DOMINO:control

Integrated Product Serialisation Solution

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*DOMINO Systems Integration Group*

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Outline

◆ **DOMINO Control Integrated Solutions Group**

◆ **Track and trace solutions**

    ◆ At the point of manufacture

    ◆ Complete track, trace and authentication using mobile technology

◆ **DOMINO Control Software product**

◆ **Projects**

    ◆ BRIDGE Pharma Traceability Trial

    ◆ Haemophilia Blood Trial

DOMINO Control Integrated Solutions

◆ **A complete range of systems integration services**

  ◆ **Leading AIDC technologies**

  ◆ **Robust, industry leading software platforms**

  ◆ **Professional services**

◆ **Customer-driven** solutions

◆ **Regulation-compliant**

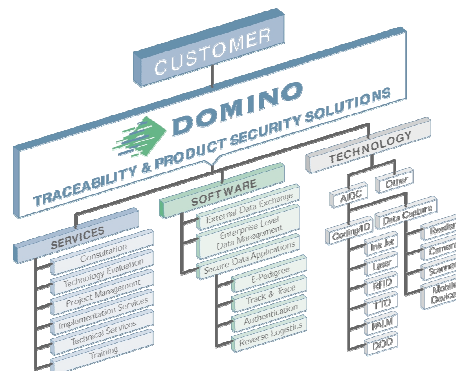 **(EFPIA, California e-pedigree)**
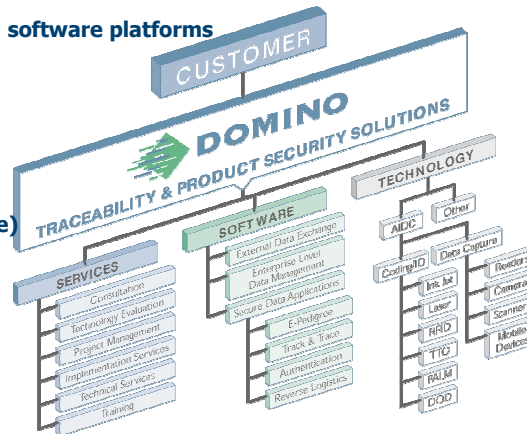
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DOMINO Control Integrated Solutions

◆ **50+ people globally**

◆ **Experienced in** product identification, data collection, mobile communication, RFID and Wireless

◆ **DISG group:** expertise in RFID

◆ **Control acquisition**

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Coding and Traceability at the point of manufacture

◆ **Proven expertise in the Manufacturing Area**

◆ Fully automated, **mass serialization**
using 'best-of-breed' coding, marking or electronic
technologies (inc. RFID)

◆ **Ability to track** a range
of ingredients,
raw materials
and packaging
from the point of entry…

…to the point of despatch

◆ **Integrated to all relevant software**
(e.g. number acquisition, generation,
management and control etc.)
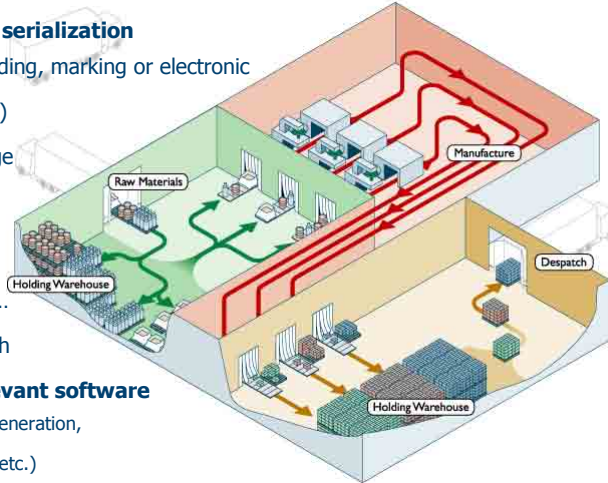
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Printing, Validation, Verification and Aggregation

◆ **Codes are allocated and printed.**

◆ **Encoded data are verified at
every stage along the
manufacturing line.**

Secure Code and Number Generation
Association & Aggregation

02 0000A68 00010D 00112DED
02 0000A68 00010D 00124DED
02 0000A68 00010D 00113DED
02 0000A68 00010D 00117DED
02 0000A68 00010D 00116DED
02 0000A68 00010D 00172DED
02 0000A68 00010D 00119DED
02 0000A68 00010D 00116DED

