

### **3D**EXPERIENCE<sup>®</sup>

**Chemical Management:** A multifunctional approach for delivering a robust chemical management program

Presented by: Tom Lillie



## Tom Lillie – President, MLM Consulting

• 25 years at P&G

**DS BIO**VIA

- Led the raw material group and integrated LIMS capabilities in Health Care Analytical
- Established an integrated Quality Assurance and Chemical Safety program for F&HC R&D
- Led the deployment of CISPro across 18 technical centers in 8 countries







### Why Chemical Management

Why Chemical Management should really be Material Management

The Cost of Material Management

Anatomy of a Material Management System

Implementation – The Rollout

Post – Implementation Insights



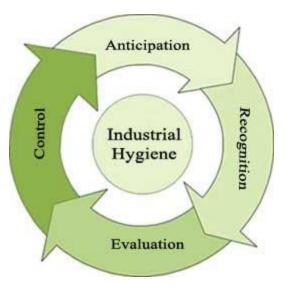


# Industrial Hygiene Goals

- No chemical accidents
- Ability to control risk versus usage
- Exposure monitoring
- Accurate Inventory
- Easy compliance reporting
- Reduction in the volume of chemicals
- Compliant disposals

**S BIO**VIA

• Reduction in dollars spent on material





### **Chemical Users Goals**

- No chemical accidents
- Available when needed
- Not contaminated
- Expected quality
- Easy to order
- Barcoded for easy identification
- Technical data readily available





### **Other Chemical Users Goals/Needs**

- One place to go to manage all lab inventory
  - Supplies, Equipment, Components
- EHS data should be the same as data in development tools
- Information should flow into an experiment
- Materials should be tied to registration system
- Materials received should be checked for quality (when needed)
- Difficulty in ordering materials should be eliminated (individual chemicals and those for an experiment/batch)



### **User Behavior**

- How much are users willing to participate in effort
  - Inventory not a high priority for most
- What benefit will they gain out of managed inventory
- What inventory do they need managed
- Users need trust in data, inventory level and ability for central organization to deliver "fast"





# Agenda

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### **Definition of a Material**

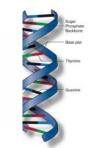
Includes....

