CONNECTED ENTERPRISE

MODERNIZING QUALITY MANAGEMENT SYSTEMS

Look to the Future with Connected Life Sciences

Joe Goodman, VP Global Solution Engineering and Engagement



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AGENDA



Introduction to Sparta/Honeywell | Makers of TrackWise



General concepts of Quality Management



Movement towards Proactive Quality



Is your platform holding you back? | Open vs. Closed Platforms



Common KPIs that can help drive Transformation | Global + Site Specific



Building a robust business case to transform your quality business

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SPARTA & HONEYWELL CONNECTED ENTERPRISE

CONNECTED ENTERPRISE

4000+
Global Employees

1300+
Software Engineers

150+
Data Scientists & AI Experts

Largest staff focused on Quality in industry

Global scale and network

Relentless focus on innovation

LIFE SCIENCES
Providing solutions for 30+ years

INDUSTRIAL
Serving 1 out of 3 plants worldwide

BUILDING
10M global install base; 4000 patents globally

WORKFORCE
550M global PPE users

CYBERSECURITY
Leading OT practice

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SPARTA SYSTEMS INDUSTRY EXPERIENCE



Pharma

27 of the Top 30



Medical Device

32 of the Top 50



CDMO / CRO

15 of the Top 20

28+ Years market leadership

1000+ Global implementations

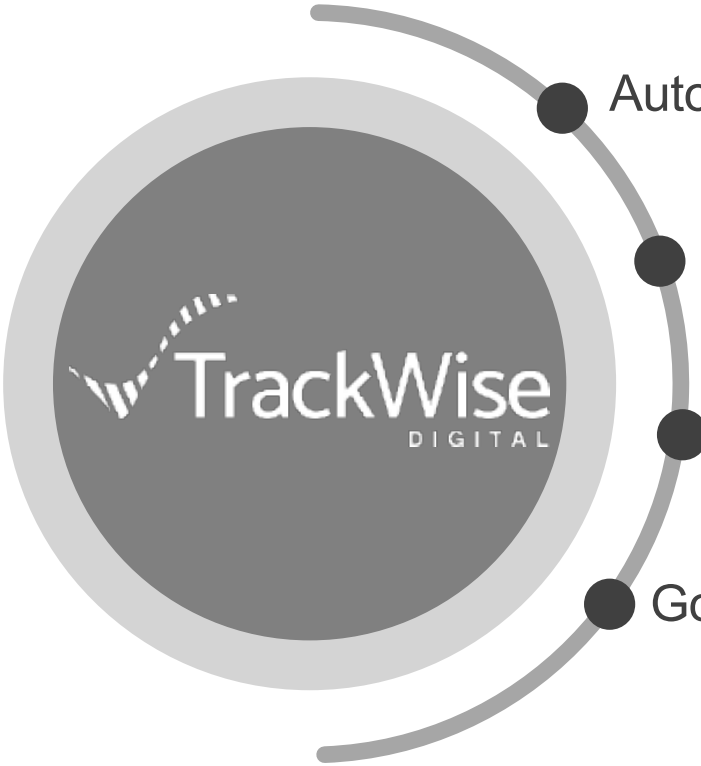
1M+ Users

500+ TrackWise Customers

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WHY IS QUALITY MANAGEMENT CRITICAL?



- Automates quality processes for product manufacturing
- Captures quality events and tracks remediation
- Serves as system of record for regulatory compliance
- Governs ability to ship product

Protects patients

Manages regulatory risk

Enables continuity of supply

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TRACKWISE DIGITAL

Most Trusted Brand in EQMS to Deliver End-to-End Quality Management

Integrated Quality Processes

Harmonized & optimized processes built on 25+ years Industrial expertise

Supplier Quality Management

Supplier quality management and collaboration

Document Management & Training Management

Integrated to QMS



Easy to Use, Manage & Collaborate

Access from anywhere, easier upgrades & validation, robust reporting & analytics

Regulatory Compliance

Extensible, supports 21 CFR Part11/EU Annex 11 & ISO 9001, electronic reporting & submissions

Built on Salesforce Platform

Largest SaaS platform for built-in, robust security, scalability, integrations and usability

Quality Process Accelerators

- Quality Event
- Complaint Handling
- Risk Management
- CAPA
- Supplier Quality
- Doc Control
- Audit
- Global Change Control
- Training
- And More…

QMS: FORMALIZING THE DOCUMENTATION PROCESS

Of What Went Wrong & What You Need To Do About It!!



