De stand van zaken van data management software in het laboratorium

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- Independent consulting to address harmonization, integration and consolidation in science based processes
- Degree in Analytical Chemistry
- Introduced to Lab automation since 1981
- 30+ years @ international companies
- Founder of the annual Paperless Lab Academy
- International publications
- Active ISPE member (GAMP DI SIG & QbD/PAT)
- After work... Sailing & Music



ndustrial Lab

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Is less more in a paperless laboratory?





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

OW TO IMPROVE DATA INTEGRITY



Empowering the eData Life Cycle

Delivering scientific evidence to data consumers

"eConnect, eManage, eDecide, eArchive"

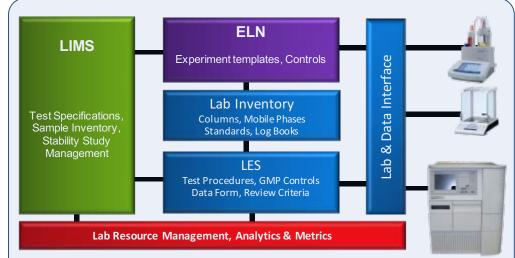
"eConnect"

- Effective workflow based selfdocumenting data capture strategies
- New data capture approaches to embrace Internet of Lab Things IoLT
- Models to embed intelligent software in instrumentation and sensors
- Integrating external collaborators and scientific literature knowledge

"eManage"

- Innovative methodologies to manage scientific master and meta data
- Concepts to prepare for new regulatory and data integrity challenges
- Strategy to harmonize / reconcile taxonomies and ontologies to boost insight





"eDecide"

- Adopting data analytics and visualization tools to materialize scientific knowledge
- Strategies to ease access and reduce complexity to non-scientific data consumers
- Enabling the power of Industry 4.0 to the laboratory

"eArchive"

- How to reduce the struggle finding the right data in the growing digital universe
- Essentials to secure long-term multidepartmental archiving
- Approaches to manage cost, sustainability and infrastructure processes



www.paperlesslabacademy.com



PUBLICATIONS Peter Boogaard - Industrial Lab Automation

Free Download @ www.industriallabautomation.com/Publications.php

ROADMAP TO DIGITAL Data intensive science is becoming mainstream, and new technology will change the dynamics CONVERGENCE of how scientists will work together. Many cross-industry best practices can be used to enable cross-functional collaboration between internal information silos to transform scientific information into actionable insights. What will the Internet of Lab Things (IoLT) bring in the fguture?



Trends In Laboratory Informatics. Just like almost anywhere else, informatics is the normality in lab operations. Data intensive analytics create gap-less knowledge management systems also

E lectronic L aboratory N otebooks ELN Means Many Things to Many People

ELN means many things to many People. ELNs mean many things to many people. This article starts with the end user in mind and look at the application from a user centric perspective. What is an Electronic Laboratory Notebook (ELN)? What

function does it serve? Where does it fit within my laboratory informatics strategy? Do we need an ELN, and if so what would be best for my company's needs? When should I use an ELN, or a LIMS or both?

TO IMPROVE DATA INTEGRITY

Data integrity is currently one of the highest cited areas in regulatory observations. Yet, data integrity is not a new requirement. In this article I will highlight the how can reduce data integrity inconsistencies

Linking an Instrument to a Tablet For how long do we need to be professor to link an instrument to a tablet in the laboratory? Why can we connect almost any smartphone using Bluetooth in our personal lives ourselves and why do we need a professor to transfer simple results in the laboratory to our ELN, LES or LIMS



In this article, I will share experiences and observations how the scientific high-tech community, can benefit from adopting paperless processes in the laboratory. Is it because paper doesn't require any significant investment budget, or is it the low barrier to access, since paper even works without power or the need to have access to an information infrastructure, or is it just simply that the "what's in it for me" question hasn't been answered satisfactorily for the scientists?

New scientific data consumers are increasing the value of laboratory. Research, manufacturing and regulatory procedures have been unchanged for years. There is an urgency TO DELIVER MORE VALUE to revisit these. The need to integrate the legacy silo based departments is becoming a top priority agenda item in many boardrooms.

JOINING UP

MANAGING CHANGE

IN THE LABORATORY

It is **pure waste** to perform labour-intensive hunting for information across multi-vendor. multi-technique databases, manual transcription checking and to manually create reports. What are these challenges to create value for the consumers of the laboratory data?



When considering data integration, we must first stop thinking 'technology'. Integration is not just about instruments or other software platforms. Instead, it is about integrating processes, accelerating ideas and facilitating mandatory compliance requirements more economically.

Less is More: Adopting a Self-documenting Paperless Mindset

The power of a Paperless Laboratory is the ability to enable organizations to implement self-documenting processes that produces GxP-compliant documentation to support corporate Cost of Goods Sold (COGS) optimization



Headaches about upgrading your software? Considerations for software expansions and Software Expansions and Upgrades upgrades. Before you decide to rock the boat, several key decision-making steps can help to ensure a smooth and successful upgrade. The last thing to do is to start is a project to change

a working enterprise application

Informatics: The Glue to Build Enterprise Knowledge

It is time to put more emphasis on the preventing facet and re-order the sequence of the CAPA abbreviation into PACA. It is proven that his theory to adopt continuous improvement strategies to decrease variability resulted in significantly better products and financial

Facing Cross-Industry Challenges n the Food and Pharma Industries

Food companies are becoming pharma companies. In this publication several overlaps and differences are discussed to spur a discussion on how both pharma and food industries may benefit from adopting the best practices.

Publication Download pages www.industriallabautomation.com/publications

performance.



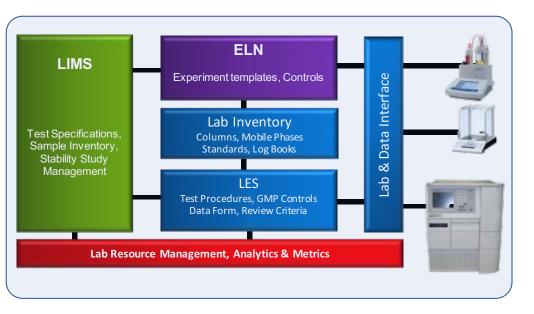
What general technology needs to be improved significantly, to accelerate the acceptance to work electronic?







Lab informatics expectations (2016)



Increasing data usability in and out of the laboratory	58.3%
Implementing a laboratory informatics system (LIMs or ELNs)	54.2 %
Investing in practical software/hardware solutions to increase efficiency of the workflow	39.6%
Access and data mining	35.4%
Migrating data into a new system	25%
Integrating legacy systems	20.8%
Integration of other non-informatics software systems	16.7%
Data security	16.7%
Mobility integration	12.5%
Other	8.3%



Data-intensive

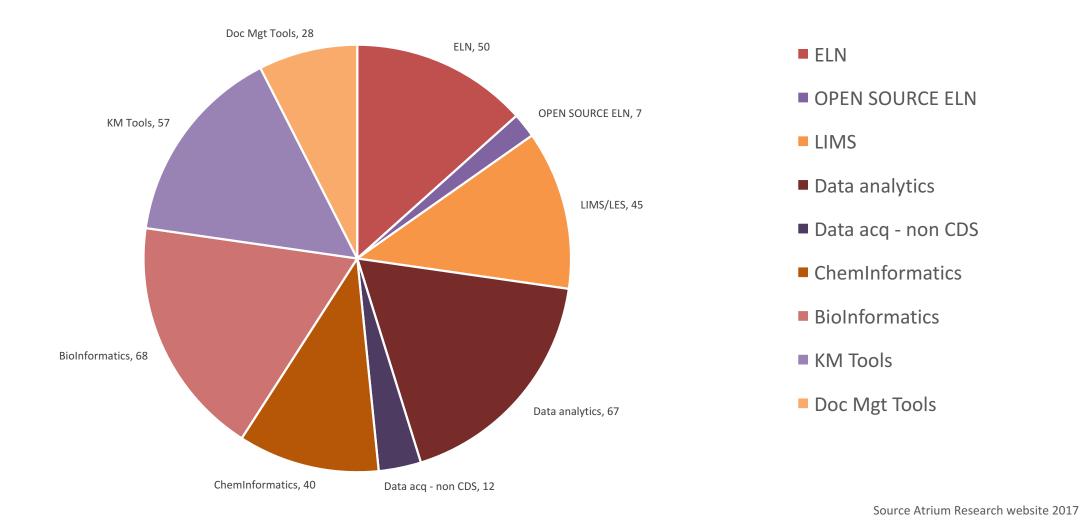
science is

becoming

mainstream



Scientific Application Landscape (total 374)