◆ The data is recorded
and aggregated to the
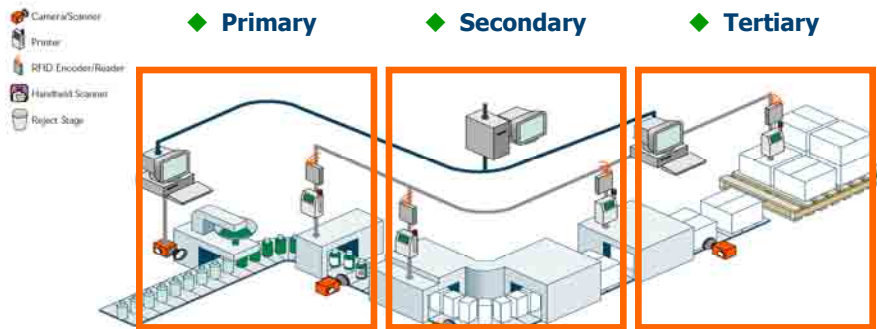production line database
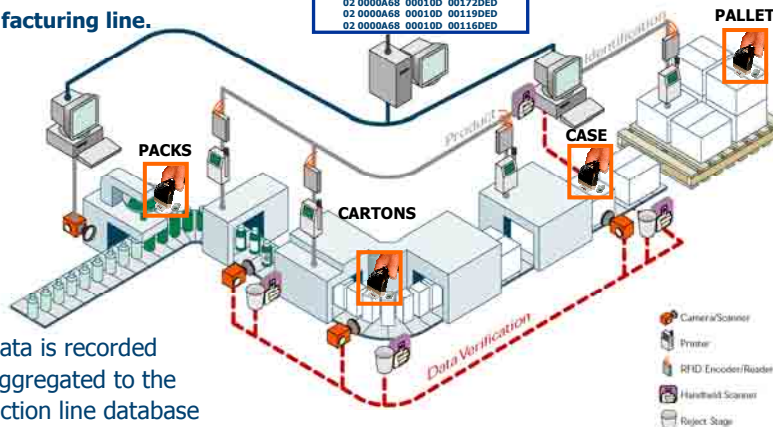
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Process Repeated from Primary to Secondary to Tertiary

◆ **Record and verify aggregation (parent-child) relationships.**

◆ **T&T from blister pouch and strip, to item, bundle, case and pallet level .**

Camera/Scanner
Printer
RFID Encoder/Reader
Handheld Scanner
Reject Stage

◆ **Primary**   ◆ **Secondary**   ◆ **Tertiary**

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DOMINO Control Integrated Solutions

◆ **Complete Integrated System:**
Integrates into your existing software systems

◆ **DOMINO control software:**
A fully functioning, integrated production line software system

◆ Connectivity *and bi-directional data exchange* with ERP, MES and other systems.

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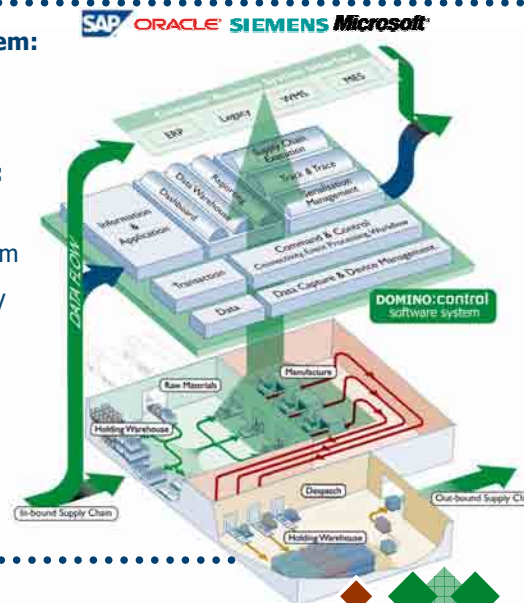
Introduction to Control System Software

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Proposed System Configuration:

