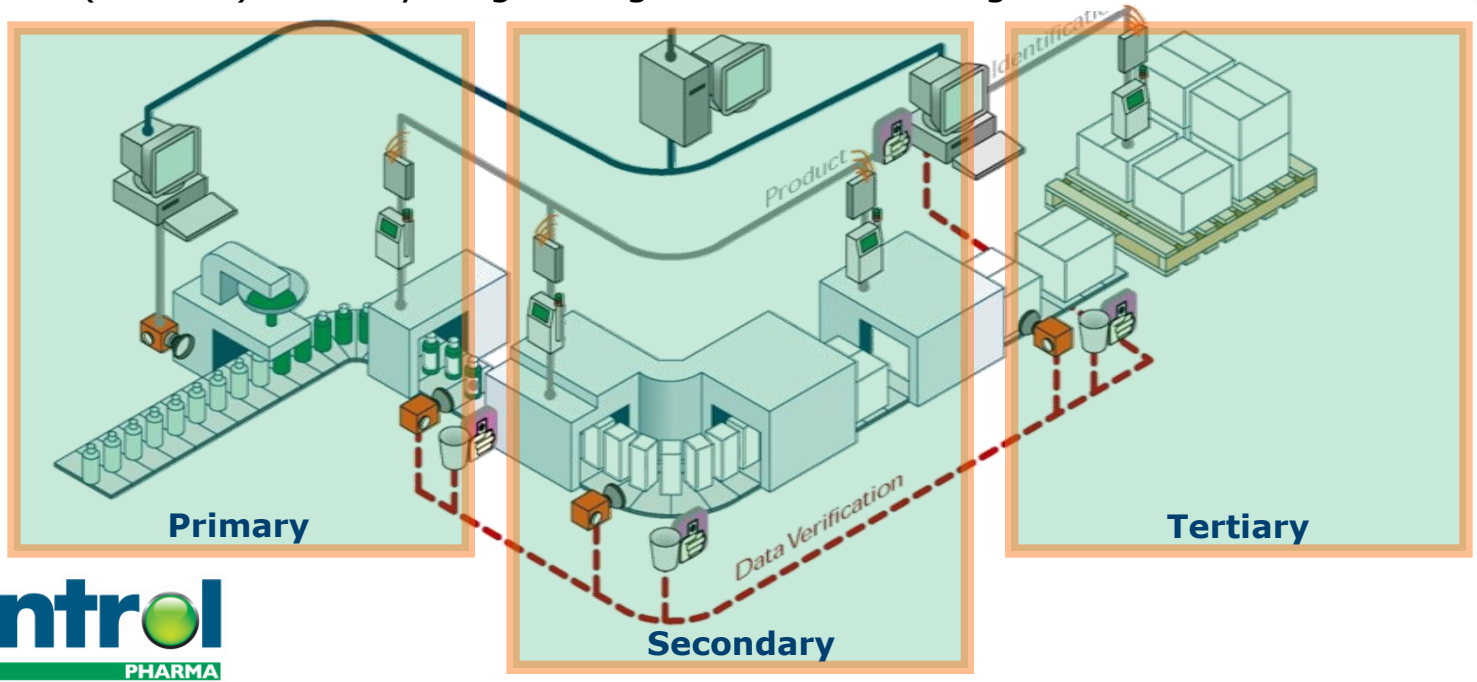
Process Repeated:
from Primary to Secondary to Tertiary

- Codes are allocated, printed or written and the encoded data checked (verified) at every stage along the manufacturing line