Industrial Lab

Scientific Software landscape



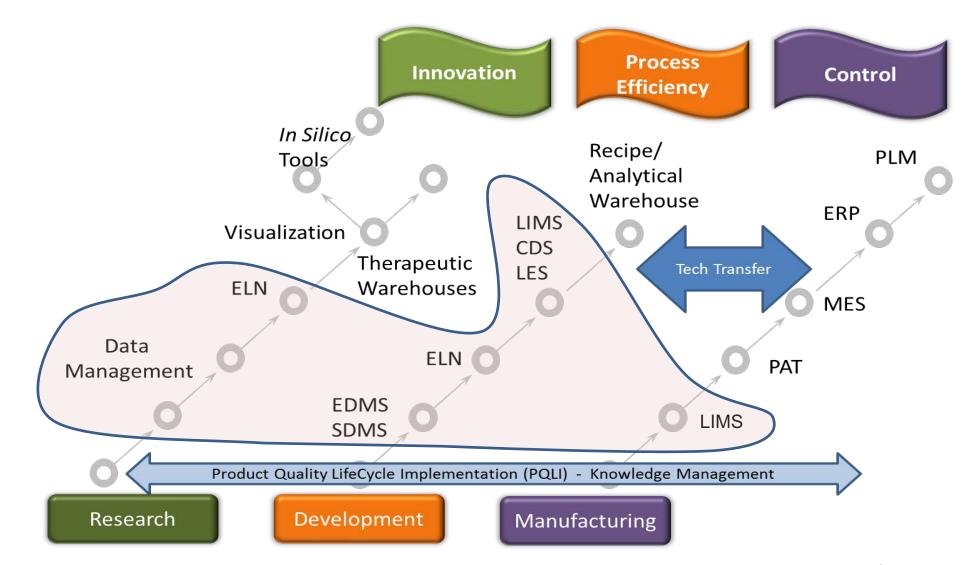






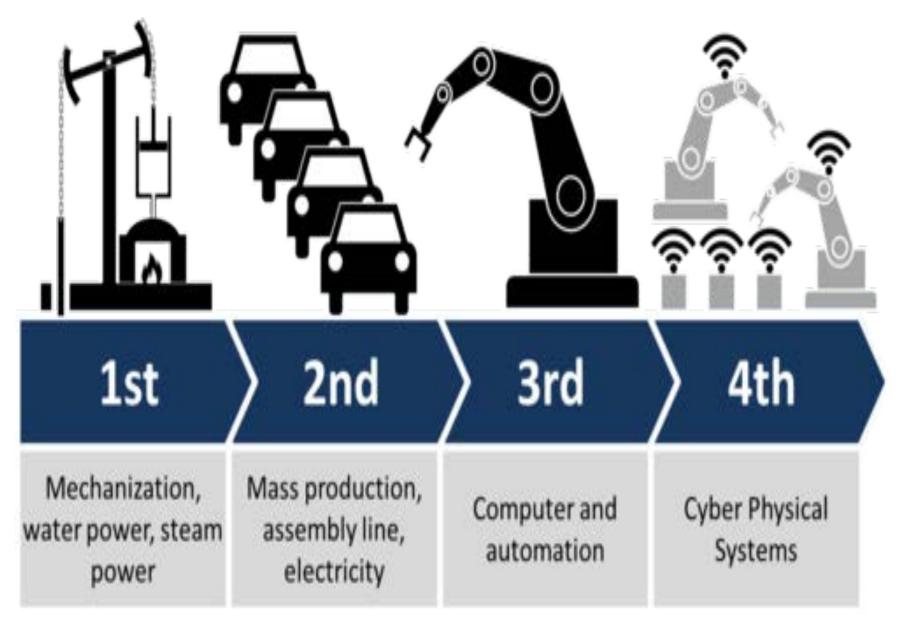


Scientific Software landscape





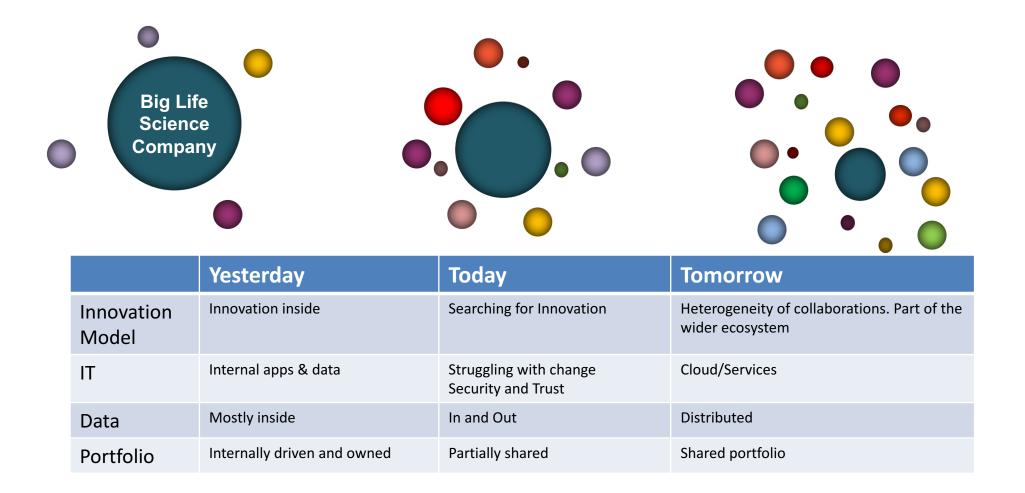
Industry 4.0 The Digital Revolution in Manufacturing





Scientific Information Landscape

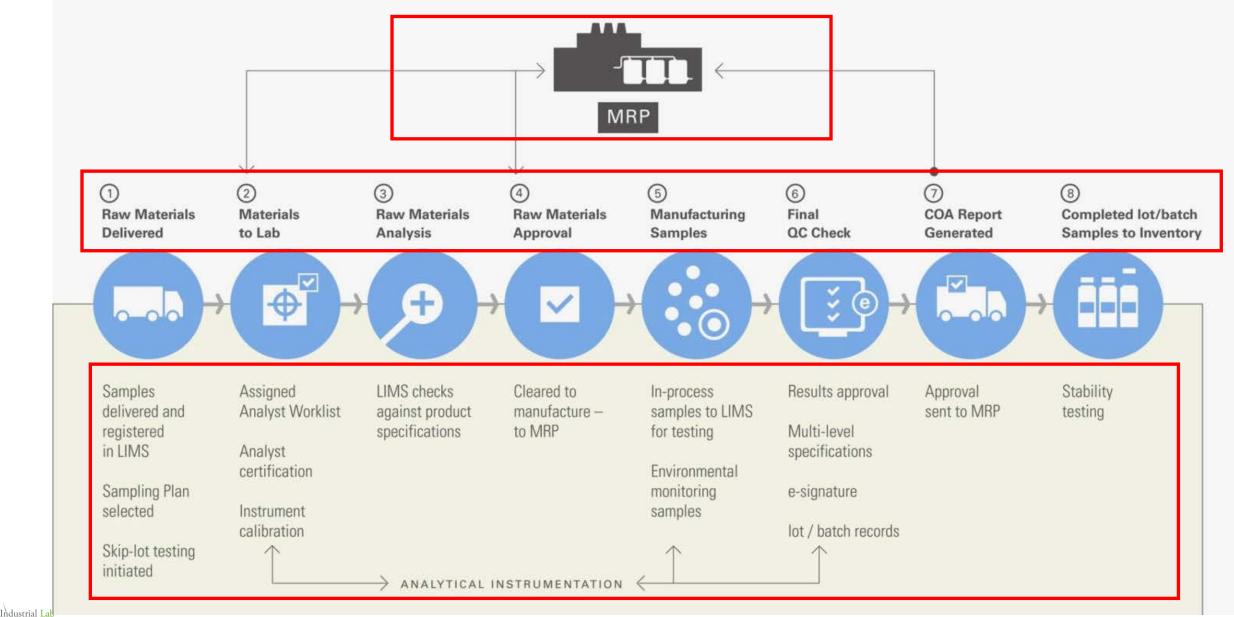
A rapidly evolving ecosystem





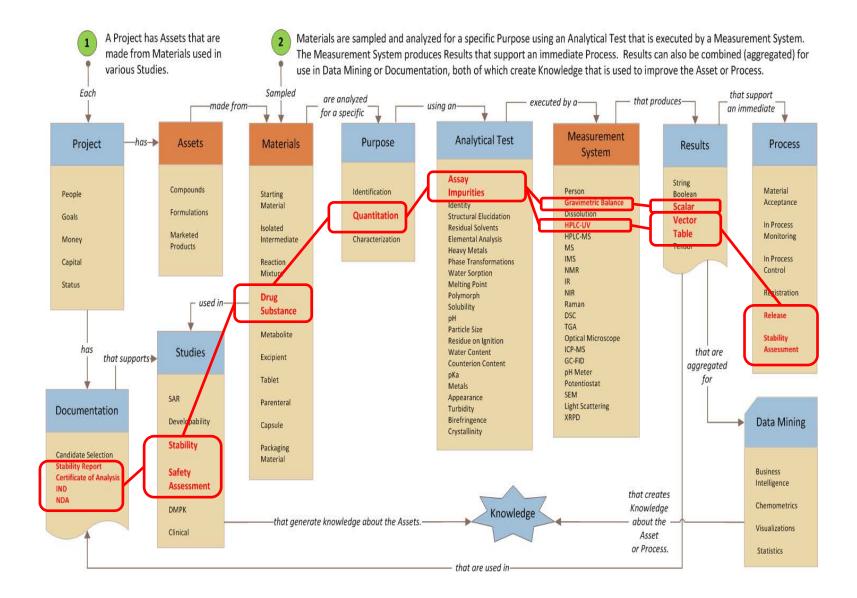
Typical LIMS manufacturing workflow process

MANUFACTURING ENVIRONMENT



Automation

Example of Laboratory Data Life Cycle model





#1 CHALLENGE

UNDERSTAND DATA **CONSUMER NEEDS**

& THEIR OBJECTIVES

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

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

Industry Challenges Source: | 18

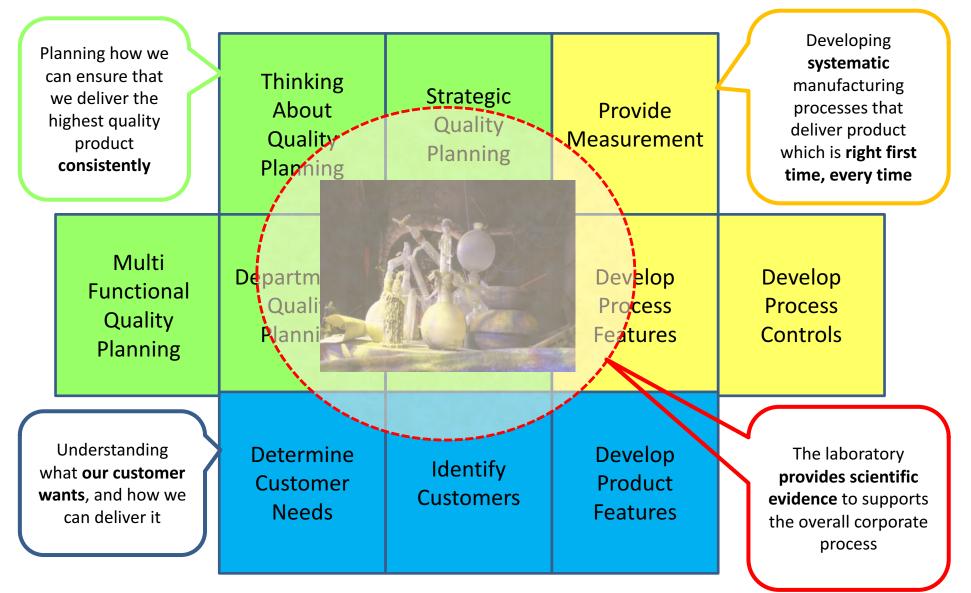
Read full article

Boogaard

Peter

Computing by

Defining the holistic process





Source: Gawayne M. Jones & P.J. Boogaard



Gran Hotel Rey Don Jaime

FINDING the SPEED to INNOVATE

Strategies to effective materialize laboratory knowledge

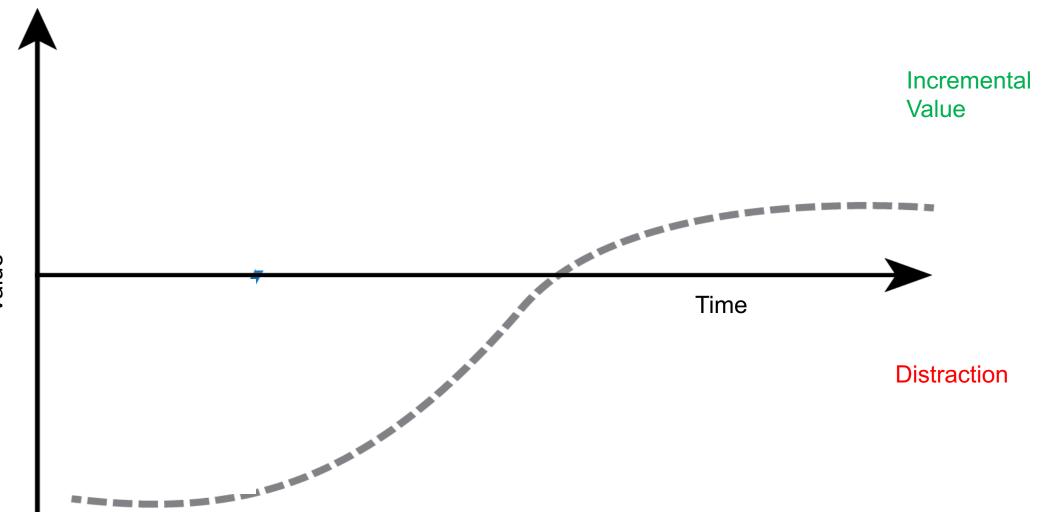
Create "Strategic Speed"

