



# 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?



**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



Sales amounting to  
**€2.103** billion



A large installed base of  
**86 900** systems



**19** bioindustrial  
(manufacturing) sites  
worldwide



**90%**  
of international sales  
(150 countries)



Almost  
**10,000**  
employees worldwide





## 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<sup>†</sup>)



# 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  - Out of date systems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



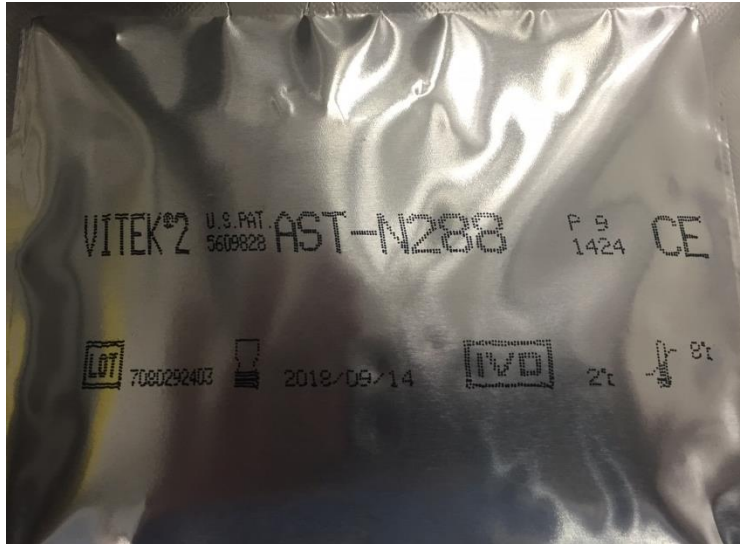
## Our Project

- >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

0103573026124567  
1711010101010123456789

VIDAS® B-R-A-H-M-S PCT		VIDAS® B-R-A-H-M-S PCT PCT	
<b>LOT</b> 0123456789	<b>STR</b> 101010-2	<b>REF</b> 30 450	<b>REF</b> 30 450
<b>S1</b> 000003 C2 000004 <b>S2</b> 000001 S2 000002	<b>2010-10-10</b>	<b>CE</b>	
<p><b>bioMérieux SA</b> 65280 Marcy l'Étoile - France</p>		<p>13207E www.biomerieux.com/techlib</p>	

## After

01103573026129392  
171170810  
101005101740

VIDAS® PCT		VIDAS® B•R•A•H•M•S PCT™	
<b>LOT</b> 1005101740	<b>STR</b> 60	<b>REF</b> 30450	<b>REF</b> 30450
<b>2017-08-10</b>	<b>S1</b> 2 x 2 mL (-> 2 mL H2O)	<b>CE</b>	
<b>2016-08-25</b>	<b>S2</b> 2 x 2 mL (-> 2 mL H2O)	13207G www.biomerieux.com/techlib	
<p><b>bioMérieux SA</b> 376, Chemin de l'Orme 66280 Marcy-l'Étoile - France</p>		<p>2017-08-10 <b>LOT</b> 1005101740</p>	



# 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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