Risk-Based Thinking and the Digital Transformation of Quality

Tim Lozier, EtQ

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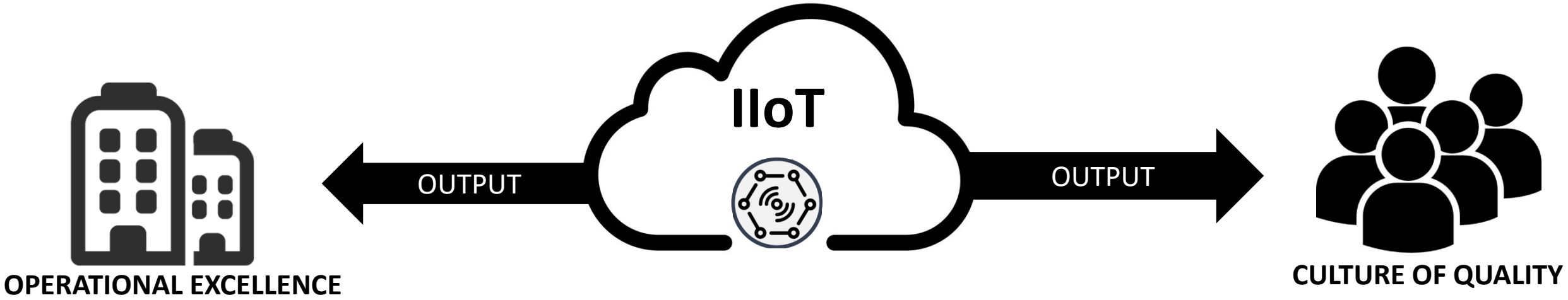
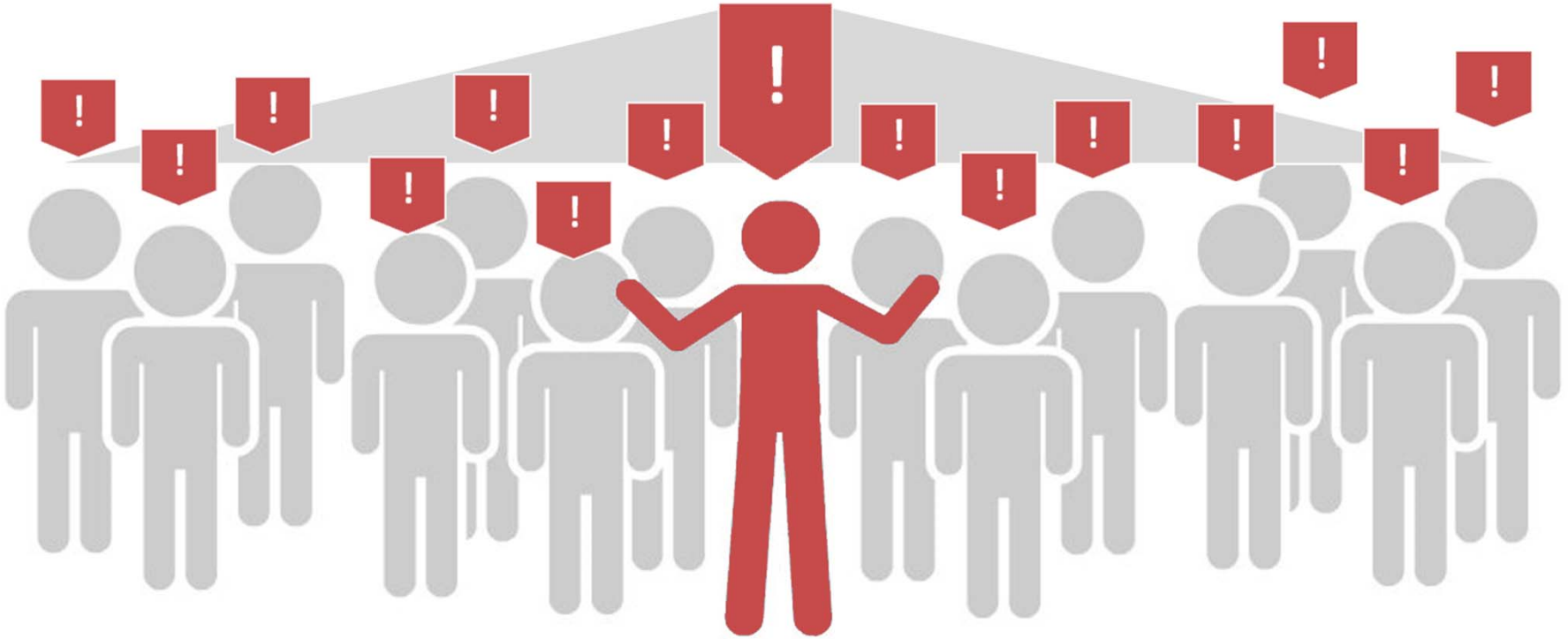
Agenda

- Looking at risk-based thinking as a catalyst for a shift in the digital transformation of quality
- How to build a risk-based thinking approach
- How quality is contributing to the digital transformation and Quality 4.0
- What is quality's role in the overall Industry 4.0 / Factory of the Future



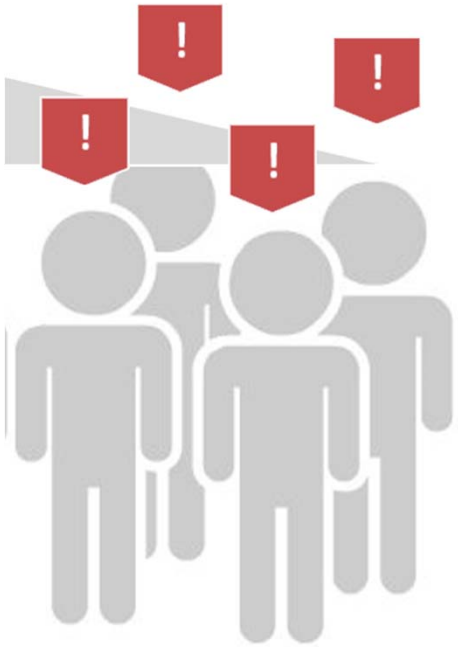
ISO 9001:2015….It's Not Just Requirements

It's a company mindshare of Quality.



There should be a company-wide commitment/leadership around Quality

ISO 9001:2015 View on Risk



Section 5: Leadership

Provide leadership by encouraging a focus on quality

Promote the use of risk-based thinking.

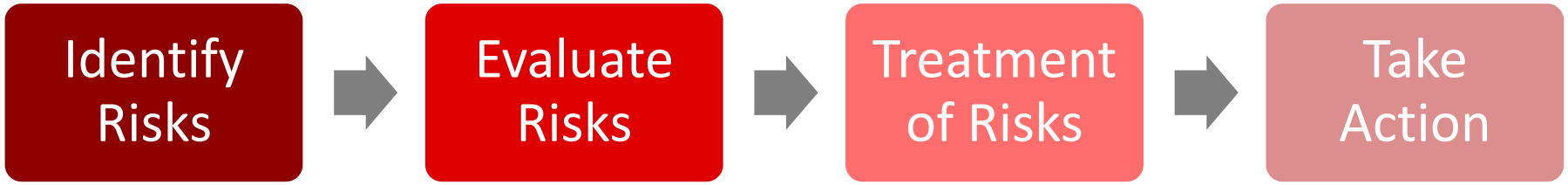
Section 6: Planning

Consider risks and opportunities when you plan your QMS

Plan how you're going to manage risks and opportunities

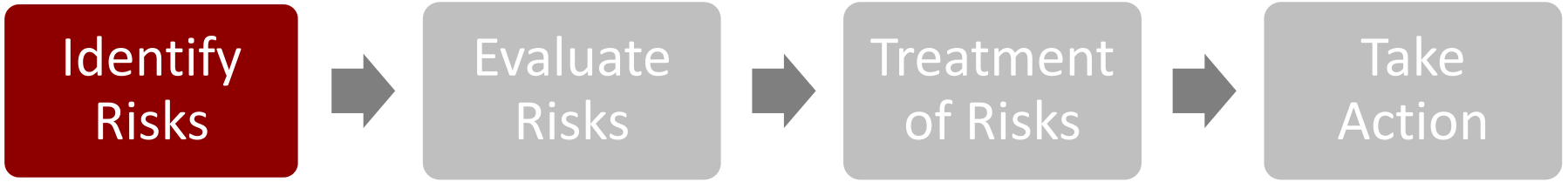
DISCLAIMER: The ISO view on risk is SIMPLY STATED. "Use Risk-based thinking" to manage and plan…. But what does that really mean? Broad, and simple – lots of interpretation!

Planning Your QMS with Risk in Mind

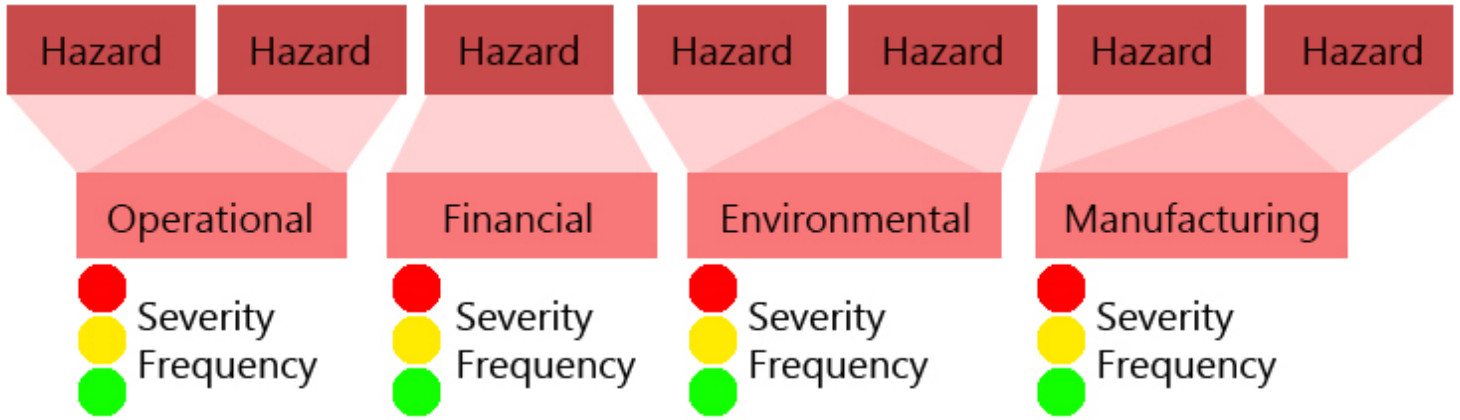


- Identify risks and opportunities to influence QMS performance
- Determine how you're going to measure those risks
- Build risk treatment options
- Define actions to address these risks