Minimize Time to Value; Maximize Value Over Time



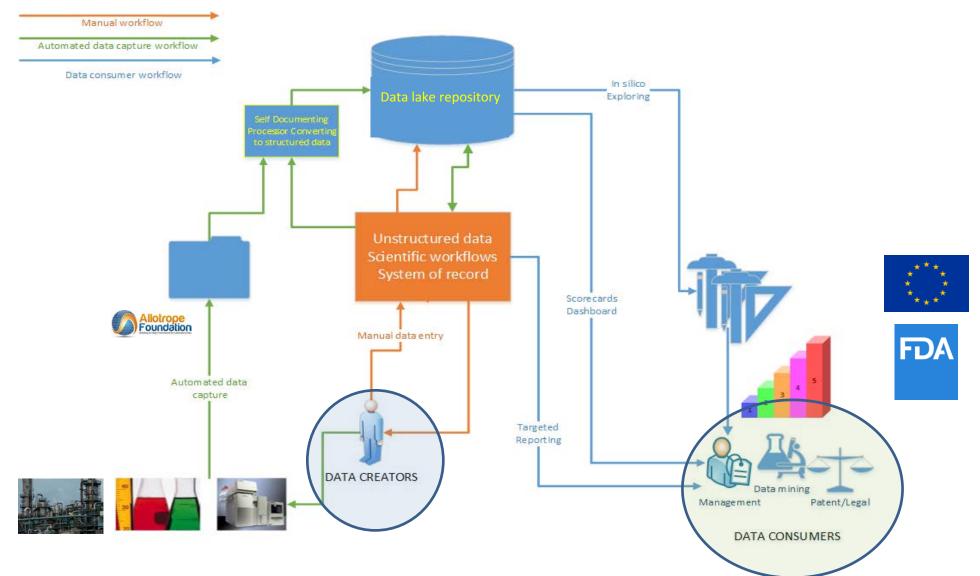
Create "Strategic Speed"

Minimize Time to Value; Maximize Value Over Time





Value of lab data will be expanded by understanding the data consumer need





#2 CHALLENGE

USING THE RIGHT

TOOLS

ELN

Regulated

Chemistry

General chemistry and reactions Medicinal chemistry Synthetic chemistry Cheminformatics Process chemistry Analytical chemistry

Biology R&D assays Computational biology Bioinformatics Omics research Pathway exploration Protein modeling

Documentation of Experiments Non procedural / free form **Robotic Automation Electronic Record Keeping** Patent Evidence Creation Security and external data access

Translational Medicine Healthcare informatics Clinical trial analytics

Engineering Design engineering Test engineering Materials simulation Process engineering **Process manufacturing**

R&D analytical support Paper-on-glass execution

R&D analytical support

Structures & unstructured support

Data analytics

Core ELN capabilities

Formulation Formulation development Design transfer **Pilot production** Materials blending

Procedural Execution Paper-on-glass execution QA/QC SOP execution Quality GxP studies R&D analytical support Analytical formulation Self-documenting data capture

LES

QC Manufacturing Analytical instrument capture Quality manufacturing Repeatable analytical processes Lab resource planning

Core LES/LIMS capabilities Compliance Secured Lab Information hub Enterprise content feeder **Electronic SOP's Paper-on-glass** Self documenting Paperless lab Simplifies repeated operations

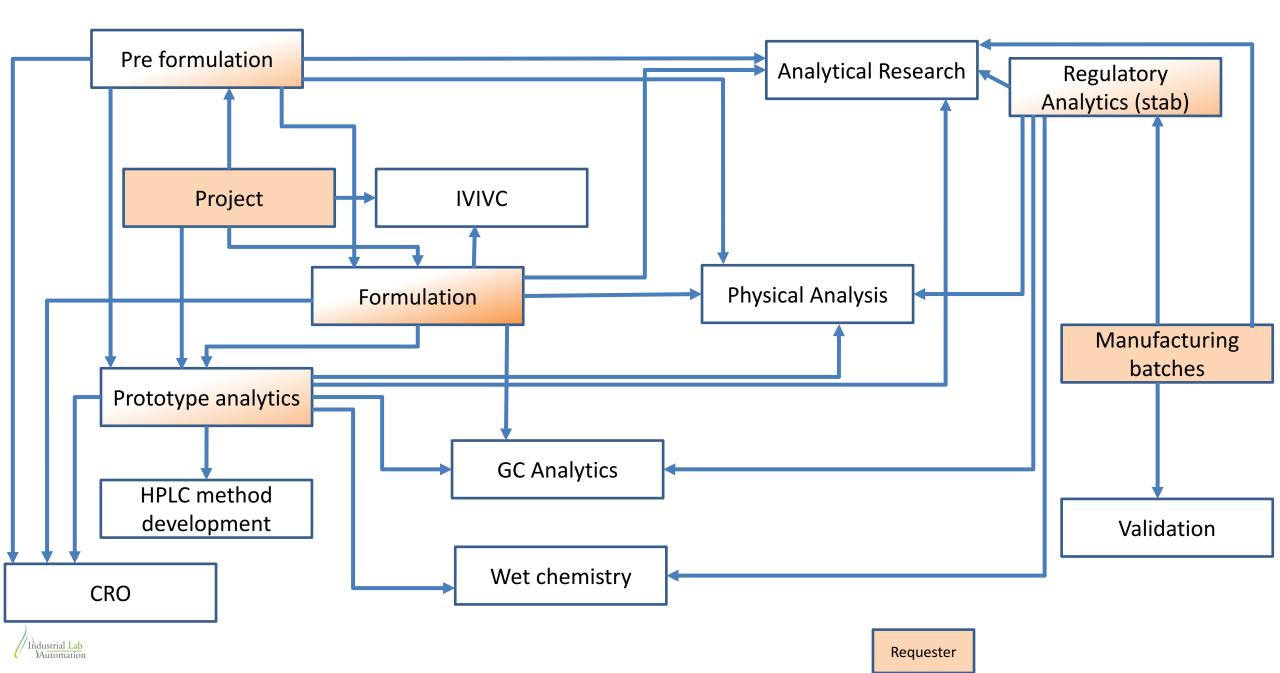
Analytical services Method development **Stability studies Environmental monitoring** Inventory management Instrument maintenance

Enterprise integration Empower/CDS integration CAPA processes **ERP** integration **MES** integration **CRM** integration

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24

Requester workflow



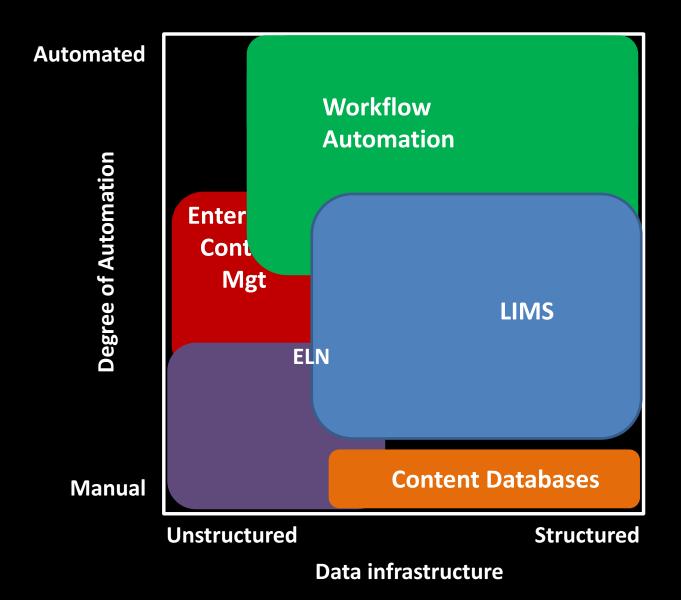
In its simplest form, an Electronic Laboratory Notebook can be thought of as for an electronic embodiment of what is currently being done in a paper laboratory notebook.

It is a tool that facilitates workflows that play out in laboratories.

Having said that, Laboratory Information Management System (LIMS), Electronic Laboratory Notebook (ELN) and Lab Execution System (LES) applications all support this basic definition, to a greater or lesser extent.

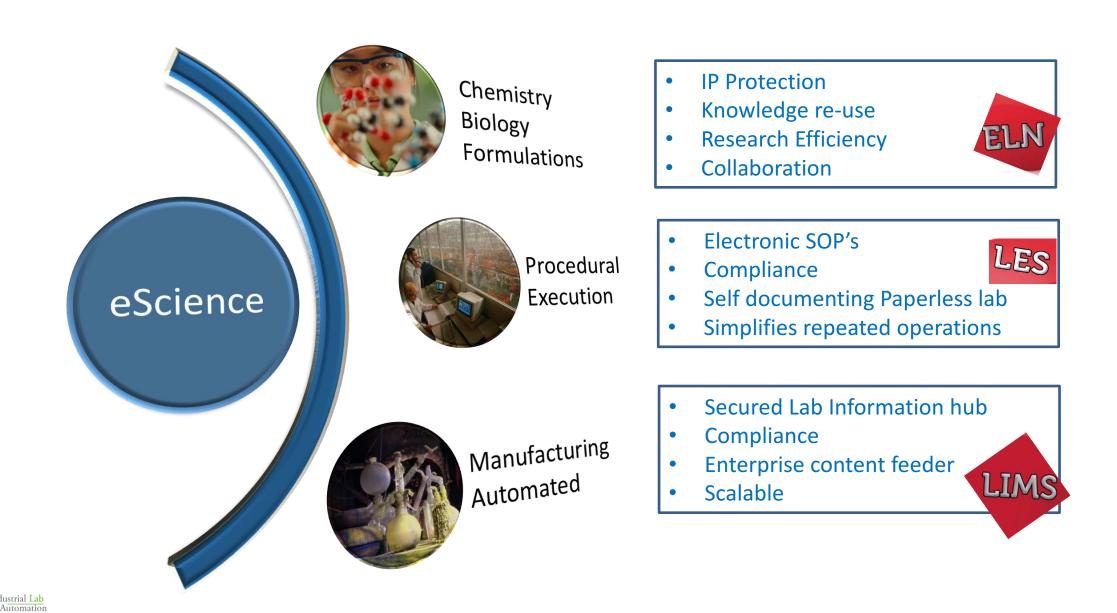


So why bother?

