

“Opportunity Based Thinking; Is this a Paradigm Shift for a Quality Professional?”

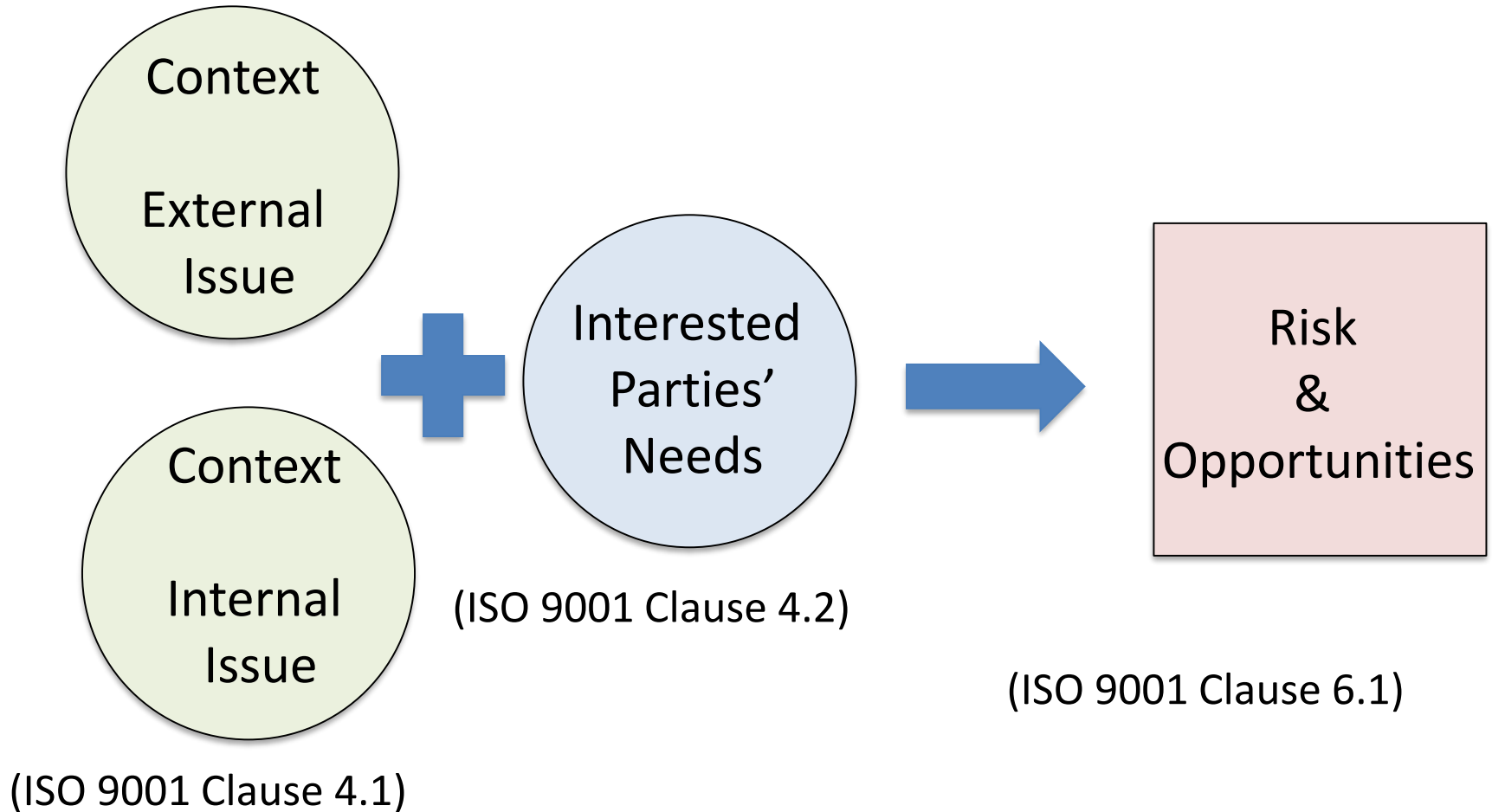
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Agenda

- Risks & Opportunities - What we learned during ISO 9001:2015?
- Risks and Opportunities
- Traditional vs Evolving Quality Environment
- Where can a Quality Professional make an Input
- Conclusions

Risks & Opportunities - What we learned during ISO 9001:2015 Implementation?

Quality System Planning



Quality System Planning(cont.)



(ISO 9001 Clause 6.1)



