UDI Implementation: A Journey in Progress

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Our UDI Journey

Agenda

• Introduction (Context)
• Project Execution
  - Define Scope
  - Assign Resources
  - Evaluation of “as is” & Targets
• Examples
• Take Away Lessons

“In this age, which believes that there is a short cut to everything, the greatest lesson to be learned is that the most difficult way is, in the long run, the easiest.”
- Henry Miller
Who is bioMérieux?

- Sales amounting to €2.103 billion
- 90% of international sales (150 countries)
- A large installed base of 86,900 systems
- 19 bioindustrial (manufacturing) sites worldwide
- Almost 10,000 employees worldwide

2 LEADERSHIP POSITIONS IN MICROBIOLOGY GENERATE 2/3 OF SALES

+ 50 YEARS OF EXPERTISE IN IN VITRO DIAGNOSTICS

+ 20 YEARS OF EXPERTISE IN INDUSTRIAL MICROBIOLOGY CONTROL
Outline the Plan

Define the Scope

- Identify all concerned products
  - Countries of sale
  - Regulatory status
  - Commercial interest?
- Determine Priorities
  - Are there other conflicting projects?
  - Are there other compliance issues?
- Tip: Decide if there is interest in applying standards to other products

Our US Project

- Class III: 2 products
- Class II: 250 products
- Class I: 130 products
- Next step: EU products (on-going assessment)
Build the Team

• Cross-functional team with product knowledge
  - Regulatory, Quality, Manufacturing, Labeling, Data Management, Information Systems, R&D
  - Support functions as needed: Purchasing, HR, Training
  - Project Management
• Task forces to focus on specific aspects of UDI
  - Labeling; data management; quality systems
• Executive support is critical
  - Budget
  - Resources
  - Priorities & arbitration
Evaluate the “As Is” Situation & Set Targets

**Equipment & Systems**

- Labeling software and printers
  - Are they capable?
- Data Management tools
  - Do tools exist?
  - Is the data in the system at the right time?
- Supply chain
  - Capabilities & process assessment
- Codes (attribution of GTIN)
- Bar code verifiers

**Our Main Gaps**

- No standard labeling software or equipment
  - Out of date systems
  - Hand labeling in worst case
- No data management tool (only partial ERP)
- Supply chain mostly equipped
- GTIN attribution mostly correct
  - Stop adding “our” GTIN to trade products
- No bar code verifiers
Evaluate the “As Is” Situation & Set Targets

Training & Procedures

- Understanding UDI its importance
- Labeling (Design, Quality Verification)
- Supply Chain
- Data Management

Our Actions

- 20 minute E-learning module (in French & English) for all employees
- Establish company policies
  - E.g. barcode grade on release
- Update of corporate procedures to require UDI across multiple functions
Evaluate the “As Is” Situation & Set Targets

Data
- Electronic or Paper?
- Quality of data
- Data synchronization possibilities
  - GDSN
  - Manual entry

Our Challenge
- 21 impacted sites with no central data repository
- Partial data in ERP with questionable data quality
  - Temperature used for two different purposes
- No synchronization provider
- Excel sheets & manual synchronization first → Master Data Management tool & synchronization to GDSN long term
Evaluate the “As Is” Situation & Set Targets

**Labels**
- Space
- Requirements
- Physical support
- Availability of information at printing time

**Our Project**
- >15,000 labels each individually managed
- No standardization (size, content, process, responsibility)
- Culture change mandatory
  - New tools
  - New process
  - New guidelines
Equipment & Support Limitations

Before

After
Lack of Space & Redesign

Before

After
Finding our way through the maze

Key Lessons Learned

- Treat it as a company-wide project & engage all the right people
- Separate short term solutions (manual) versus mid/long term solutions (automate)
- When possible, harmonize:
  - GS1 code applied to all products regardless of UDI status
  - Standard software / equipment / practices across all sites
- Make it an opportunity rather than an obligation

"Complexity creates a maze between you and success. Simplicity ensures a clear line of sight.”
- Lee J. Colan
Questions

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