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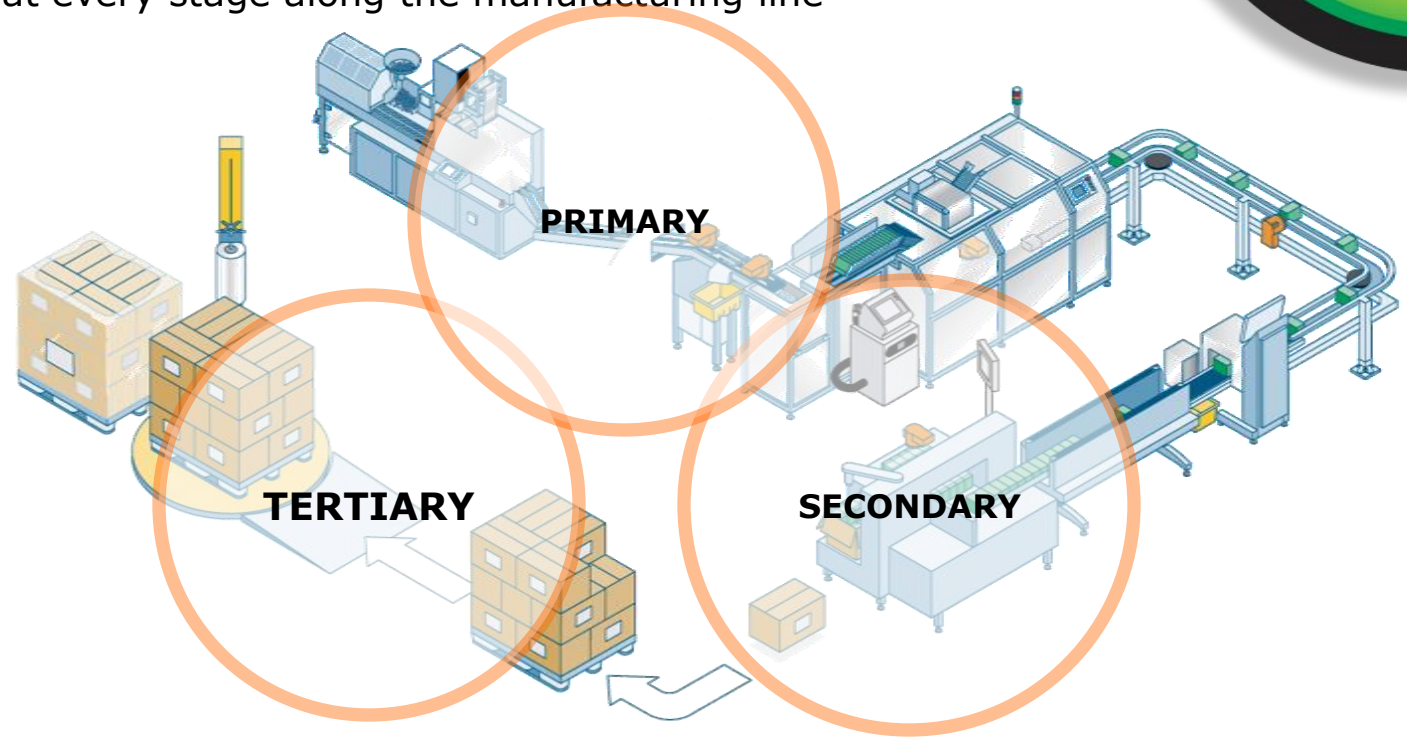

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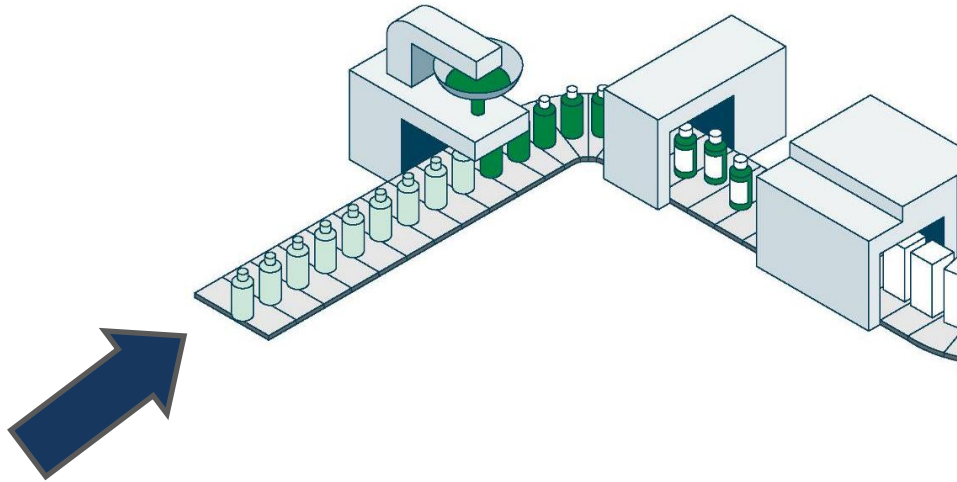
Checking Product, Packaging & Materials onto line

- To begin the full Track and Trace process it is important and in some instances a requirement to identify product, packaging materials, ingredients and raw materials that enter the production line.
- These items will need to associated with finished product packaging as it moves through the production process and into the supply chain.