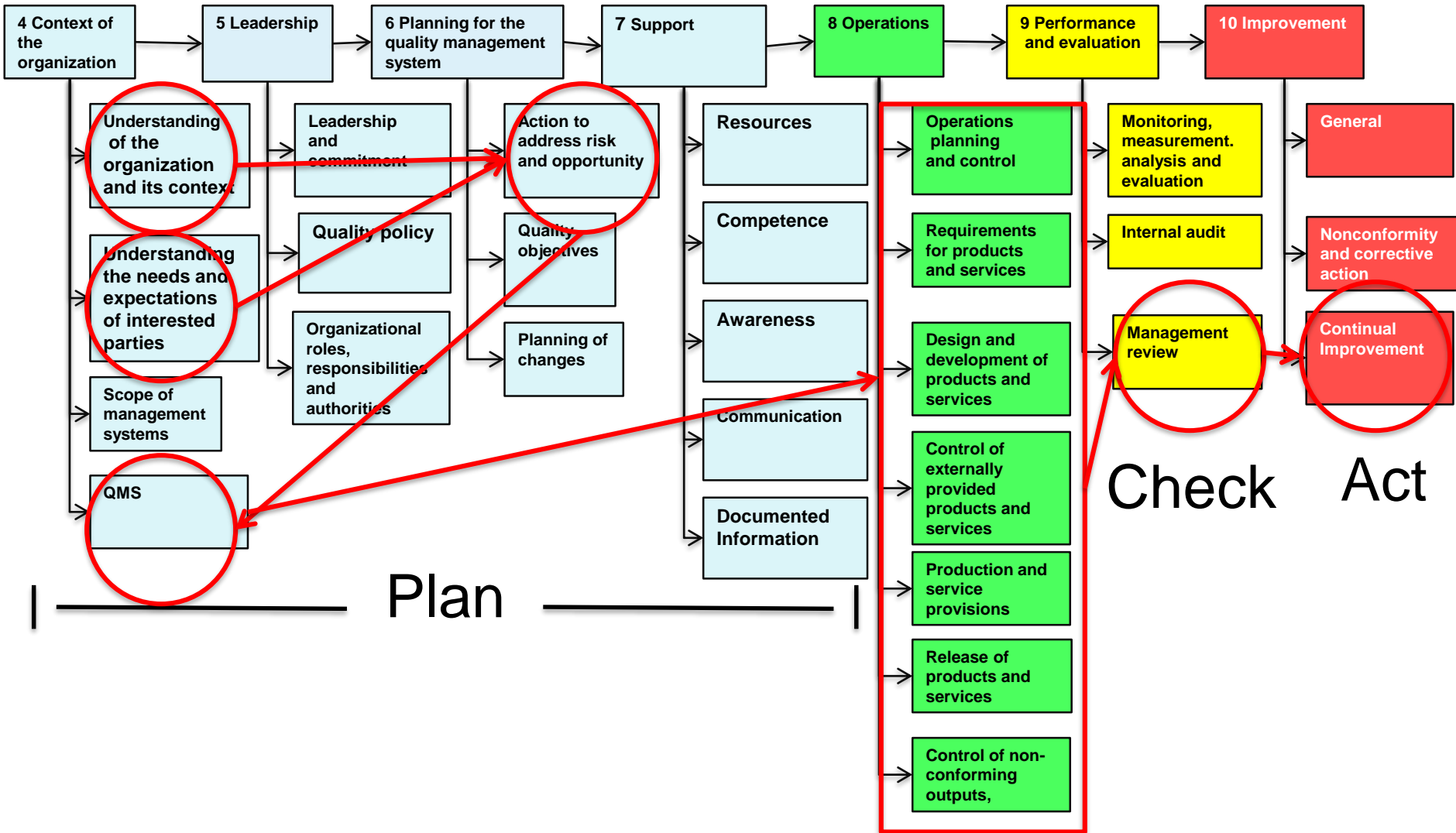
Plan: Determine Action Plans to address Risks and Opportunities
(Clause 6.1.2)

Do: Integrate and implement actions into its quality management system processes (Clause 4.4)

Check: Evaluate effectiveness of actions taken
(Clause 9.3)

Act: Learn from results and reassess Context and Interested Parties
(Clause 10.3)

ISO 9001:2015 Structure



What is Risk?

Risk: the effect of uncertainty on an organization's ability to meet its objectives
(ISO 31000:2018)

or

Risk is the possibility of events or activities impeding the achievement of an organization's strategic and operational objectives.

Risk Definitions

Risk can often be defined by two parameters

- Severity

- This is the Seriousness of the harm

- Probability

- This is the Likelihood that the harm will occur

Risk Assessment - Quantitative

RISK OUTCOME					
	<div style="display: flex; flex-direction: column; gap: 5px;"> <div style="background-color: #90EE90; width: 20px; height: 10px; margin-bottom: 2px;"></div> Low </div> <div style="display: flex; flex-direction: column; gap: 5px;"> <div style="background-color: #FFFF00; width: 20px; height: 10px; margin-bottom: 2px;"></div> Moderate </div> <div style="display: flex; flex-direction: column; gap: 5px;"> <div style="background-color: #FFA500; width: 20px; height: 10px; margin-bottom: 2px;"></div> Significant </div> <div style="display: flex; flex-direction: column; gap: 5px;"> <div style="background-color: #FF0000; width: 20px; height: 10px; margin-bottom: 2px;"></div> High </div>				
Likelihood	Consequence				
	Insignificant	Minor	Moderate	Major	Catastrophic
	1	2	3	4	5
Almost Certain 5	5	10	15	20	25
Likely 4	4	8	12	16	20
Possible 3	3	6	9	12	15
Unlikely 2	2	4	6	8	10
Rare 1	1	2	3	4	5

Increasing Risk

Risk Guidance (ISO 9001)

Options to address risks can include:

- avoiding risk,
- taking risk in order to pursue an opportunity,
- eliminating the risk source,
- changing the likelihood or consequences,
- sharing the risk, or retaining risk by informed decision.

Quality Professionals have done a good job guiding businesses in identifying, mitigating and evaluating the effectiveness of actions taken.

What is Risk?

Risk is the possibility of events or activities impeding the achievement of an organization's strategic and operational objectives.

What is Opportunity?

Opportunity is the possibility of events or activities enhancing the achievement of an organization's strategic and operational objectives.

