

Why we should embrace learnings from other industries



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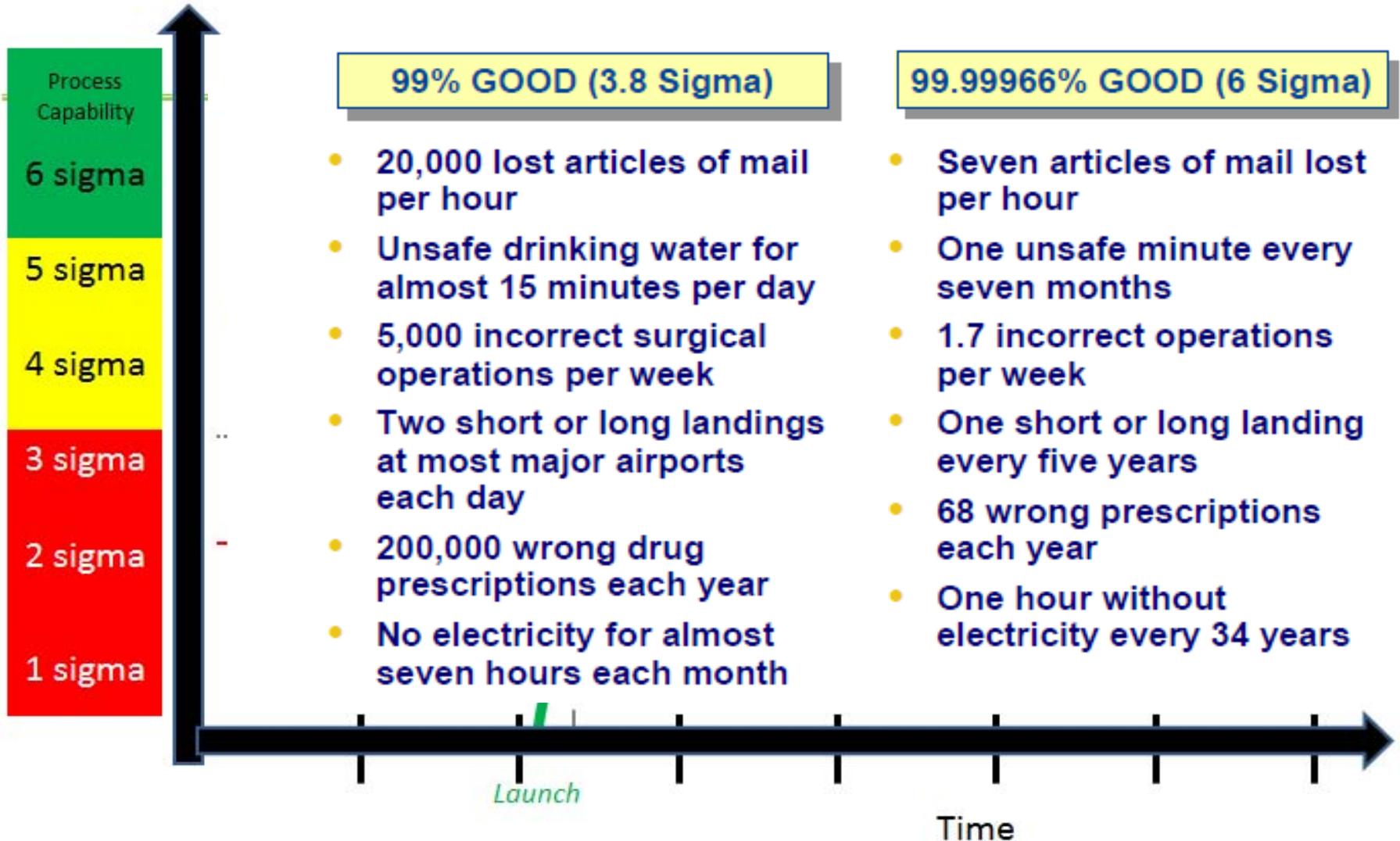
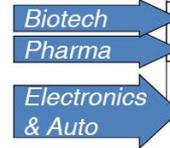


*Measurement, Information & Innovation
Digital Disruption in the Chemical Sciences*



More than 50% of chief executives believe that their business model is currently undergoing a fundamental transformation

Sigma	ppm Defects	Yield	Cost of Quality
2σ	308,537	69.2%	25-35%
3σ	66,807	93.3%	20-25%
4σ	6,210	99.4%	12-18%
5σ	233	99.98%	4-8%
6σ	3.4	99.99966%	1-3%

