

Nieuwe software applicaties voor het laboratorium, hoe vinden we de weg?





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SPREADSHEET LIMS
CDS ELN
SDMS
LES DATABASE



Nieuwe
Software

Data
Information
Knowledge

Waarom nodig?

Data
Integriteit

Hoe doen
we het nu?



Testing

Training

3 plaatsen
terug

Go

Paperless
or
less paper?

Validatie

Eigen system

€€€€
Meer budget



Integreren

Haalbaarheid



The browser of a scientist.

century-old papers that will never be read until next browser crash

problemsets that should be turned in yesterday and today

most visited tabs perfectly camouflaged in the jungle of stale old 'journal and papers'

gadgets intended to help focus but never ever initialized

bookmarked b/c they SHOULD be there

unread = new excitement

read = soon to be forgotten

bookmarked b/c they NEED to be there

'available' only b/c they have an iphone app or rmt desktop never turned off

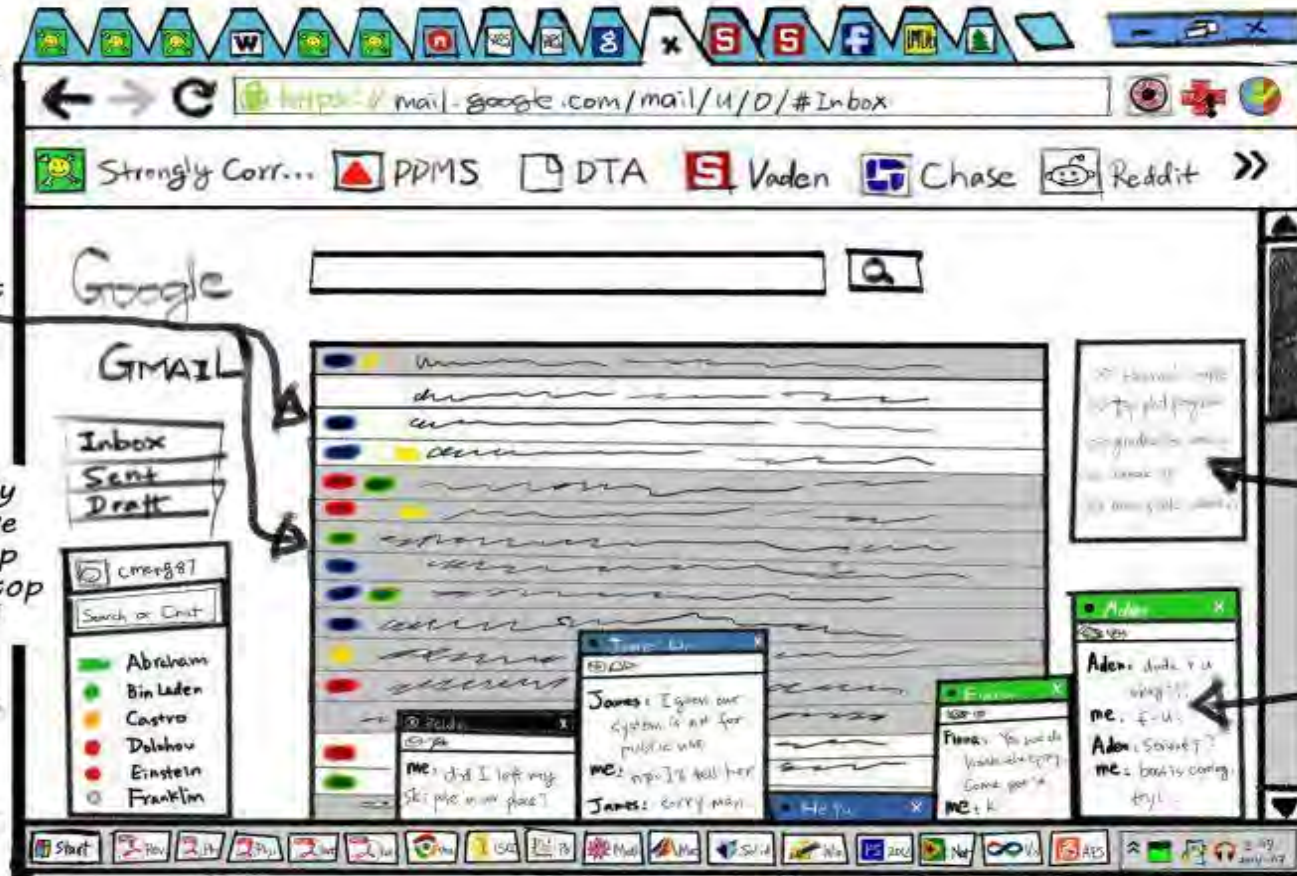
'away' = truly busy

'busy' mostly means they are available

'offline' is useless b/c you will send offline msg anyway; some invisible men will be uncovered

google suggested ads usually end up catching embarrassing keywords

cascades of chats are always shooting up like baby bamboo



stacks of pdf paper to be read but never timely finished until next system crash

super RAM monsters that never fail to freeze your Xeon 16 core computer, and you don't get to turn them off very often

CPU usage always high annoying system updates postponed a million times b/c it wants to restart your never-ready computer



Meet @ /

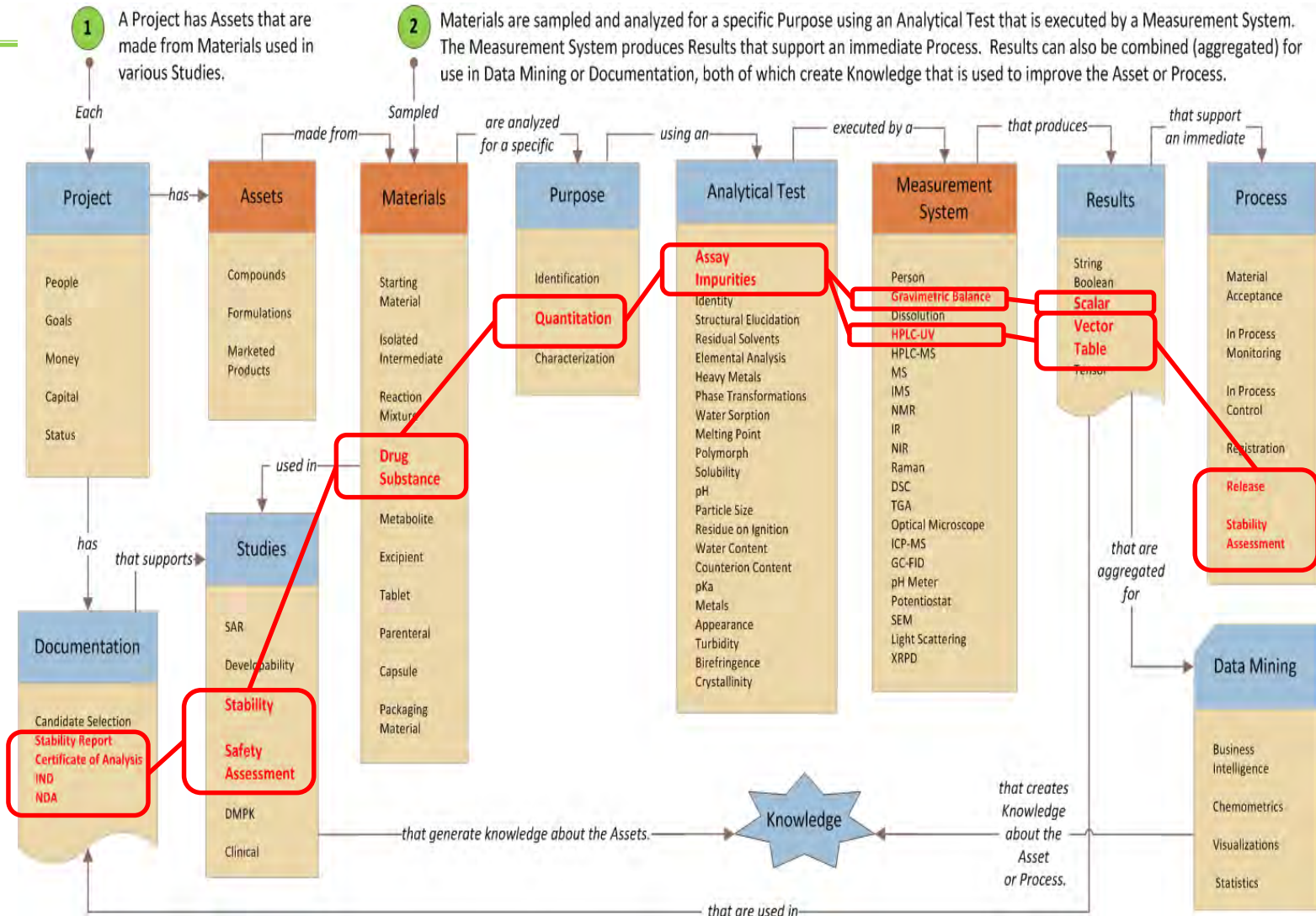
e

*Creatieve mensen hebben geen
rommel, die hebben overal ideeën
liggen*

Waarom integreren?

- Goedkoper
- Verlagen van risico's
- Hogere efficiency
- Reduceren van de kosten
- Beter gebruik te maken van externe partner samenwerking
- Bereiken duurzaamheidsdoelstellingen.
 - Bijvoorbeeld papier volume verminderen
- Vereenvoudiging (vermindering van het aantal systemen)
- Verkrijgen van betere meetbare doelstellingen (KPI's)
- Significante verbetering van data consistentie
- Verbeten van (Prior) Knowledge sharing
- To please management

Laboratory Life Cycle model



Ik weet het verschil
tussen **DATA**,
INFORMATIE en
KNOWLEDGE

JA

Mmmm...