Risk Definitions

Risk can often be defined by two parameters

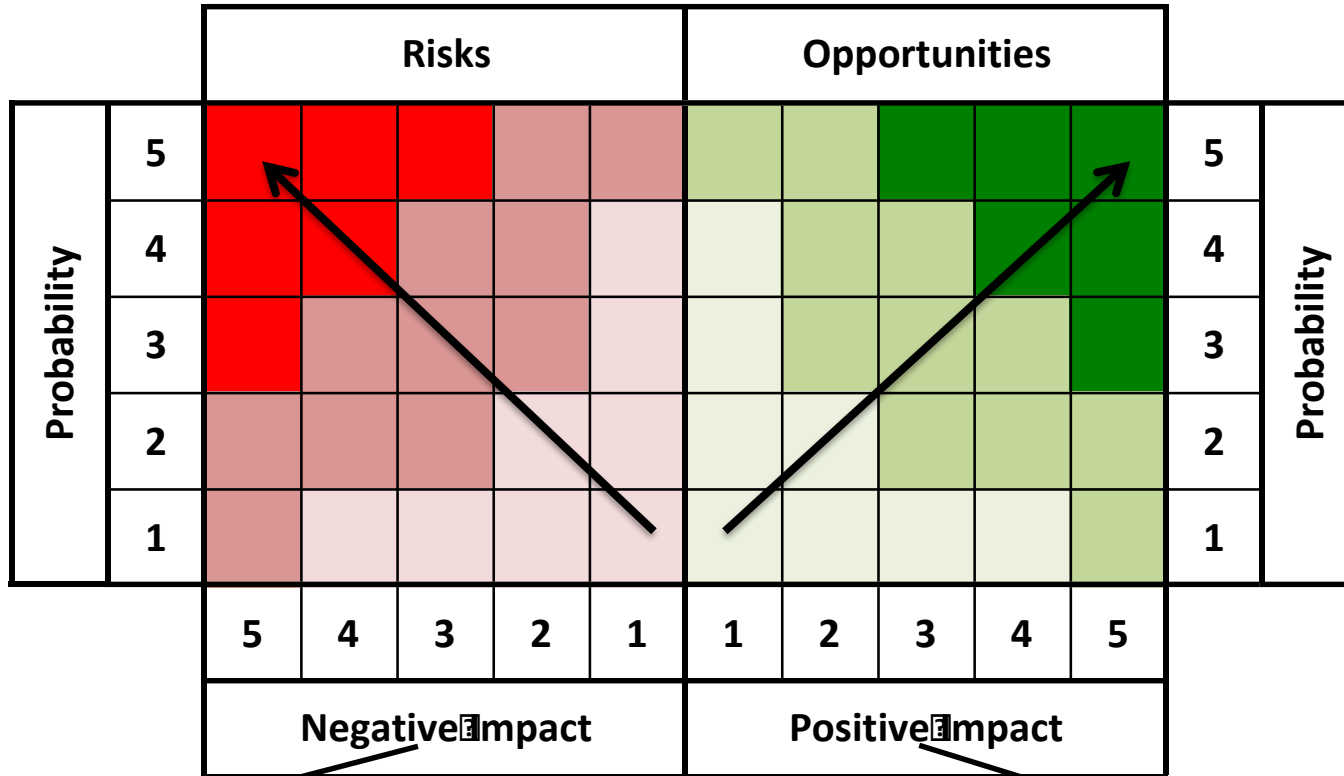
- Severity
 - This is the Seriousness of the harm
- Probability
 - This is the Likelihood that the harm will occur

Opportunity Definitions

Opportunity can often be defined by two parameters

- Benefit
 - This is the Positive Effect of the event
- Probability
 - This is the Likelihood that the event will occur

Risk & Opportunity



Declining Financials and Profits
 Loss of Reputation
 Lower Customer Satisfaction
 Day to Day Operation Disruption
 Employee Discontent

Increasing Revenue and Profits
 Best in Class Reputation
 Positive Customer Satisfaction
 Growth in Day to Day Operations
 Employee Security and Rewards

Opportunity Guidance (ISO 9001)

Opportunities can lead to:

- the adoption of new practices,
- launching new products,
- opening new markets,
- addressing new customers,
- building partnerships,
- using new technology and
- other desirable and viable possibilities to address the organization's or its customers' needs.

Opportunity Guidance (ISO 9001 –cont.)

- Opportunities for Improvement (Mgmt. Review -Clause 9.3.3)
- The organization shall determine and select opportunities for improvement.....
(Improvement – Clause 10.1)

Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization

So where will a Quality Professional make an Impact?

Where Does the Quality Professional Focus?

Traditional Quality (Product & Service)

- By the Numbers – 3P, 5S, 6 σ , 8D
- By the Colors – White, Yellow, Green, Black
- By the Acronyms – JIT, SPC, DOE, DMAIC, etc.
- System Approach/Data Driven Decisions/
Continual Improvement/Customer Focus

Future Quality (Product & Service & Data)

Environmental Scan

Today's decisions require large quantities of data but.....

- The right data is not always available
- The data is not formatted for easy analysis
- The data is incomplete
- The data is not current and out dated
- Tools to make good decisions are not always available

Environmental Scan (cont.)

New tools and technologies being developed to improve quality of the data

- Artificial Intelligence
- Block Chain
- Machine Learning
- Data Analysis Tools
- Pattern Recognition
- Predictive Maintenance
- Others...

Environmental Scan (cont.)

Bigger data may not be the ultimate solution to decision making, enabling new tools and techniques or improving operational efficiencies

Maybe the ultimate solution to small, medium, or large data sets is the “Quality of the Data”

How can a Quality Professional demonstrate their value in this new and evolving environments?
(Quality 4.0)

Opportunity

5	10	15	20	25	5 Almost Certain	Probability
4	8	12	16	20	4 Likely	
3	6	9	12	15	3 Possible	
2	4	6	8	10	2 Unlikely	
1	2	3	4	5	1 Rare	
1 Insignificant	2 Minor	3 Moderate	4 Major	5 Break Thru	Benefit	

Data Quality

Increasing Revenue and Profits
 Best in Class Reputation
 Positive Customer Satisfaction
 Growth in Day to Day Operations
 Employee Security and Rewards

How?