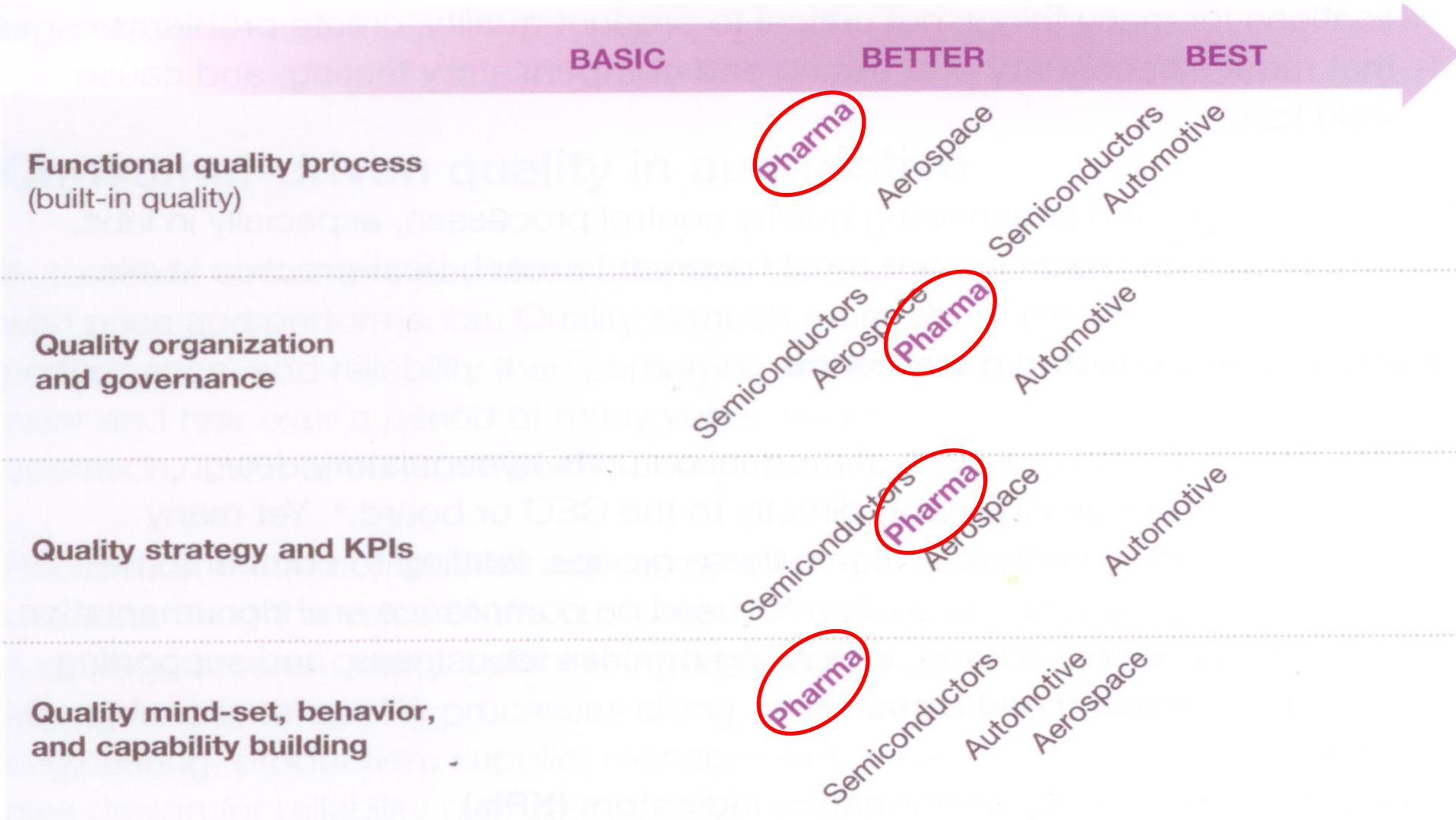


Operations in Pharmaceuticals Compare Poorly to Other Industries

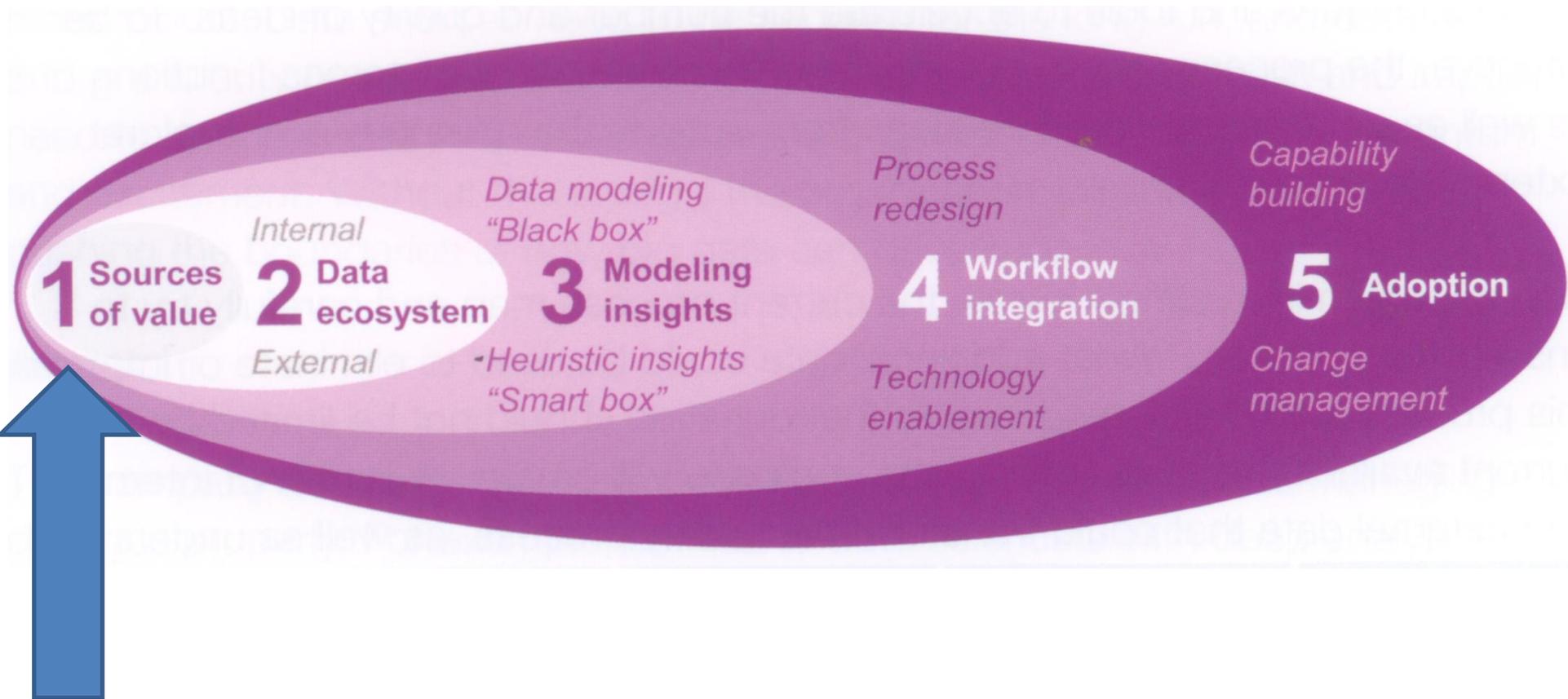
The pharmaceutical industry lags similar industries in key measures of operations performance, most notably in overall equipment effectiveness, labor value-add time and direct/indirect labor ratio, McKinsey's Ted Fuhr told the recent CDER on CMC conference in Bethesda, Md. Many of the shortcomings reflect poor quality practices and represent cost savings opportunities for the quality by design paradigm. Estimates are from McKinsey Operations Practice.

Measure	Pharma	Automotive	Aerospace	Computer	Consumer Packaged Goods
Overall equipment effectiveness	10% to 60%	70% to 85%	50% to 70%	80% to 90%	70% to 90%
Annual productivity improvement	1% to 3%	5% to 15%	5% to 10%	1% to 3%	5% to 15%
First-pass yield – zero defects	60%	90% to 99%	70% to 90%	90% to 99%	90% to 99%
Production lead times in days	120 to 180	1 to 7	7 to 120	5 to 10	3 to 7
Finished goods inventory in days	60 to 90	3 to 30	3 to 30	5 to 50	10 to 40
Labor value-add time	20%	60% to 70%	60% to 70%	60% to 70%	60% to 90%
Direct/indirect labor ratio	1:1	10:1	10:1	10:1	10:1

Quality Maturity assessment across industries



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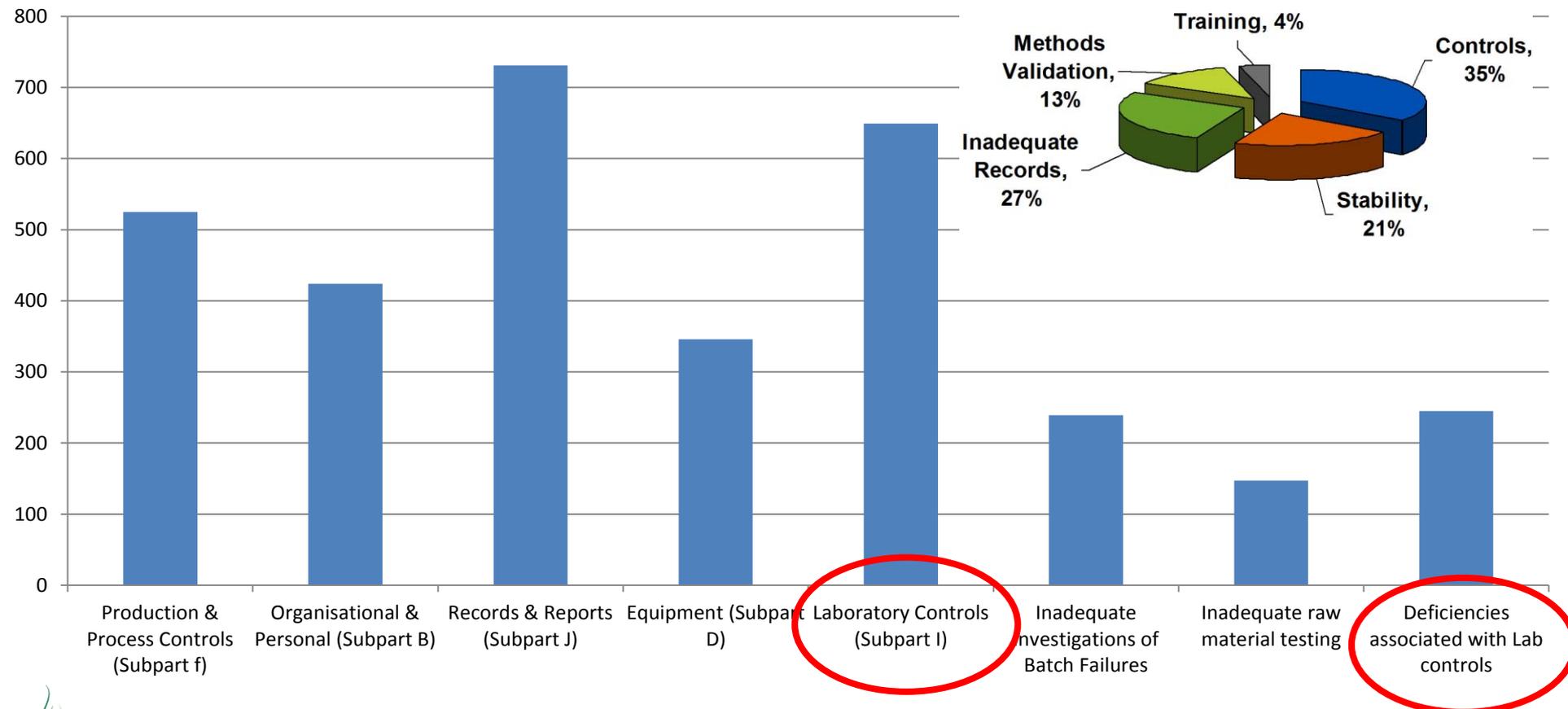