◆ Server/client model

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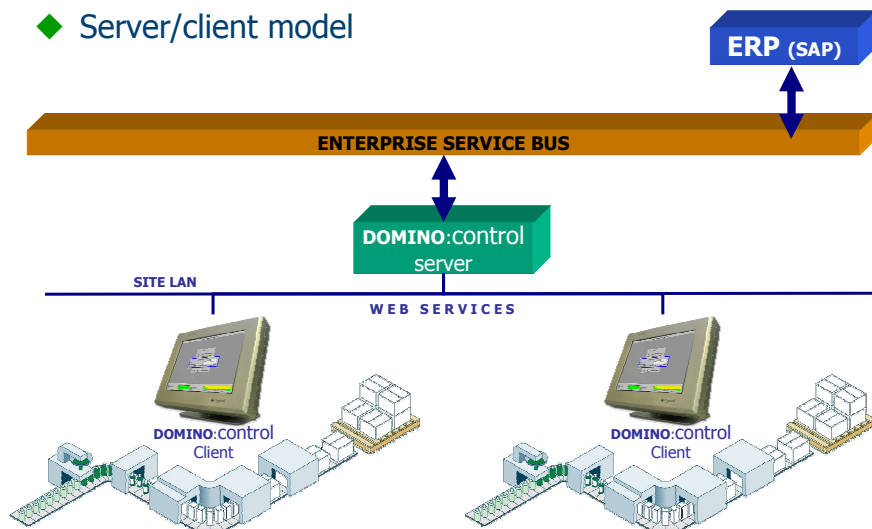
Device Management - Machine Interfaces

◆ Hardware agnostic- Integrated drivers for over 70 variations of equipment

◆ Connection via standardized process interfaces
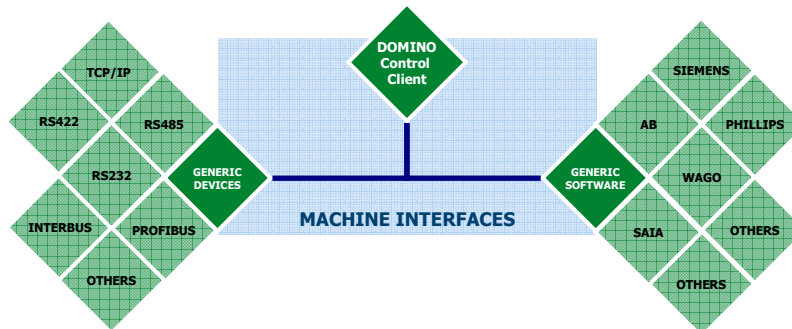

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Device Management – Machine interfaces

◆ **Integration with a wide range of equipment:**

  ◆ Inkjet and Laser Printers
  ◆ Label print & apply
  ◆ 1/2D scanners and RFID
  ◆ PLCS
  ◆ 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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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
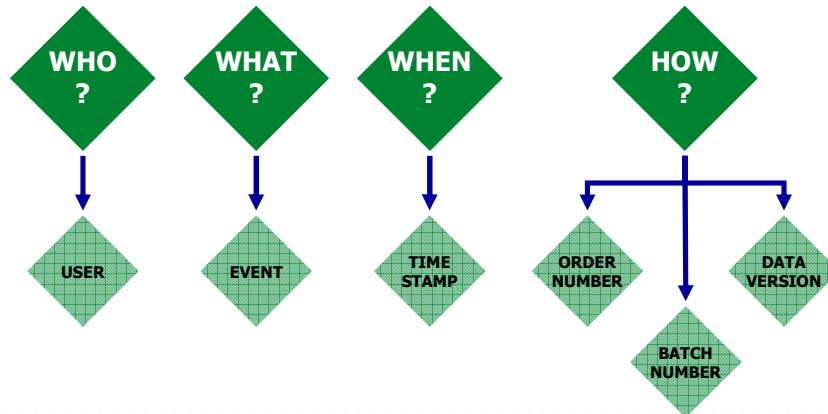
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Beyond Track and Trace

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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DOMINO Control Software Product Philosophy

◆ Server-based approach

◆ Modular system design

◆ Customizable at customer level

◆ Java-based system → OS independent, runs on every OS that supports Java

◆ Global, open standards (HTML,TCP/IP, ...)

◆ Interfaces to all "common" proprietary ERP systems

◆ EPCIS-compliant (to-be)

◆ Simple, secure operation

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Pharmaceutical Expertise

◆ **Regulation-compliant solution**

  ◆ 21CFR - Part 11

  ◆ FDA requirements

  ◆ ISO9001:2000 by Lloyds Registered and UKAS

  ◆ GAMP 4 (URS, FAT, SAT, Performance testing...)