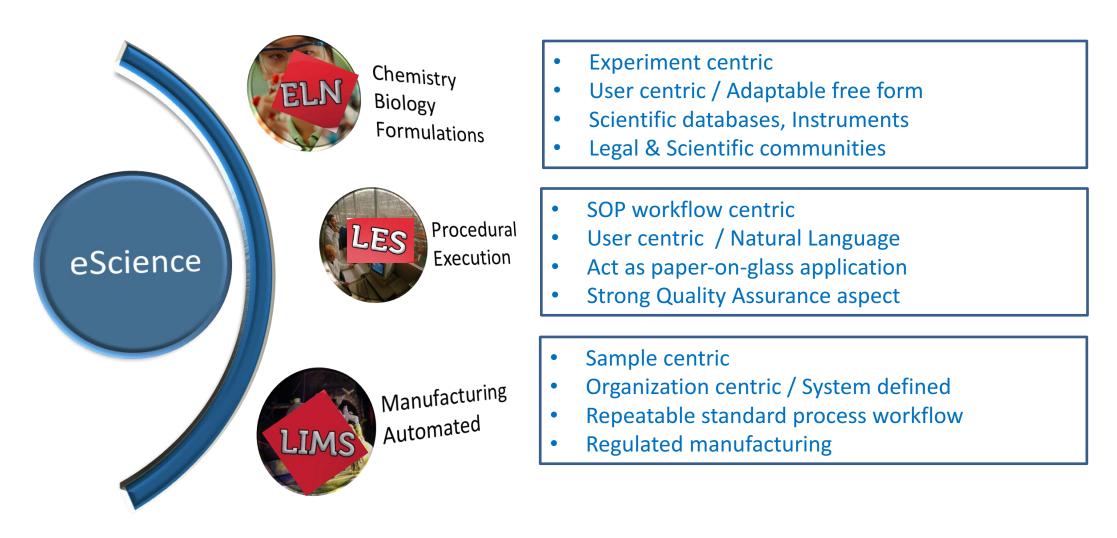




The role of Lab Data management software



Summary - Behavior of Lab Data management software





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Log

All Attributes | Grid Attributes



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Sample + 2	0 mL 1 I	N NaOH	Weig	ht (mg)	Titra	nt 1	N H2SO4 in mL	
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Sample 1	
Sumple 1	
Sample 2	
Sample 3	

Calculation: ((Blank – Sample)(180.2)(N H2SO4/ N NaOH) = mg Product

%RSD = (SD/average)*100

Sample	mg
Sample 1	
Sample 2	
Sample 3	
Average	
%RSD	

Performed by:

Date:

SO P: 2007 0219_rev05

Typical Objectives for LIMS/LES

- Validated source for regulatory compliance
- Automate manufacturing workflows
- Electronic Batch Record (EBR) support
- Facilitates self Documenting processes
- Enables cross functional KPIs
- CAPA / PACA evidence
- Complement manufacturing/ERP processes
- Achieve data integrity quality data consistency
- Stability studies
- Environmental monitoring
- Complements CDS systems
- Resource to enabling workflow optimization



Typical Objectives for ELN

- Enables to re-use scientific insight
- Facilitates prior knowledge sharing
- Resource for data analytics and formulation optimization
- Self Documenting data acquisition processes
- Exposing KPIs
- Integrates external partner collaboration
- Achieve sustainability goals reduce paper volume
- Support migration from hybrid (paper) legacy processes
- Achieve data integrity quality data consistency
- IP protection (legal)
- Simplifies tech transfer processes
- To attract new scientists

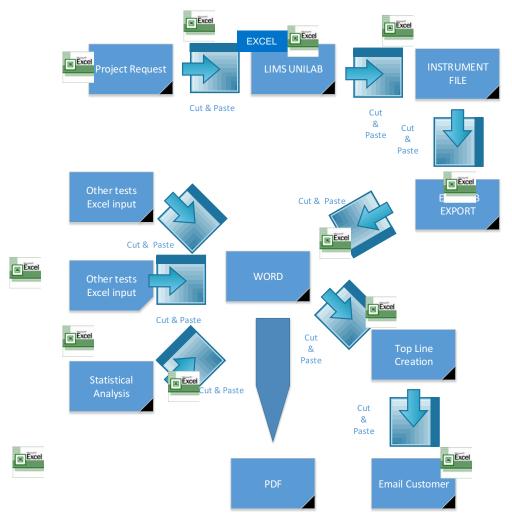


Data Integrity starts @ the source





Data Integrity nightmare COPY/PASTE Madness





Metadata, why important?

• Without Meta data this is just a photo.





Meta data: Speed, when, where, photo ID, last calibration, ...



Self-documenting processes

Reduces the value of data integrity at the source





Source: How to Improve Data Integrity Laboratory Informatics Guide (LIG 2016) / Scientific Computing World



Self-documenting processes

Reduces the value of data integrity at the source



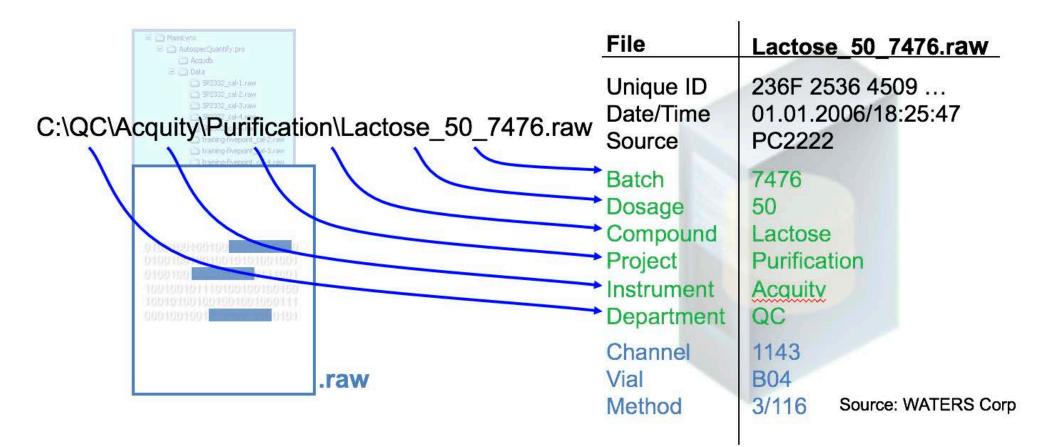


Example of Self documenting processes in the laboratory

SDMS automated acquisition extracts system and fixed metadata plus metadata from file name and folder structure

and metadata from file content

dustrial Lab



#3 CHALLENGE

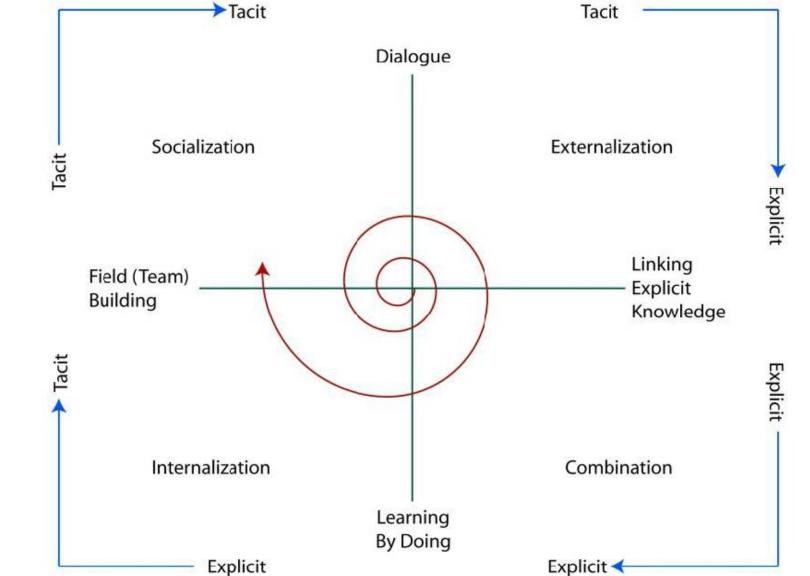
CREATING THE RIGHT CONTENT

Knowledge is of no value un ess you put it into

practice



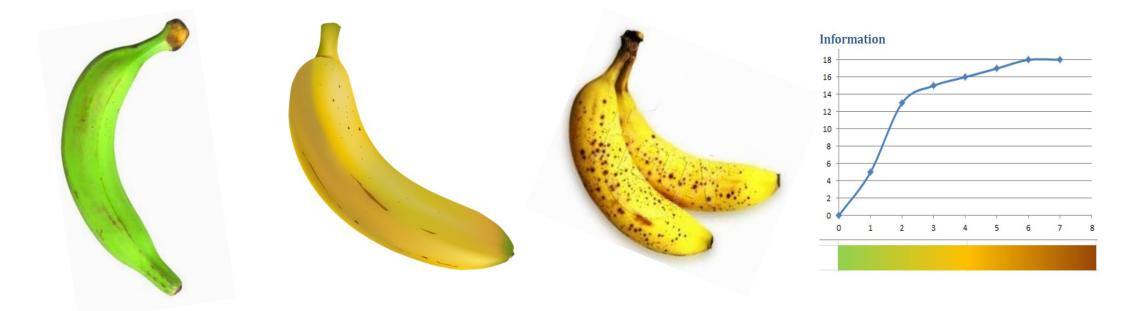
Anton Chekhov- writer



Nonaka's Spiral of Knowledge framework for learning



Do we speak the same language?