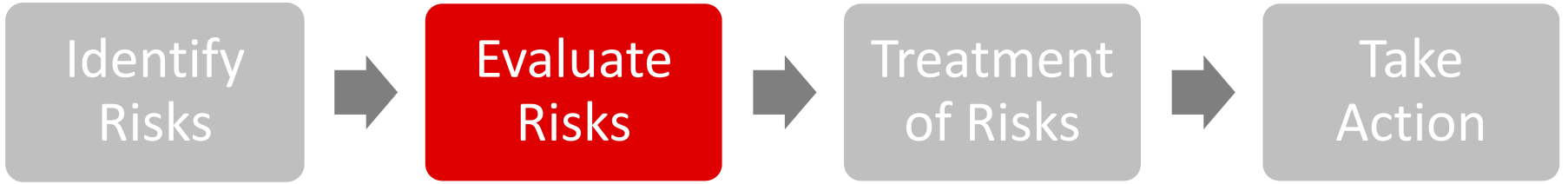
Planning Your QMS with Risk in Mind



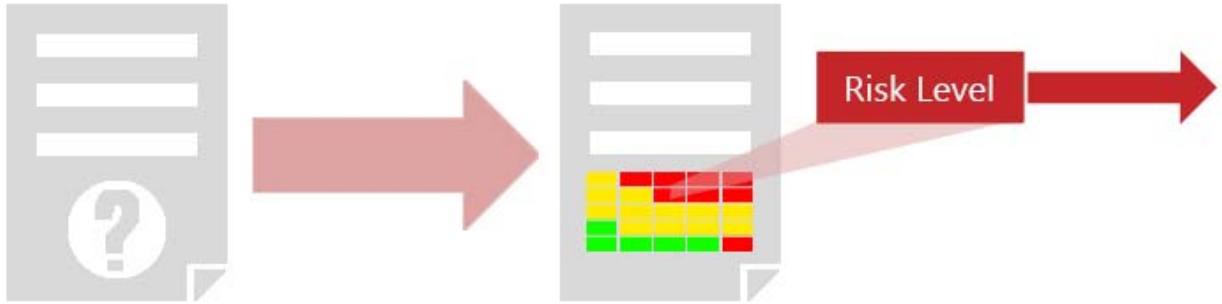
- How to start Identifying risks?
  - Survey your operations
  - Audit, Survey, collect, analyze



Planning Your QMS with Risk in Mind



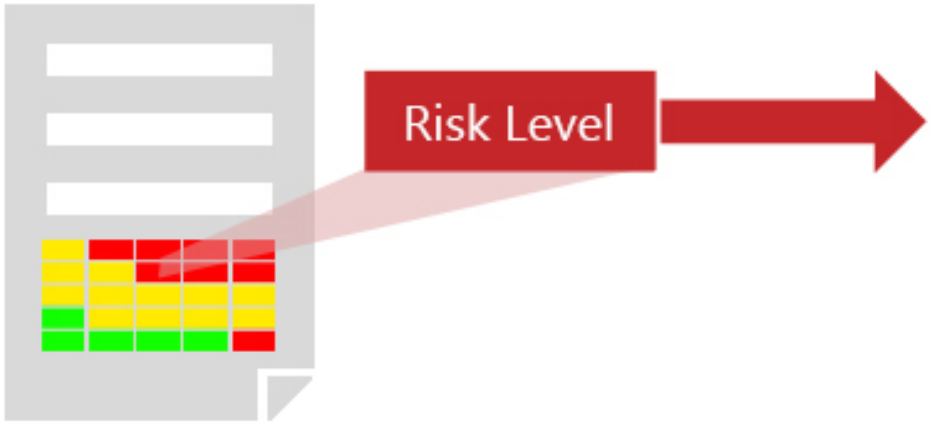
- Evaluate How to handle the risk
- Risk Assessment
  - Should be repeatable, objective
  - Should be backed by REAL-WORLD DATA
- Quantitative means to build a risk assessment



Planning Your QMS with Risk in Mind

Identify Risks → Evaluate Risks → **Treatment of Risks** → Take Action

- We know the risk….how do we handle it?



Acceptance: “Worth it”
Reduction: “Mitigation”
Compensation: “Insurance”
Transference: “Move it”
Avoidance: “Stop it”

Planning Your QMS with Risk in Mind

Identify Risks → Evaluate Risks → Treatment of Risks → Take Action

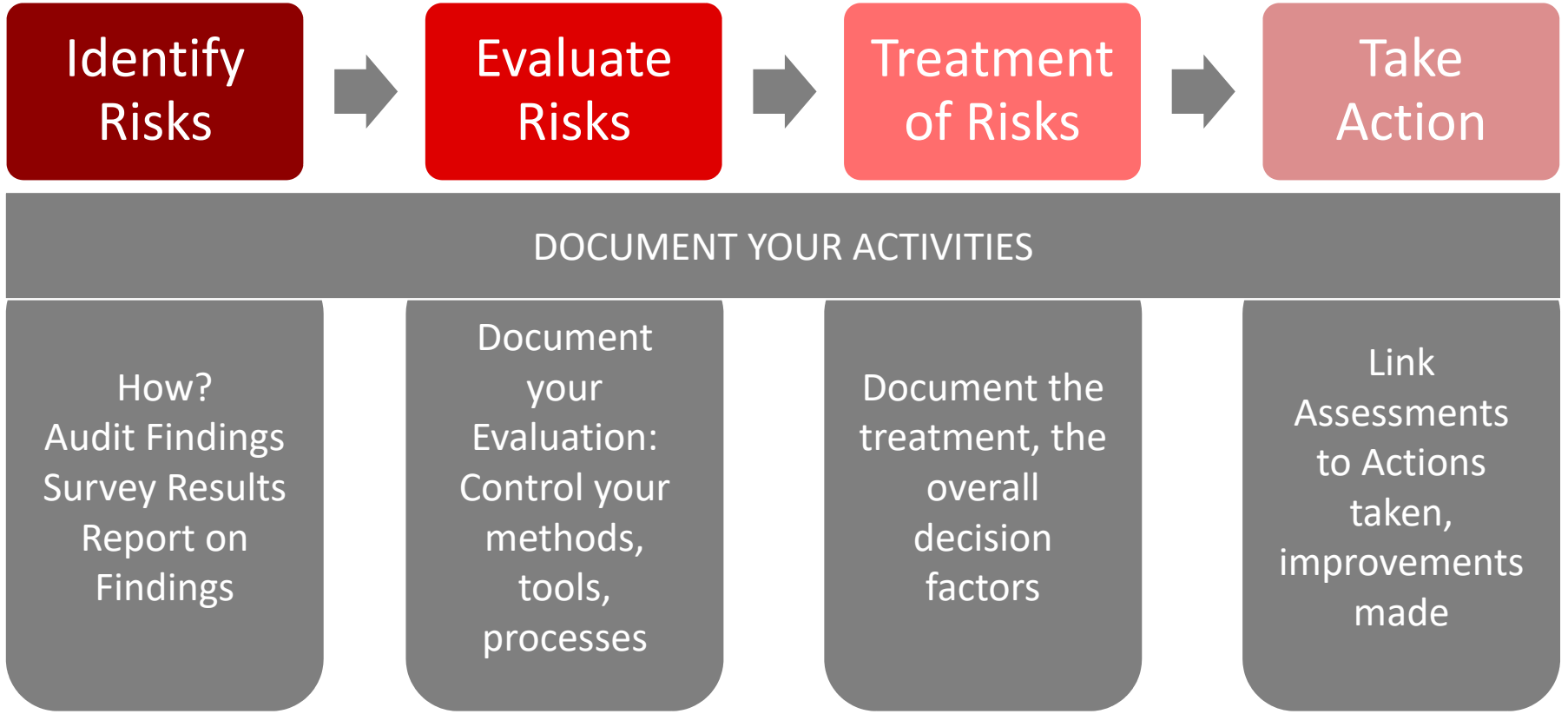
- Take Action: Create Visibility and Control the Risk