Uitdagingen voor de moderne wetenschap



DATA

To tell the color
To tell what object
represents



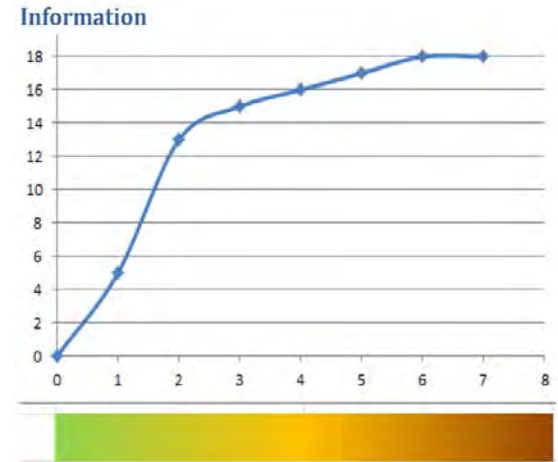
INFORMATION

From color
Physical attribute
establish
sugar content
Chemical attribute



KNOWLEDGE

What to buy
Make decision by **linking**
Information
to the objective

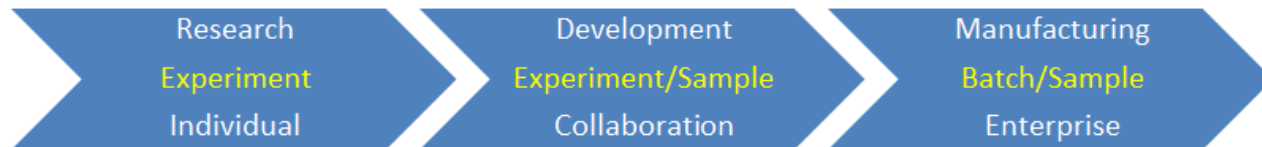


Uitdagingen voor de moderne wetenschap

Ranking	Knowledge needed	Created by	Used by	Explicit or Tacit	Where it is	Impact
1	Discovery	R&D	Scientists	Tacit	Scientists	Yellow
				Explicit	ELN	Green
2	Discovery	CRO	Project team	Explicit	Secured ELN	Red
3	Summary of lab development	Analytical	Registration team	Explicit	Local teamwork space	Green
4	Performance of similar product	Development	Scale-up team	Tacit	Local sites	Yellow
5	Tech Transfer	Development	Manufacturing	Explicit	Manufacturing databases	Red
6	CAPA	Development	Quality	Explicit	CAPA database	Yellow
7	Backup	IT	Organisation	Explicit	IT Infrastructure	Yellow
8	Security	IT & Quality	Legal	Explicit	Validated LIMS	Green
9						



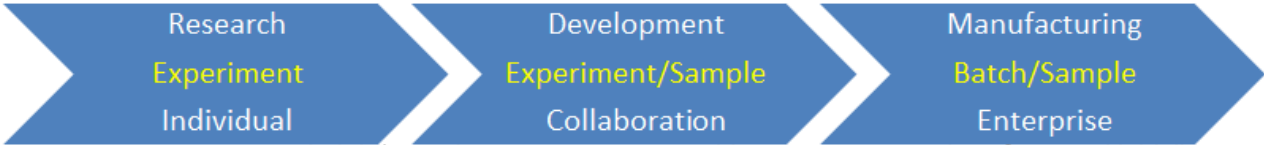
Laboratorium software landschap



Lab information mgt means many things to many people - Concept Heidelberg

Nov 2015

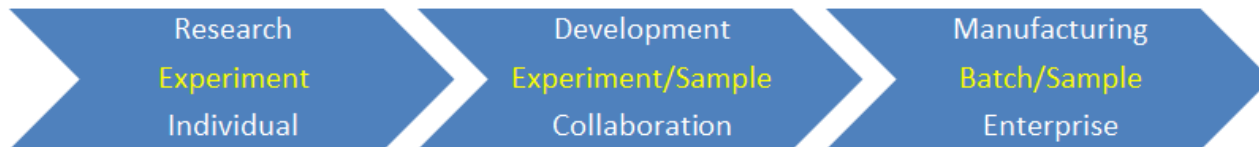
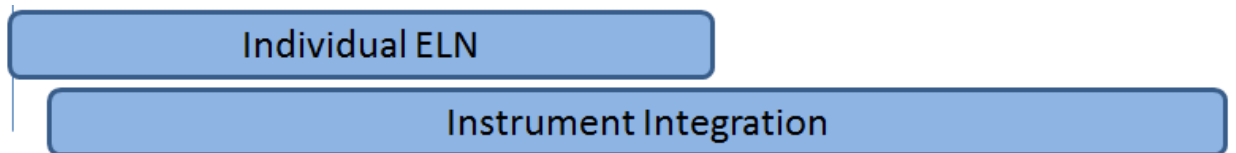
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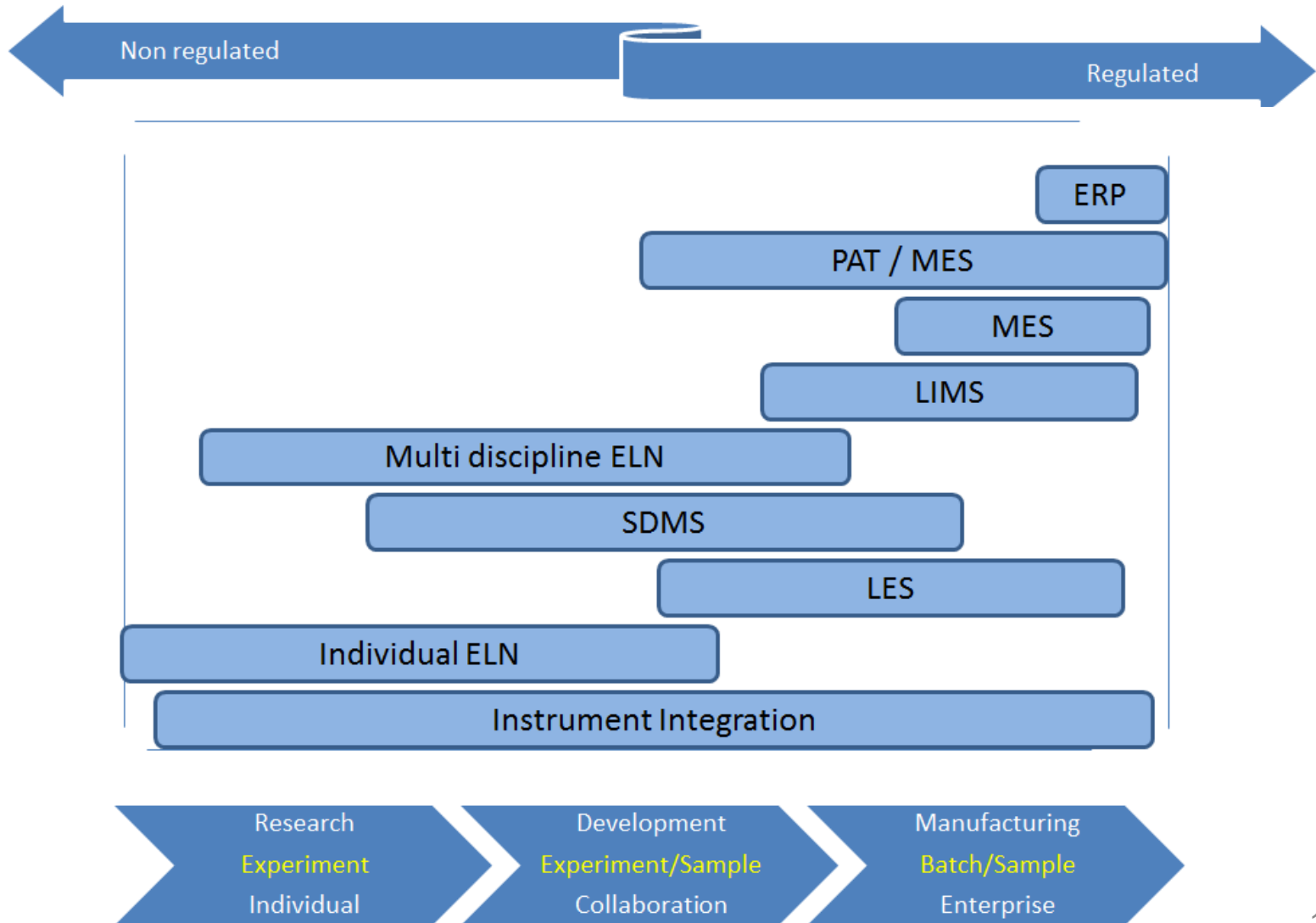
Laboratorium software landschap