DATA

To tell the color To tell what object represents

INFORMATION

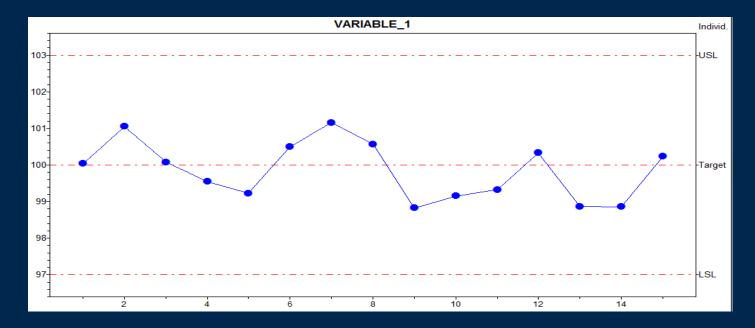
From color Physical attribute establish sugar content Chemical attribute

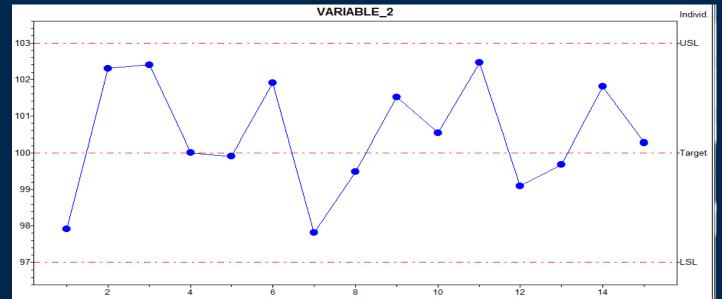
KNOWLEDGE / INSIGHT

What to buy Make decision by linking Information to the objective



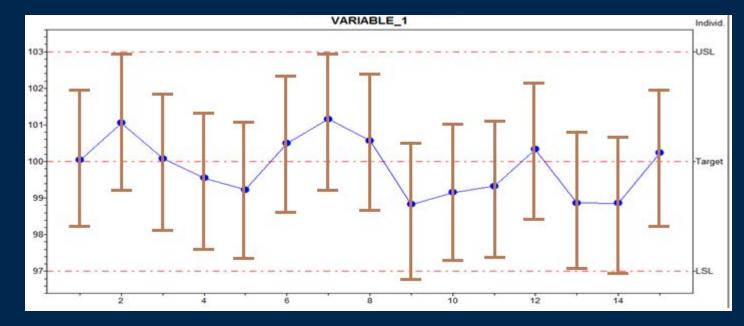
Measurement Uncertainty – which results do you like?

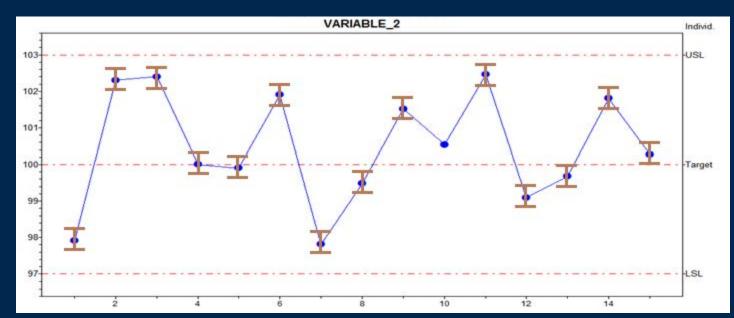




Source: Northwest Analytics

Measurement Uncertainty – which results do you like!





Source: Northwest Analytics

Graph Technology gains traction

Numbers

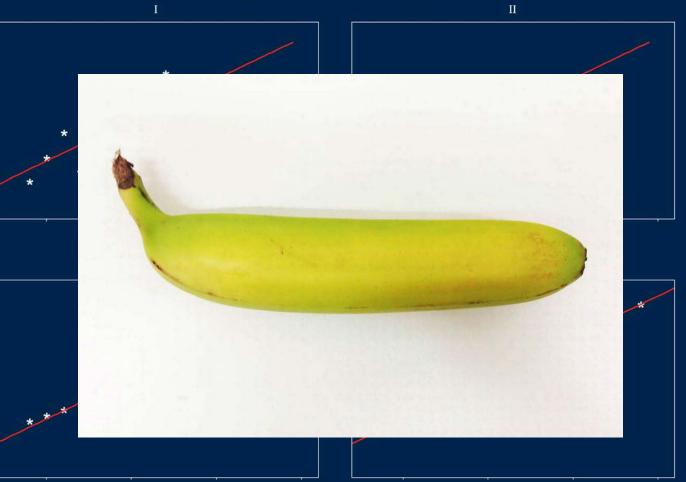
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9	8.81	9	8.77	9	7.11	8	8.84	
11	8.33	11	9.26	11	7.81	8	8.47	
14	9.96	14	8.1	14	8.84	8	7.04	
6	7.24	6	6.13	6	6.08	8	5.25	
4	4.26	4	3.1	4	5.39	19	12.5	
12	10.84	12	9.13	12	8.15	8	5.56	
7	4.82	7	7.26	7	6.42	8	7.91	
5	5.68	5	4.74	5	5.73	8	6.89	

F. J. Anscombe "Graphs in Statistical Analysis", American Statistician, 27 (February 1973), 17-21

Statistics

Data pairs = 11 mean of X's = 9.0 mean of Y's = 7.5 standard deviation of X's = 3.32standard deviation of Y's = 2.03correlation = .82regression line: Y = 3 + 0.5 X r-squared = .67slope t-statistic = 4.24standard error of regression = 1.24

Graphical Analysis



Scientific Data Sources

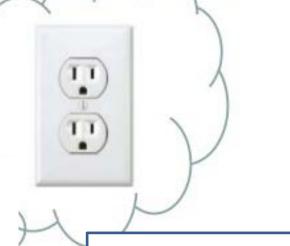
	DAT	A SOURCE (Instrument/Se	ensor)
	RAW data	Meta data	Secondary data
	K		
File stock CRC Check Archive Embedded device in Data characteristic Security		Capture process Units Date/time Batch # Experiment reference Project Location Origin Owner Retention Search	Conformity Processed Version # Reporting trail Audit trail Archive Release parameters Workflow history Calculations Access control

RESULT – Consolidation

Importance of standards Yes I have power....



Apply consistent ontologies and taxonomies to assure finding the right data







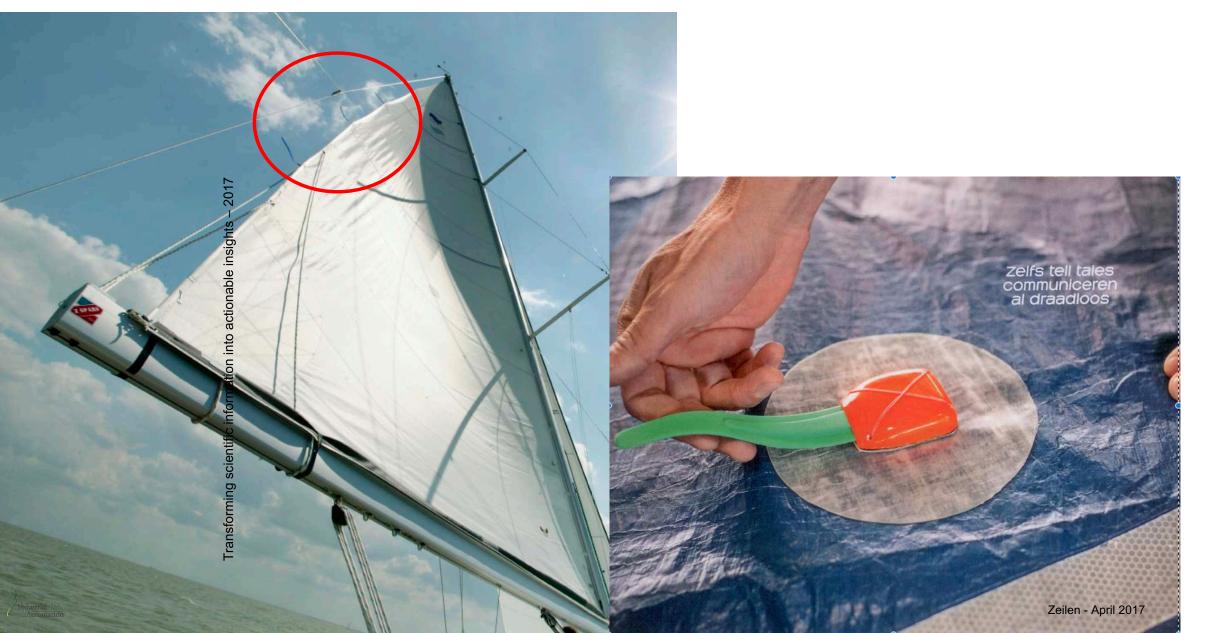


#4 CHALLENGE

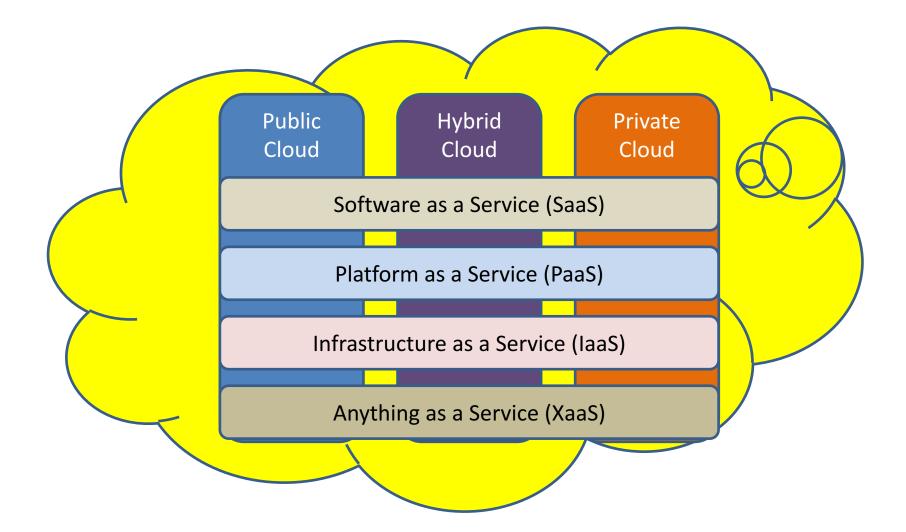
EXPLORE NEW CAPABILITIES



Internet of Things (IoT)



Cloud related acronyms





SaaS ≠ Cloud

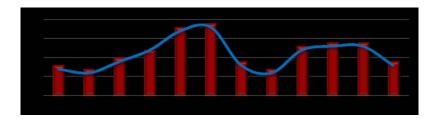
Cloud

- Service Level Agreement
- Where is my data?
- Emergency & escalation plan
- Back-up services
- On-demand scalability
- On-demand capacity
- Ownership