Big C:
Corrective Action Preventative Action

The Systematic Corrective Action
Cause Investigation
Corrective Action
Effectiveness Verification

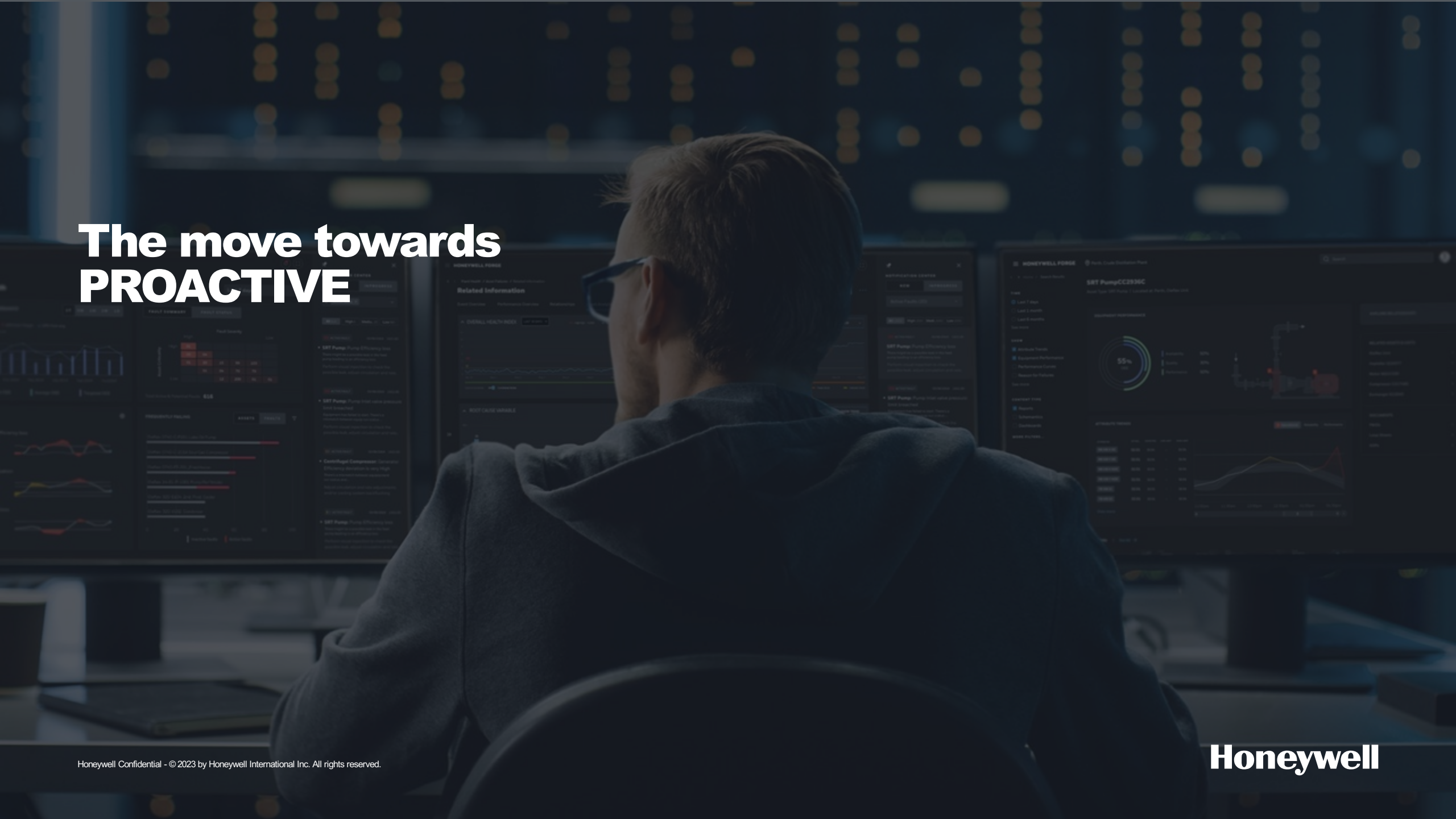
Little C:
Near Term Correction / Action

The Immediate Action
Just DO IT!