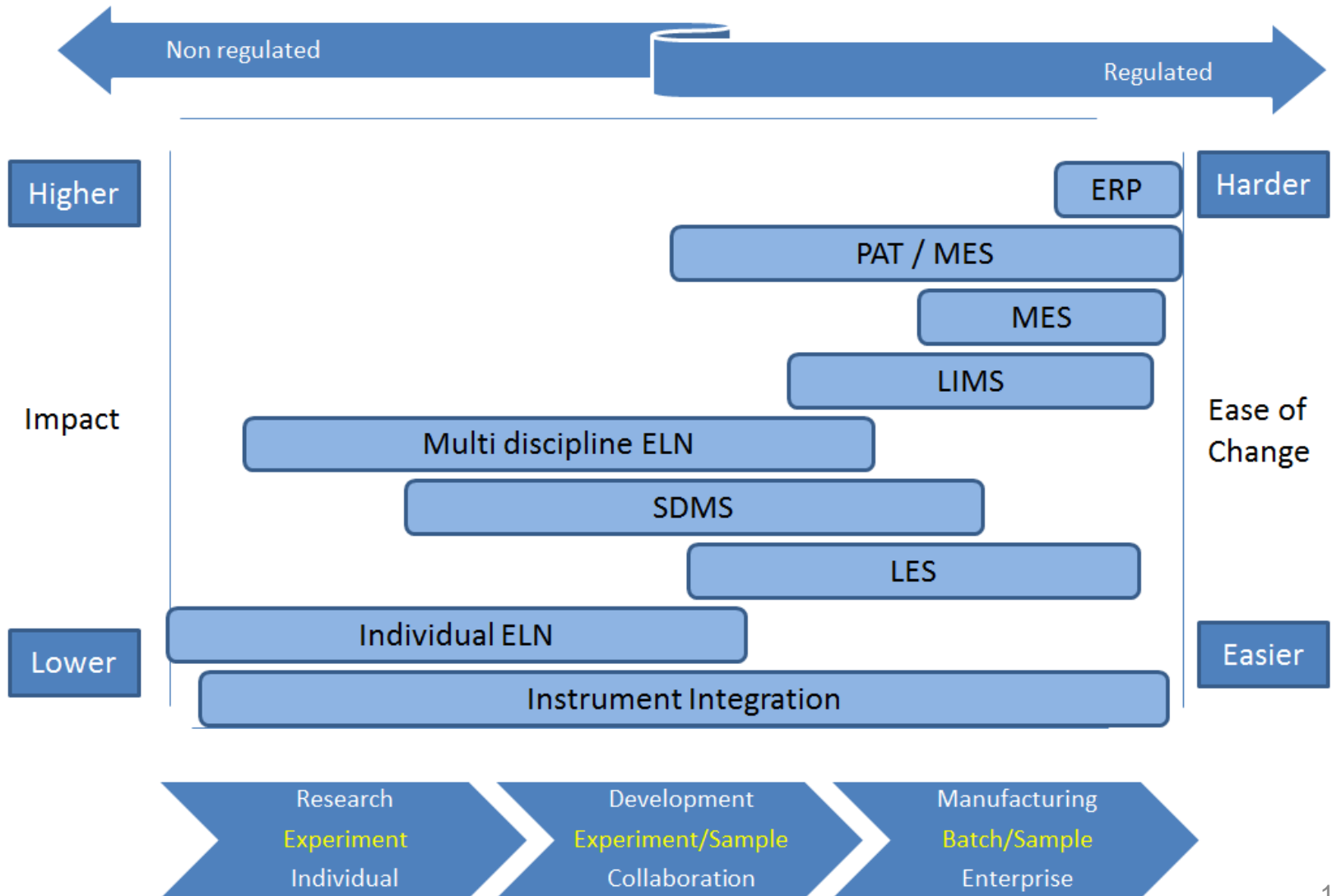
Lab information mgt means many things to many people - Concept Heidelberg