SaaS

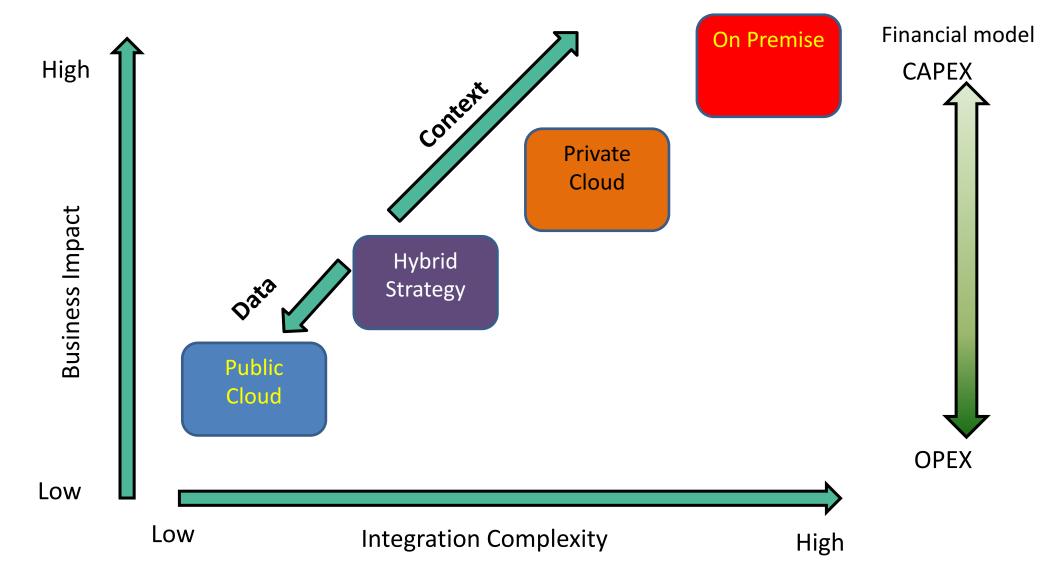
- Subscription
- Free and paid services
- Application consultancy
- Application support
- Automatic updates
- No investment in software
- Minimal hardware investment







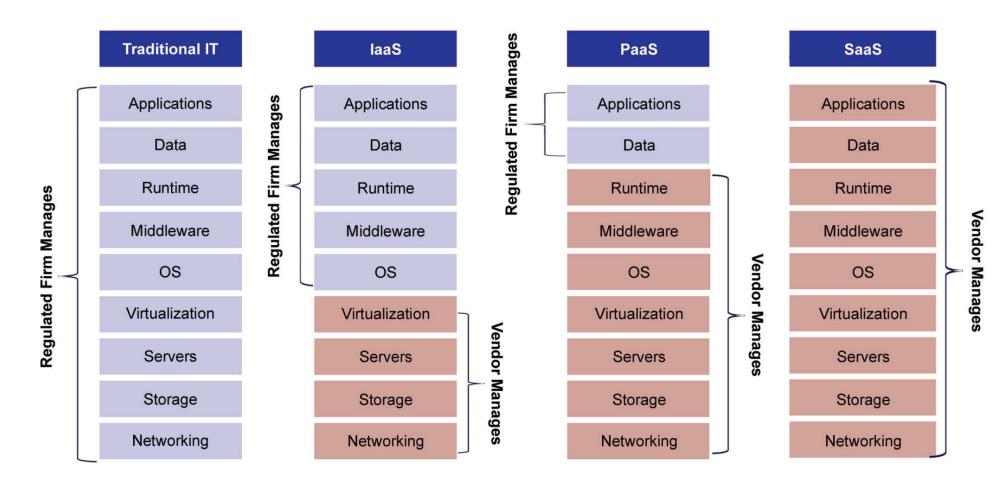
Accepted cloud strategies





The Route to clarity

GAMP Cloud Computing Special Interest Group (SIG)





LAB {SaaS + Cloud} candidates for the laboratory

- When prototyping requiring a lot of IT infrastructure
- Applications that require mobile access
- Applications outside of the core business
- Applications that require a high upfront investment (CAPEX vs OPEX)
- Projects requiring intensive (external) collaboration
- When fast access to increased scalability is a required
- Applications where **21CFR** is not a direct requirement



Industry 4.0 IoLT Potential for Laboratories

Real-time Data Capture	Self-documenting process to include meta data and content in
	single process
Predictive maintenance	Predict equipment failures before they happen, and
	systematically prevent them
Remote monitoring	Remote monitoring solutions collect live data from assets, and
	use that data to trigger automatic alerts and operational actions
	based on current conditions, such as remote diagnostics and
	maintenance requests.
Deep learning data analytics	Ability to include big-data in R&D projects
Instrument interaction	Auto registers material and equipment that you are using. E.g.
	predict reagent consumption and initiate action when reagent is low
	with supplier
Customer/Consumer	Will provide contextualized and personalized C2C experience. Focus
experience	on customer experience, including physical safety and security
Enables multi technology	Ability to automatically compare real-time test results from
validation	multiple technologies on a large scale
Automate to transform	Integrate with existing Lab applications and explore to re-use
	existing dead-data silo's
Location tracking	Biometrically knows who you are. Automates user
10454	authentication process and reduces keystrokes. Simplifies
	application experience



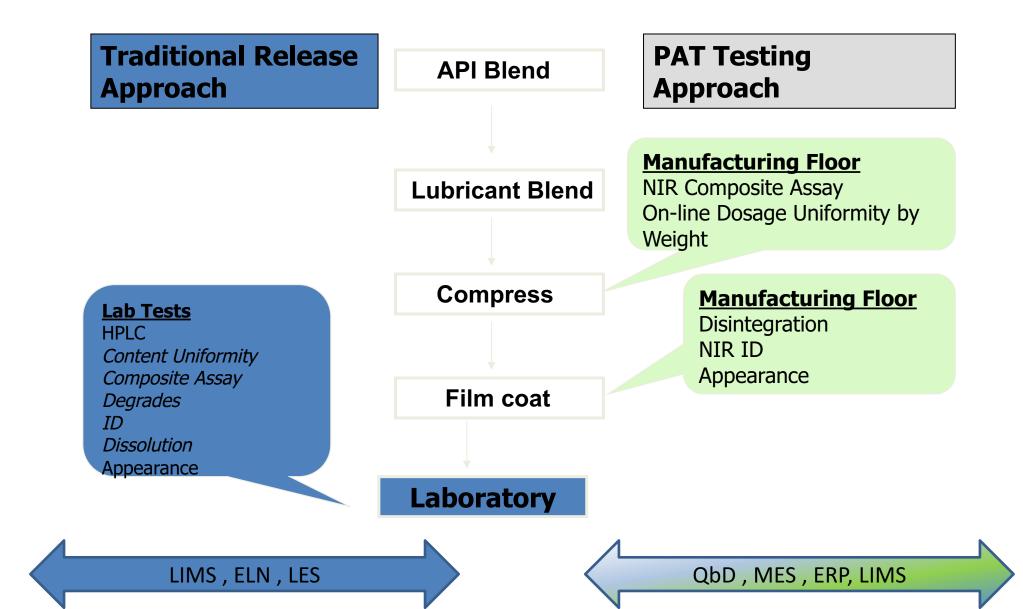
Source: Roadmap to Digital Convergence - Laboratory Informatics Guide (LIG2017) / Scientific Computing World by Peter Boogaard

New areas of scientific expertise

More QA and less QC



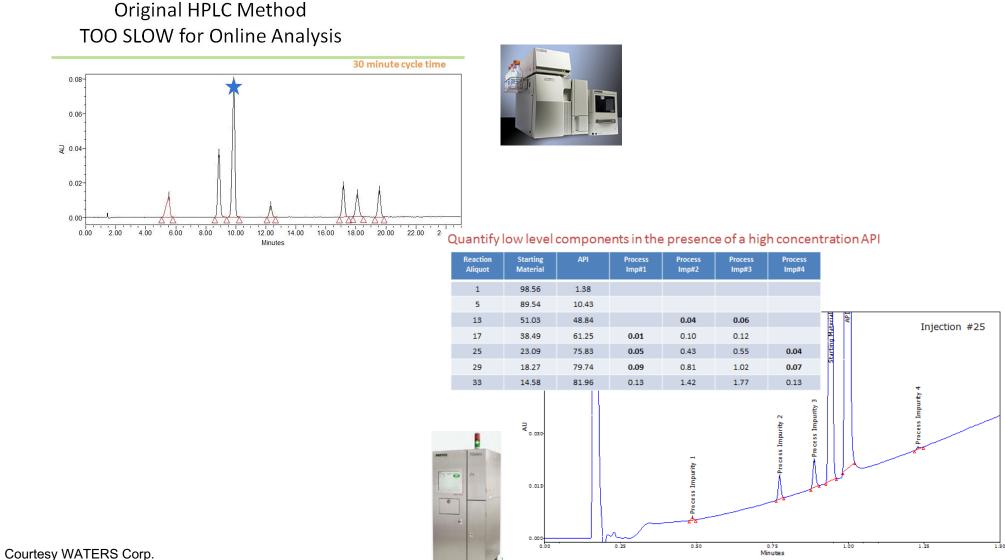
JANUVIA ™ RTRT Control Strategy



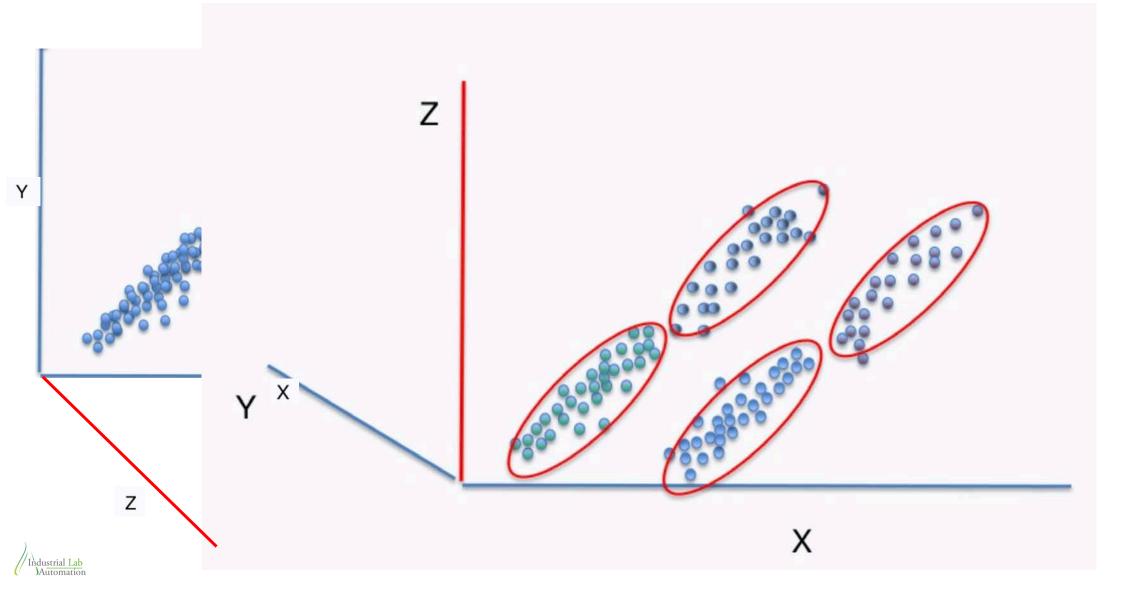
Industrial Lab

Automatio

The scientist no longer just in the laboratory



Multivariate analysis can reveal a change in correlation structure not visible with univariate analysis





XXXL

Big Data

Massive amounts of information derived from dry /wet lab investigations, feasibility studies and clinical trials.

Big Science

Research silos are evaporating with the merging of scientific methods. Traditional hypothesis-testing studies will couple with data-driven research.