Corrective/Preventive Action

Controls/Action Plans

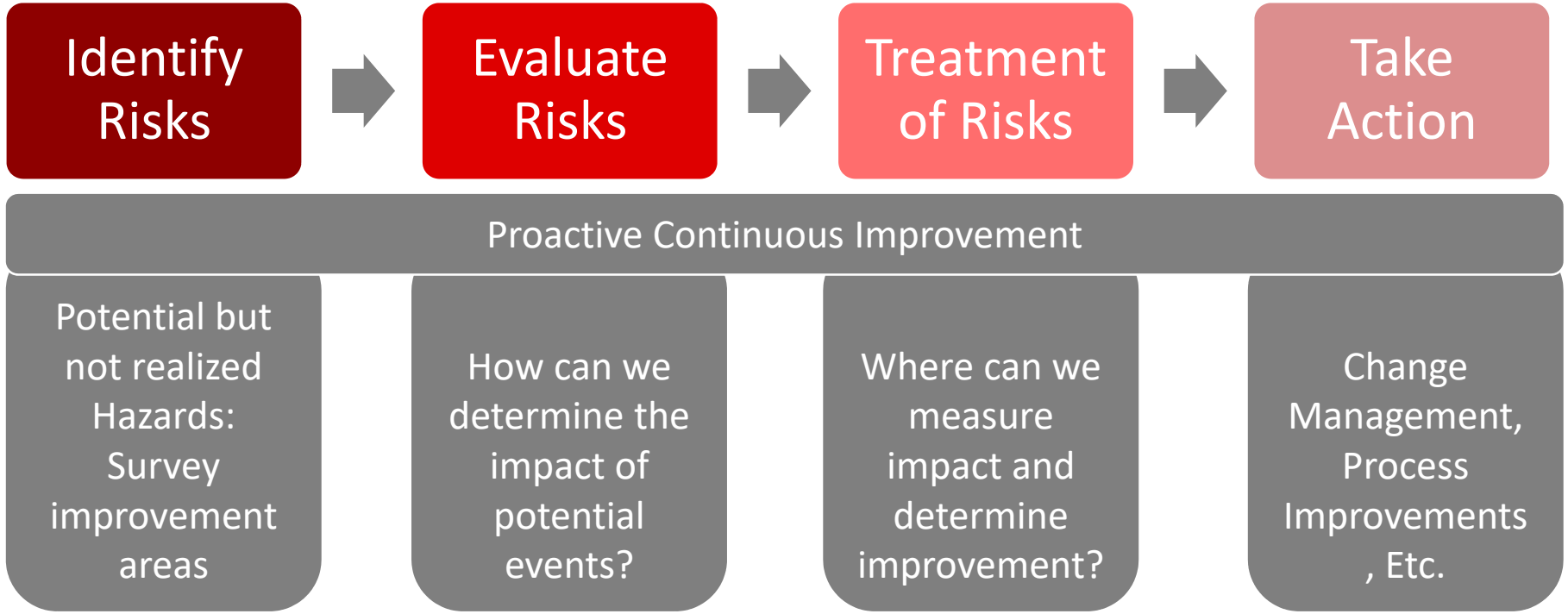
Reporting/Trending

Planning Your QMS with Risk in Mind



- Document the process in order to have traceability.

Planning Your QMS with Risk in Mind



- It's not all for just the Risks! Identify Opportunities too!

Where Technology Meets Risk-based Thinking

Risk-based Tools

Risk in Operations

Risk Analytics and Reporting

Where Technology Meets Risk-based Thinking

Risk-based Tools

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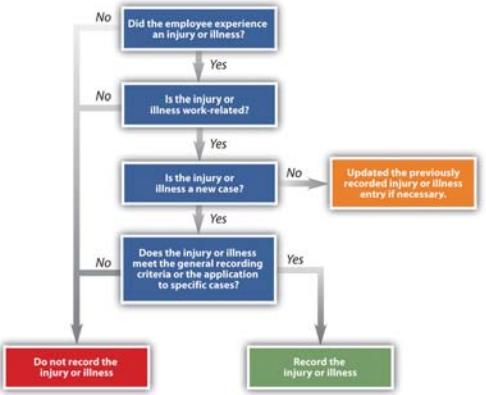
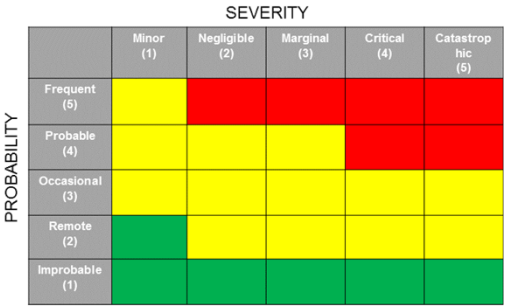
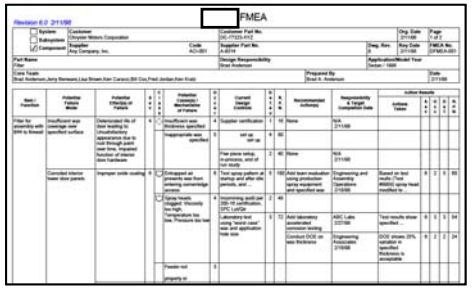
Risk Analytics and Reporting

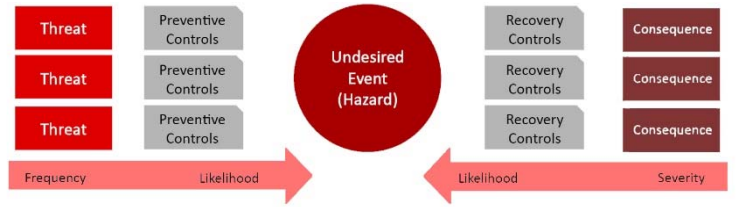
Quantitative Methods for measuring and treating risk:

- Decision Trees
- Risk Matrix
- FMEA
- BowTie
- (plenty of others)









Where Technology Meets Risk-based Thinking

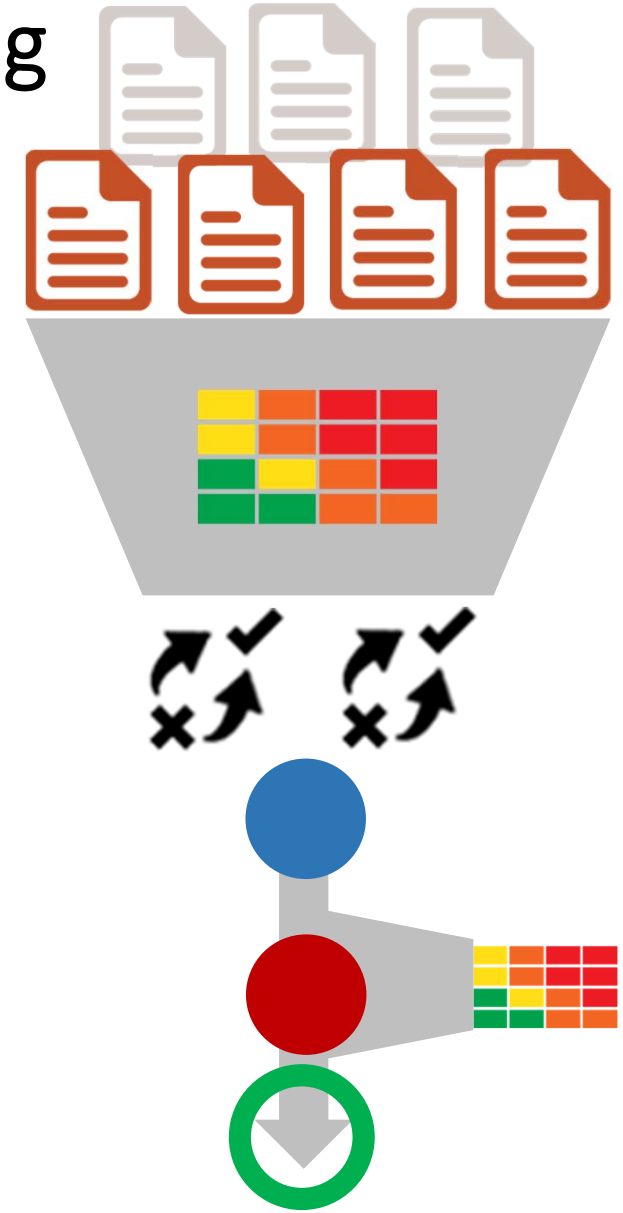
Risk-based Tools

Risk in Operations

Risk is used to

- Filter Events
- Determine Severity
- Prioritize
- Effectiveness

Risk Analytics and Reporting



Where Technology Meets Risk-based Thinking

Risk-based Tools

Risk in Operations

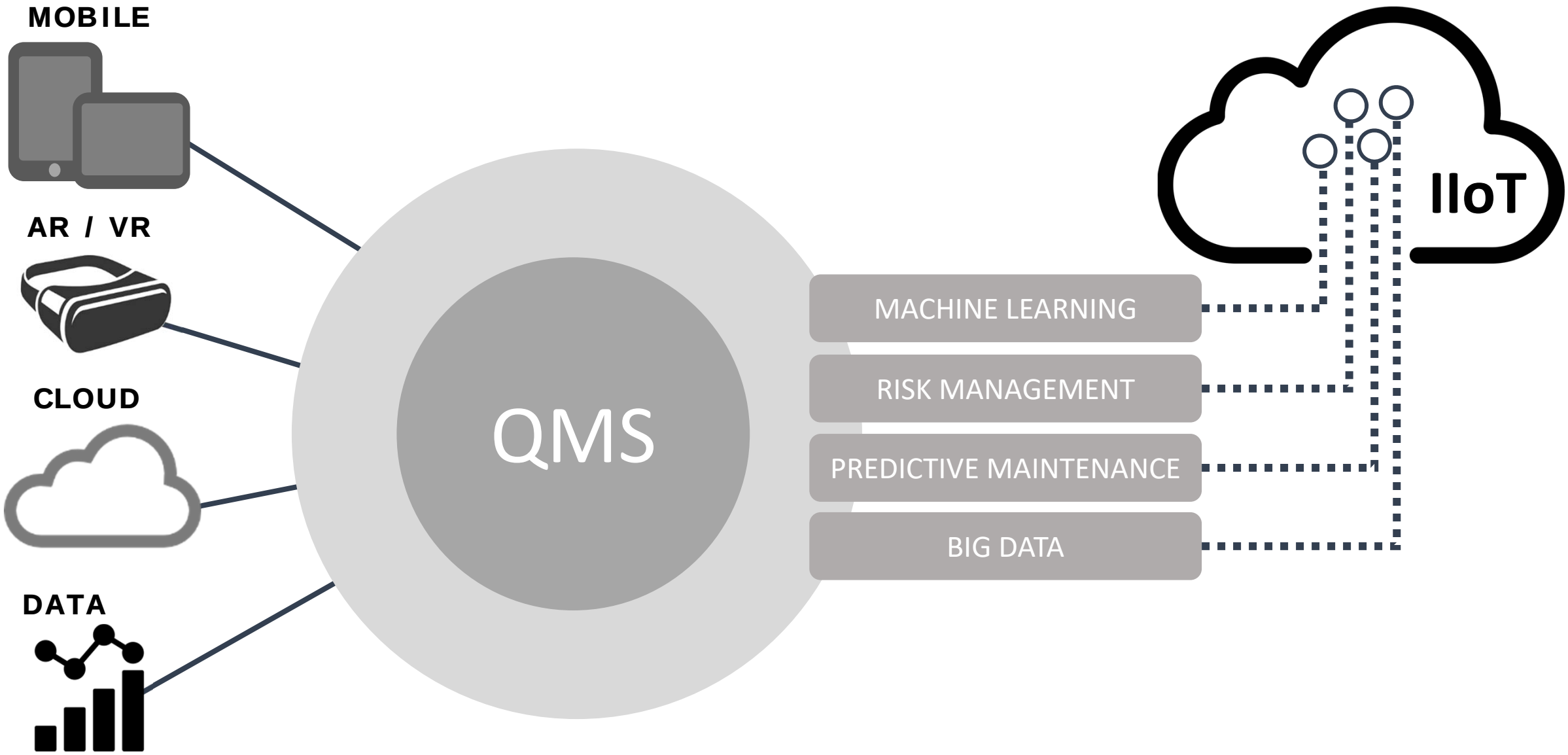
Risk Analytics and Reporting

Risk Reporting

- Data Analysis
- Risk-Based Data
- Knowledgebase
- Trending on Risk

Risk Register

What is Quality's Digital Transformation?