Nov 2015

Laboratorium software landschap



Laboratorium software landschap

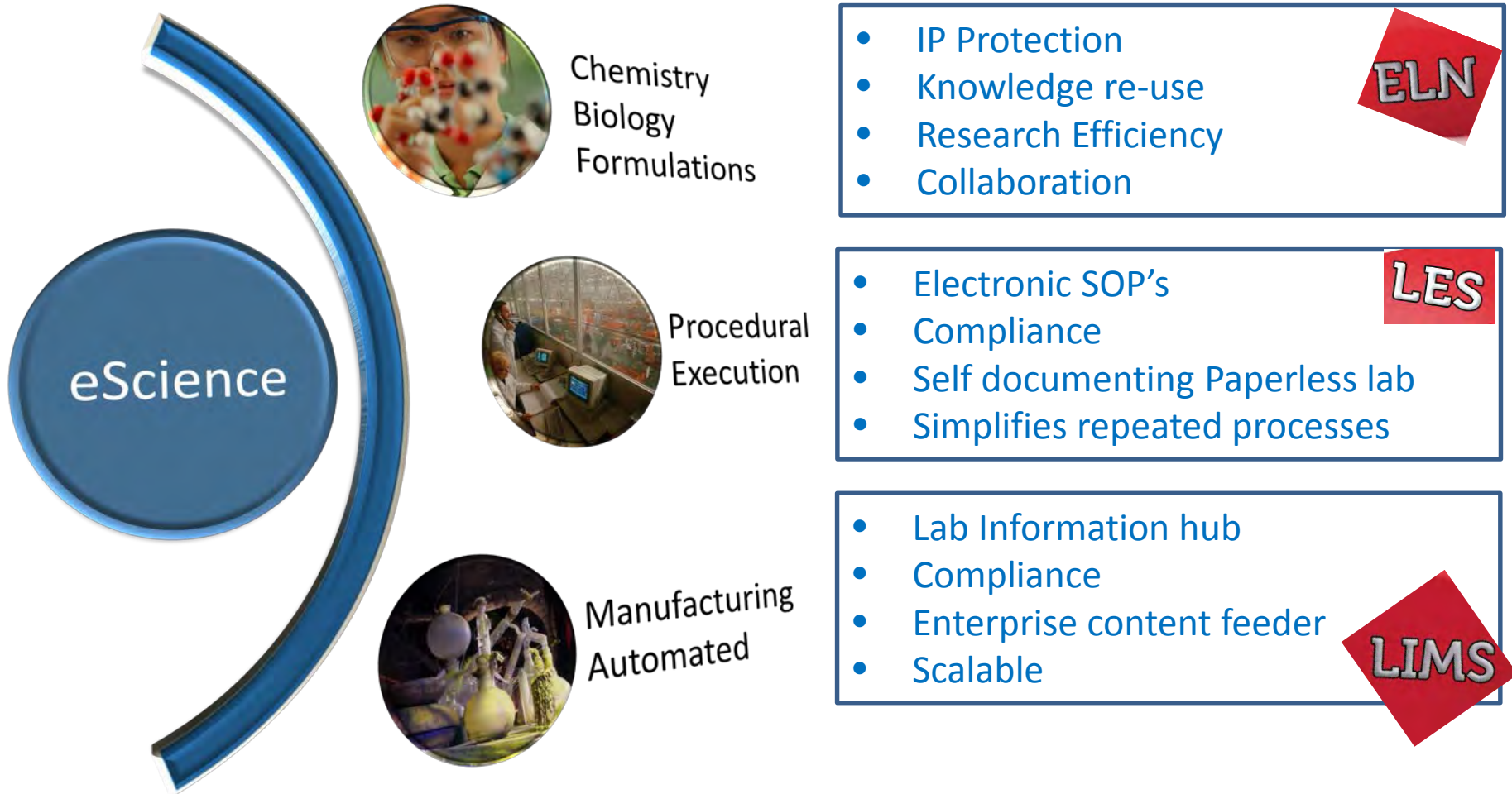


Ik weet het verschil
tussen ELN, LES,
SDMS & LIMS

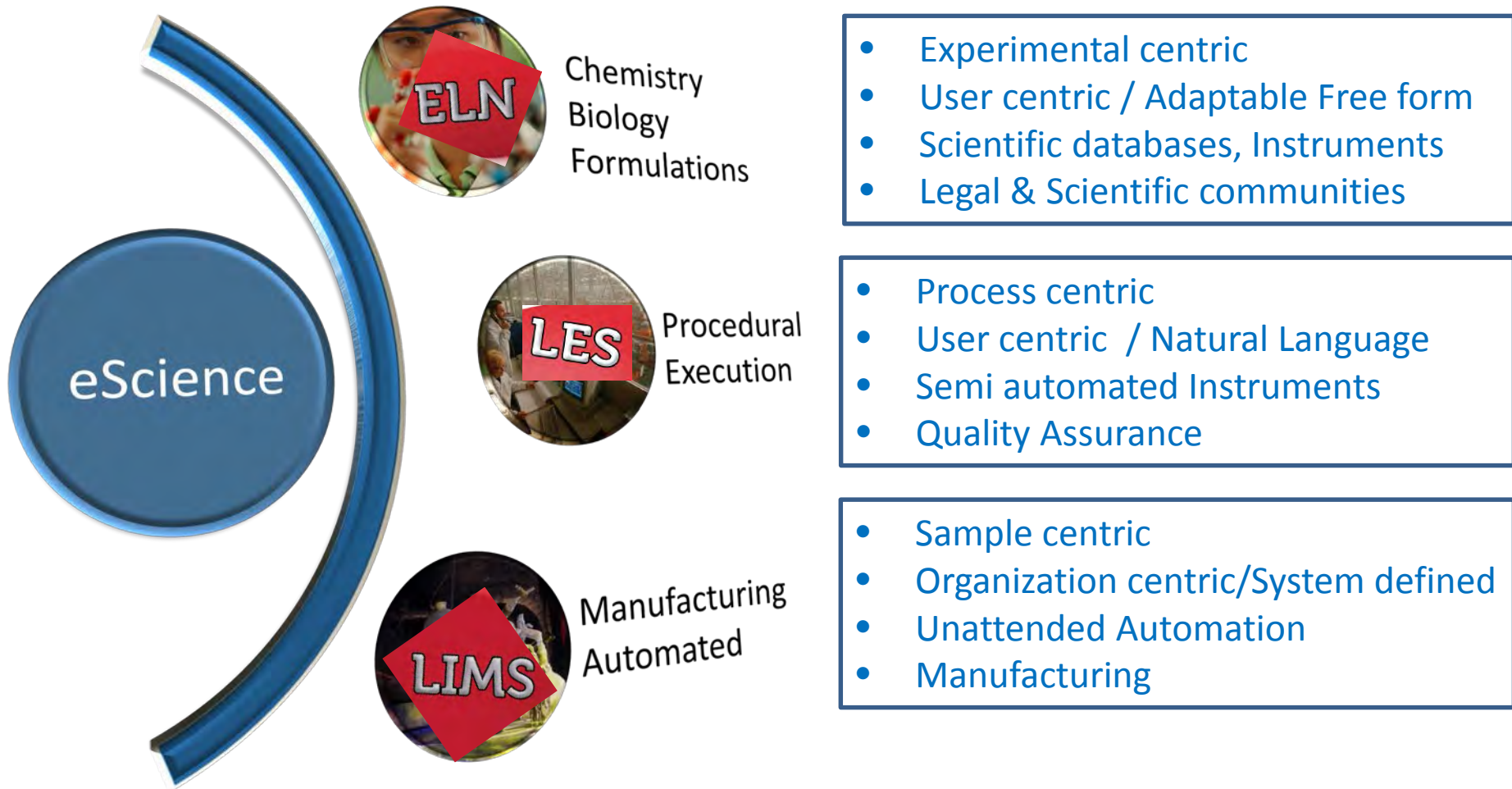
JA

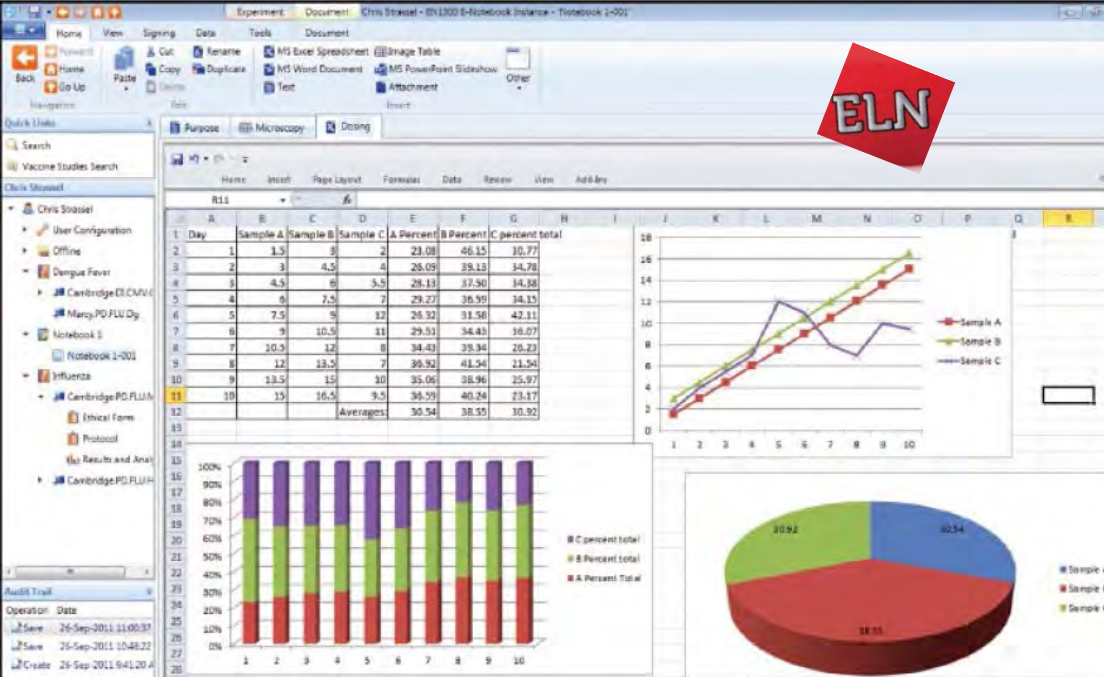
Niet zeker

De rol van Lab Data management software



Gedrag van Lab Data management software





ELN



Study Management Interface:

- Study: SAMPLE GROUP
- Study Datagroup: GLOBAL
- Submission ID: 100000246
- Log Priority: 4
- Material Type: CRYSTAL GEYSER
- Material Datagroup: GLOBAL

Sample Plan	Material Name	Sample ID	User Sample ID	Priority	Qty	Location
<input checked="" type="checkbox"/> AIR PARTICLE COUNT	WATER	200000928	My Sample ID 1	6	3	
<input checked="" type="checkbox"/> RINSEWATER	WATER	200000929	My Sample ID 2	6	2	
<input checked="" type="checkbox"/> MIXER SWAB	WATER	200000930	My Sample ID 3	3	5	
<input checked="" type="checkbox"/> WALL SWAB	WATER	200000931	My Sample ID 4	1	8	
<input checked="" type="checkbox"/> FLOOR SWAB	WATER	200000932	My Sample ID 5	8	7	
<input checked="" type="checkbox"/> WATER PURITY	WATER	200000933	My Sample ID 6	6	1	

LIMS

Titration Worksheet

LES

Product:	PROPOFOL	Lot Code:	
SOP	20070219_rev05	Current?	
Balance ID		Calibrated?	
pH Meter ID		Calibrated?	

Titrants

HaOH	Normality	Expiration
H2SO4	Normality	Expiration

Blank

Blank	mL	Titrant	mL
NaOH		H2SO4	

Sample + 20 mL 1 N HaOH	Weight (mg)	Titrant 1 N H2SO4 in mL
Sample 1		
Sample 2		
Sample 3		

Calculation: $((\text{Blank} - \text{Sample}) \times 180.2 \times \text{N H}_2\text{SO}_4 / \text{N NaOH}) = \text{mg Product}$
 $\%RSD = (\text{SD}/\text{average}) \times 100$

Sample	mg
Sample 1	
Sample 2	
Sample 3	
Average	
%RSD	

Performed by: _____ Date: _____

SOP: 2007 0219_re v05

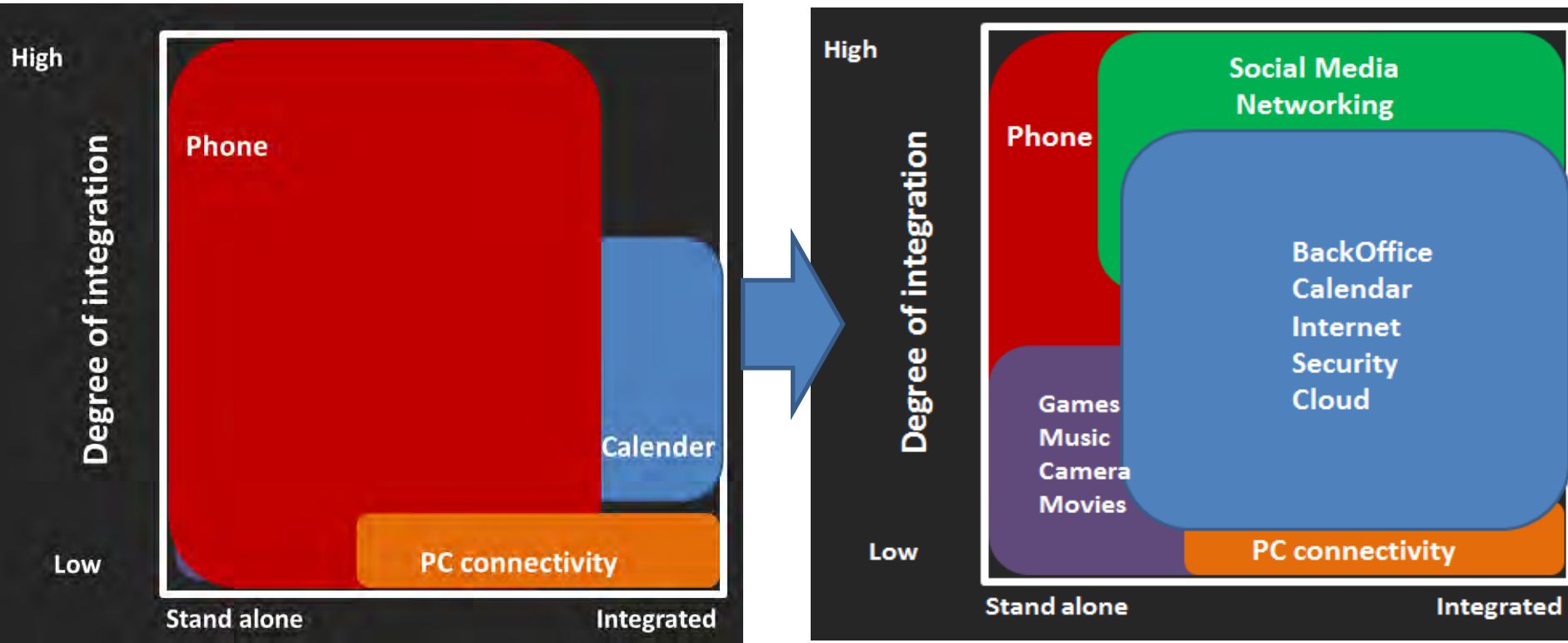
E_{lectronic} L_{aboratory} N_{otebooks}