- Understanding scientific and quality processes
- Assure at-the-source self-documenting data integrity
- Ability to integrate on & off-line data

Source: McKinsey & Company - From Measuring Failure to Building Quality Robustness in Pharma

US FDA Observations Summary (2013)

21 CFR Part 211 Observations CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS +50% Data Integrity citations



DATA INTEGRITY

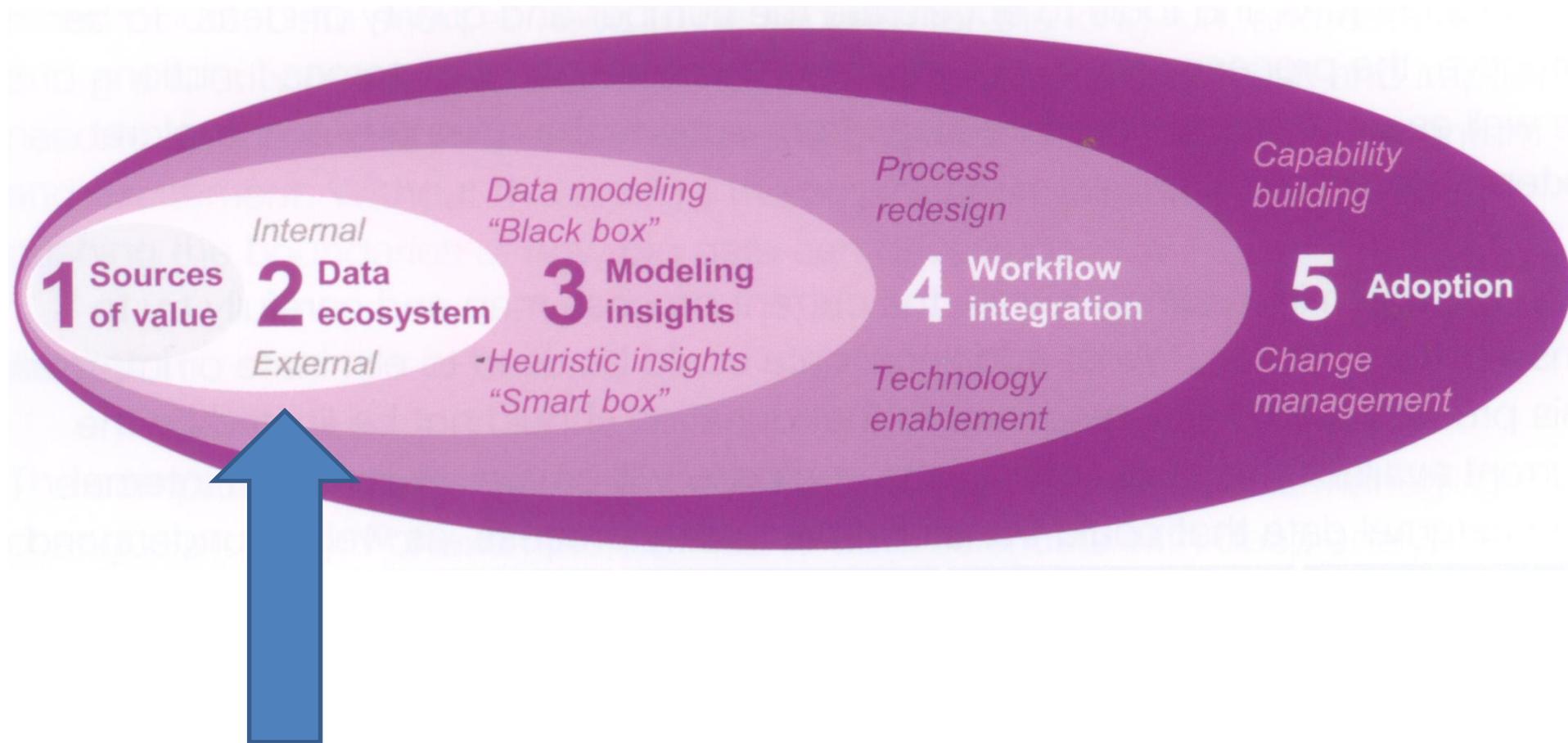


Self-documenting processes

Reducing DI at the source



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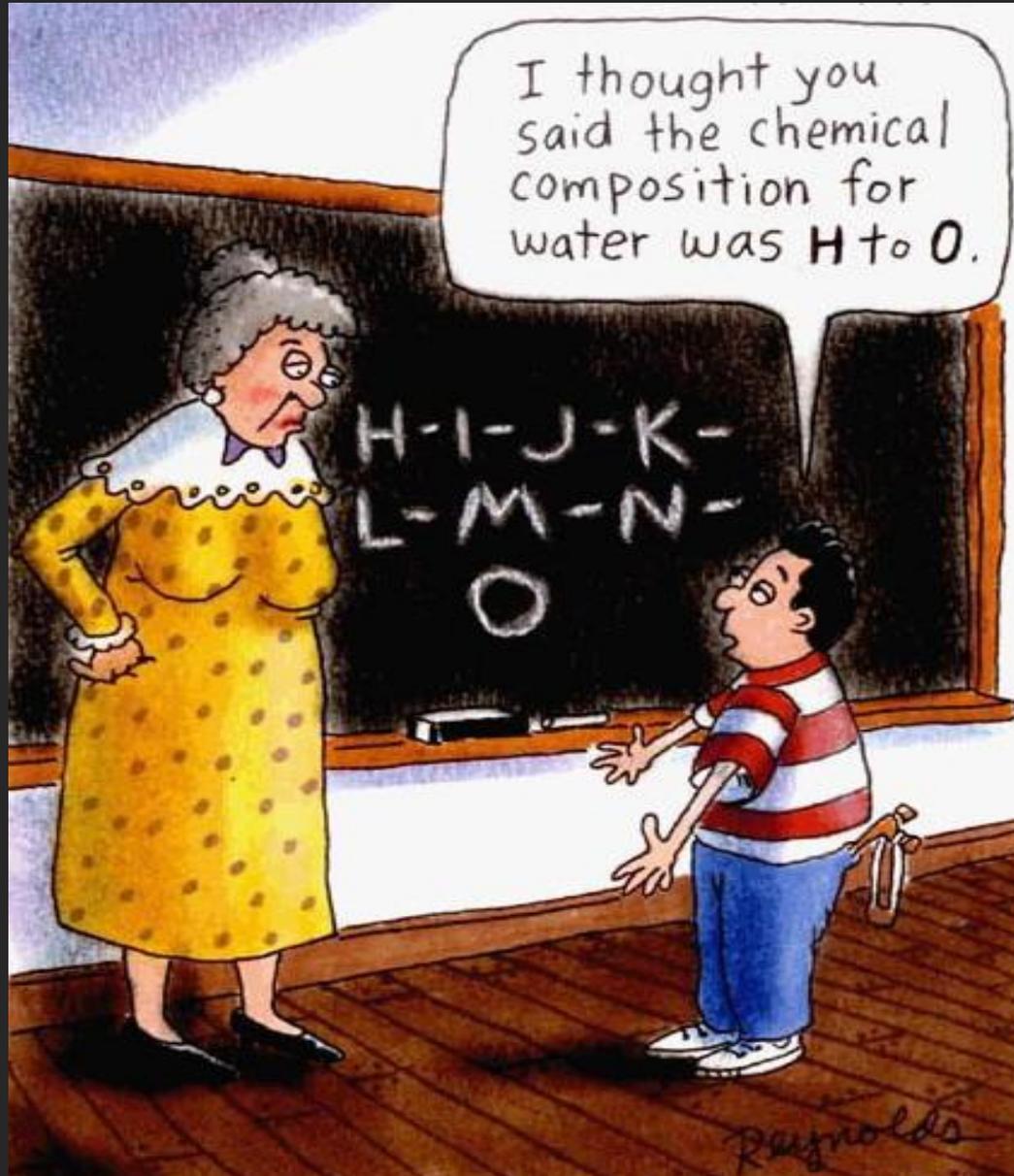
- Establish common data structures, nomenclatures, understanding of data, security
- Establish cross functional data integration (laboratory, sensors, external sources)