- Chemicals
- Biologics
- Engineered Materials
- Supplies



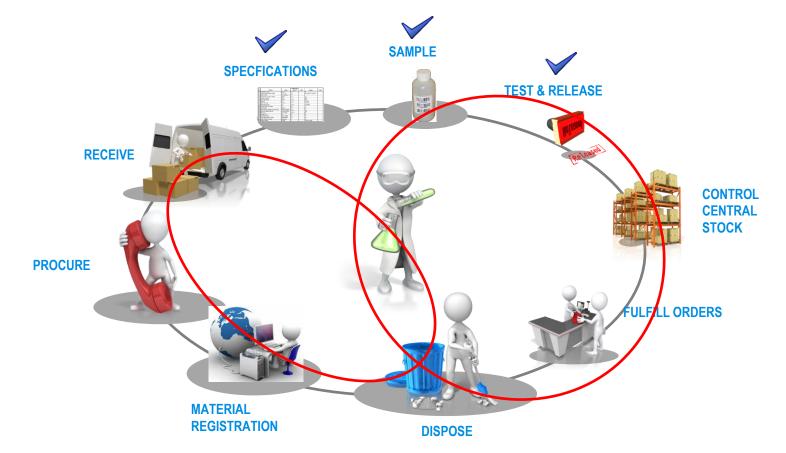








### Work Processes (CISPro with MLM)



### **Current Issues in Material Domain**

To reduce the data overlap and improve quality a holistic data model is needed

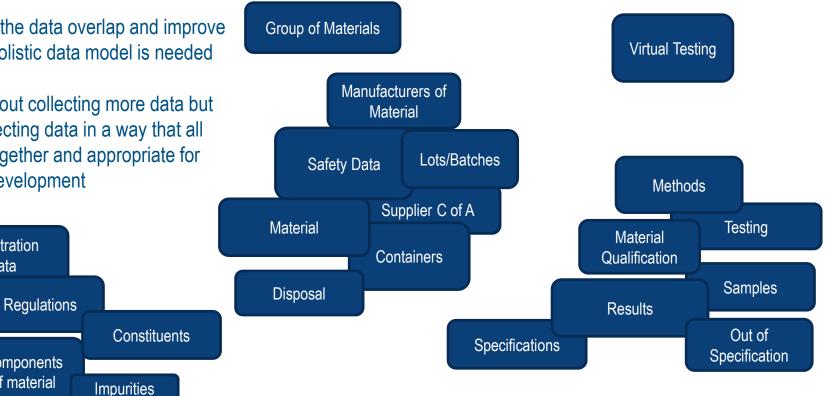
It is not about collecting more data but about collecting data in a way that all data fits together and appropriate for stage of development

Registration

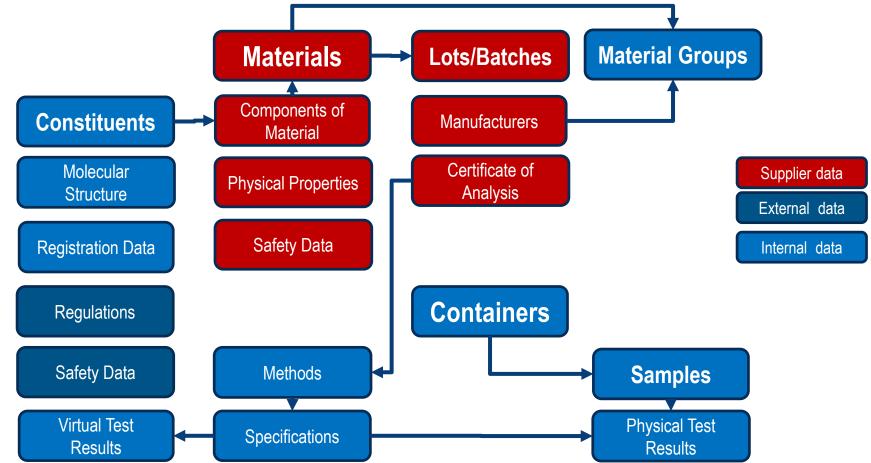
Data

Components of material

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### Tying the Data Elements Together





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### Materials – Need by Function

Field Name	Data Standard	RMG/QA	HS&E	PD	PS&RA	Source stage	Source A
Material common name	Free Text	х	Х	Х	Х	1	Bottle/Container
Material IUPAC name	STN Lookup	Х	Х	Х	Х	1	MSDS
Material trade name	Free Text	Х		Х	Х	1	Bottle/Container
US INCI name	CTFA Lookup	Х		Х	Х	2	Database
EU INCI name	CTFA Lookup	Х		Х	Х	2	Database
Japan INCI name	CTFA Lookup			Х	Х	2	Database
CAS #	Structured Field	Х	Х	Х	Х	1	MSDS
Alternate CAS #	Structured Field		Х		Х	3	Direct supplier contact
EC Number (EINECS, ELINCS, NLP)	Structured Field	Х		Х	Х	1	MSDS
Catalog Number	Free Text			Х		1	Technical data sheet
Product Number	Free Text	Х		Х	х	1	Bottle/Container
FEMA#	Free Text				Х	3	Database
COE#	Free Text				х	3	Database
Color Index	Free Text	Х		Х	х	2	Technical data sheet
Chemical Group(s)	Structured Field	Х		Х	х	3	Technical data sheet
	Totals	38	28	42	64		

Data collected reduced by over 80% 
□ Data quality improved 
□ System usage increased