ELN Means Many Things to Many People

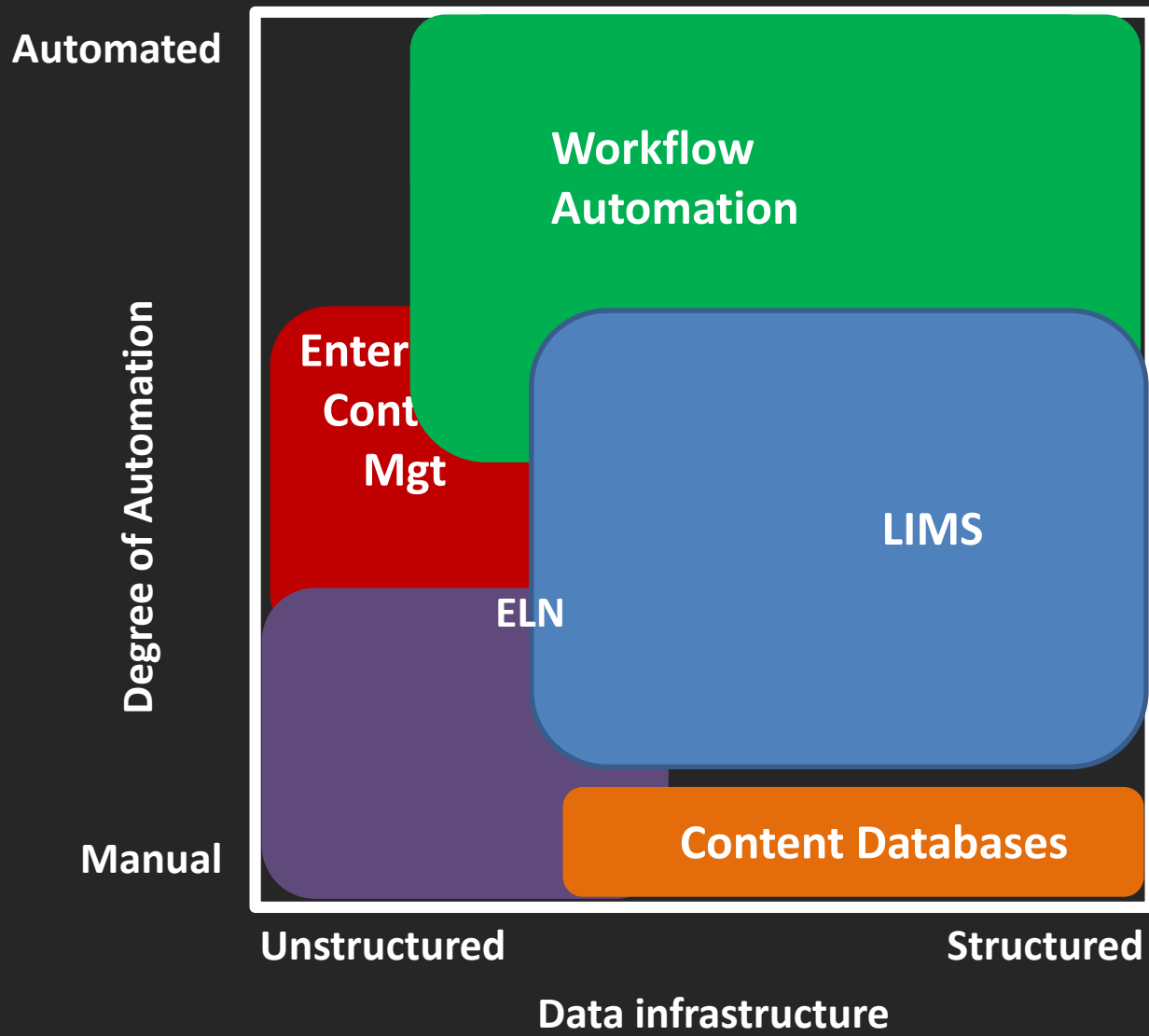
	Research ELN	LES	LIMS
Where in use	Chemistry & Biology Research & Development	Analytical Testing laboratories	Analytical Testing laboratories
Main purpose	<ul style="list-style-type: none"> Intellectual Property Protection Knowledge re-use Research efficiency 	<ul style="list-style-type: none"> Electronic SOP's Compliance Error reduction 	<ul style="list-style-type: none"> Secured laboratory information hub Compliance Reoccurring processes
Database focus	<ul style="list-style-type: none"> Document centric 	<ul style="list-style-type: none"> Transactional 	<ul style="list-style-type: none"> Transactional
Typical IT infrastructure	<ul style="list-style-type: none"> Windows workstation Web client Cloud SaaS 	<ul style="list-style-type: none"> Windows workstation web client Tablet App store 	<ul style="list-style-type: none"> Windows workstation Web client Client/Server
Application behavior	Experiment centric	Sample/Process centric	Sample/Process centric
User Interface behavior	<ul style="list-style-type: none"> User centric Free form & adaptable 	<ul style="list-style-type: none"> User centric Procedural Natural language 	<ul style="list-style-type: none"> Organisationally centric Procedural System defined
Related Applications	Scientific databases	LIMS, ELN, Instruments	LES, ERP, SDMS, CAPA
Licensing models	<ul style="list-style-type: none"> Named user SaaS 	<ul style="list-style-type: none"> Named user Concurrent user Instrument 	<ul style="list-style-type: none"> Named user Concurrent user Virtual user Enterprise
Compliance support	+/-	++	++
Sponsors	<ul style="list-style-type: none"> Legal departments Academia networks Scientific communities 	<ul style="list-style-type: none"> QA directors Lab managers 	<ul style="list-style-type: none"> Production managers QA directors

Download - <http://www.industrialautomation.com/Publications.php>

Market trend



Source: Industrial Lab Automation



Courtesy Atrium Research

Evolution CDS

Instrument & embedded calculation

Instrument & Calculation

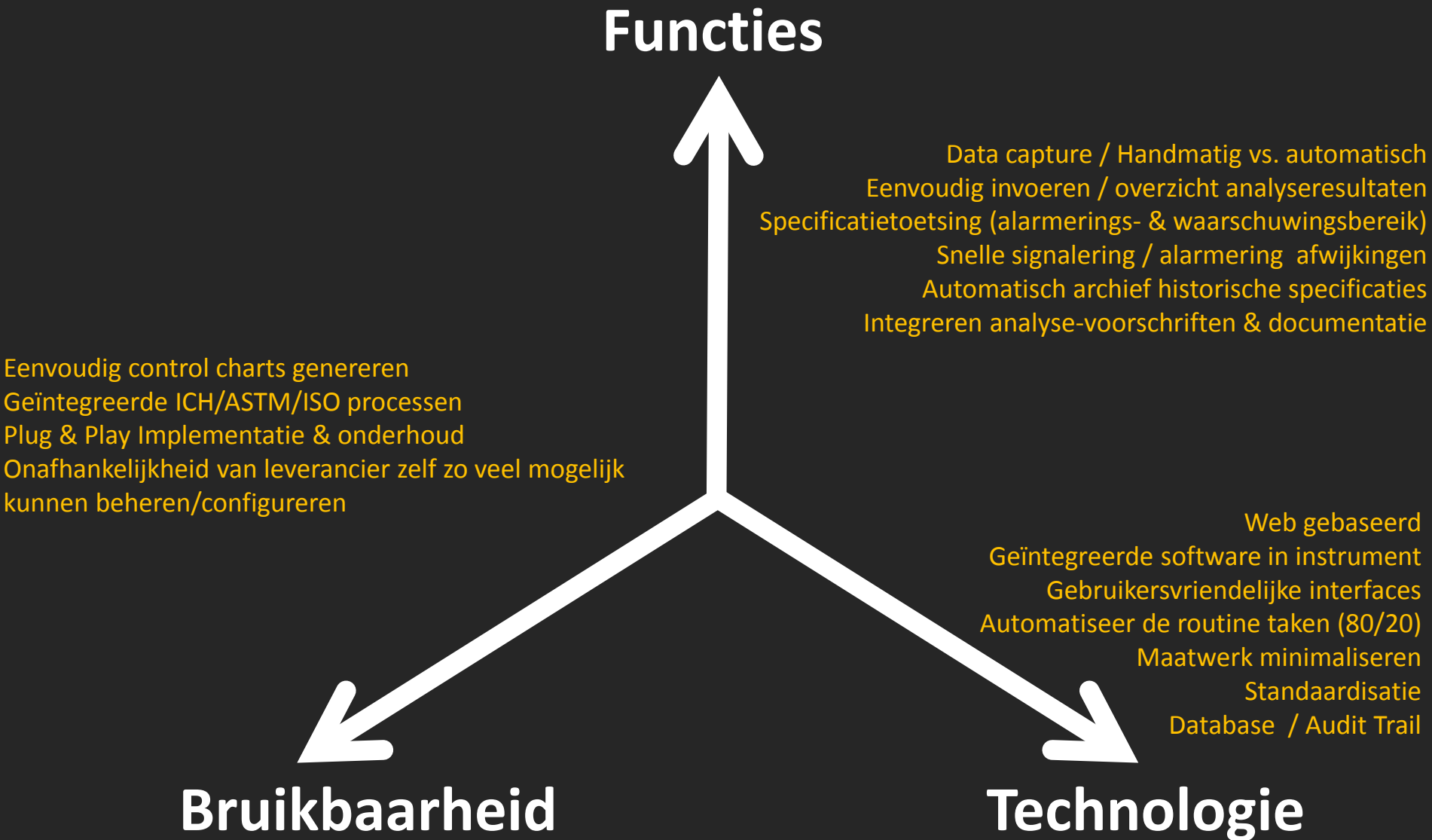
Software

Instrument

Workflow

Software

Denk eerst wat er nodig is, daarna pas in producten



Kennnen we
onze
klanten?