Adopt and use data industry standards & processes

**“Yes, we have enough
power for your
equipment”**



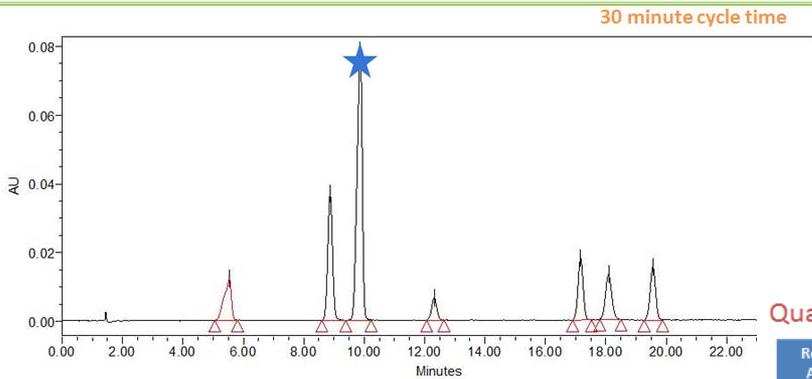
Common understanding is as important as data standards



Ability to integrate on & off-line data

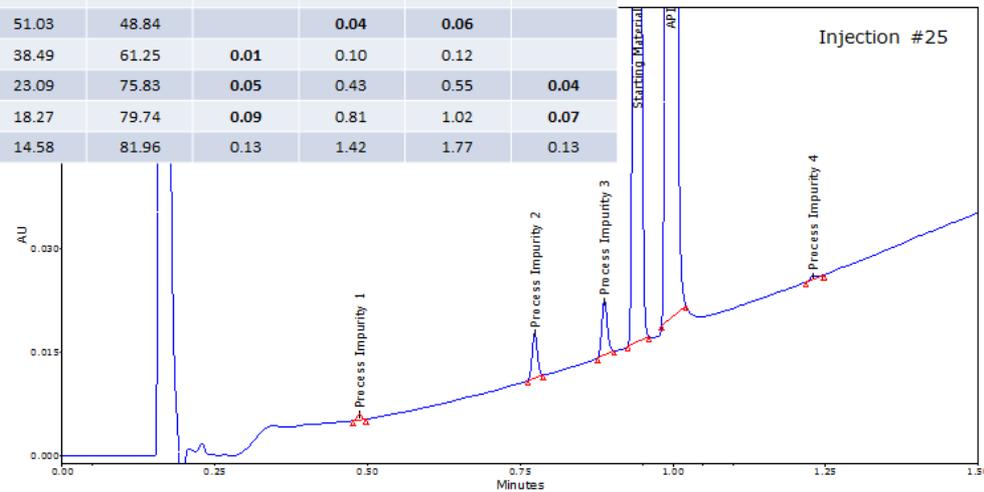
The Scientist Is No Longer In The Laboratory,
But Integrated In The Overall Quality Process