Dilemma & Opportunity

Dilemma:

Large corporations are well on their way to leveraging big data

- They have intact IT organizations (Keeper of the Data)
- They have Data Analysts and Tool Developers in multiple organizational functions
- The Quality Function is not necessarily in the Data/Information Stream

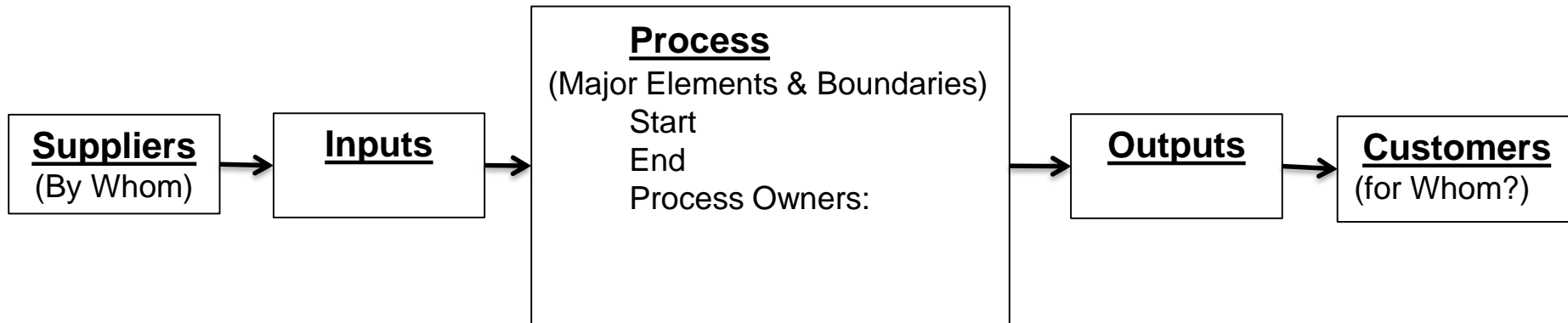
Dilemma & Opportunity (cont)

Opportunity:

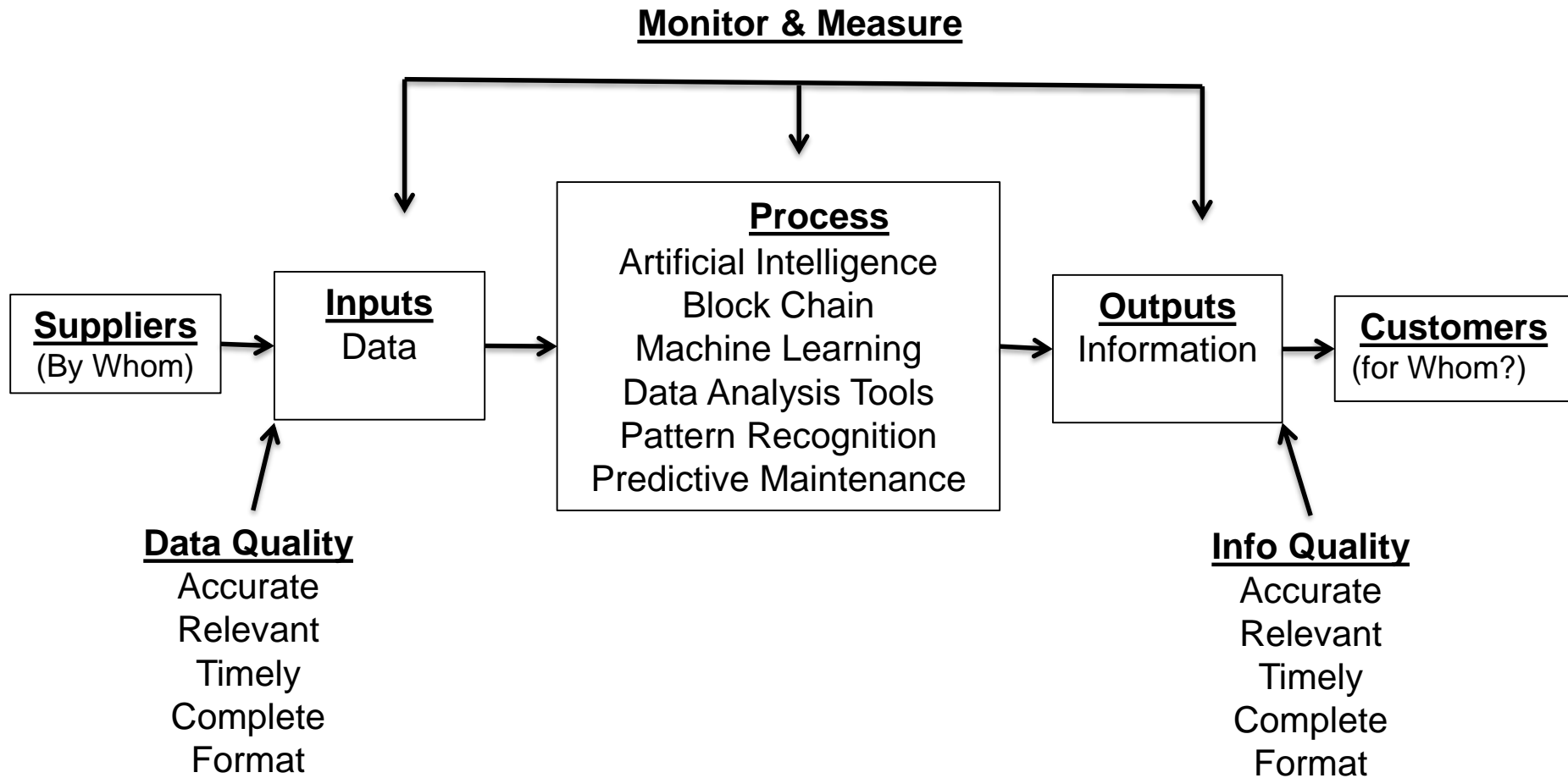
Need Leadership to see the need for systems to control data quality