◆ **5 item-level pharmaceutical production line serialisation projects**

  ◆ Mass serialisation + aggregation

  ◆ Currently operating on over 70 pharmaceutical production lines

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Complete Track, Trace & Authentication System

APPLIED TO PRODUCT & PACKAGING
Codes to Data Matrix format applied to products, packaging & pallets. Codes registered on the secure database and parent-child data created

PRODUCTION

DISTRIBUTION

PRODUCT DESTINATIONS
At EVERY shipping location products can be scanned by mobile phone to monitor movements or verify authenticity. Data is relayed using standard SMS text messages.

RETAIL

CUSTOMER
Business customers monitor supply chain activities and authenticate products

CODE REQUEST
Codes are requested by any print location for label or package print

Codes are sent to Secure Web Servers via the internet

CONSUMER
Consumers check product authenticity by mobile phone.

DATA
Unauthentic products are detected in real-time. All movement and verification activity is available in custom reports. Personalised text messages can be sent to the mobile phone in response to a code scan.

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Mobile Technology

Track – Trace – Monitor via SMS

Authentication using Mobile Technology

◆ Serialised Data Matrix code on each pharmaceutical product

◆ Mobile phone with in-built camera and fitted with specially adapted de-coding software

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Reading the Code

◆ A 'photograph' of the code is taken.

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Translating the Code

- ◆ Image analysis using the special de-coding software.
- ◆ Translation of the code into its unique alphanumeric serial number.

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Global Verification

- ◆ Linking the mobile camera phone to a secure database (using mobile technology)
- ◆ 'Texting' (SMS) the data to the secure database for checking.
- ◆ Authorised database access.

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Database Response

◆ Checking the "data" from the Data Matrix Code against the secure database.

◆ Automatic reply sent to the mobile camera phone.

◆ Authenticate information such as product name, dose form, wholesaler, expiry date etc.
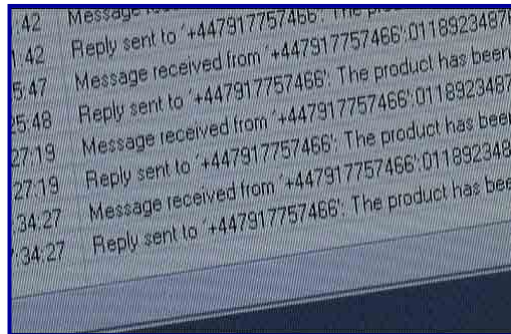
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Real-Time Response - anywhere in the World

◆ Real-time authentication anywhere in the world.

◆ Low-cost, high-speed data transfer technology

◆ No requirement for separate scanners, laptops or other computing equipment

◆ Discreet, fast and can be made very secure.

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Complete Track, Trace & Authentication Projects

◆ Objective

"To demonstrate the implementation and feasibility of improved supply chain **security, efficiency and effectiveness** for all the parties involved in the supply of medicines **from factory to patient** using **standard low-cost technologies**."

◆ Projects

◆ Bridge Pharma Traceability Pilot

◆ Haemophilia Blood Trial (Ireland)

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BRIDGE Pharma Traceability Pilot - *end to end traceability*

◆ **Full supply chain traceability** (from point of manufacture to point of use)

◆ 9 supply chain end-users

◆ 19 product lines

◆ Track and trace to the item level

◆ Product authentication at each node in the chain

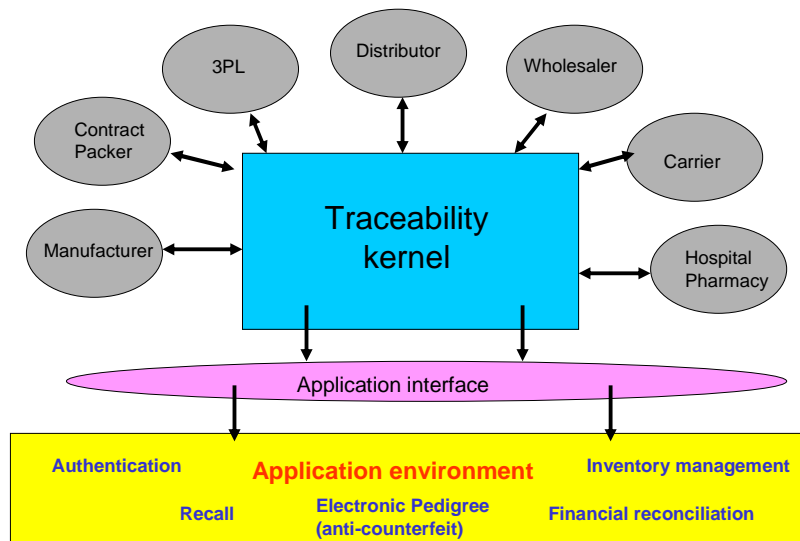**DOMINO:control** Complete Integrated Product Serialisation Solution