Fast Data

Fast Data is a range of approaches that process data that might or might not be stored.

Big Collaboration

As evidence accumulates, personalized medicine will become a reality, and patient-specific disease interventions will become available. Teams of disease specialists, researchers and bioinformaticians working in concert in a virtual frontier.





BIG DATA LANDSCAPE 2017

INFRASTRUCTURE	BIG DATA LANDSCAPE 2017 ANALYTICS	APPLICATIONS – ENTERPRISE	XI
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#5 CHALLENGE

MAKE IT EASY ACCESABLE

Barriers

Technology

Almost disappeared

Globally accessible & available

PeopleChallengeRequires a mindset change



THE GLOBAL EDITION OF THE NEW YORK TIMES

THURSDAY, MAY 16, 2013 | 7

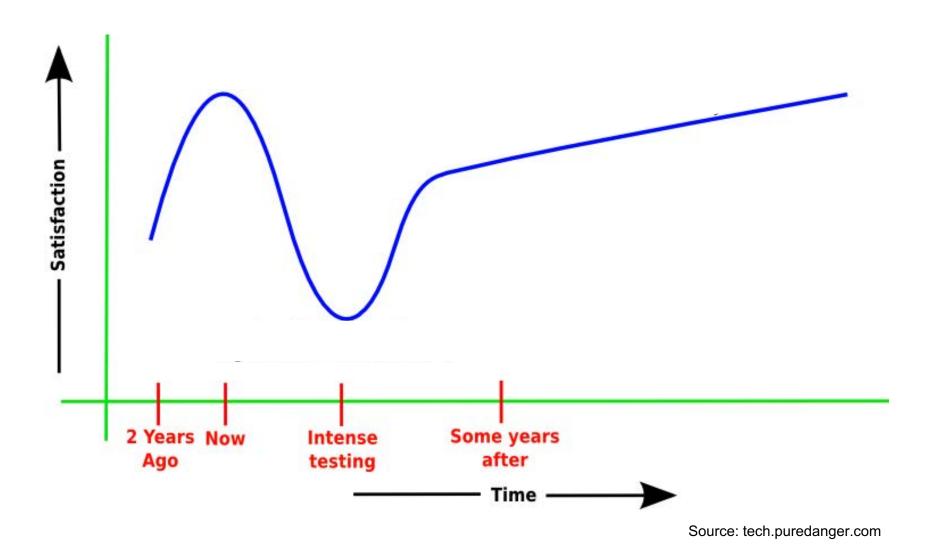
COMMENTARY LETTERS



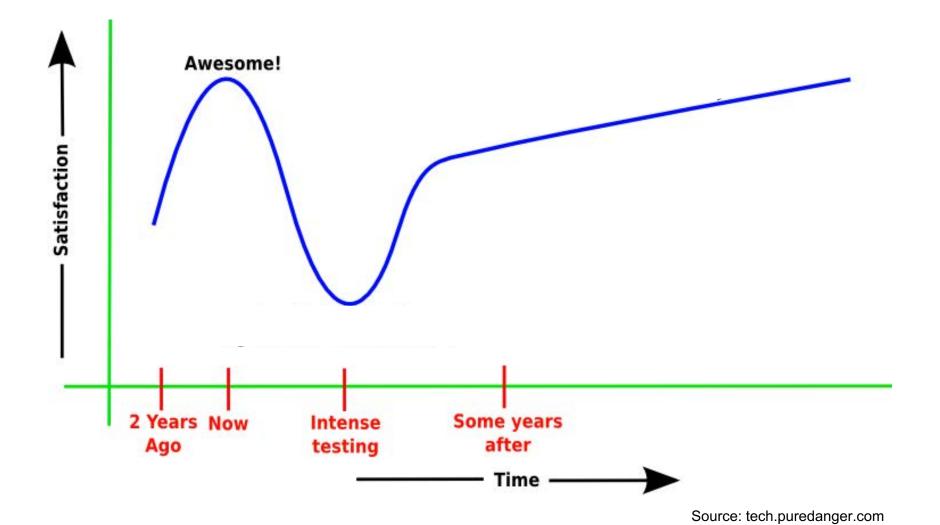
Significant challenges to meeting digital priorities

	Cultural barrier	Other barriers
Cultural and behavioral challenges	33	
Lack of understanding of digital trends	25	
Lack of talent for digital	24	
Lack of IT infrastructure	22	
Organizational structure not aligned	21	
Lack of dedicated funding	21	
Lack of internal alignment (digital vs traditional business)	19	
Business process too rigid	16	
Lack of data	13	
Lack of senior support	13	

