RFIDEA
Engineering & Applications in electronic traceability

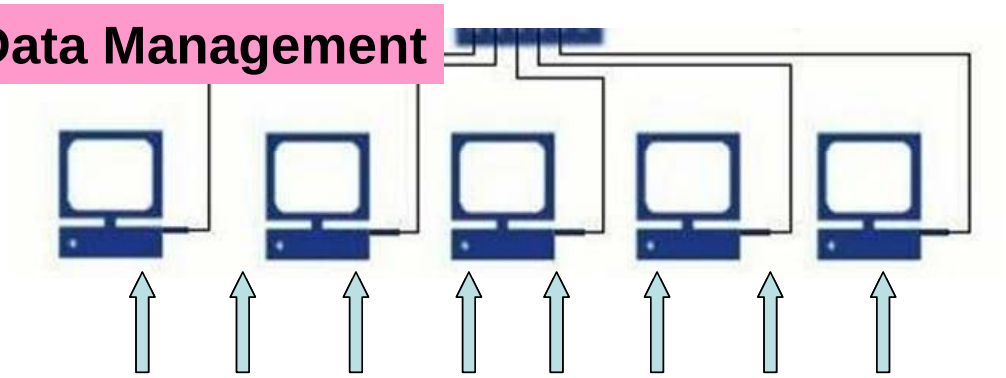
Automatic Identification in BioLogistics

David Dalla Vecchia, CEO, RFIDEA

Table of content

- Automation Pyramid
- Packaging Levels
- Drug Lifecycle
- Regulatory Background
- Codification
- Business cases
  - BAXTER R&D Europe
    - Samples Inventory Management Solution
  - GSK Biologicals
    - Anti Mix-up Solution

Automation Pyramid



Packaging Levels

Data Collection, AGGREGATION, Storage and retrieval -> Local and Global application

Data | Data | Data | Data | Data | Data

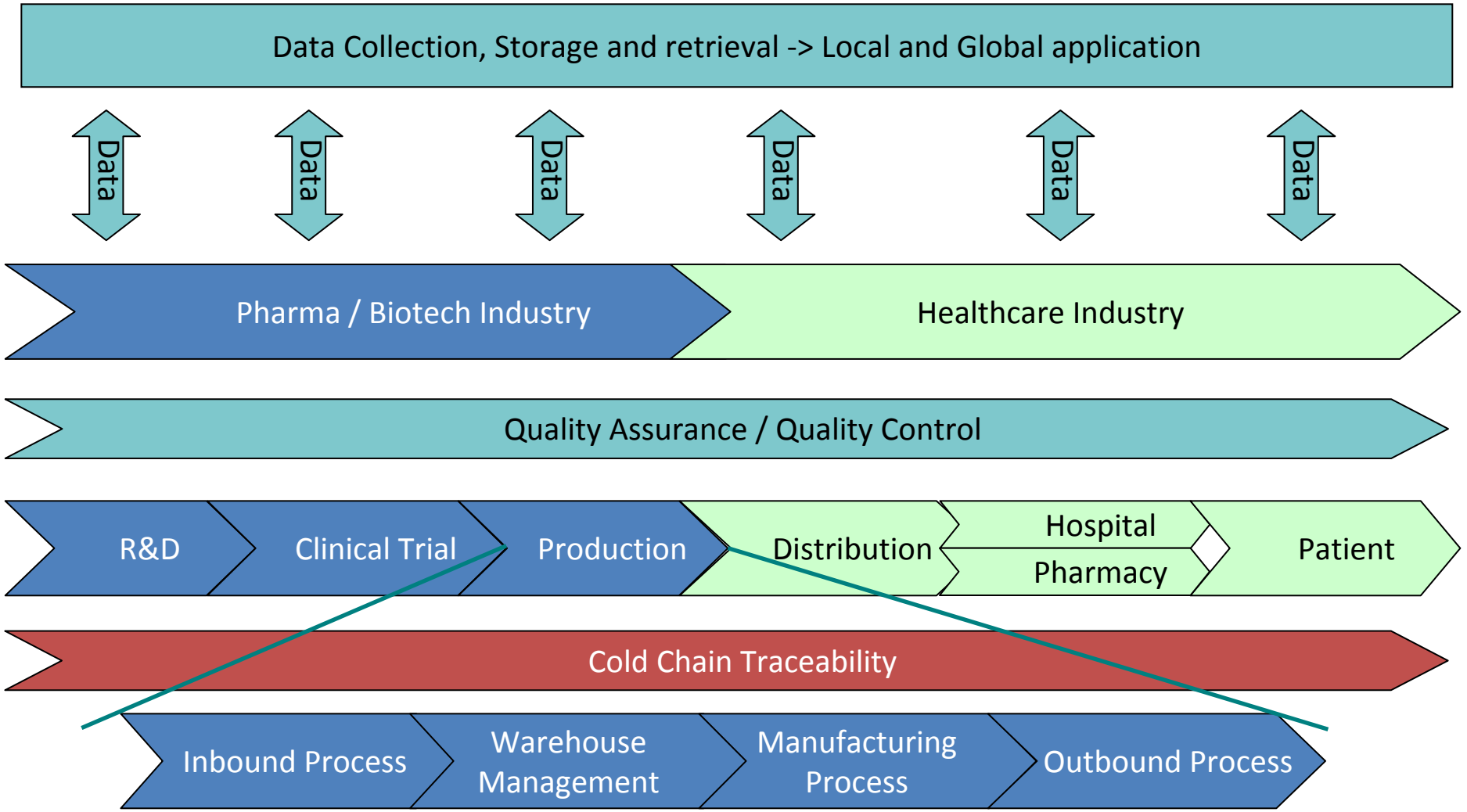
Blister | Patient Pack (Primary) | Case (Secondary) | Pallet … (Tertiary)