BRIDGE Pharma Traceability Pilot - *Rationale*

◆ **Minimise medication errors**
- ◆ Mis-identification of medicines
- ◆ Harm and death to patients

◆ **Eliminate counterfeit medicines – for branded and generic products**

◆ **Significant threats to**
- ◆ Patient safety
- ◆ Trust in safety of medicines

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Pharma e-Traceability enabling multiple applications

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BRIDGE Pharma Traceability Pilot - Solution

◆ EPCGlobal compliant - Distributed database architecture

◆ Data carrier independent

  ◆ Mix of linear, 2-D Data Matrix and RFID/EPC tags

  ◆ For all/most levels of packaging

◆ Due date: June 2008

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Blood Trial - Background

◆ First 100% successful EFPIA-compliant supply chain track and trace trial.

◆ Initiated by the Government of Ireland (NHCD).

◆ Rationale:

  ◆ Faulty batch of blood derivative released to hospitals in Ireland.

  ◆ Infection with Haemophilias HIV and hepatitis C.

  ◆ Hundreds of patients were infected and 78 died.
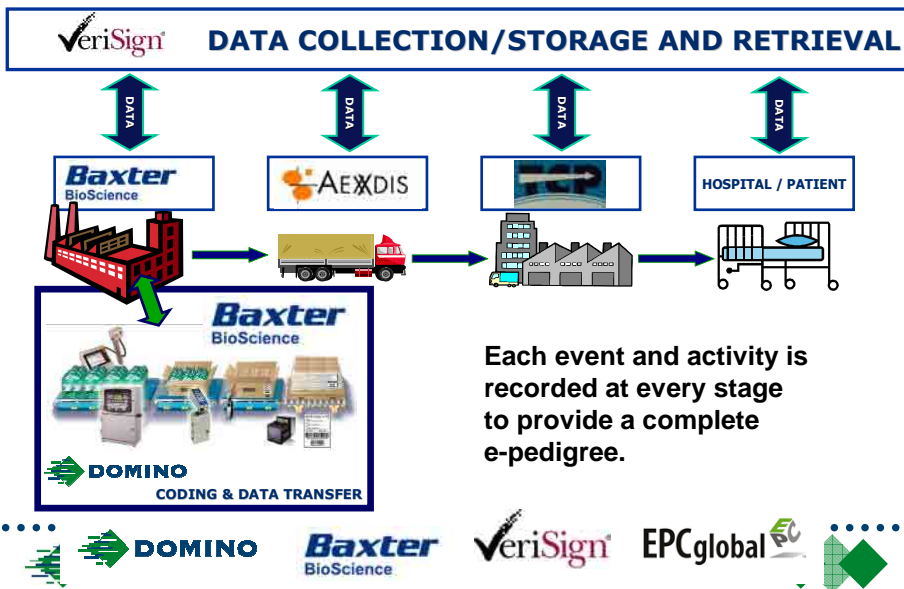
DOMINO   **Baxter** BioScience   **VeriSign**   **EPCglobal**   Ospidéal Naomh Shéamais · Seirbhís Dé agus A Phobail

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Overview

DATA COLLECTION/STORAGE AND RETRIEVAL

Each event and activity is recorded at every stage to provide a complete e-pedigree.

CODING & DATA TRANSFER

Solution

◆ Complete e-pedigree for each product and patient

◆ Unique identification of

    ◆ Products

    ◆ Patients

    ◆ Refrigerators

◆ Data exchange among the different supply chain players using EPC Global standards (EPCIS, ONS and Discovery Services).

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Conclusions

- *We provide:*
  - **Fully integrated solutions:** Hardware, Software, Services

  - **Production-line focused** ⎰ Track and Trace

    Production planning, OEE

  - **Supply-chain focused:** Authentication using mobile technology

- *Pharmaceutical expertise:*
  - Regulation-compliant solutions
  - Pilots, installations

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Integrated Solutions

Track, Trace, Authentication and Production Process Management Software

Any Questions?

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Θεοδώρου