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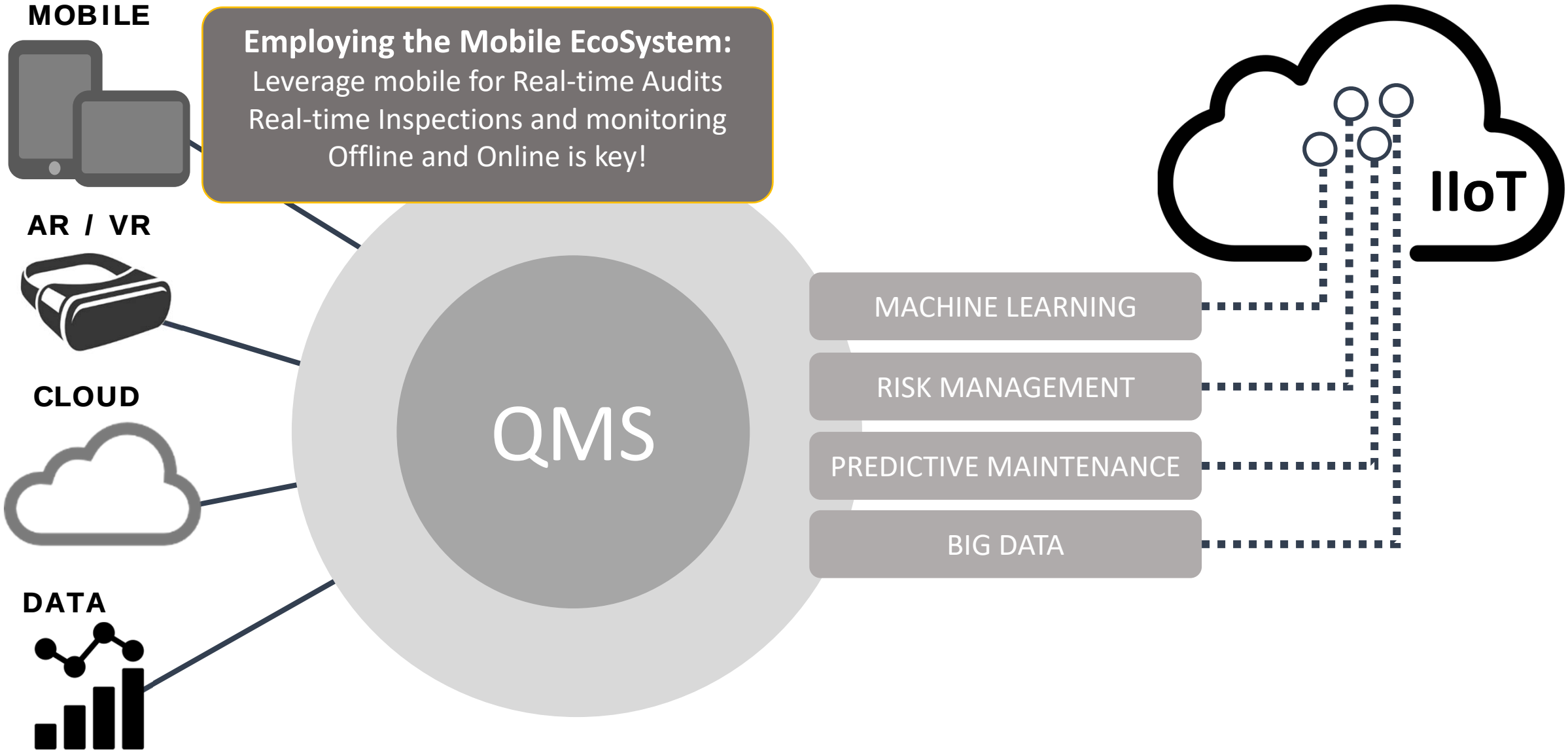

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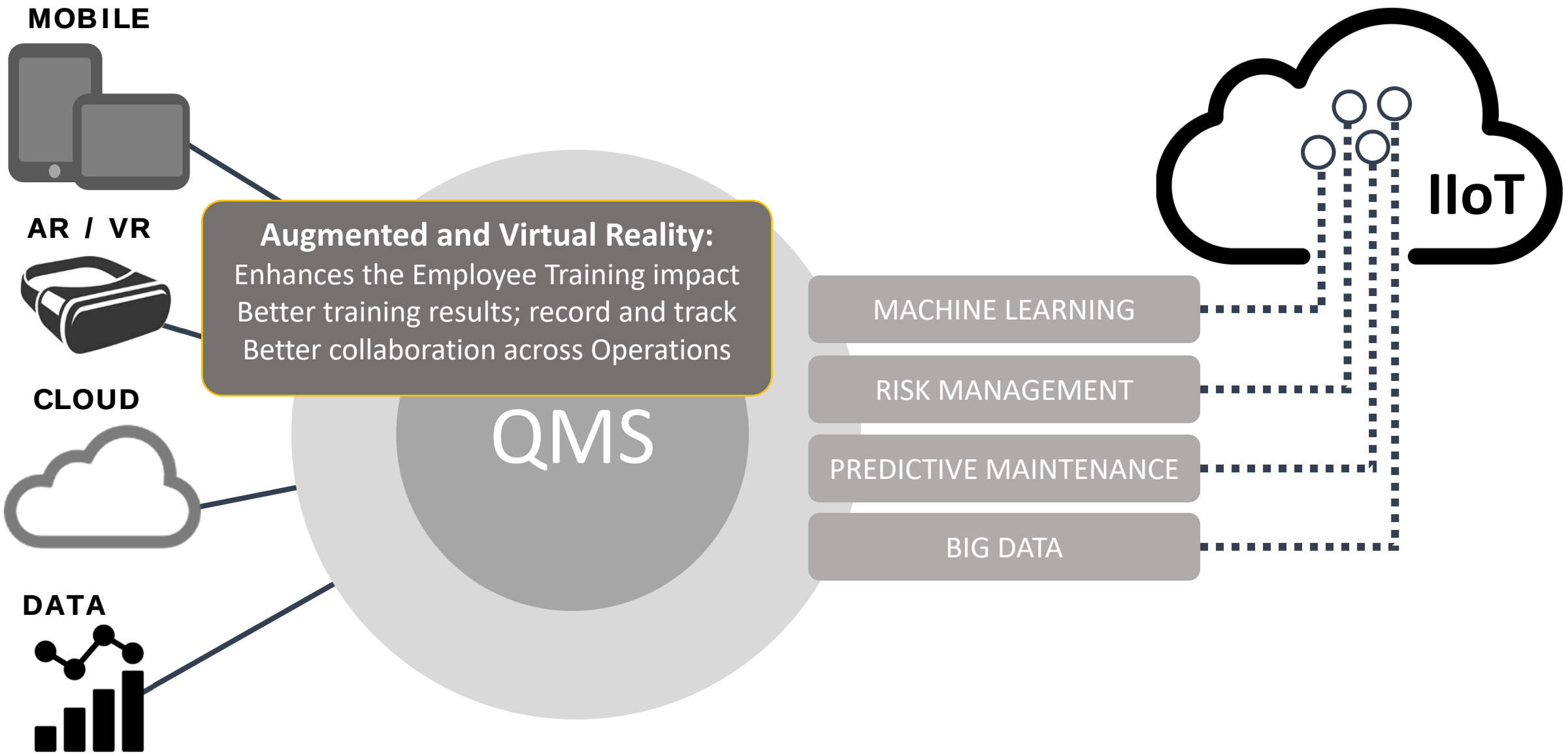

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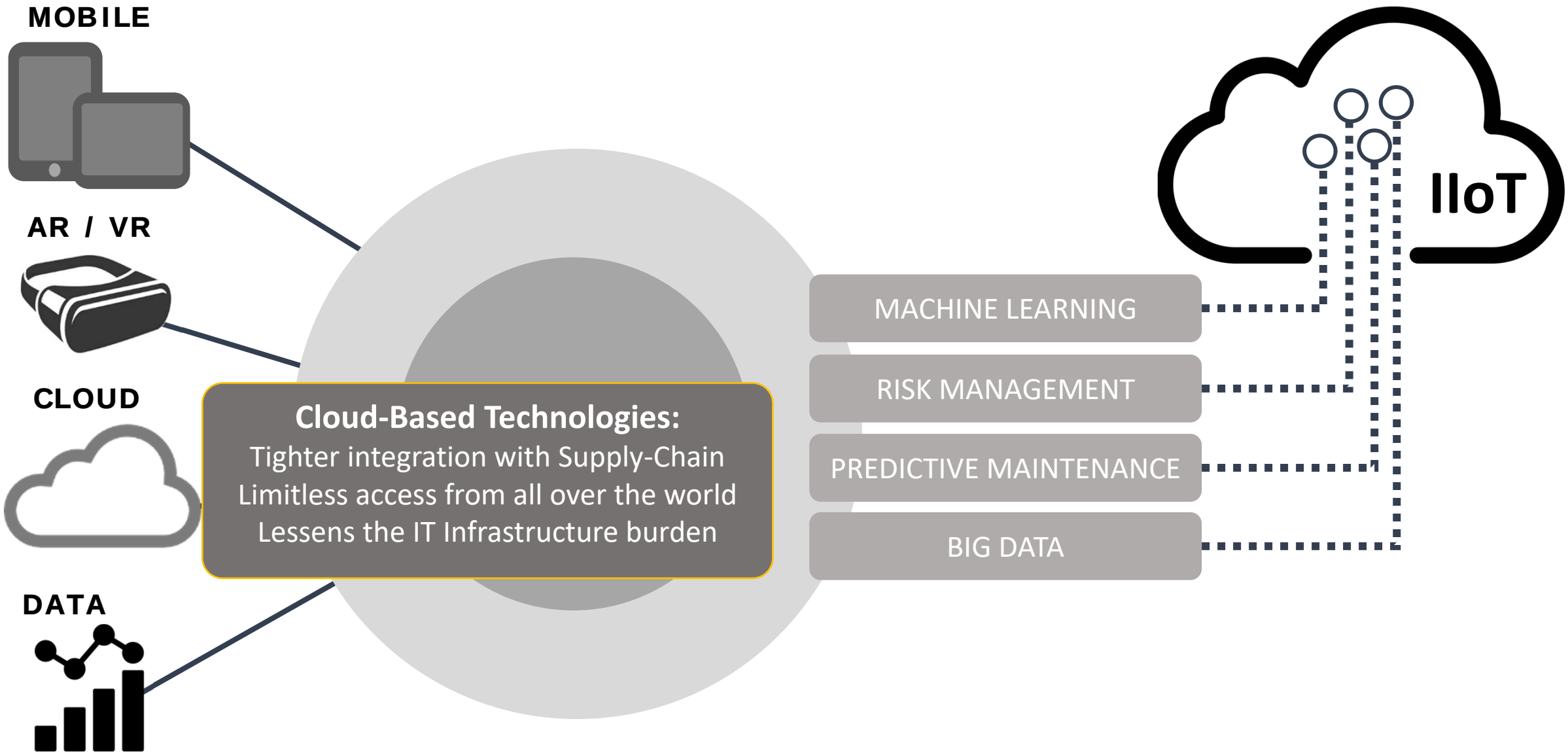