- Process Approach/System Thinking
- Data Driven Decision Making
- Customer Perception and Satisfaction
- Continual Improvement
- Future - Simple tools and techniques that can be delivered to smaller organizations

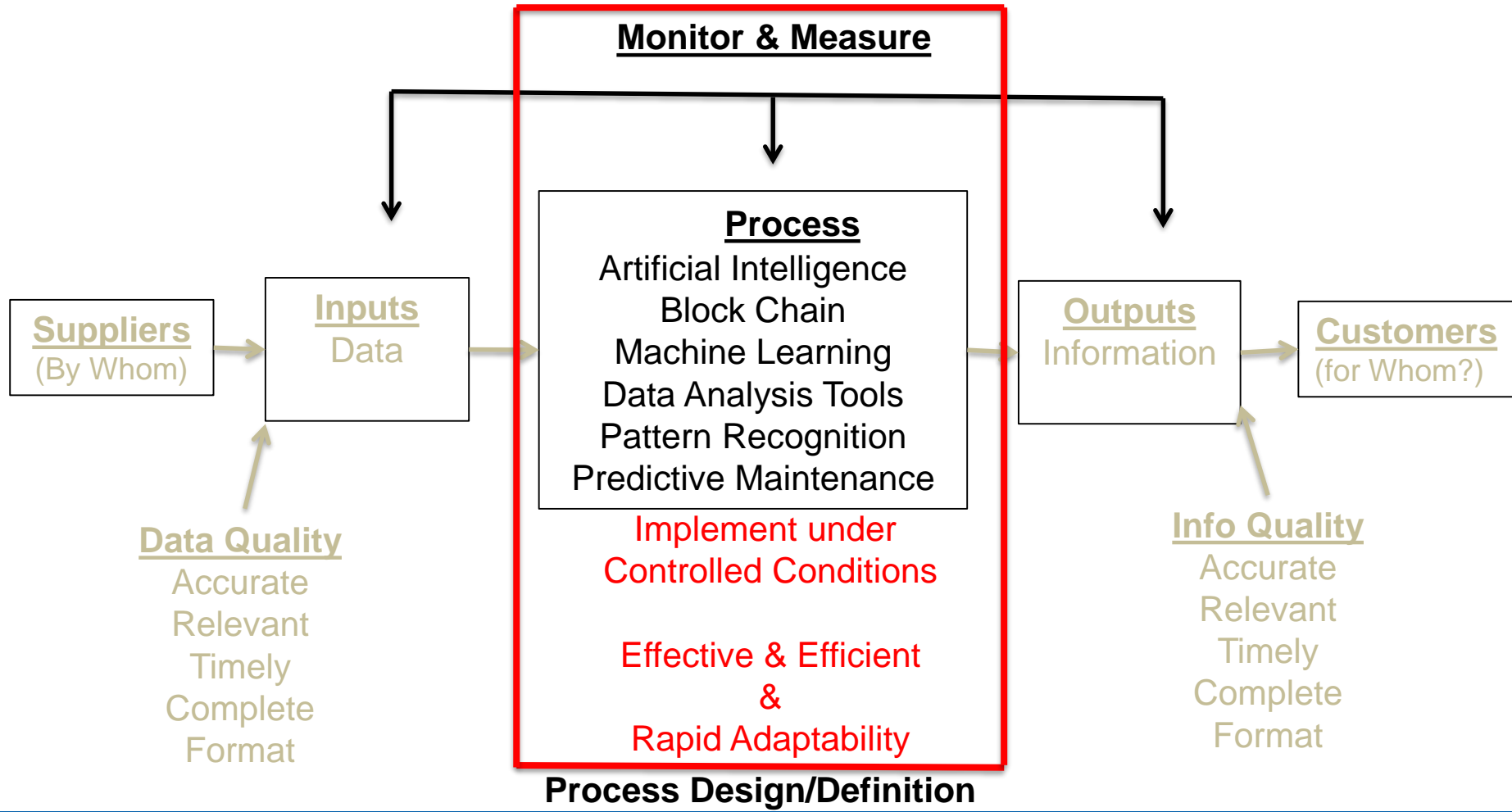
Process Approach (SIPOC)