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The move towards PROACTIVE



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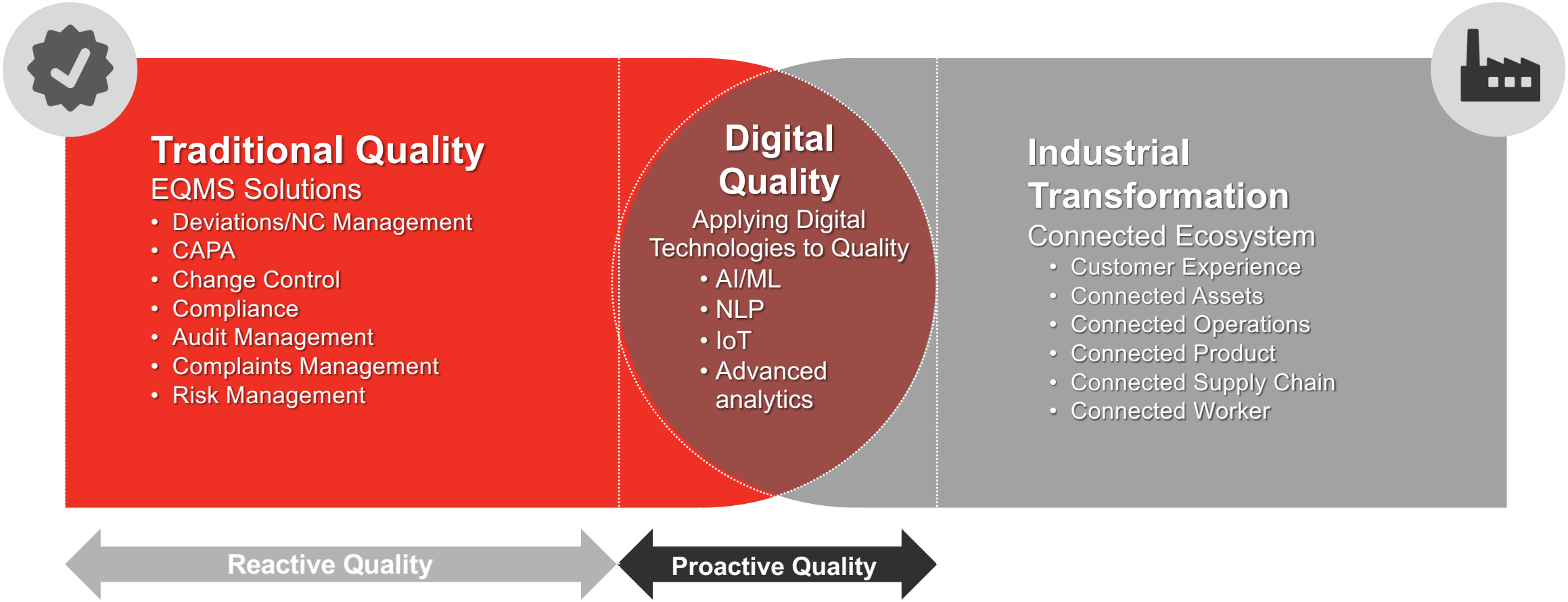
HOW DO WE MOVE TO PROACTIVE QUALITY?

- Focus on **complete** external collaboration
- Focus on **customer/patient** centricity
- Focus on completing the data handoff and **visualized output** between systems
- Focus on **enabling** the workforce



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APPLY DIGITAL TECHNOLOGIES TO ENABLE PROACTIVE QUALITY



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DIGITAL QUALITY UNLOCKS THE POWER OF QUALITY AND OPERATIONAL DATA

- Single source of truth to unify quality data and processes across enterprise
- Leverages data and insights to optimize processes, predict and prevent problems
- Real-time visibility of business aligned quality metrics across the value chain
- Drives proactive quality



VALUE

- ↑ Improved Product Quality
- ↑ Speed NPI
- ↓ Supplier Defect Rate
- ↓ Cost of Poor Quality

Source: LNS Research, Inc.