Original HPLC Method
TOO SLOW for Online Analysis

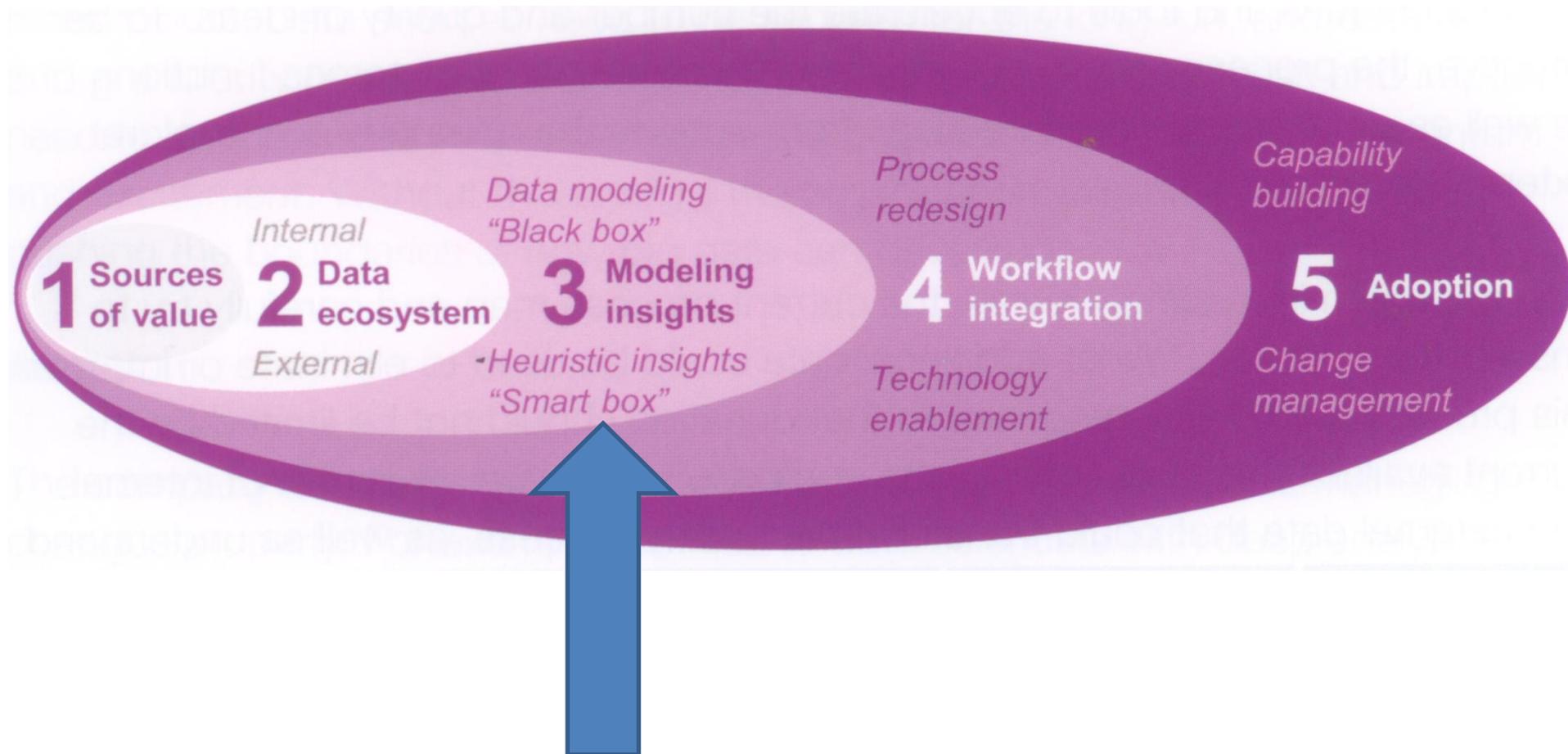


Quantify low level components in the presence of a high concentration API

Reaction Aliquot	Starting Material	API	Process Imp#1	Process Imp#2	Process Imp#3	Process Imp#4
1	98.56	1.38				
5	89.54	10.43				
13	51.03	48.84		0.04	0.06	
17	38.49	61.25	0.01	0.10	0.12	
25	23.09	75.83	0.05	0.43	0.55	0.04
29	18.27	79.74	0.09	0.81	1.02	0.07
33	14.58	81.96	0.13	1.42	1.77	0.13



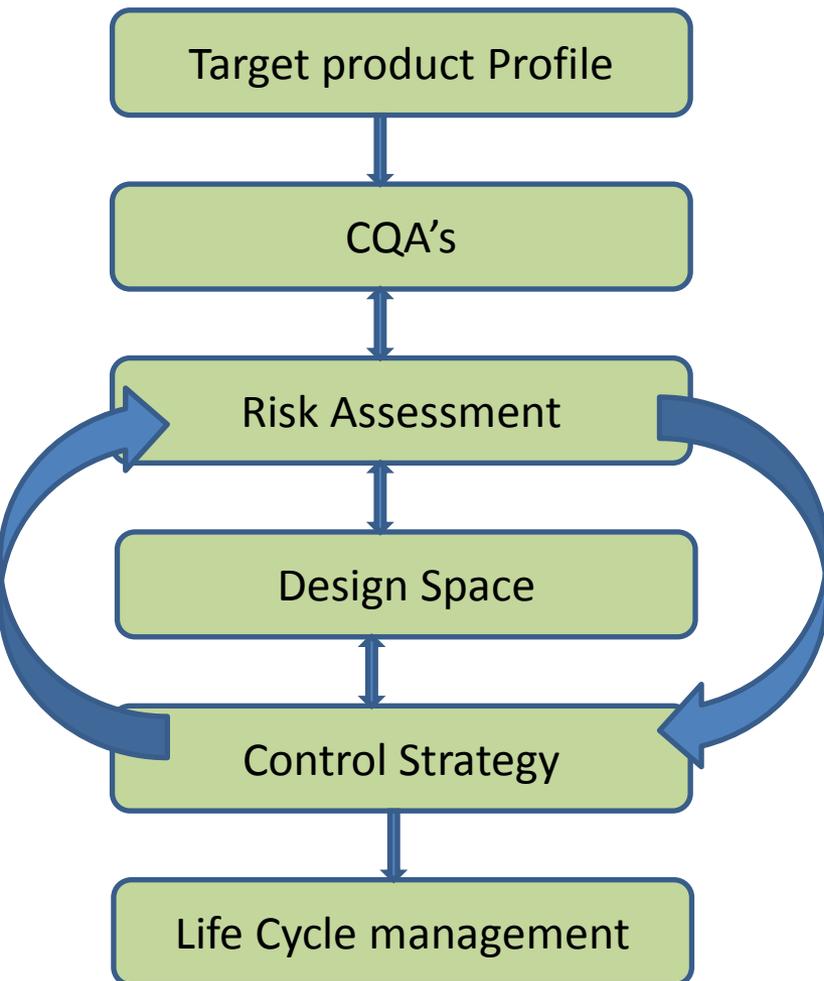
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- Apply advanced life cycle view based statistical analysis.
- Explore iterative /heuristics models to enhance and increase speed