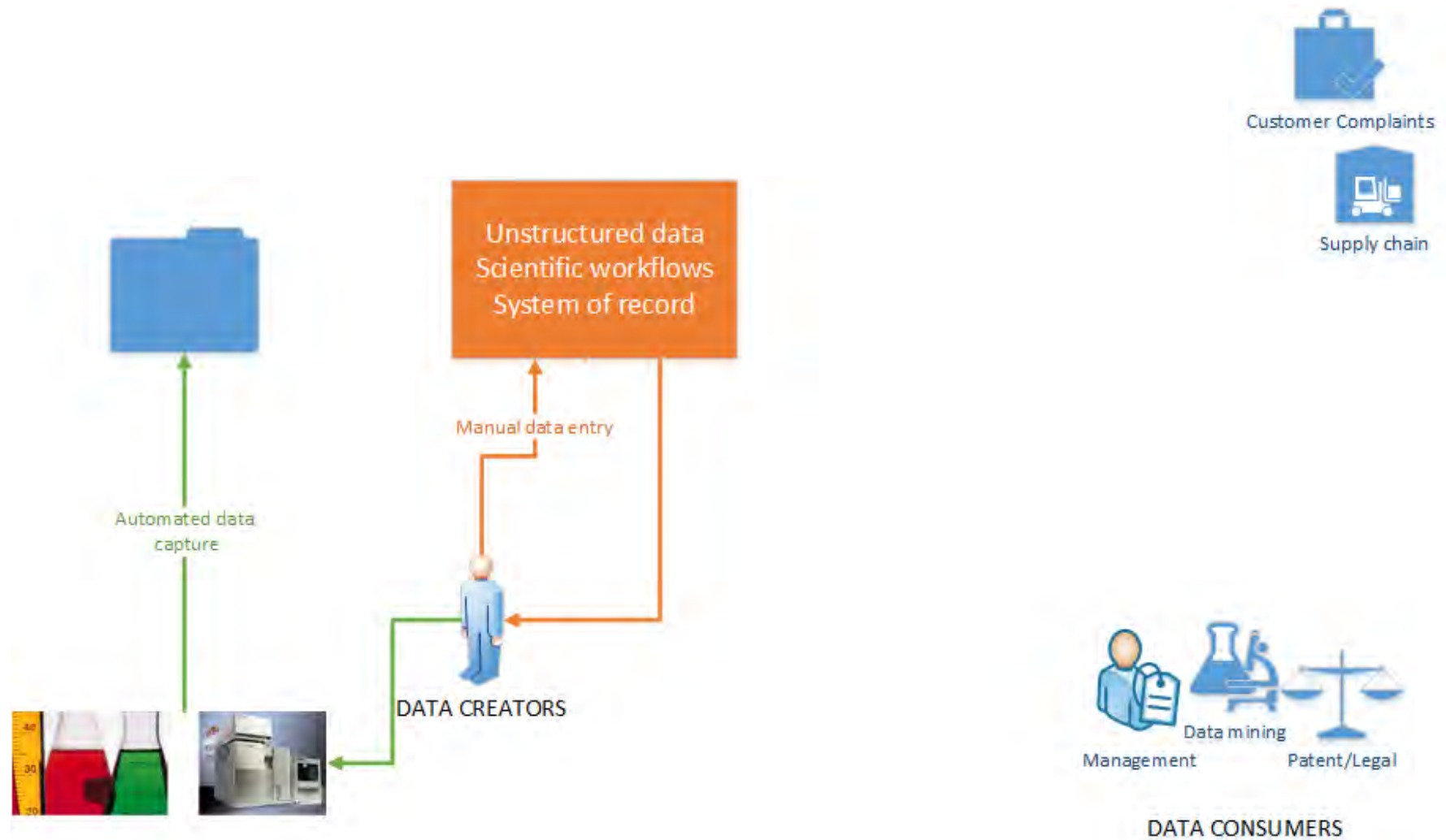
JA

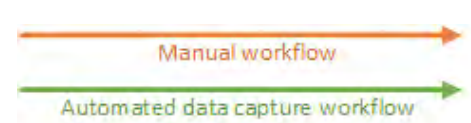
Mmmm...

Laboratorium data gebruikers

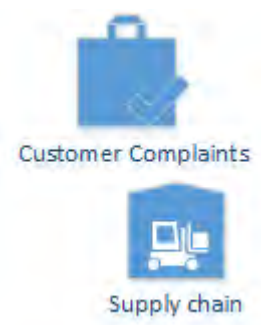
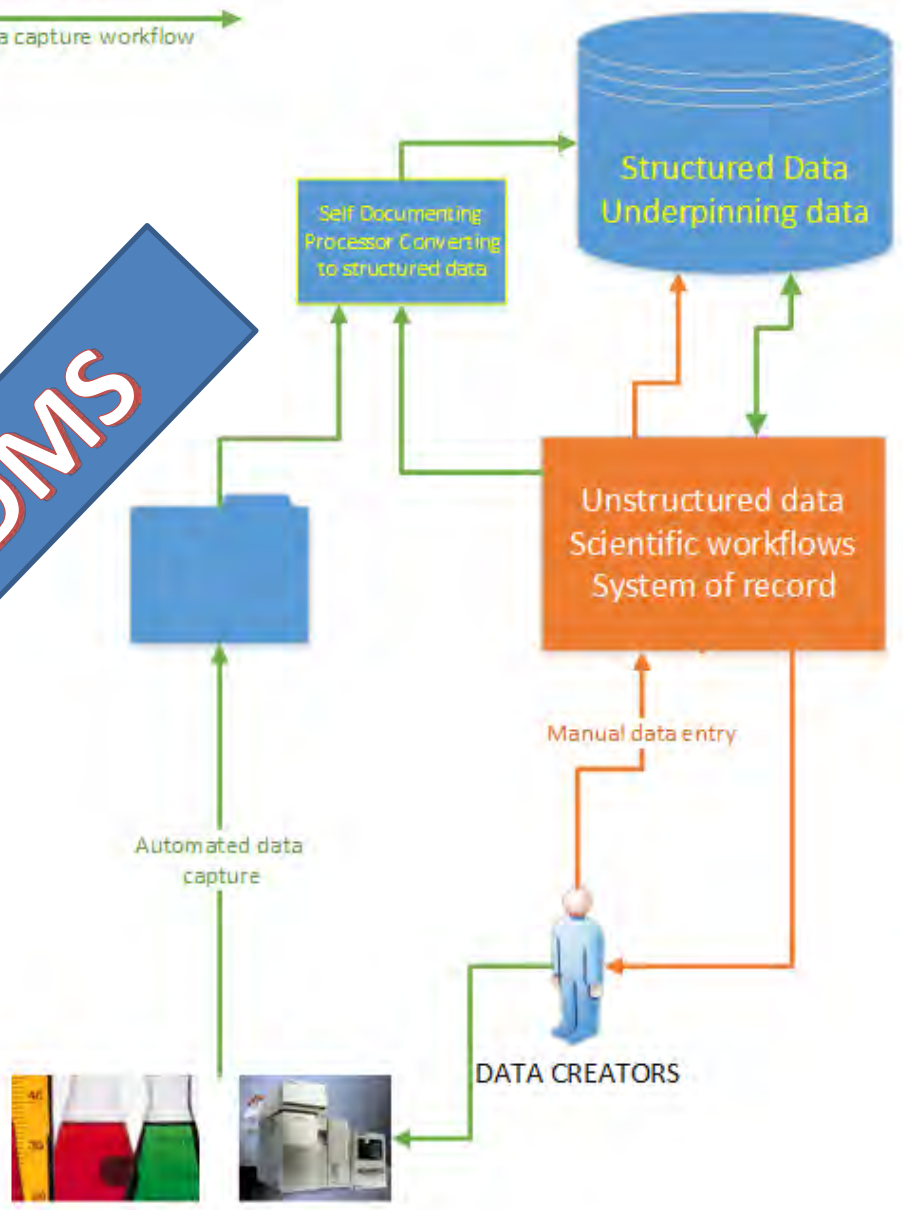


Laboratorium data gebruikers

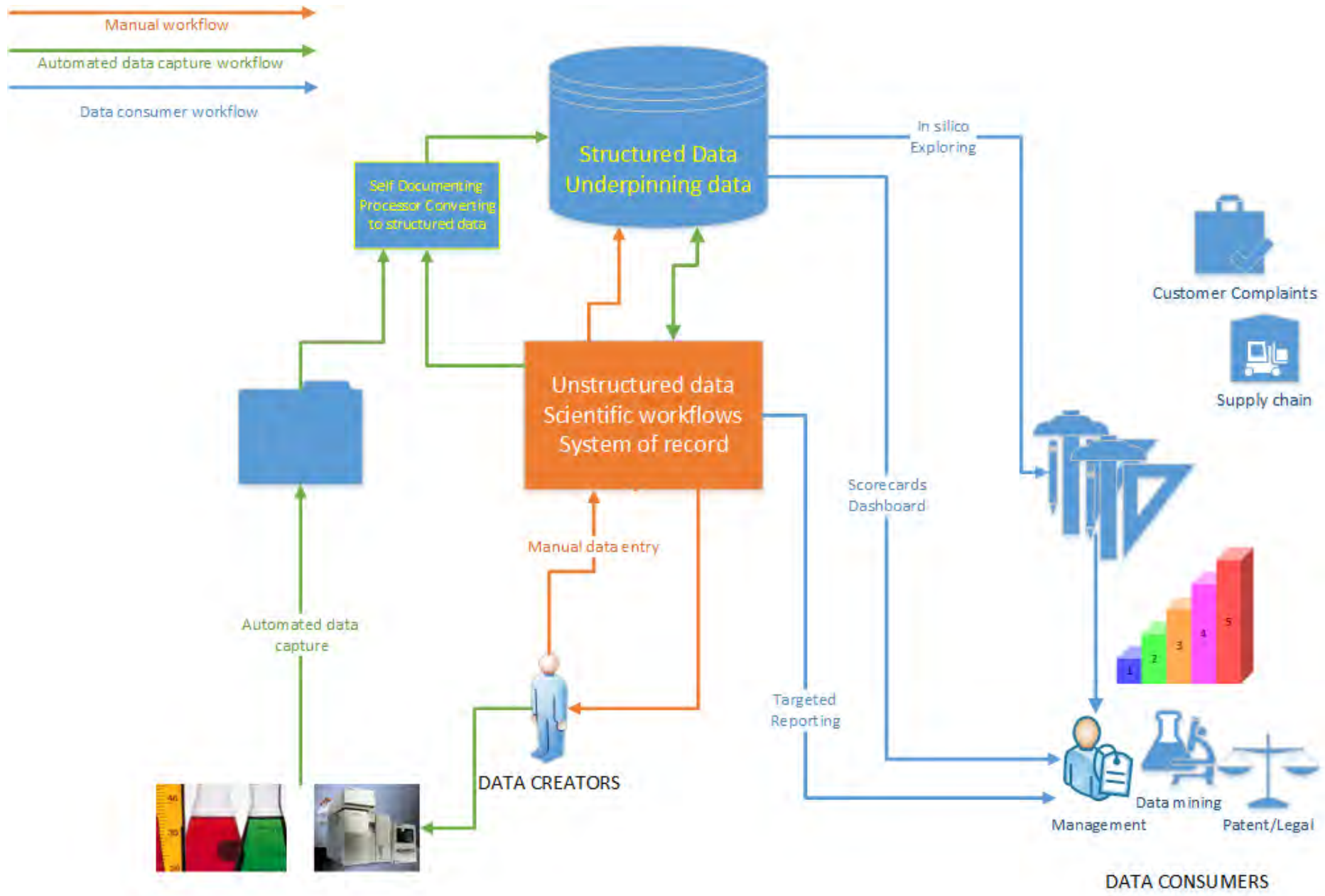




SDMS



DATA CONSUMERS



Ik weet het verschil
tussen een
database en een
spreadsheet

JA

Mmmm...