### Cost of Data Collection and Maintenance

Field Name	Cost of Data	HS&E	PD	QA	PS&RA	Source stage	Needs Review	Source A
Material common name	\$1.00	1	1	1	1	1		Bottle/Container
Material trade name	\$1.00		1	1	1	1		Bottle/Container
Manufacturer's Hazard Classification	\$1.00	1	1	1	1	1	1	Bottle/Container
Site Clearance	\$100.00	1				3	1	Internal source
Pictograms	\$1.00	1	1	1	1	1	1	Bottle/Container
Regulatory restrictions (prop 65, etc)	\$1.00	1	1		1	1	1	MSDS
Storage and handling conditions	\$1.00	1	1	1		1		MSDS
Constituents (chemical make up of material)	\$100.00	1		1	1	1	1	MSDS
Constituent target level	\$250.00			1	1	1	1	MSDS
Constituent Function	\$5.00				1	1		Internal source
Maximum ingredient level by use	\$250.00				1	3	1	Internal source
ВР	\$1.00	1				1		MSDS
FP (flashpoint)	\$1.00	1	1	1	1	1		MSDS
Molecular structure (for constituent)	\$10.00				1	2		Database
Specific gravity	\$1.00	1	1	1		1		MSDS
Supplier(s)	\$5.00	1	1	1	1	1		Internal source
Manufacturer(s)	\$25.00		1	1	1	1		Direct supplier contact
Manufacturing process	\$1,000.00			1	1	3	1	Supplier questionaire
Origin of feedstock (synthetic, animal, plant, etc)	\$500.00				1	3	1	Supplier questionaire
Manufacturer qualified for material	\$1,500.00			1		3	1	Direct supplier contact
Experimental ID	\$10.00		1	1	1	2		Internal source
GCAS #	\$10.00		1	1	1	3		Internal source
Testing results (per Lot)	\$500.00		1	1		2	1	Internal source
Shelf life (expiration date)	\$1.00	1	1	1		1		Technical data sheet
C of A from manufacturer (per lot)	\$10.00		1	1		2		CofA

\$6,540.00

### **Factors Affecting Data Cost**

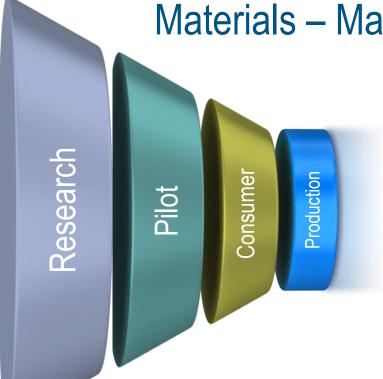
- Multiple users of data, high overlap of data need between users
- What attributes should be included?
- Static versus dynamic data, cost to maintain
- No such thing as a data bible, different suppliers will provide different data
  - The original version of CISPro enabled like materials to be grouped
  - Combining materials actually cost more, and did not provide granularity that user needed











### Materials – Managing the Growth of Data

Collecting data only when it is needed reduces overall material data management cost







Collecting data only when it is needed reduces overall material data management

Safety - Exposure Risk

Regulatory - Consumer Risk





### Effective Cost

### Cost to collect material data (per 1000 materials)



Why Material data is an Asset - Imagine the cost if you had 1,000,000 materials

Field Name	Combined Cost
Material common name	\$1.00
Material trade name	\$0.50
Manufacturer's Hazard Classification	\$1.00
Site Clearance	\$100.00
Pictograms	\$1.00
Regulatory restrictions (prop 65, etc)	\$1.00
Storage and handling conditions	\$1.00
Constituents (chemical make up of material)	\$100.00
Constituent target level	\$75.00
Constituent Function	\$0.10
Maximum ingredient level by use	\$5.00
BP	\$1.00
FP (flashpoint)	\$1.00
Molecular structure (for constituent)	\$0.20
Specific gravity	\$1.00
Supplier(s)	\$5.00
Manufacturer(s)	\$12.50
Manufacturing process	\$300.00
Origin of feedstock (synthetic, animal, plant, etc)	\$10.00
Manufacturer qualified for material	\$450.00
Experimental ID	\$5.00
GCAS #	\$5.00
Testing results	\$5.00
Shelf life (expiration date)	\$1.00
C of A from manufacturer (per lot)	\$5.00
	\$1,663,600.00

By only collecting data when needed the total cost is reduced

### **Benefit of Holistic Material Management**

- By consolidating data needs across functions/organization you will see:
- Reduction in overall cost to collect and maintain data
- More users exposed to data
- Better quality data
- Reduction in system cost