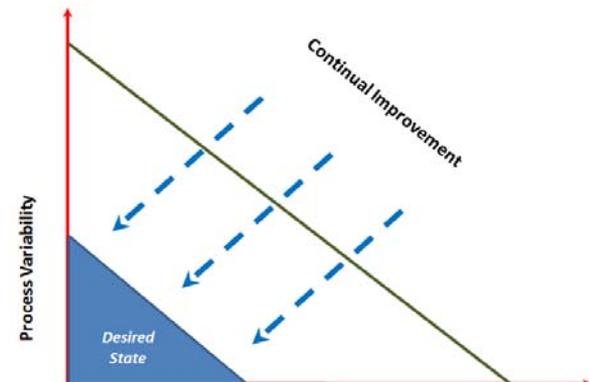
Iterative processes

Common practice in many industries

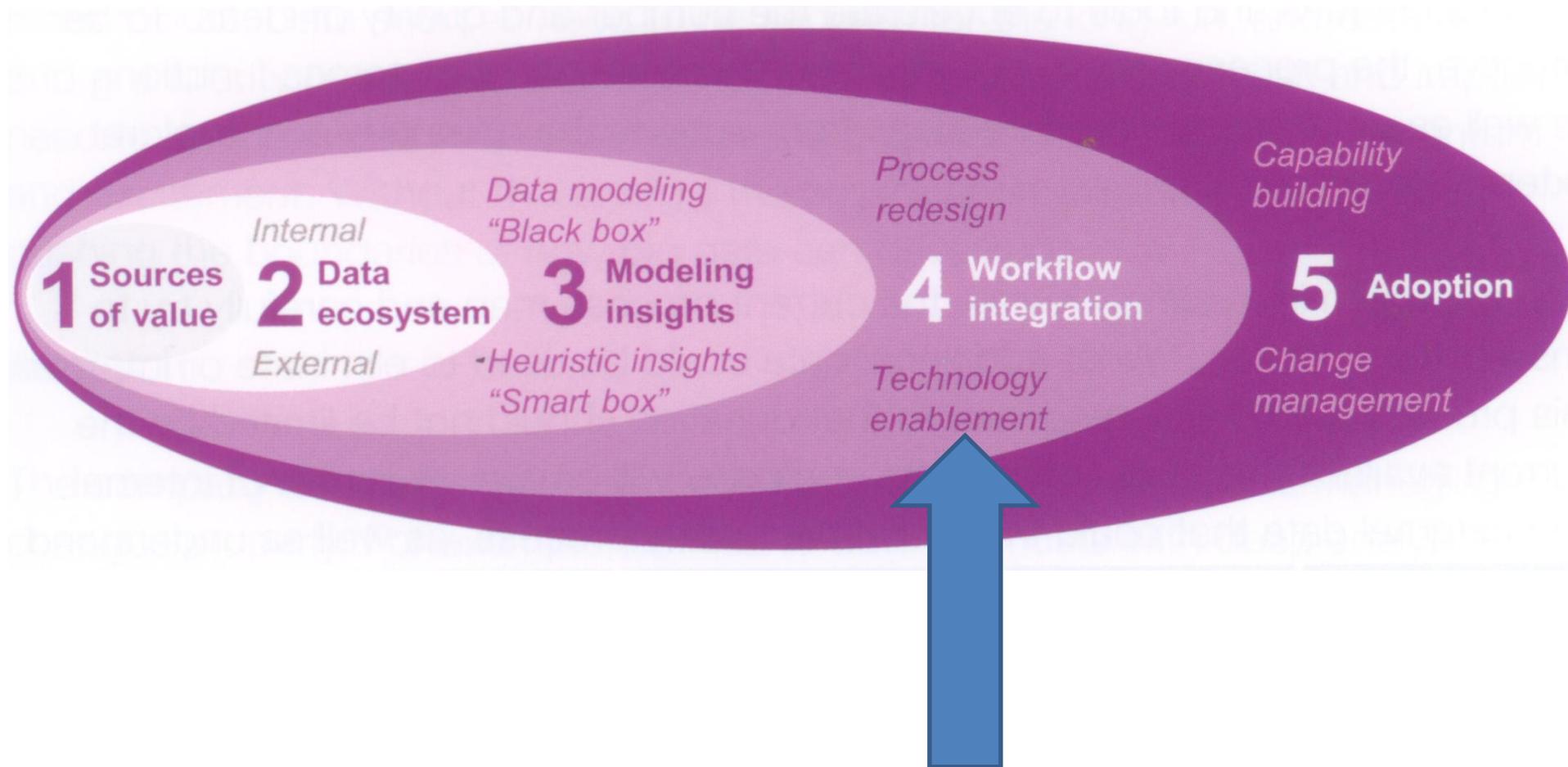


Development of a control strategy for a product is an **iterative activity as knowledge** about the product and manufacturing process **evolves**

Knowledge is also shared between development and supply **over the product lifecycle** to enable continual improvement

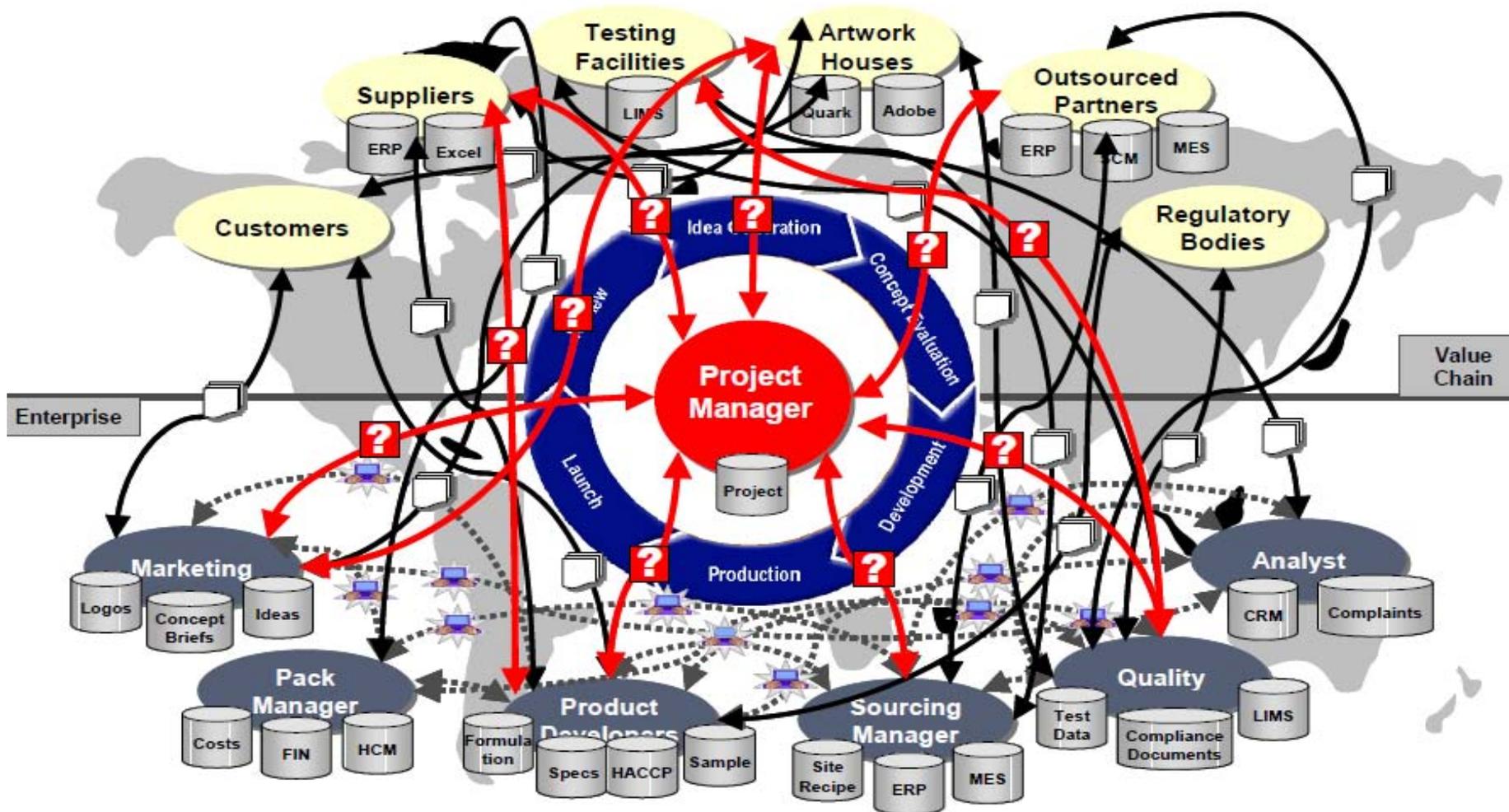


Why we should embrace learnings from other industries



- Harmonize / redesign processes to embed rules in the workflow across silo's
- Reduce, simplify & automate based on risk assessment process
- Reduce, simplify, & automate execution step processes

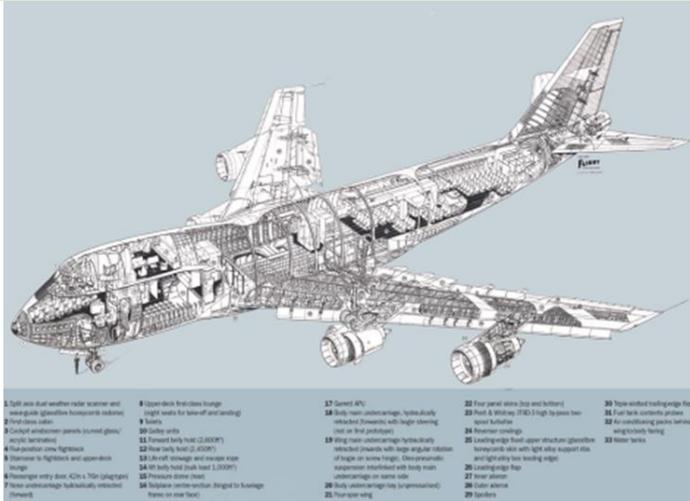
Familiar?



If you can't describe
what you're doing as
a process, you don't
know what you are
doing.