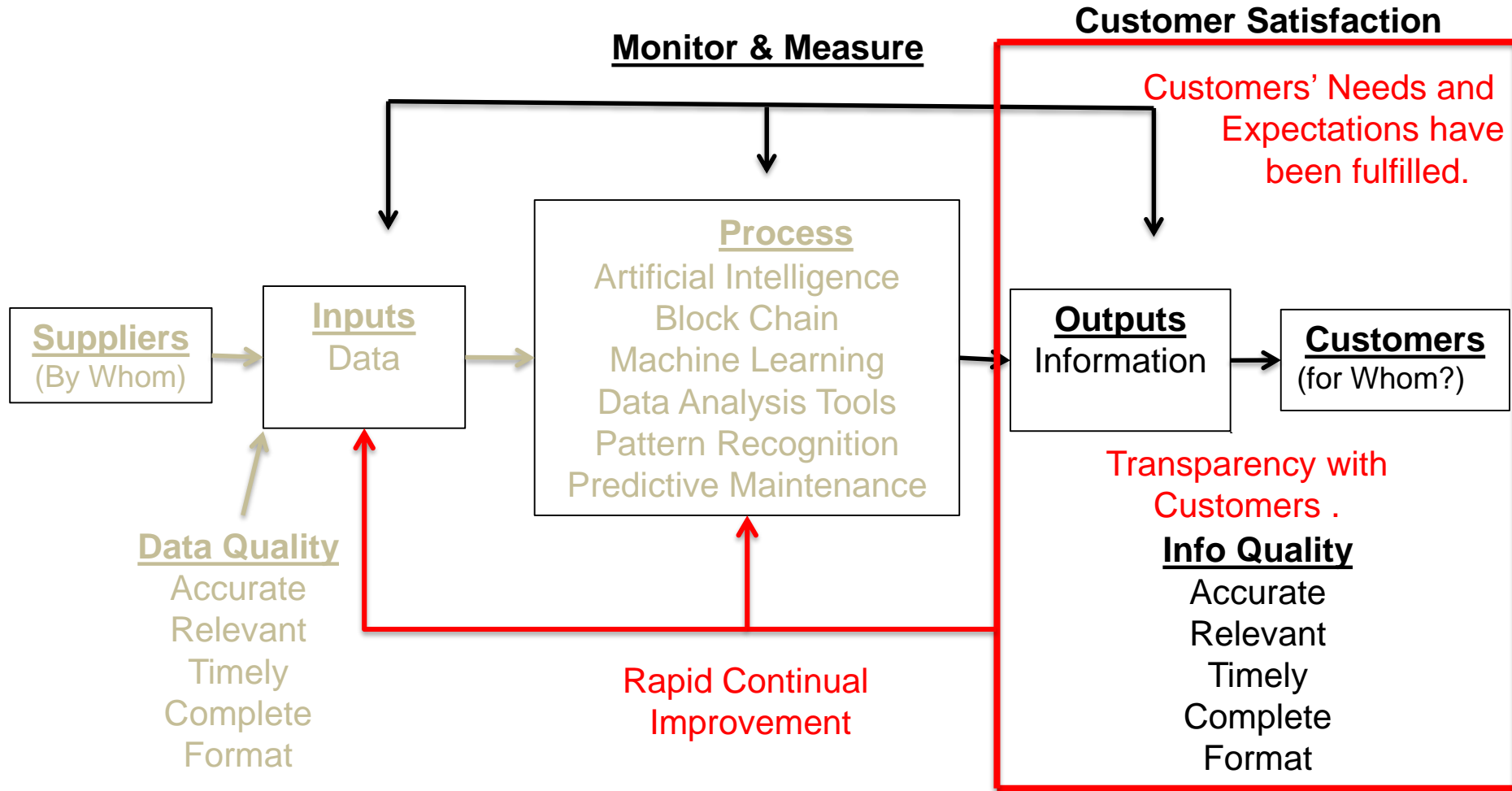
Process Approach (Data)



Process Approach (Data)



Process Approach (Data)



Process Approach (Data)

External Provider Management

Monitor & Measure

Conform to Requirements

Evaluate, Select, Monitor
Performance, and
Re-Evaluate

Suppliers
(By Whom)

Inputs
Data

Process
Artificial Intelligence
Block Chain
Machine Learning
Data Analysis Tools
Pattern Recognition
Predictive Maintenance

Outputs
Information

Customers
(for Whom?)

Transparency with
Customers .