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### **Supplier Part**

- Supplier Part Provides...
  - The minimum information to be traceable
  - Low cost to start
  - Can be used for <u>Purchased</u> and internally <u>Developed</u> materials
  - Enables full CISPro work flow
  - Enables building of complete data set <u>as needed</u>, <u>when needed</u>
  - All SDS data entered (structured) on each receipt

Supplier	Rodac Plates <u>Becton Dickinson</u> 210340	Supplie	e 100 mL HDPE bottle r <u>Accupack</u> B234-100
Name	CD3+ Pan T Cells	Name	Experimental Substance
Supplier	<u>HemaCare</u>	Supplier	<u>Companies name</u>
Number		Number	Registration number
Name	Acetone	Name	Experimental Formula
Supplier	Mallinckrodt Baker, Inc.	Supplier	<u>Companies name</u>
Number	H451	Number	Formula #

Examples of minimum data needed to define a Supplier Part

### **Components – Common Definition**

#### Kathon 886 \ DSK BioPharma Inc. \ DSN0044946

Edit Options •										
	Name <sub>Kai</sub> Supplier <sub>DS</sub> Number <sub>DS</sub>	<u> </u>	nc.						Recei	est 🔹
Chemical Components Receipt	Lots Con	ainers M	LM EP	Hazards	GHS	Physical	Structure	Documents	Testing	History
Add • More •										
Add •   More •										
Components										
		Percentage F	lange	CAS No	Compor	nent Role	MDL #	Hazardous Repor	tir	
Components		Percentage F >0.27 to <0		CAS No 2682-20-4		nent Role nal Component	MDL # MFCD01742315	Hazardous Repor Y	tir	
Components Constituent		_	.5 [0.37]		Functio				tir	
Components Constituent 2-Methylisothiazol-3(2H)-One		>0.27 to <0	.5 [0.37]	2682-20-4	Functio	nal Component nal Component	MFCD01742315	Y Y	tir	
Constituent Constituent 2 -Methylisothiazol-3(2H)-One 5-Chloro-2-Methylisothiazol-3(2H)-One		>0.27 to <0	.5 [0.37] [1.13]	2682-20-4 26172-55-4	Functio Functio	nal Component nal Component /	MFCD01742315 MFCD00792550	Y Y N	tir	
Components         Constituent         2 -Methylisothiazol-3(2H)-One         5 -Chloro-2-Methylisothiazol-3(2H)-One         Benzene		>0.27 to <0 >1 to <1.25 <1E-06	.5 [0.37] [1.13] [11.5]	2682-20-4 26172-55-4 71-43-2	Functio Functio Impuity	nal Component nal Component / er	MFCD01742315 MFCD00792550 MFCD00003009	Y Y N N	tir	

Procter & Gamble (P&G), one of the world's largest consumer products companies, <u>announced</u> it would be banning two controversial ingredients from all of its beauty and personal care products: phthalates and triclosan

### Tied to Suppliers and Regulatory Data

Benzene \ Sigma-Aldrich Corporation \ 319953	
Coptions •	
Name Benzene	Request
Supplier Sigma-Aldrich Corporation	Receive
Number 319953	View SDS 🔹
Chemical Components Receipt Lots Containers MLM EP Hazards GHS Physical Structure Docu	ments Testing History
Synonyms BENZENE Commonen 苯 Commoncn CYCLOHEXATRIENEIUPAC en More	Material Id M000138
CAS No 71-43-2 Container Expira	ation Locked <sub>NO</sub>
Is Tier II Yes Open Ex	pire Interval 1 Years
	tion Interval 5 Years
Subclass Substance Approved for	or Receiving Approved
Regulatory Lists California Prop 65 SARA More	
MDL Number MFCD00003009	

#### Ariel regulatory list linked via CAS number of material or components





### **Supplier Data**

 CISPro MLM provides low cost way of structuring supplier data with:

> 2. Create Containers

3. Define Properties 4. Attach SDS

5. Print Labels 6. CofA Data

Capture

- ACD catalogs for(internal/external) vendors/suppliers
- Certificate of Analysis (C of A) prompted at receipt
- Safety Data Sheets

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Formula: C2 H3 N CatalogName: Mallinckrodt Laboratory Ch Price Book CatalogNumbers: [ "H454-06", "H454-10 Purity: MIN 99,9%		fications and				
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2-methyl-4-isothiazolin-3-one		3.57	%		•	I.
5-chloro-2-methyl-4-isothiazol		10.38	%		•	s l
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- Why get involved in a global deployment?
  - 18 sites on 4 continents
- Success can be associated with 2 strategies...