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Aggregation Management

- Recording of enterprise wide parent-child relationships between any levels of the packaging hierarchy
- Customisable number of hierarchical levels
- Re-association & disassociation of parent-child relationships
- Inference management

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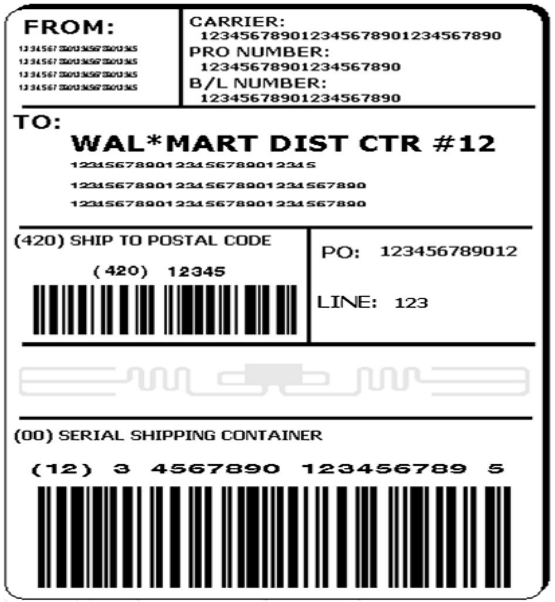
Label/Image layout Control

- Access a library of marking and label formats
- Association of different marking and label formats with different pharmaceutical products, countries and batches
- Support of various label layout tools
  - Multiple languages, standard character sets



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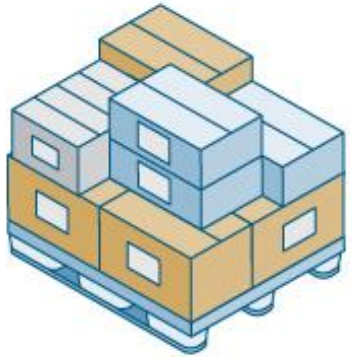
Partially filled container handling

- Detection and management of partially filled containers
- Specification of the ‘allowed’ number of partially filled containers at each level (case, pallet…)
- Allow the user to make a decision (open strategy)



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Exception Management

- Management of real time production line exception events such as rejects, rework and QA sampling.
- Varying handling of the rejected entities depending on the rejection reason.
- Recording of exception events and ‘wastage’ of respective numbers/codes.

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System Administration

- User Management
- Group Management
- Rights Management
- Device and Resource Management
- Security
  - password restrictions
  - log in time restrictions
  - undeletable data
  - lockable user
  - responsibility groups
  - rights management
  - definable password time outs

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Storage Management

- Storage of historic and event data in SQL or Oracle Databases
- Management of temporary data storage positions between modules
- Monitoring of released, locked and quarantine goods

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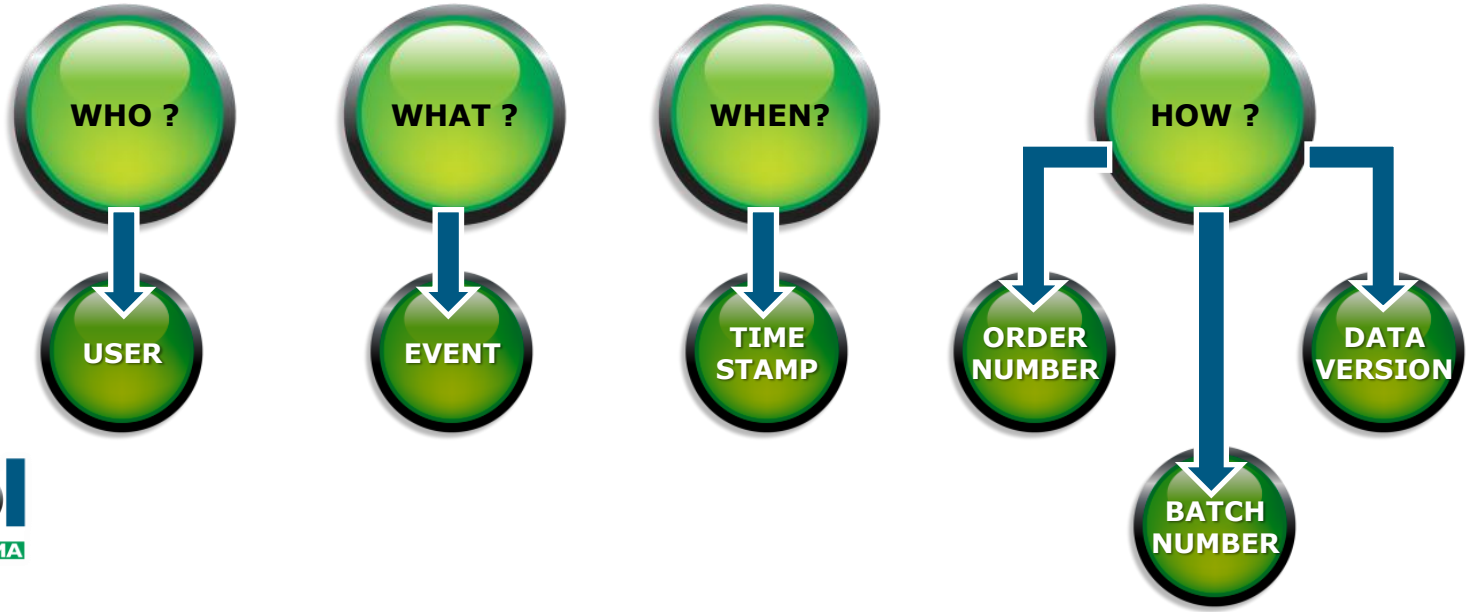
Track and Trace – Audit Trail