With the courtesy of:

Tony Walsh - Strategic Business Development Director

Control Pharma. *(a Domino Printing Sciences Company)*

Drug Lifecycle



Regulatory Background (1/3)

- Strengthening regulation towards lifelong product identification (mass serialization) and traceability around the world – USA (Florida, e-pedigree), but also Europe and Asia;

- Differentiation between the different levels of packaging:
  - Primary packaging: 2D barcode / Data Matrix
  - Secondary and Tertiary packaging: combination of DM and RFID
  - Aggregation of the information at each level (EPC IS)

Regulatory Background (2/3)

- AFSSAPS – **A**gence **F**rançaise de **S**écurité **S**anitaire des **P**roduits de **S**anté

  Code CIP 7 remplacé par le code CIP 13.
  Lien: http://admi.net/jo/20070316/SANM0720920V.html
  «En liaison avec les représentants des entreprises pharmaceutiques, l'AFSSAPS a retenu le principe du changement du code CIP de 7 à 13 caractères du code à barres 39 vers l'EAN 128 (associé à un marquage Data Matrix ECC.200) selon le système EAN.UCC.»

- FDA – **F**ood & **D**rug **A**dministration

  FDA COUNTERFEIT DRUG TASK FORCE REPORT – 2006 update.
  Lien: *http://www.fda.gov/oc/initiatives/counterfeit/report6_06.html*

  "A potential new measure to safeguard the drug supply is the use of electronic track and trace technology, such as radio-frequency identification (RFID), which creates an electronic pedigree (e-pedigree) for tracking the movement of the drug through the supply chain."
  Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs; Notice to Extend Expiration Date to December 2008.
  Lien: *http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-22818.htm*

Regulatory Background (3/3)

- EFPIA – **E**uropean **F**ederation of **P**harmaceutical **I**ndustries and **A**ssociations

  EFPIA RESPONSE TO The European Commission Public Consultation in preparation of a legal proposal to combat counterfeit medicines for human use (Page 11).

  After an in-depth reflection, EFPIA considers that in order to minimise the risk of substandard or counterfeit products reaching the patient, there is essentially only one point where one really needs to know that the product is safe, that is before it reaches the patient at the final stage of the supply chain (when it is dispensed to the end user at the pharmacy or hospital).