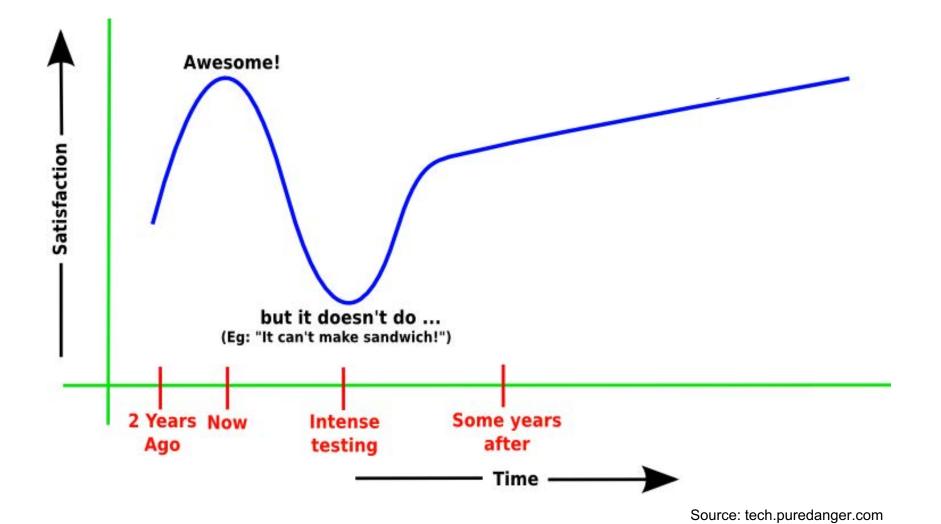




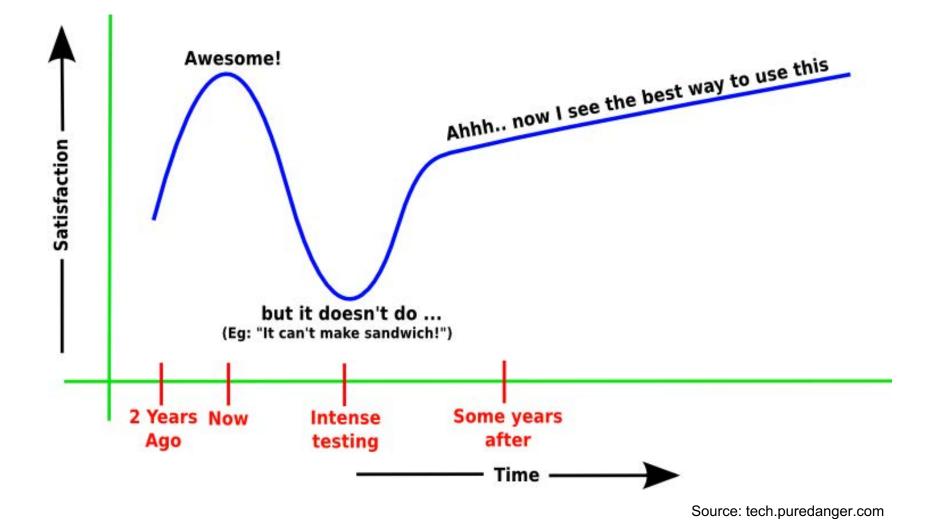




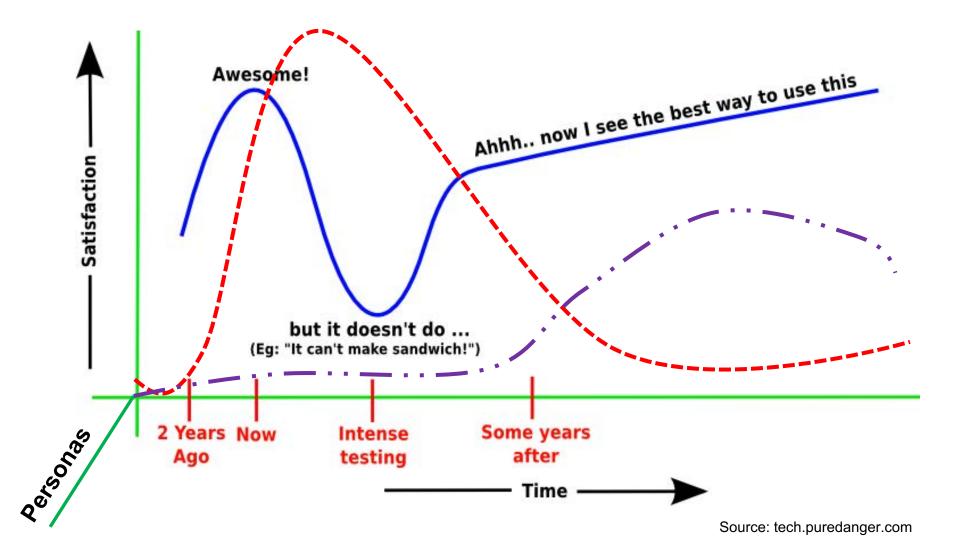






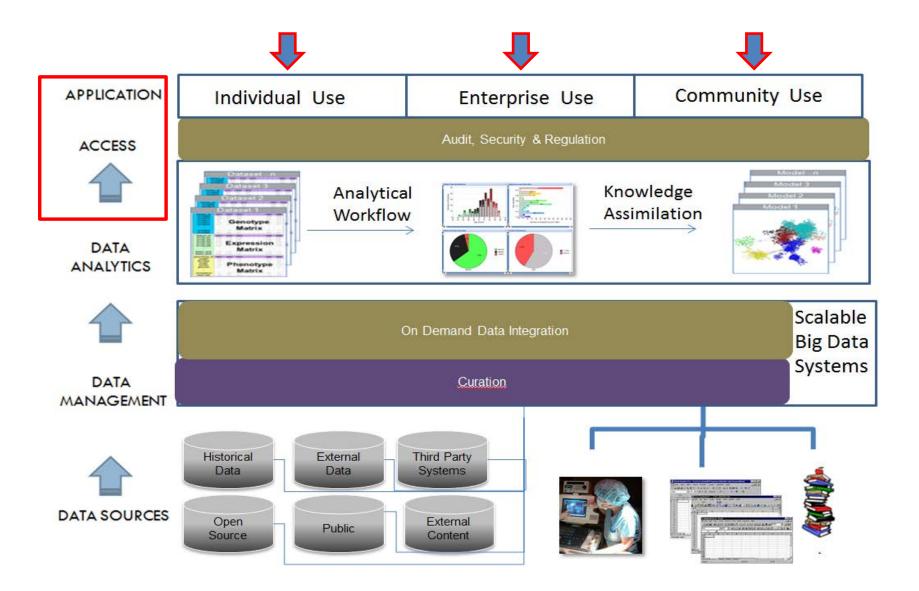






Industrial Lab Automation

Models of communication processes



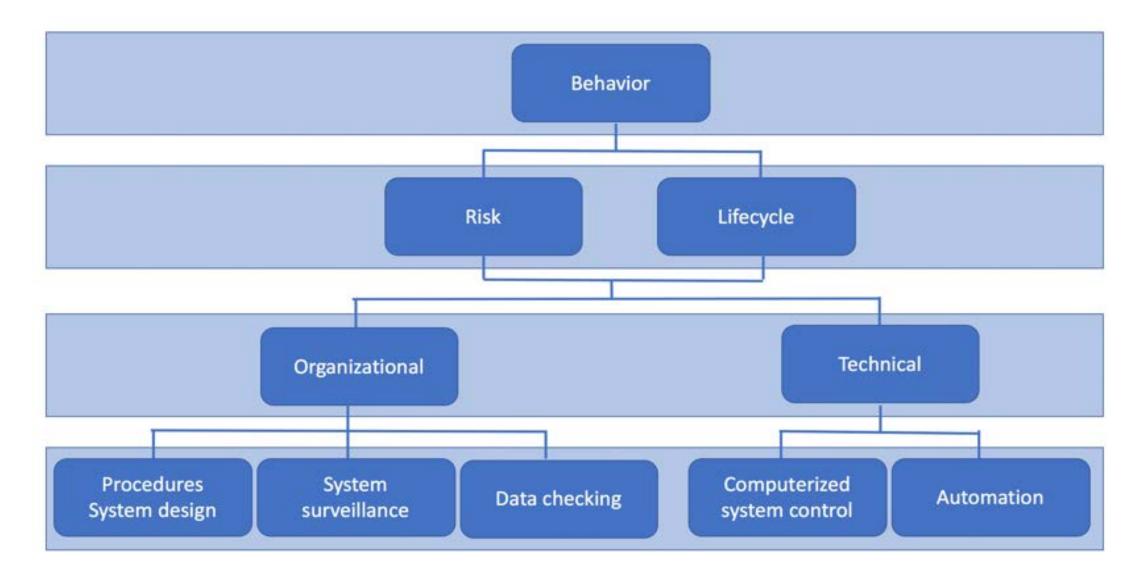


#6 CHALLENGE

ASSURE DATA GOVERNANCE

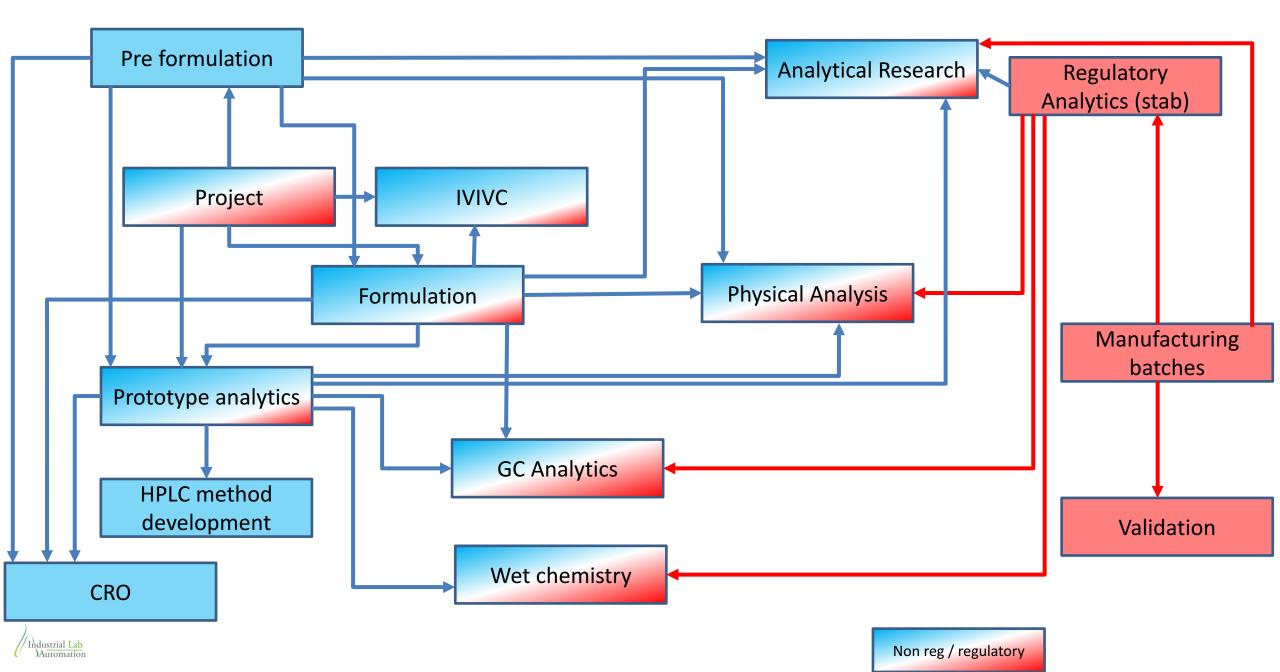
Data integrity refers to maintaining and assuring the accuracy and consistency of data over its entire life-cycle

Change management requires a data lifecycle based approach

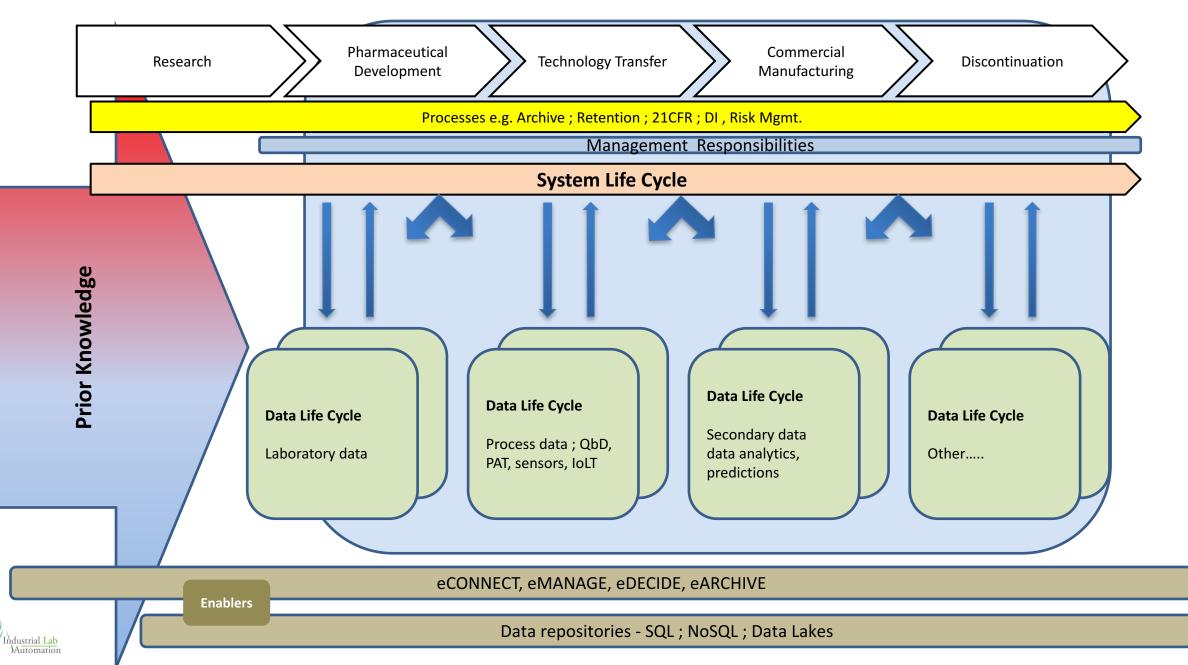




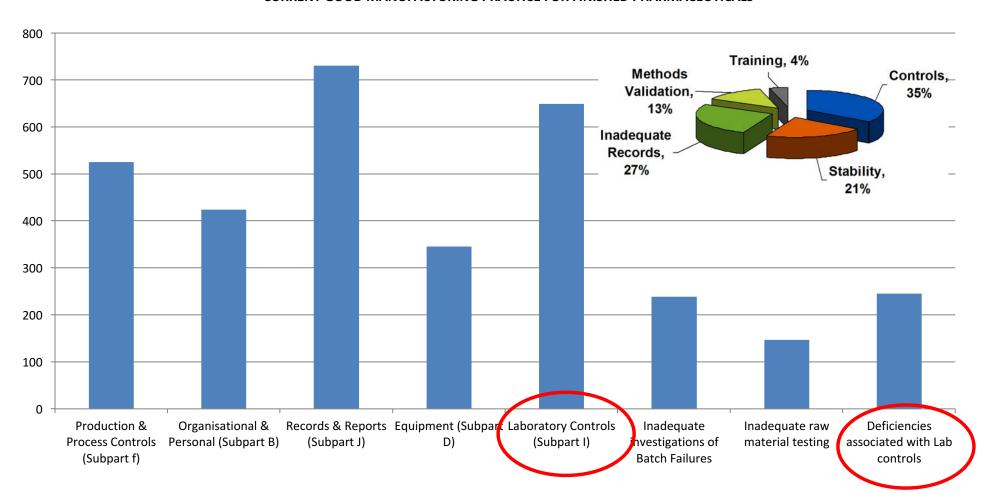
Cross departmental regulatory requirements



Empowering the e-DATA LIFE CYCLE



US FDA Observations Summary



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





Attention areas: data governance

- Data security protocols
- Master Data management
- Each interface is a potential Data Integrity challenge
- Long-term data access control
- Privacy regulations incl. new European GDPR compliance
- Enforcement of data and ontology standards



Transforming scientific information into actionable insights Take away message

- People
 - Data consumer vs data creator mindset change
 - Think data lifecycle
 - Think capabilities vs technology first
 - Avoid applying previous excuses
- Technology
 - Apply industry data access & security processes
 - Apply cross industry standard technologies
 - Apply visualization to data analytics
 - Utilize 24x7 global IT technology to reduce TOC
 - Include roadmap to address upcoming technology obsolesce
 - Go mainstream
- Processes
 - Apply as much self documenting context & meta data in all processes
 - Apply consistent standards (incl. ontologies and taxonomies) to assure finding the right data
 - Involve management to assist breaking internal silo barriers to address data life cycle
 - Define long-term ownership of master data



De stand van zaken van data management software in het laboratorium

We expect too much in 1 year And not enough in 10





Industrial Lab Automation

17 November 2017 - Wageningen - Nederland

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