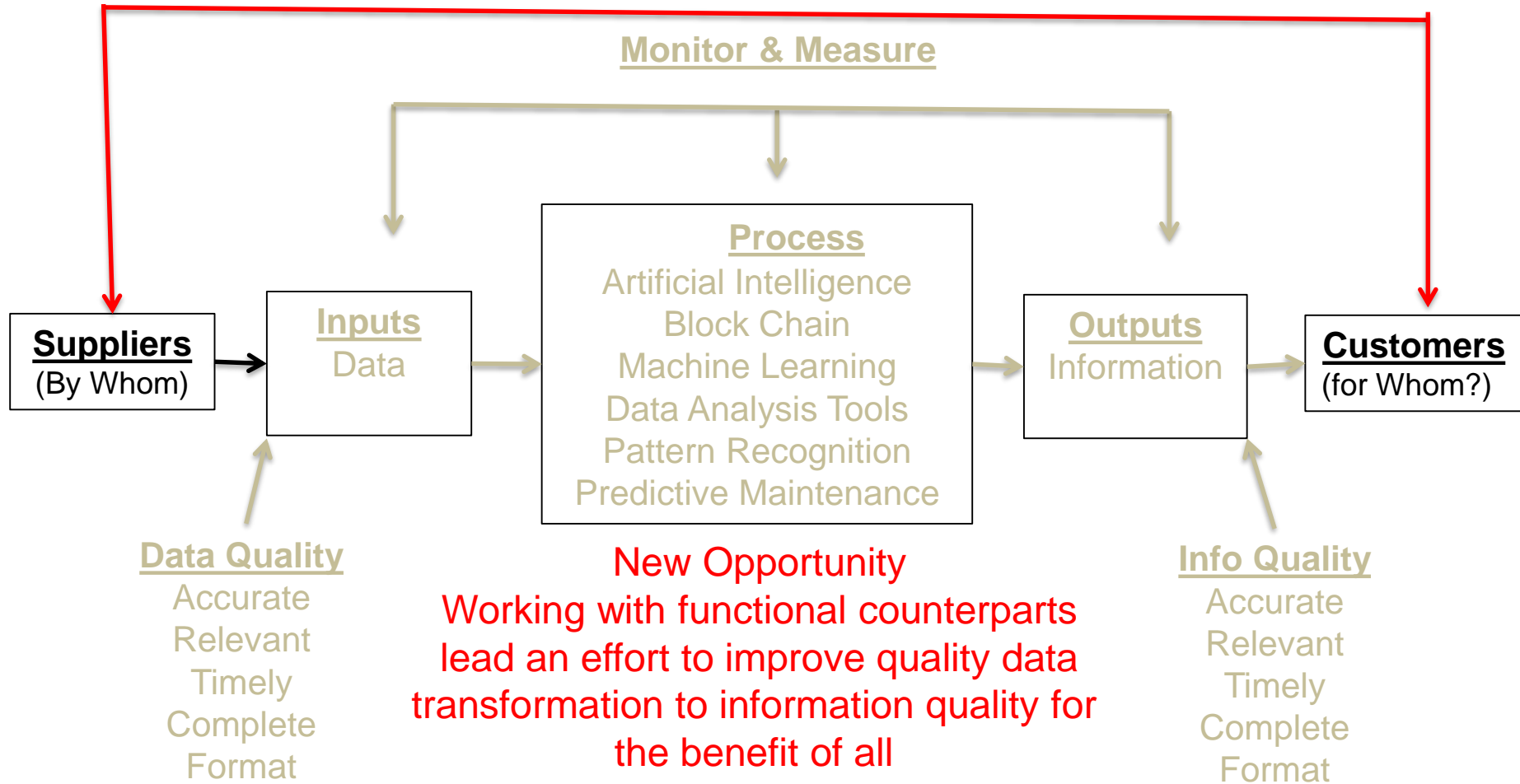
Data Quality

Accurate
Relevant
Timely
Complete
Format

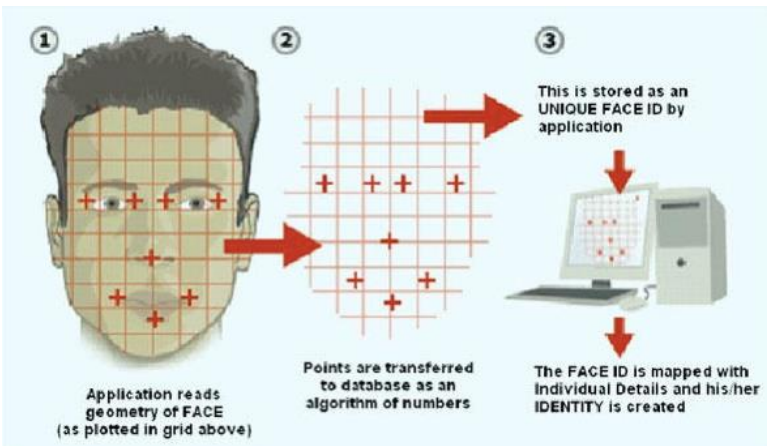
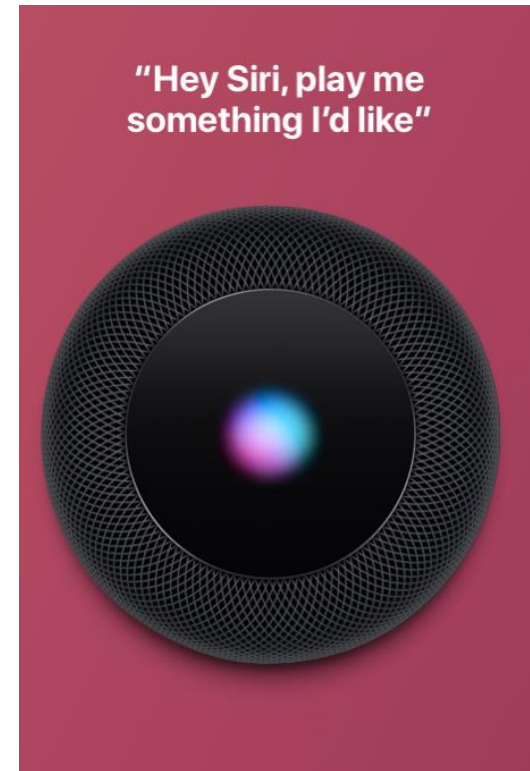
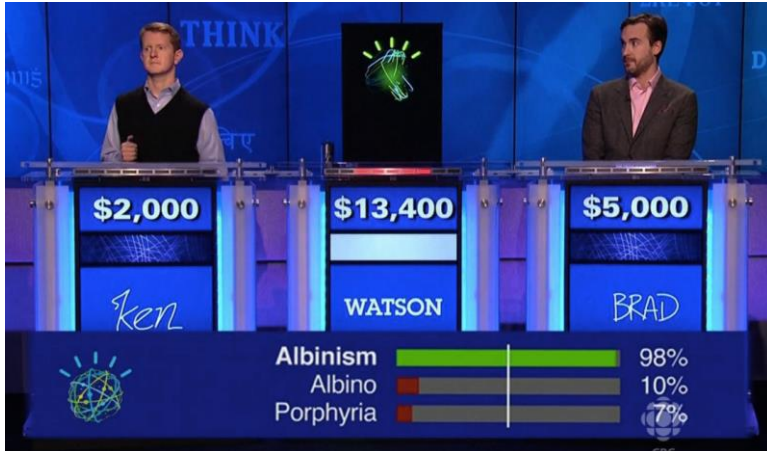
Info Quality