- Valuable quality assurance tool for FDA or other inspectors
  - 100% acquisition of all production relevant data
  - 100% coverage of all manufacturing stages



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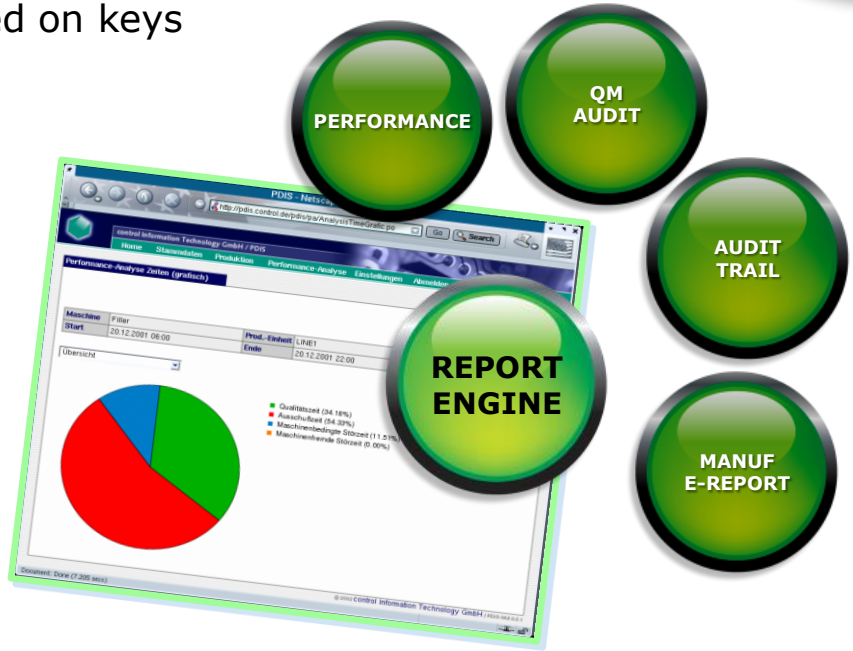
Report Engine

- Reports are customizable - free-form layouts and templates.
- Standard PDF, CSV, Excel® sheets.
- Track and trace down to item level for the entire history.
- Performance analysis and documentation based on keys i.e. devices, lines, batches, shifts or users
- Batch reports in real time



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Production Data Acquisition

- Progress monitoring, documentation and visualization in graphics and real time
- Documentation and reconciliation of finished goods and scrap
- Acquisition of operation and malfunction messages
- Customizable process alarm via email, SMS and voice

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Beyond Track and Trace

- After machines are connected their data can be delivered into a number of modules as follows:
  - Real-time production planning
  - Performance measurement/ Real-time OEE
  - Order Management
  - Reporting…

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System Implementation & Services

- Consultation (URS, technology evaluation)
- Hardware and software installation and configuration
- Complete validation documentation (URS to FAT)
- Maintenance & technical support
- Software updates
- Step by step migration
  or roll out methodology

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