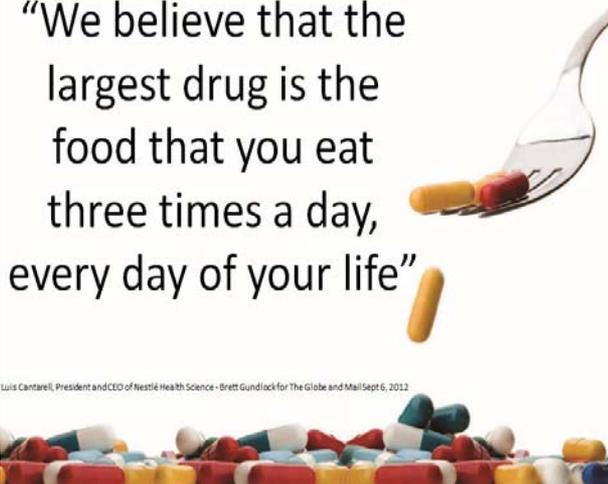
W. Edwards Deming

Learnings & Observations



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

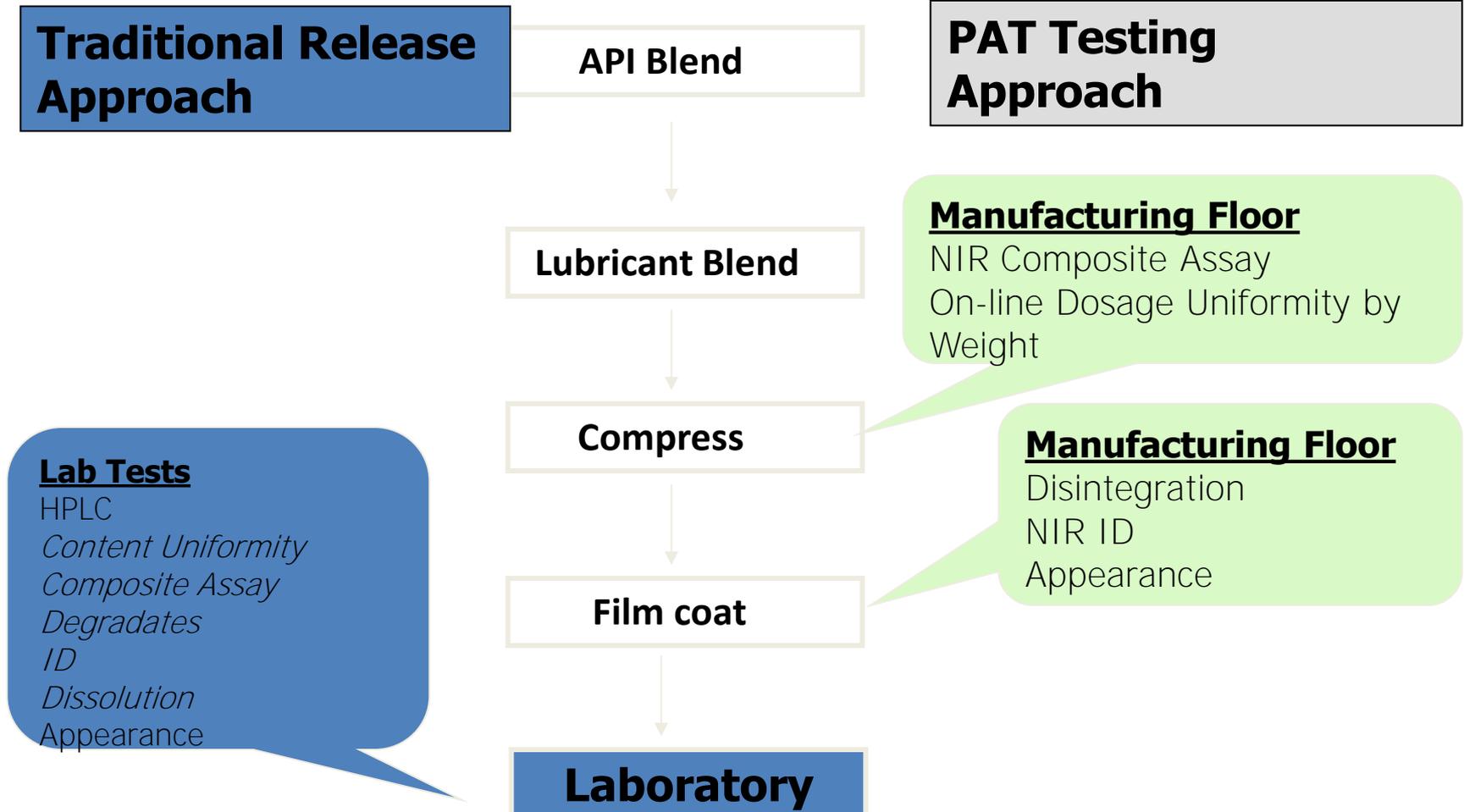
Luis Cantarelli, President and CEO of Nestlé Health Science - Brett Gundlock for The Globe and Mail Sept 6, 2012