REALIZING BUSINESS BENEFITS

- Business improvements when quality staff have…
  - …access to plant data to make timely and appropriate decisions
  - …quality data is included in holistic data model
- Proactive quality doesn't just track quality - it ***improves*** quality and business outcomes

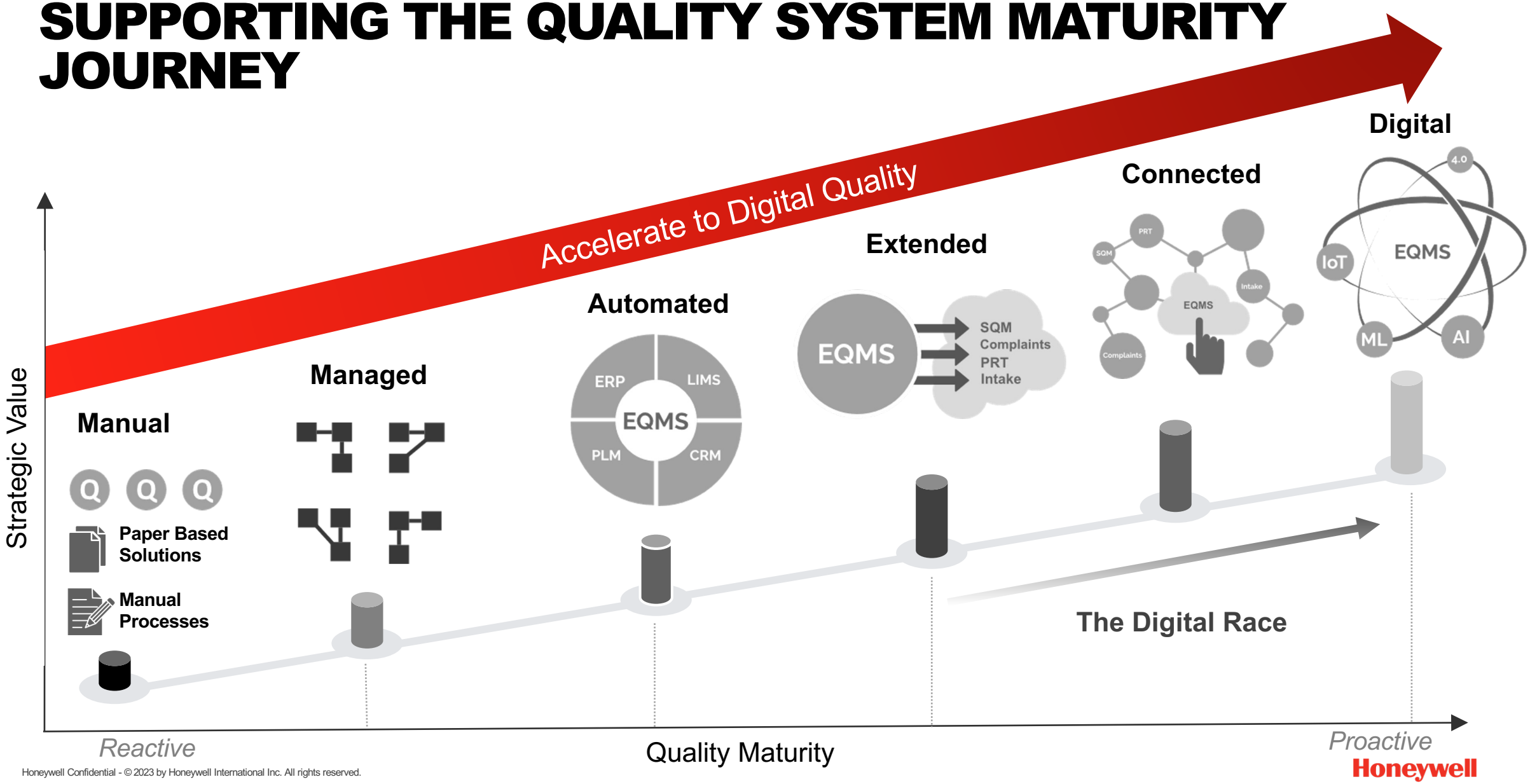
Business Metric	Y	N
On-time delivery	**90%** ↑	82%
Overall equipment effectiveness	**84%** ↑	71%
Successful NPI	**82%** ↑	72%
Capacity utilization	**85%** ↑	80%
First Pass Yield	**86%** ↑	77%
Defects per million opportunities	**2000** ↓	6000