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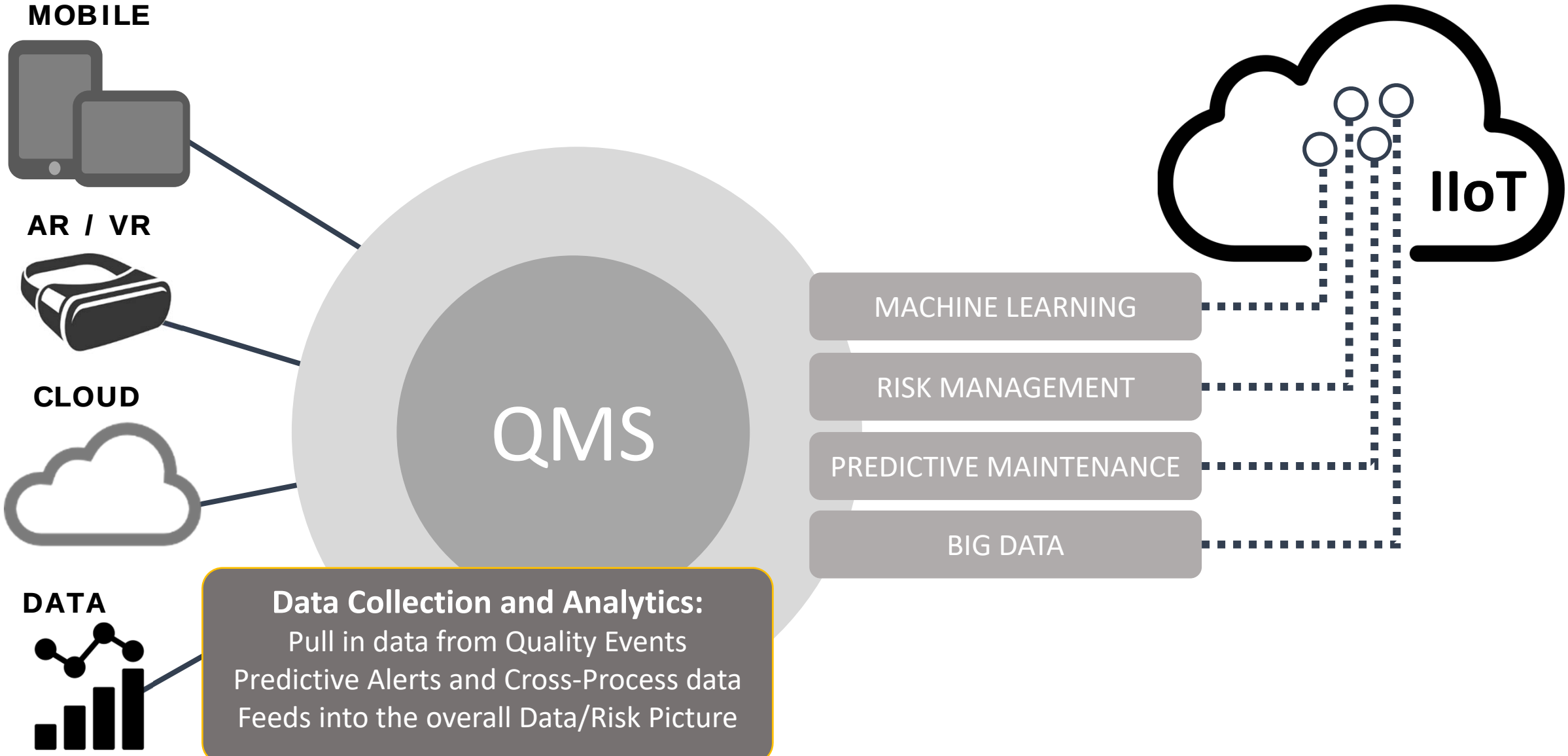

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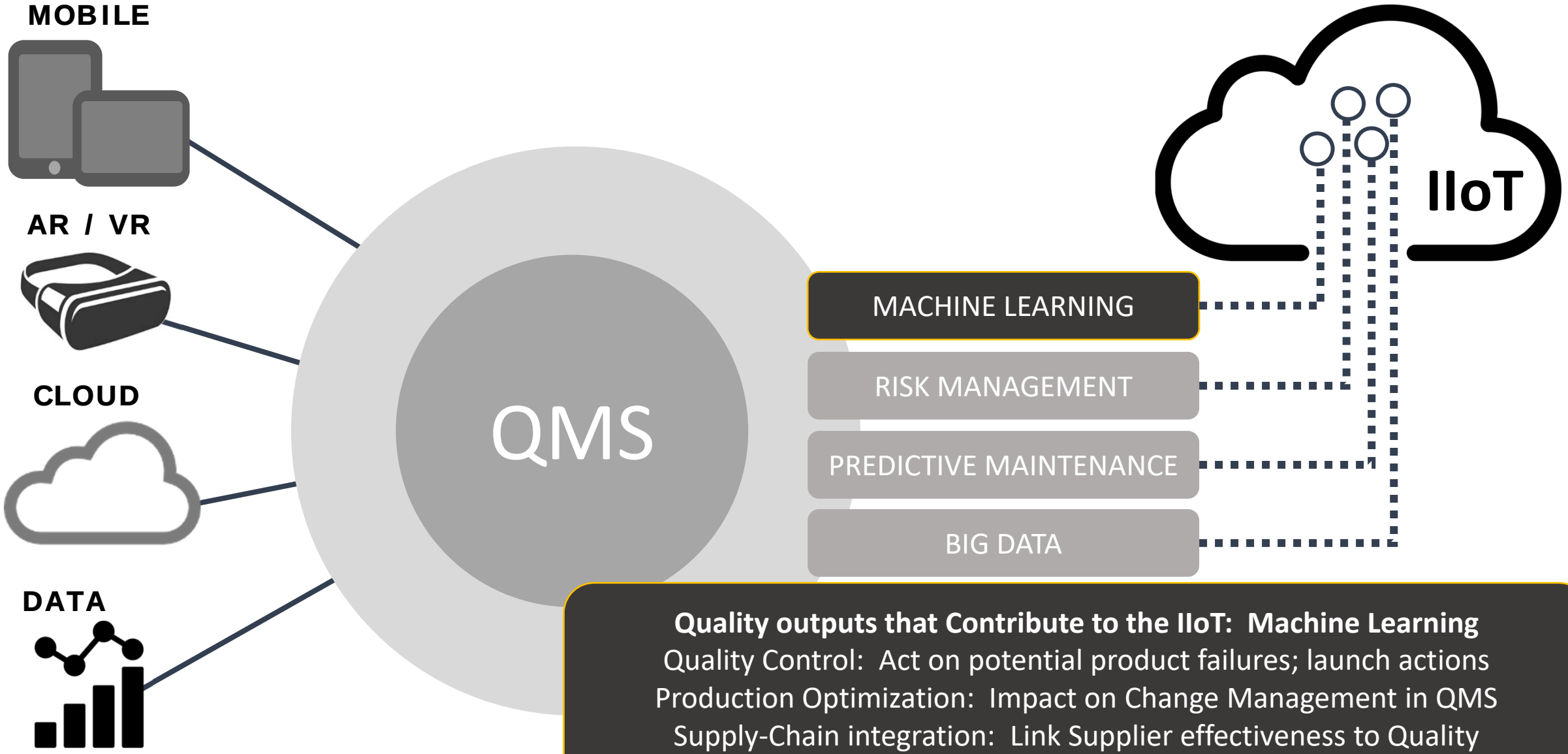