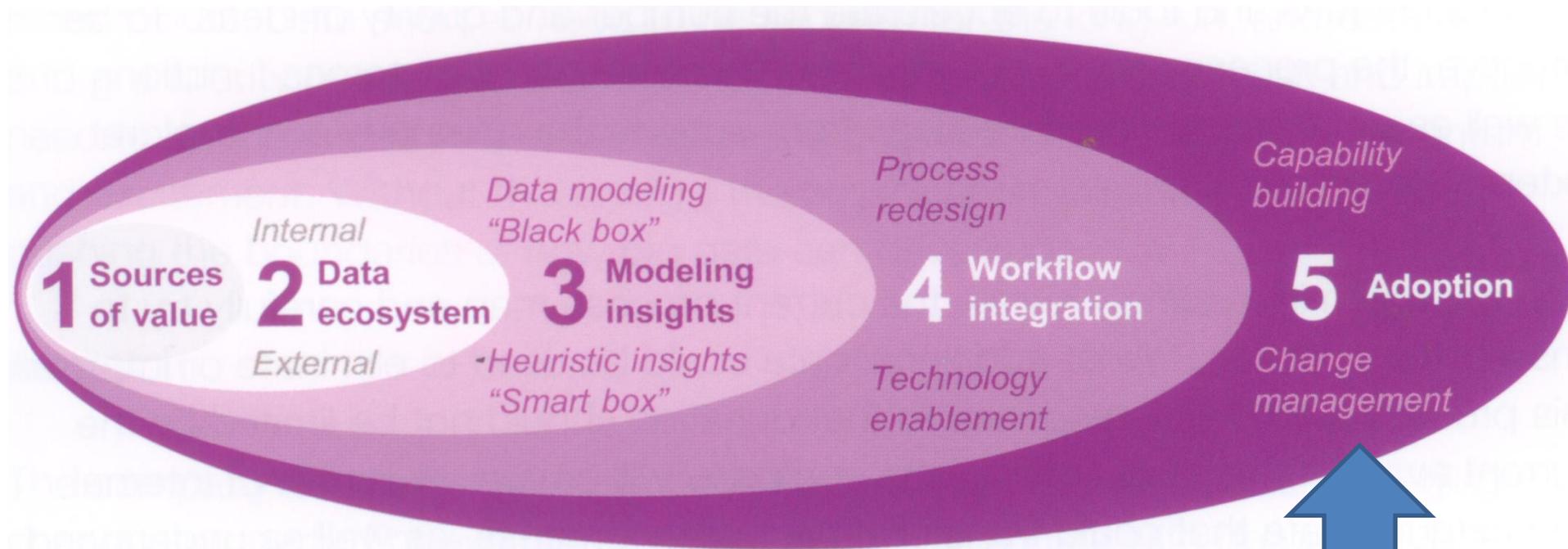
Example: JANUVIA™ RTRT



QA vs QC

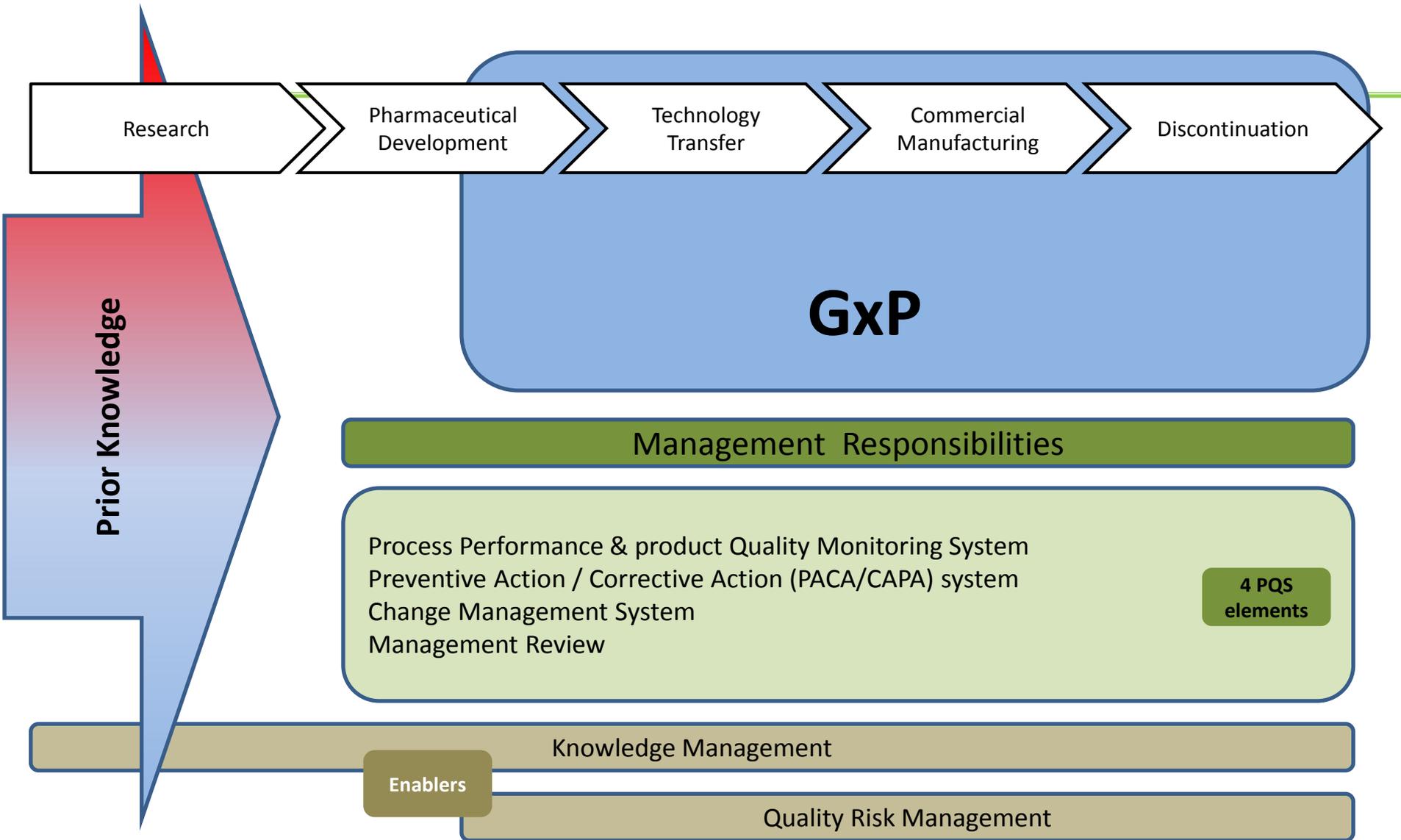


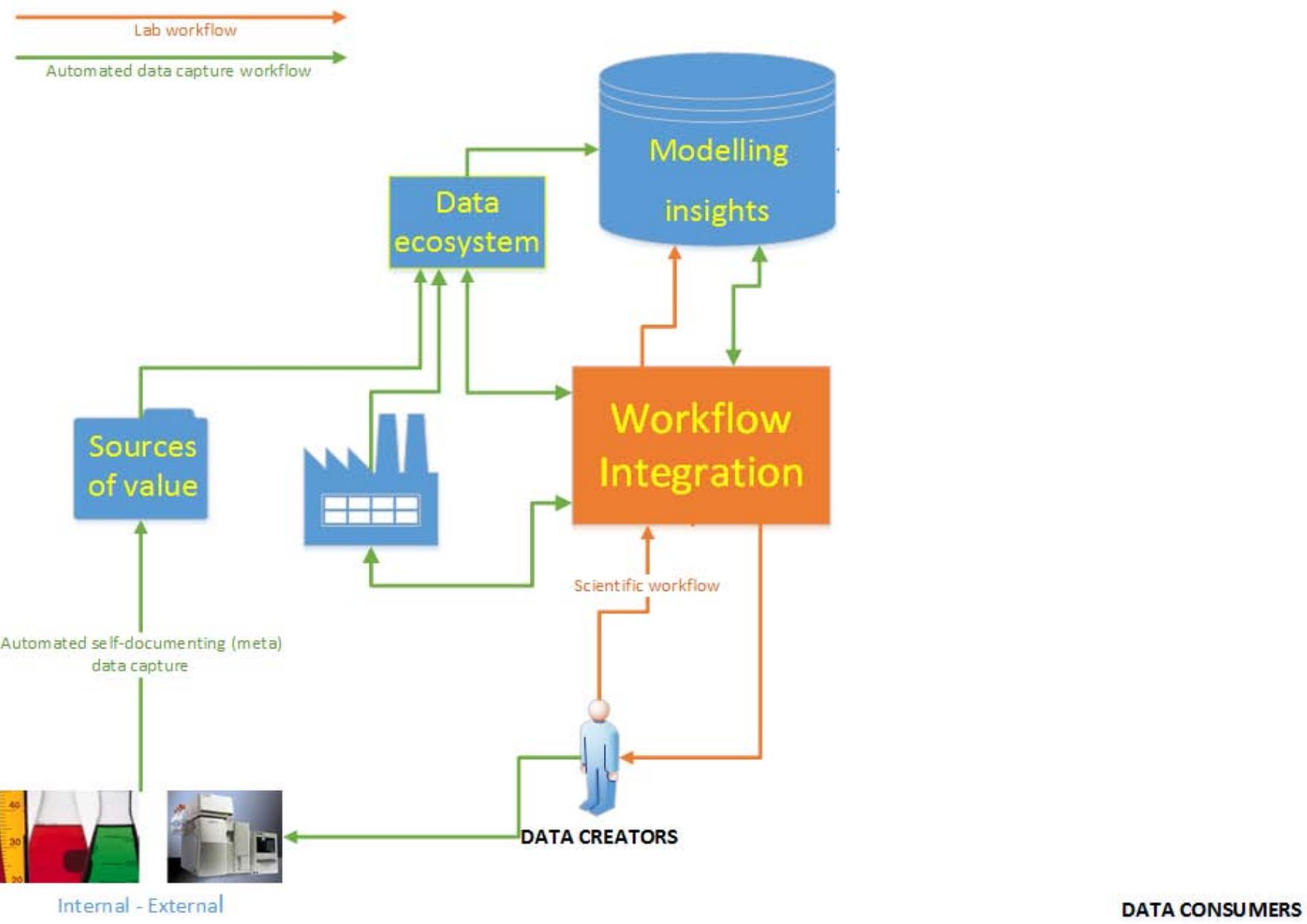
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- Establish Sr. management commitment and involvement
- Cross departmental, empowered, operational functional teams.
- "What's in it for me" change management acceptance including training

ICHQ10 Pharmaceutical Lifecycle Quality System





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Summary

- Automotive industry - Consumer driven quality
 - Move from inspection based QC to build-in Quality
- Aerospace – Safety based quality
 - Pervasive pro-active quality mind-set
- Semiconductor – Yield driven quality
 - Standardization and platforming
- Food & Beverage
 - Efficiency and continuous processing

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Why we should embrace cross industry learnings - ILA London October 2015

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?

**WHEN DATA
COMES TOGETHER**



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10 min from
Barcelona airport

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2016
Barcelona,
Spain

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