Source: LNS Research, Inc.

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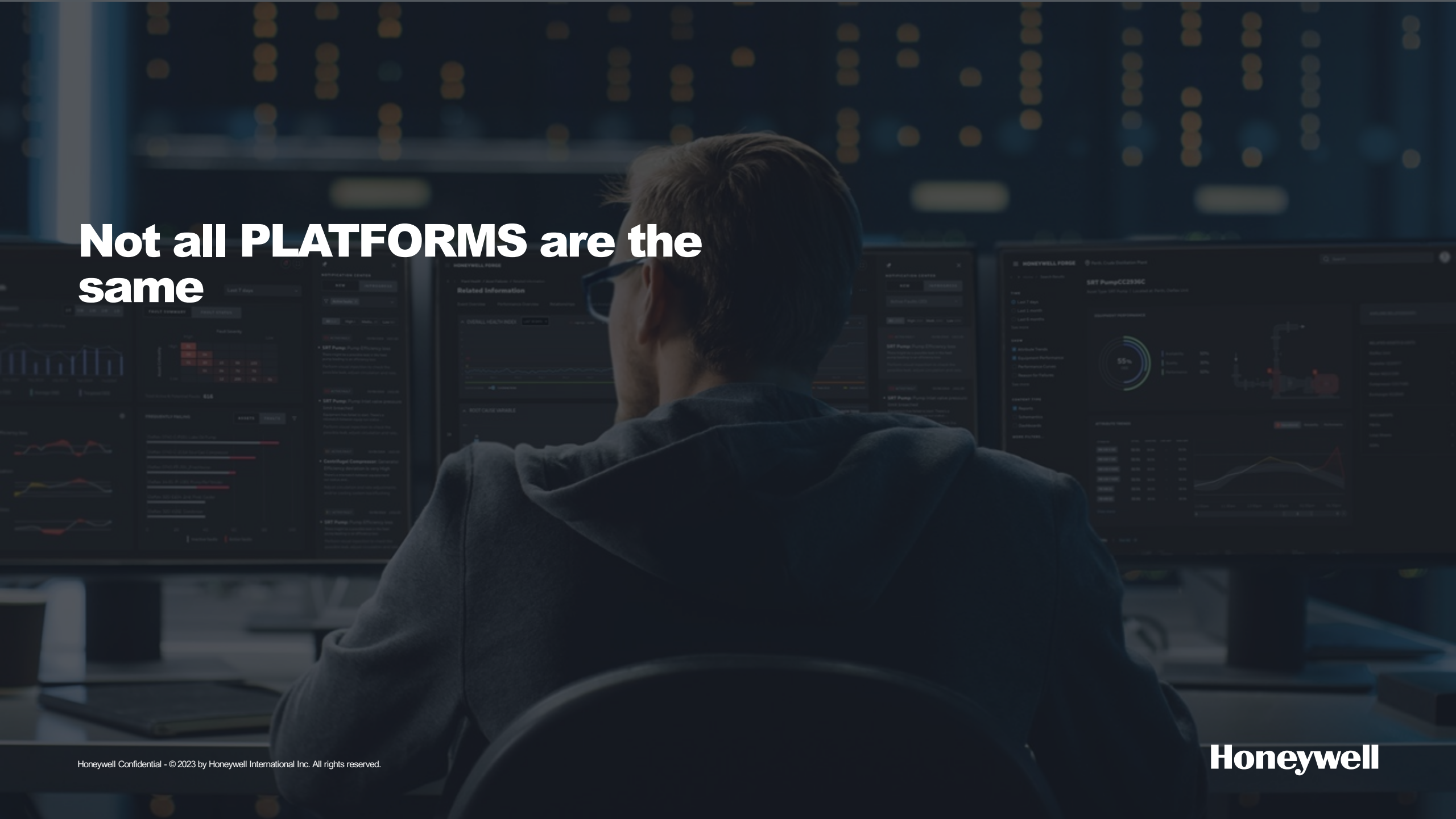
SUPPORTING THE QUALITY SYSTEM MATURITY JOURNEY