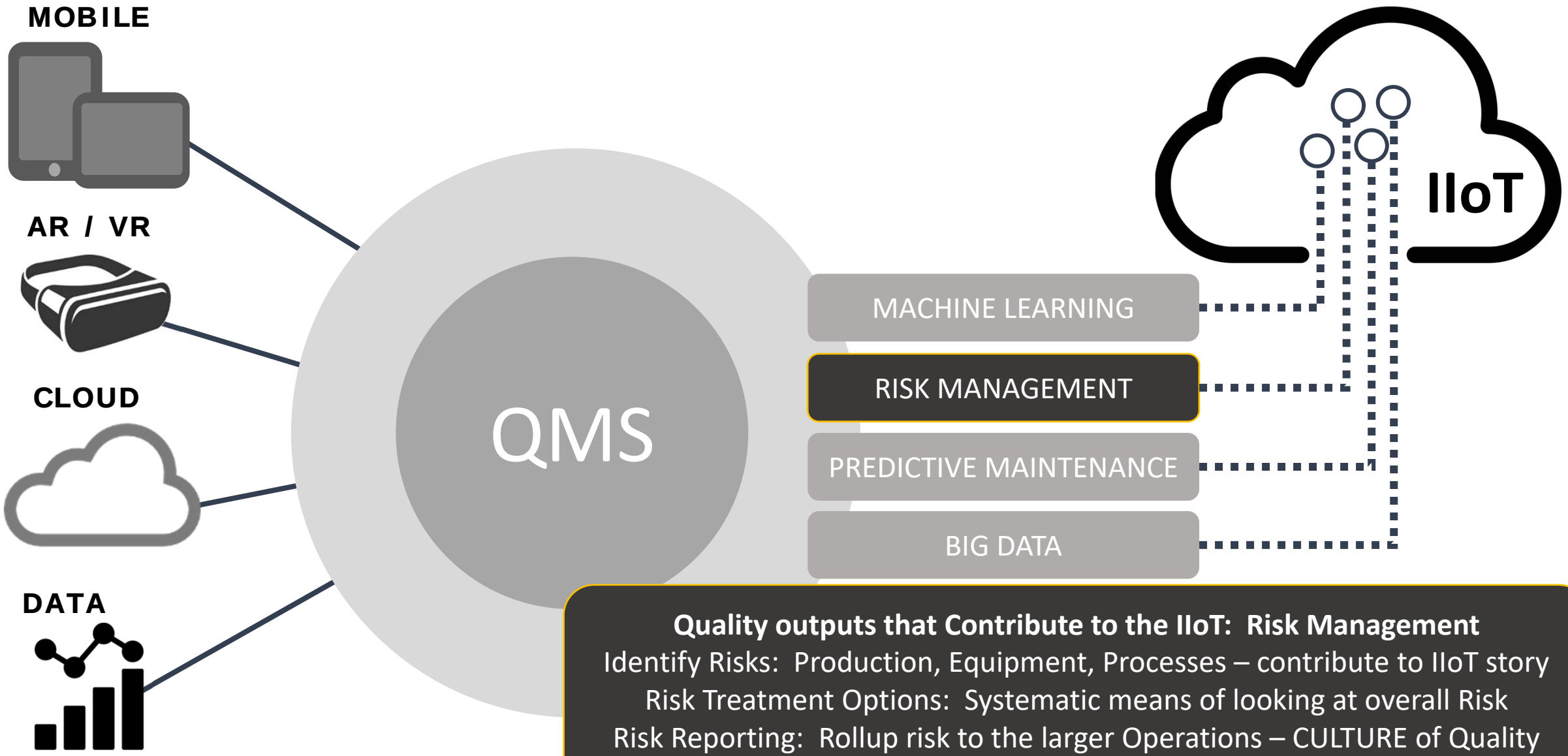
Quality outputs that Contribute to the IIoT: Machine Learning

Quality Control: Act on potential product failures; launch actions

Production Optimization: Impact on Change Management in QMS

Supply-Chain integration: Link Supplier effectiveness to Quality

What is Quality's Digital Transformation?



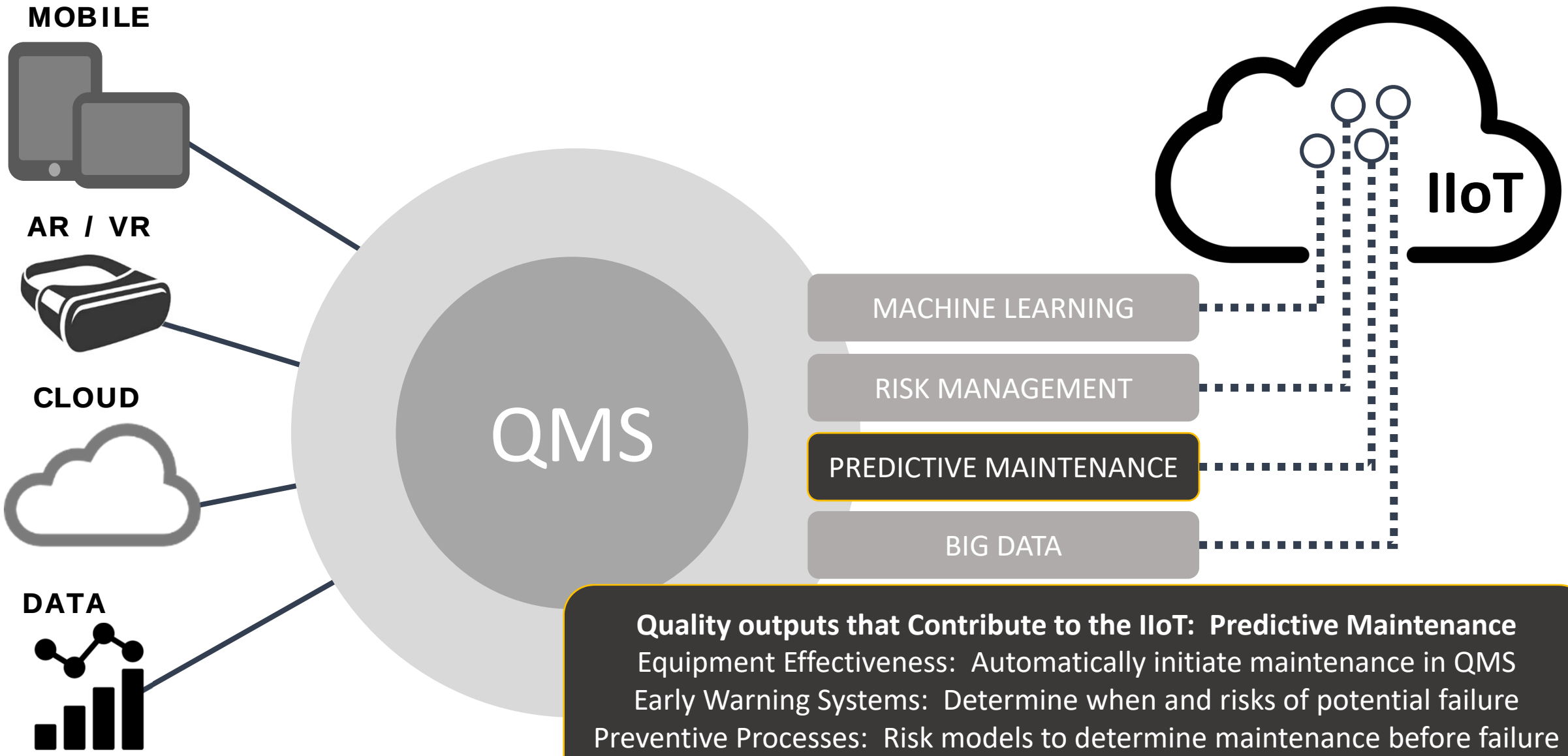
Quality outputs that Contribute to the IIoT: Risk Management

Identify Risks: Production, Equipment, Processes – contribute to IIoT story

Risk Treatment Options: Systematic means of looking at overall Risk

Risk Reporting: Rollup risk to the larger Operations – CULTURE of Quality

What is Quality's Digital Transformation?



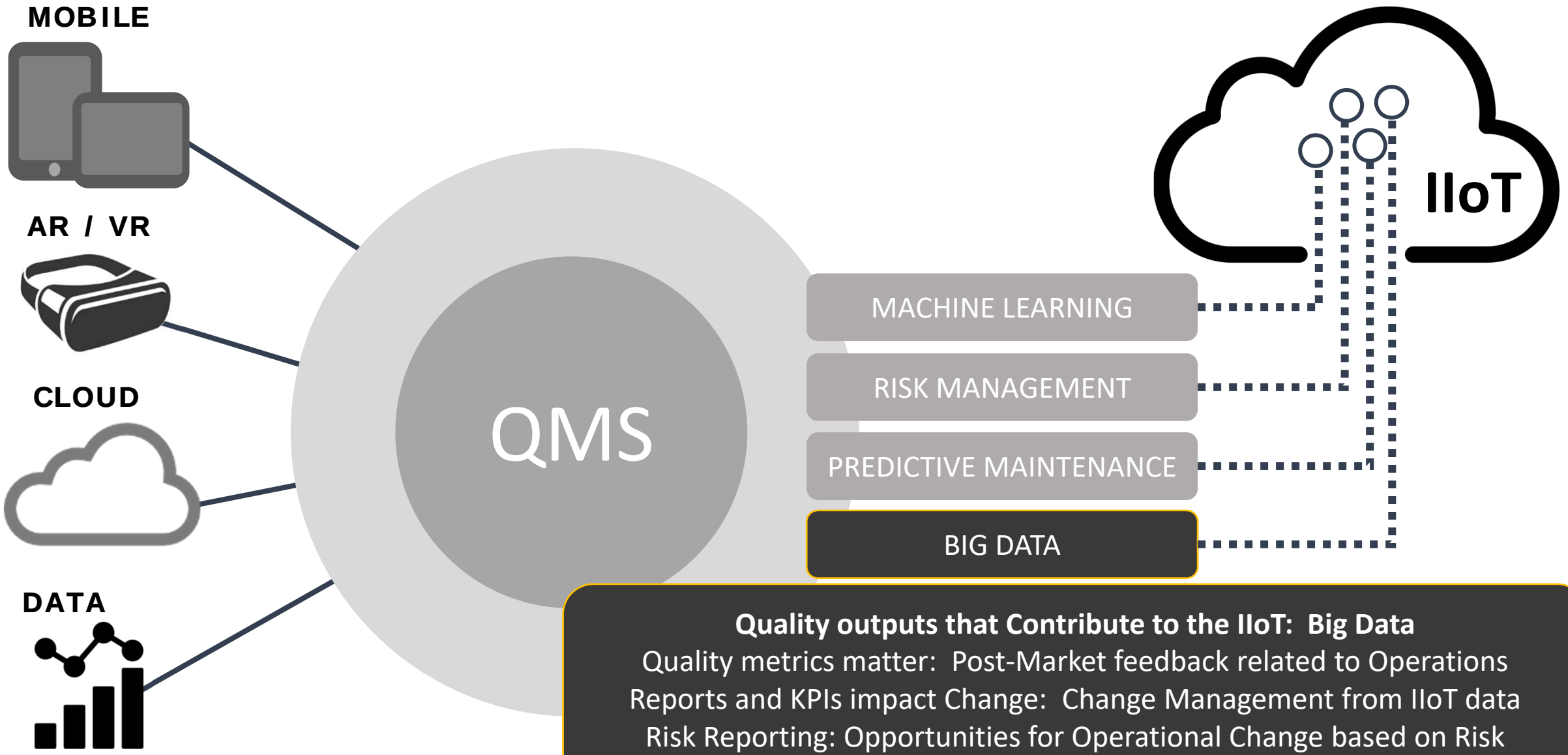
Quality outputs that Contribute to the IIoT: Predictive Maintenance

Equipment Effectiveness: Automatically initiate maintenance in QMS

Early Warning Systems: Determine when and risks of potential failure

Preventive Processes: Risk models to determine maintenance before failure

What is Quality's Digital Transformation?