Elevator pitch

DB vs Spreadsheet

- **Spreadsheet = calculator**
 - A **spreadsheet primary function** is to MANIPULATE/CALCULATE and VISUALIZE data
- **Database = information storage/retrieval system**
 - A **database primary function** is to STORE and FIND relevant data consistently using meta data and context information.
- **You need both**

Data Integriteit

OPTIE 1

Potentiële zakelijke impact

Verlies van intellectuele eigendom

OPTIE 2

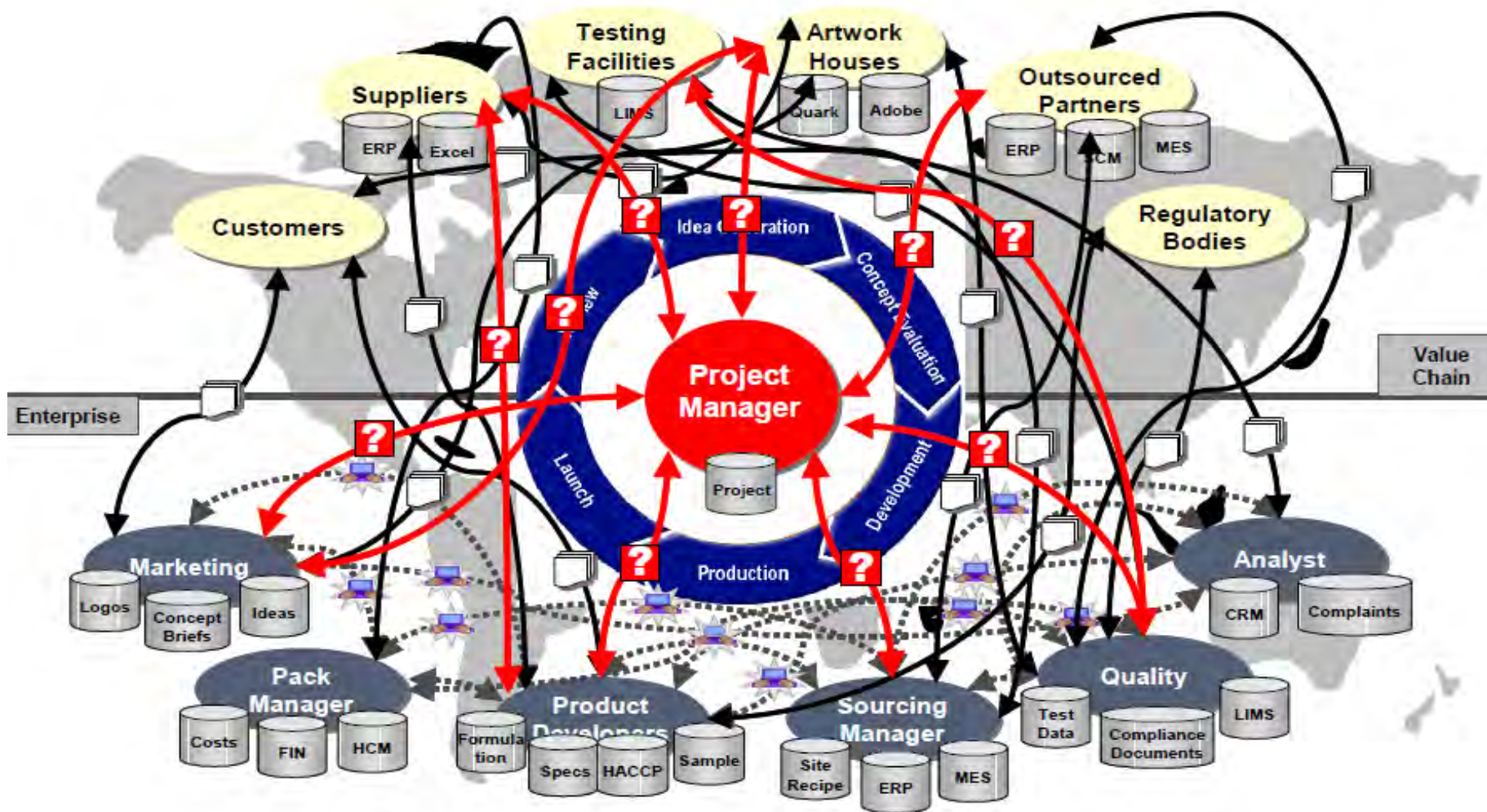
Business shutdown

Niet in overeenstemming met regelgeving

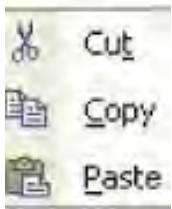
Data Integriteit



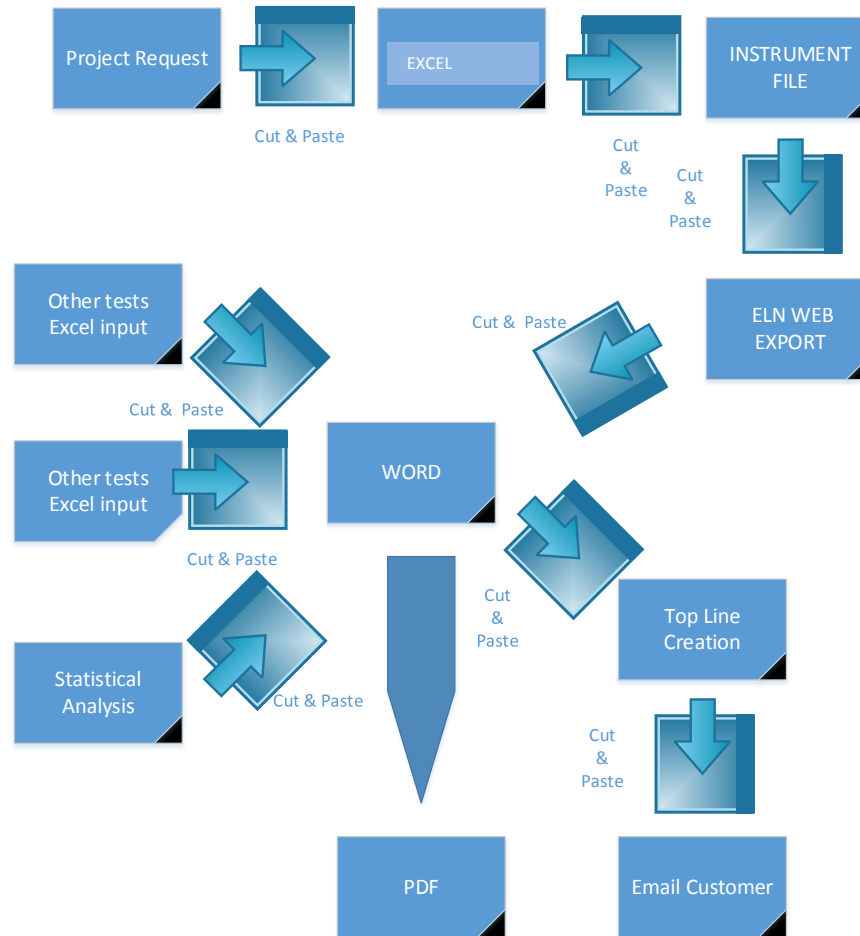
Herkenbaar?



Source AMR/Gartner



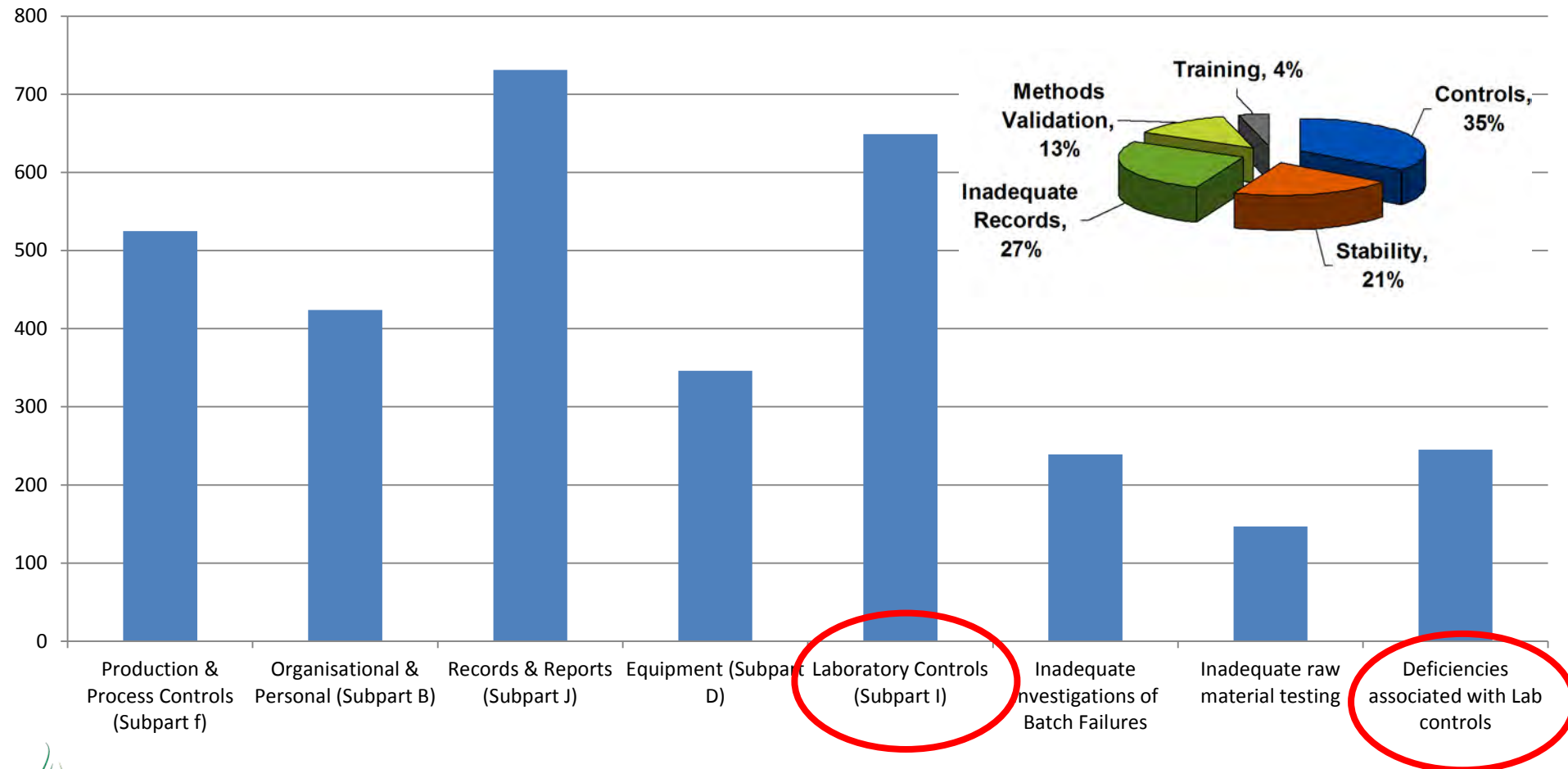
Ook herkenbaar?