Accurate
Relevant
Timely
Complete
Format

Process Approach (Data)



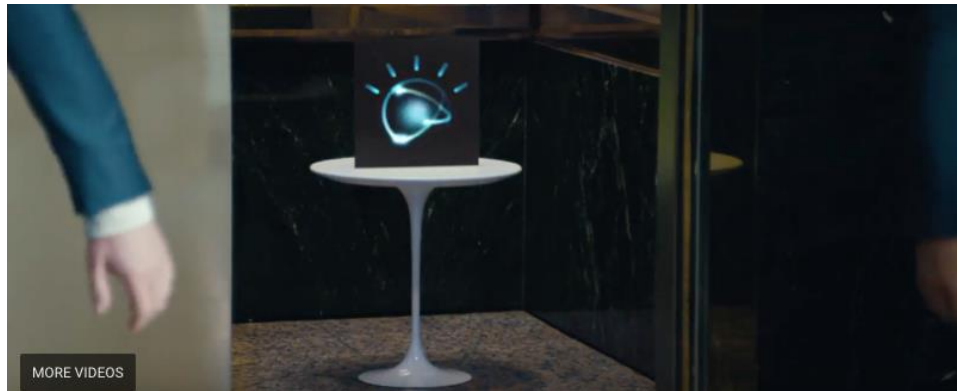
Intelligent Machines



Today- IBM Elevator Commercial



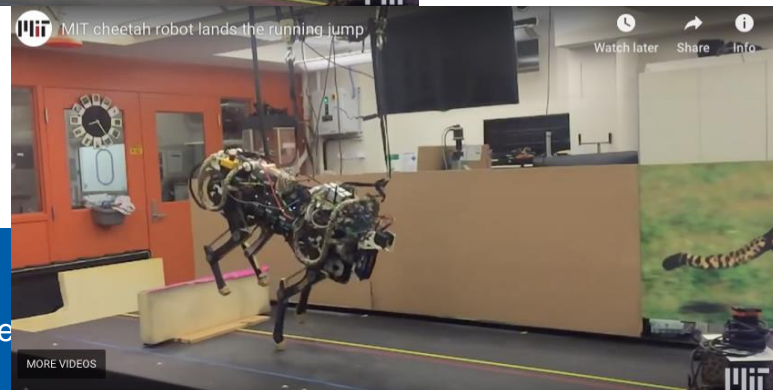
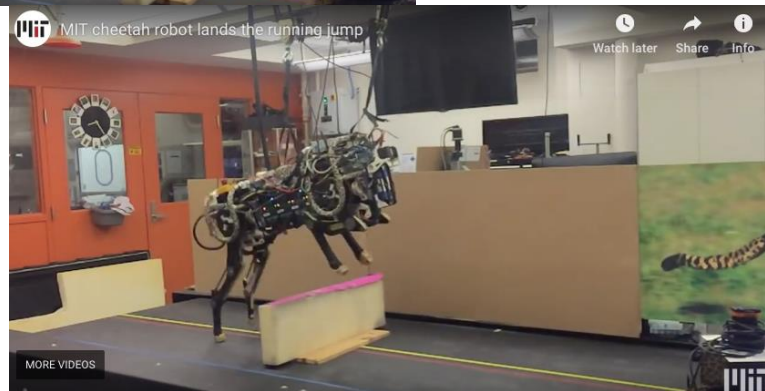
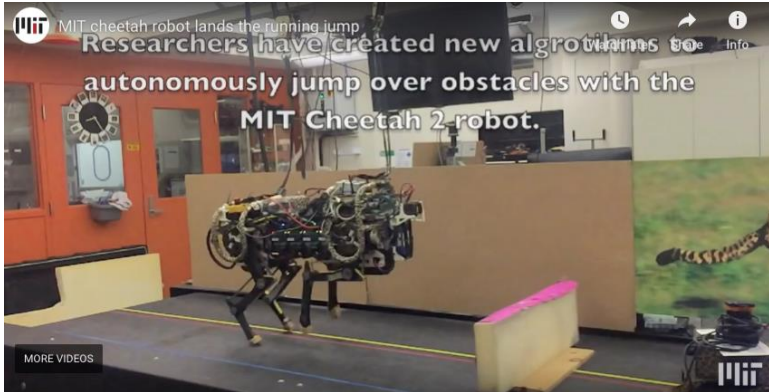
Predictive Maintenance
when elevator calls
the repair man



Today - MIT Cheetah

Machine Learning/AI

Teaching a machine to jump over a hurdle.



Conclusions

- Industries in all markets are increasing their need to make *“Data Driven Decisions”*
- Machines are getting smarter and learning.
And
- The transition from *“Data”* into *“Information”* is a *“Process”*.
- The *“Opportunity”* is for the Quality Function to work with their organizational counterparts applying traditional tools to the expanding demands of big data and its applications.

Disclaimer

The author is not advocating that Quality Professionals evolve into Data Analysts unless you want your career take this direction

But

It might not hurt if you inform yourself with brief tutorials in Artificial Intelligence, Machine Learning, or Analytics

Questions?



Thank You

References

- ISO 9001:2015 Quality management systems – Requirements
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- “*Let’s get Digital*”, Nicole Radziwill, Quality Progress, October 2018
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- ISO 31000:2018
- IBM Elevator Commercial Video
- MIT Leaping Cheetah Video