Quality outputs that Contribute to the IIoT: Big Data

Quality metrics matter: Post-Market feedback related to Operations

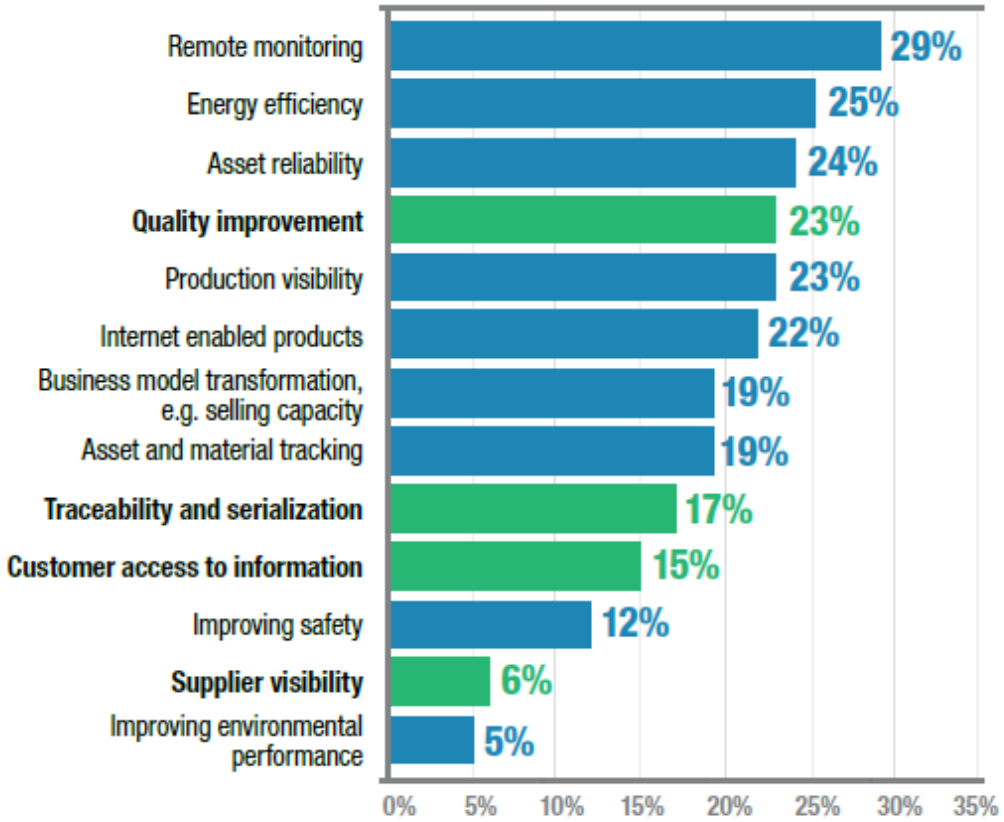
Reports and KPIs impact Change: Change Management from IIoT data

Risk Reporting: Opportunities for Operational Change based on Risk

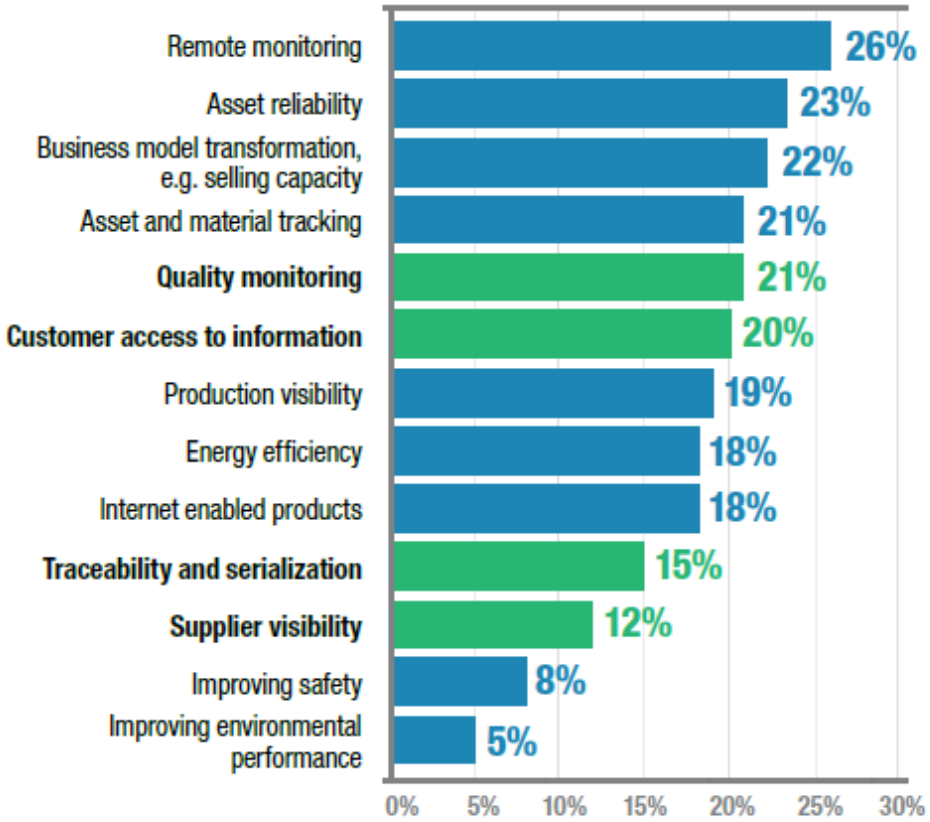
Market view on the IIoT Initiative

Download the Ebook

What are the top IIoT use cases your company is pursuing today? *(N=252, all respondents)*



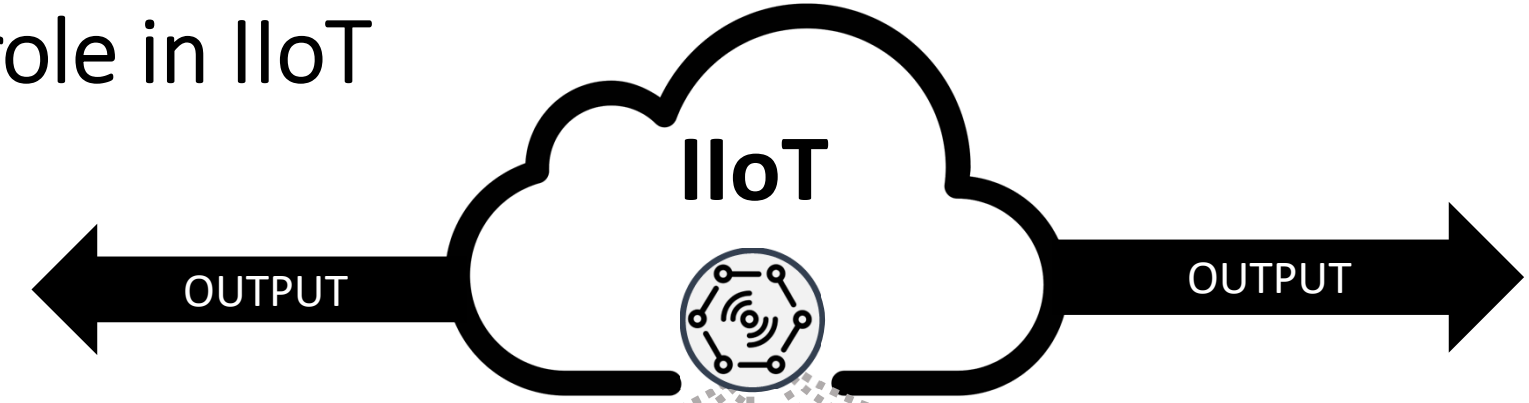
What are the top IIoT use cases your company will start pursuing in the next year? *(N=249, all respondents)*



Courtesy of LNS Research: "Quality 4.0: Get Educated, Get Involved, and Build a Successful Strategy" - 2017 www.lnsresearch.com