US FDA Observations Summary (2013)

21 CFR Part 211 Observations

CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS



Laboratory data integrity observations



- **Alteration** of raw, original data and records
- Multiple analyses of assay with the same sample **without adequate justification**
- Manipulation of a poorly defined **analytical procedure** and associated data analysis in order to obtain passing results
- **Backdating** stability test results to meet the required commitments
- Creating acceptable test results **without performing** the test
- Using test results from previous batches to **substitute testing** for another batch

Source: FDA

Methodes om integriteit te verhogen

- Reduceer complexiteit van workflows
- Documenteer experimenten met *meta data*
- Implementeer *self-documenting* processen
- Maak gebruik van standaard (analyse) protocollen
- Maak gebruik van data standaarden
- Bewaak de data *consumers*
- Reduceer *custom* software extensies

Weten we
wat meta
data is?

JA

Mmmm...

Zelf-documenterende
processen verhogen de
data-integriteit zonder
extra kosten

JA

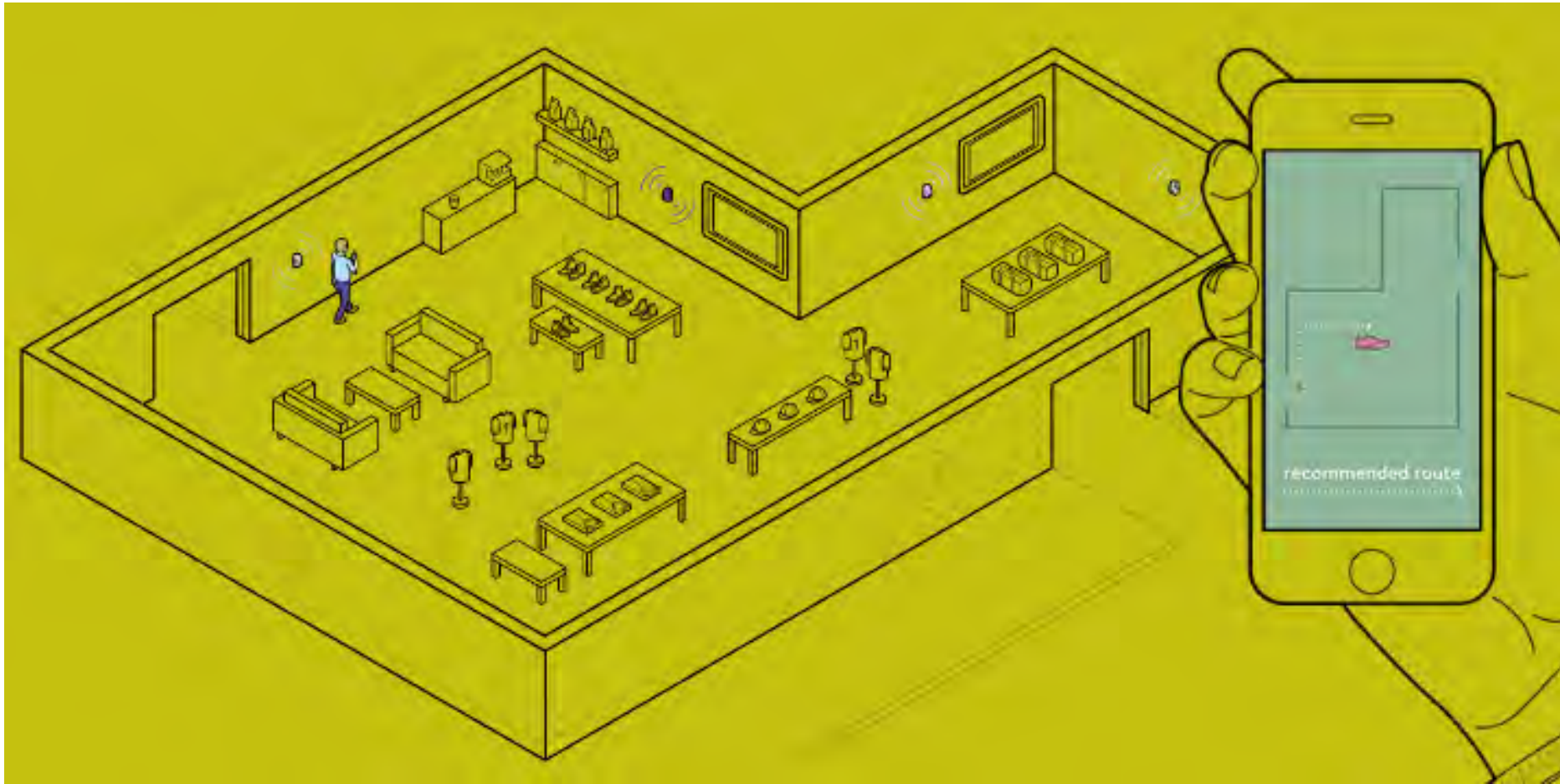
Mmm...

Self-documenting processen





Indoor location Tracking



META DATA – WIE/WAAR





Category 1

Chrom data systems (CDS)

Mass spec

Imaging

Multi media

.....

Category 2

Balances

Wet chemistry instruments

Mechanical testing

Colour

Temperature,

Leer momenten

- Eigen doelstelling niet voldoende in kaart gebracht
- Onvoldoende naar gehele proces gekeken (Silo denken)
- *Capabilities vs product* feature focus
- Denken in gadgets
- Te weinig aandacht voor impact van de menselijke acceptatie
- Goedkoop is Duurkoop
- Zwitsers zakmes syndroom





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-  [PaperlessLab Academy](#)



Suggested reading

Less is More: Adopting a Self-documenting Paperless Mindset

Informatics:
The Glue to Build Enterprise Knowledge

Considerations for Software Expansions and Upgrades
Before you decide to rock the boat, several key decision-making steps can help to ensure a smooth and successful upgrade

Facing Cross-Industry Challenges in the Food and Pharma Industries
Both industries may benefit from adopting best practices

Informatics Engine Drives Pharma Development toward Quality by Design
Learning from other industries

Linking an Instrument to a Tablet
Still a bridge too far?





Paperless Lab Academy

Gran Hotel Rey Don Jaime

10 min from Barcelona airport

19-20 April
2016
Barcelona
Spain

FINDING the SPEED to INNOVATE Strategies to effectively materialize laboratory knowledge


16 themed hands-on workshops – networking conference dinner – live demonstrations

- Leverage mindset and change management experiences
- Strategies to serve new consumers of scientific data
- Approaches to embrace social media in science
- Integrity challenges of mobile technologies & processes

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*Rules apply

scientific
computing world

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Automation

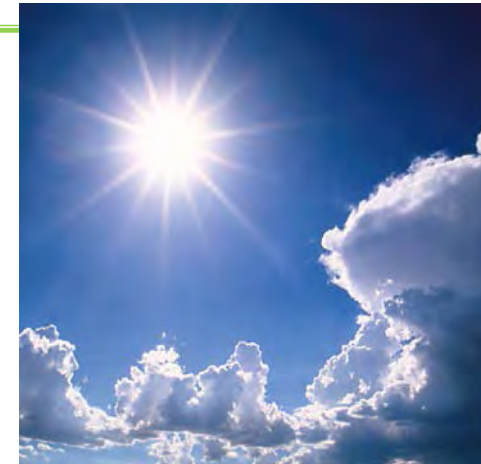
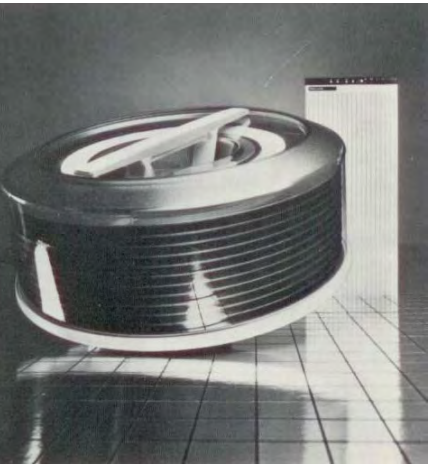
 NL42
Management Consulting

BACKUP

Why change?

We always have
done it this way...

Veranderen is ouderwets.



1985

1995

2005

2015



 **iTunes**



COMMENTARY LETTERS

Heng
CAI/NYTS

BANK



“We believe that the largest drug is the food that you eat three times a day, every day of your life”



[Read full article](#)

Luis Cantarell, President and CEO of Nestlé Health Science - Brett Gundlock for The Globe and Mail Sept 6, 2012