  This has led EFPIA to put forward a recommendation to develop a harmonised system for the coding of each pharmaceutical handling unit (individual pack level) ***based on the Data matrix code*** *(ECC 200) and containing the following information: a product code (identifying the product and its manufacturer), the expiry date of the product, a randomized serial number to enable the unique identification of each unit of sale and the batch number.*

  Lien: http://www.efpia.org/Content/Default.asp?PageID=566

  "*This has led EFPIA to recommend the implementation of a* ***standardized identification solution*** *for pharmaceutical products across Europe. This solution is a unique* ***bar code (Data Matrix)*** *supported by a pan-European verification system enabling pharmacists to check each medicine pack before dispensing it to the patient."*

Codification

- 4 strings code:
  - Product code GTIN code (Global Trade Identification Number)
  - Random unique serial number
  - Batch number
  - Expiry date

Baxter International Inc.

- A leader in health care for more than 75 years
  - Haemophilia
  - Immune disorders
  - Kidney disease
  - Cancer
  - Etc.
- More than 45,000 employees in more than 250 facilities
- Manufacturing facilities worldwide
- Local expertise drives competitive advantage in more than 100 countries

SIMS – Samples Inventory MS

- **Role of the Centre:** To perform stability studies on samples coming from manufacturing sites across Europe

- **Purpose :** To track all samples through their entire lifecycle at BAXTER R&D Europe
  - Reception of the pallets
  - Identification and storage of the cardboard boxes in the climatic chambers
  - Preparation and identification of the samples for the laboratory
  - Tracking of the usage in the laboratory by the analysts
  - Destruction of the samples

Some Figures

- Warehouse capacity > 1000 m³
- 1 000 locations
- 15 000 boxes stored
- 160 000 samples stored
- 100 000 received samples per year
- 1 5000 samples prepared per week

Baxter

Technology

Baxter

Biolog Insight 2009

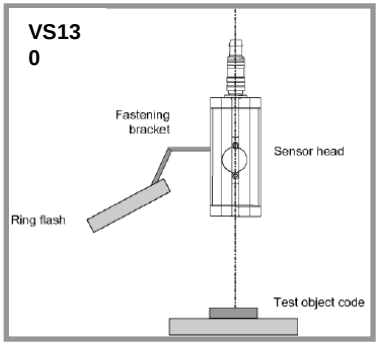
ADVANTAGES (1/2)

- Space availability
  - Accurate availabilities for each single storage location
    - Cardboard boxes volumes defined in the system
    - # Units/box defined in the system
    - Location volume defined in the system
  - Forecast availabilities at the different storage conditions
    - Dedicated report
- Samples identification
  - No double-check required *(one by one, sequentially)*

ADVANTAGES (1/2)

- Laboratory samples tracking
  - Automated using tunnel & wallmount
  - Enforced logical workflow
  - Information more complete
  - Information can be queried easily
- GAMP5 Category Documentation & Validation
  - User Requirements Specifications
  - Supplier Audit (RFIDEA)
  - Functional / Design Specification
  - Factory Acceptance Testing
  - Installation Qualification
  - Site Acceptance Testing
  - Operational Qualification

GSK Biologicals



- Client situation:
  - Loading – autoclaving – unloading of the various batches and sub-batches of syringes on trays (stainless steel and/or polycarbonate);
  - Several batches and sub-batches are processed at the same time, thus creating the risk of mix-ups;
  - Need to associate each tray with the batch and sub-batch which it contains;
  - "GAMP critical" environment.
- Solution:
  - Unique data matrix laser engraved on each tray (9.000 so far)
  - Installation of data matrix camera on loading and unloading conveyors
  - RFIDEA Anti mix-up management application

Thank you for your attention… Questions?

RFIDEA SA
Rue des Chasseurs Ardennais 10
4031 Angleur
Belgique
www.rfidea.com info@rfidea.com

David Dalla Vecchia
dda@rfidea.com
Tel.: +32 (0)4 364 26 20

Jérôme Coulon
jco@rfidea.com
Tel.: +32 (0)4 364 26 20

- Thanks!

Module 1: The efficiency of the biologistic supply chain

- *Introduction* • Marc Fourny, Acclivity
- *Biobanks and cold chain management* • Barry Grayson, Steelgate
- *Traceability* • David Dalla Vecchia, RFIDEA
- *International express transport: first miles-last miles* • Niky Terzakis TNT
- *Specialist logistics in emerging markets. A focus on China*
  - Barrie Sears, Biocair

- Panel discussion
- Biolog Insight cocktail and networking session