- Organization transformation
  - Know when you're good enough to start
  - Real learning does not take place until the system is being used
  - Understand the hard points and soft points
  - Don't expect to get it right the first time and always continue to improve
  - Dollars available for continual improvement (every 3 months for first 2 years)

Organization excepted less than perfect knowing it would get better





- Agility
  - The larger the organization the more likely that the starting point will be different

No matter how hard you push the organization will control the pace

JLT | The 3DEXPER

- System needs to be able to support different starting points in moving toward final goal
- Accept the different starting point and enable each organization to take steps towards the overall goal at the pace their business can afford to move



- 1. Partnered with ChemSW to build global capable system that would scale to P&G.
- 2. July 1 (project initiated)
- 3. December development spec set
- 4. June First site deployed
- 5. December Last site of 18 sites deployed!





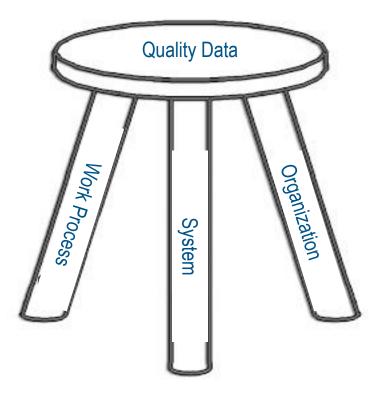
### Material Management Organization

- Creating the organization
  - Lower employee cost versus being managed by scientist/engineers
  - Stewardship of data quality
  - Review incoming material SDS versus current data
  - Ensure all chemicals are correctly entered in system
  - Can gate material delivery based on material hazard and user training
  - Since it is a large percentage of their work you can both
    - Hold accountable
    - Reward for work well done



# Deployment

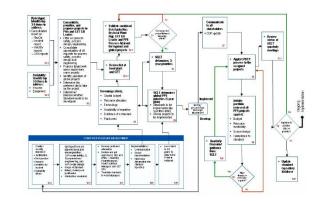
- Deployment is not about turning on the system
- The goal is collecting the quality data that enables effective running of the business
- The building of the organization capability and transformation of work process are far harder than expected
- Training is not about how to click through the application but rather on how to deliver value to the user
- Data available from older system is often difficult to clean up.

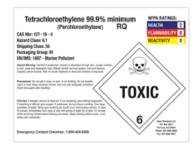






### **Impact on Work Process Changes**





- Simply making the current work process electronic will not provide the most value
  - Digitizing a poor work process will give you a poor digital process
  - Must understand what the power of the system provides to change/eliminates aspect of the current work
- Work Processes affect users perception of their value
  - Implementation can eliminate jobs
  - The person doing similar work might not be appropriate for the new work



### Implementation – The Roll Out



- You are providing a service, make sure sites know what they are getting
  - The benefit that moves the site may be different than your goal
- The drivers that made material management a win-win in Japanese technical center
  - Pilot plant scheduling hindered by not being able to predict material availability
  - By using MLM material management capability we were able to increase capacity of pilot plant by over 200%
    - Eliminated need to build new pilot plant



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### **Insights After Implementation**

• Cost savings - Eliminate material hoarding



The storage of chemicals in the laboratory is a function of the reliability of the availability from other sources.

By establishing a central materials group that can rapidly order and deliver materials to the user the amount of chemicals stored in the lab is reduced

Must overcome trust issues





### **Unexpected Benefits**

- The power of the data
  - Same lot of material sent to multiple site -
    - Why test twice?
  - Same lot of material sold as different grades
    - Why pay too much?
  - Faster reaction to material shortage
    - What other materials might be equivalent for this use?
  - Early warning of manufacturer's changes
    - Why did suppliers C of A change?





### Let's Take A Poll . . .

# Do you have a system in place to track chemicals? Yes No

# 2) If yes, are you looking to upgrade your system in 2016?YesNo