Quality's role in IIoT

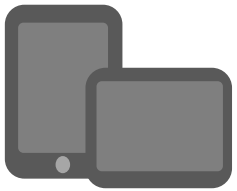
OPERATIONAL EXCELLENCE

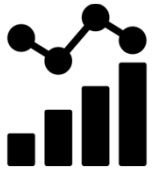


CULTURE OF QUALITY

ERP | PLM | QMS | MES | SCM

MACHINE LEARNING | RISK MANAGEMENT | BIG DATA | PREDICTIVE MAINTENANCE





Quality's role in IIoT

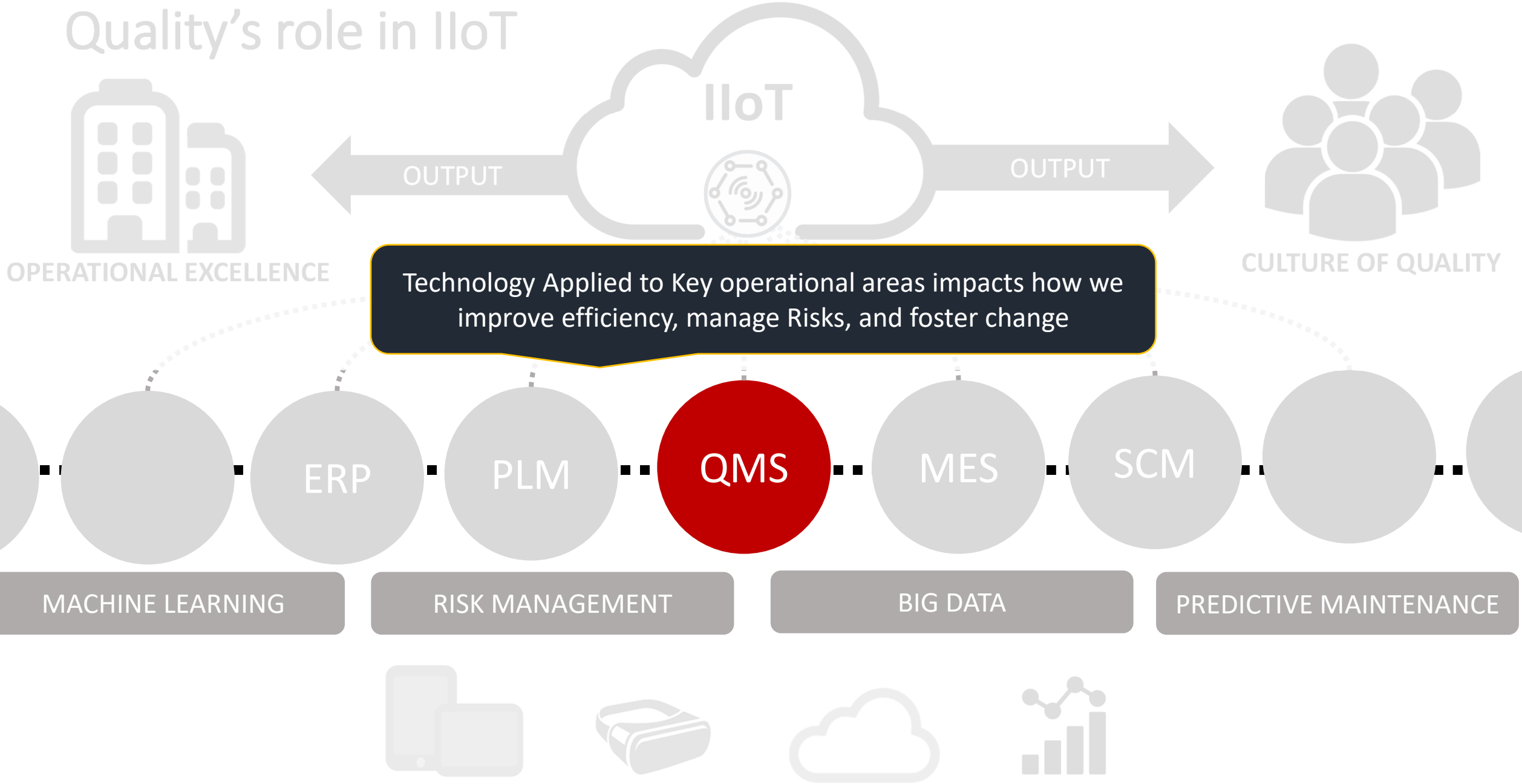
ERP PLM QMS MES SCM

MACHINE LEARNING

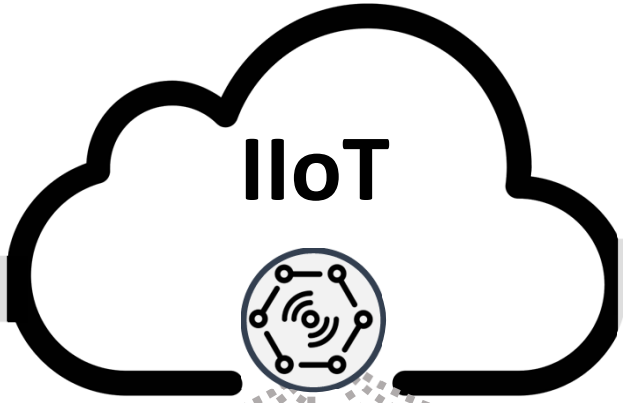
PREDICTIVE MAINTENANCE

Digital Transformation introduces new technologies to consume Quality Management

Quality's role in IIoT



Quality's role in IIoT



OUTPUT

OUTPUT

OPERATIONAL EXCELLENCE

CULTURE OF QUALITY

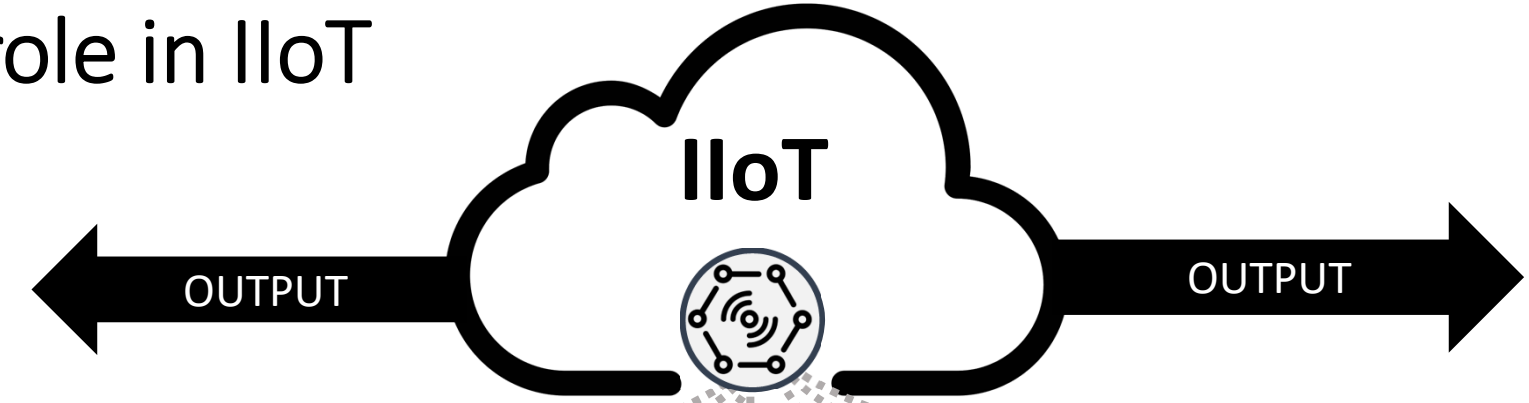
Everything feeds into the Industrial Internet of Things and provides a complete, holistic view of Operations – Quality 4.0 adds the concept of Quality as a key driver in transformation

ERP PLM QMS MES SCM

MACHINE LEARNING RISK MANAGEMENT BIG DATA PREDICTIVE MAINTENANCE

Quality's role in IIoT

OPERATIONAL EXCELLENCE



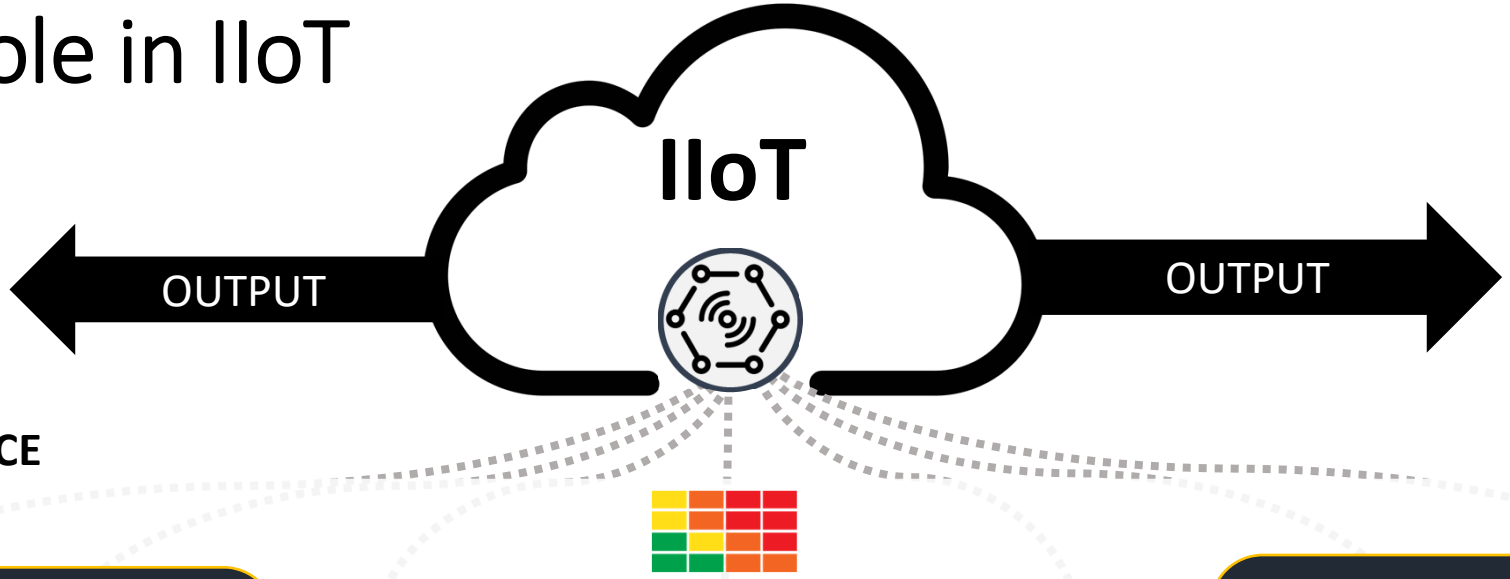
CULTURE OF QUALITY

Breeds better insights into operations, OOE, Efficiencies = OPERATIONAL EXCELLENCE

Fosters a broadening of the Quality effort beyond the Quality Department – a true culture of Quality

Quality's role in IIoT

OPERATIONAL EXCELLENCE



CULTURE OF QUALITY

Breeds better insights into operations, OOE, Efficiencies = OPERATIONAL EXCELLENCE

Risk-Based Thinking in the QMS is the beginning of this transformation = Extends Quality beyond the department

Fosters a broadening of the Quality effort beyond the Quality Department – a true culture of Quality

MACHINE LEARNING | RISK MANAGEMENT | BIG DATA | PREDICTIVE MAINTENANCE

eBook Download:

Quality 4.0: Get Educated, Get Involved, and Build a Successful Strategy

By LNS Research

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