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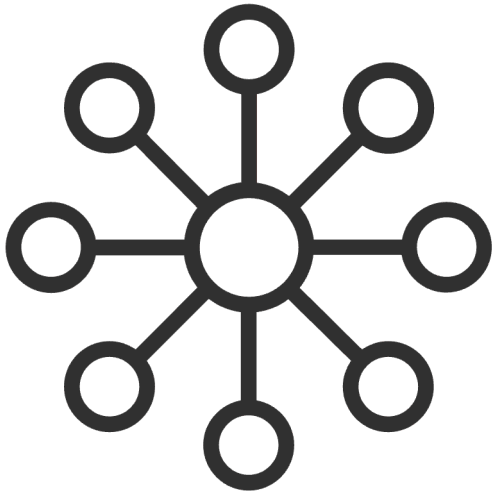
Not all PLATFORMS are the same



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2 PLATFORM CONCEPTS



Enterprise Digital Platform

e.g. SFDC, AWS

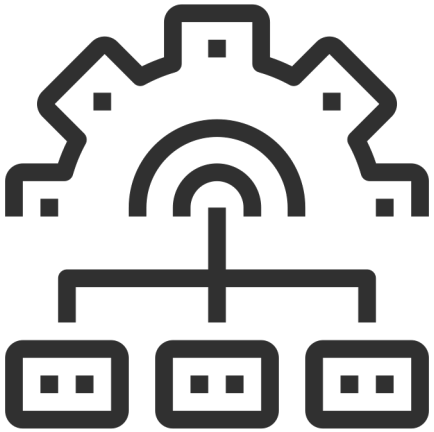
Open Market

Competitive options

Drives Innovation

Interoperability

vs.



Enterprise Application Platform

e.g. ERP, DMS

Closed Market

No options

Paced Innovation

Custom integrations

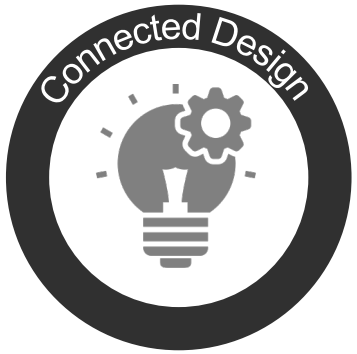
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SUPPORTING THE VALUE CHAIN

SOLUTION

NEED | Problem / Opportunity | Business Application | KPI | ***OUTCOME***





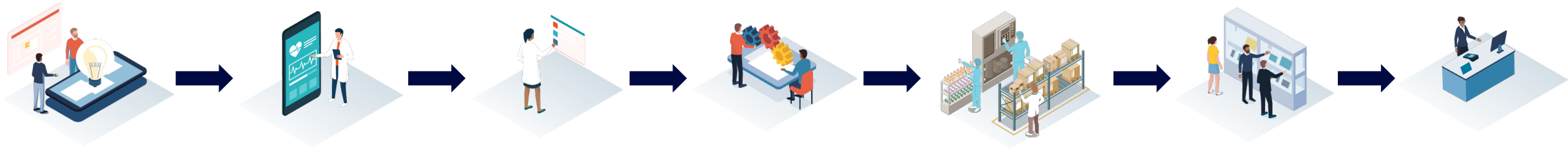








R&D | **CLINICAL AFFAIRS** | **REGULATORY & MEDICAL AFFAIRS** | **QUALITY & COMPLIANCE** | **MANUFACTURING & SUPPLY CHAIN** | **COMMERCIALIZATION** | **POST MARKET SURVIELLANCE**

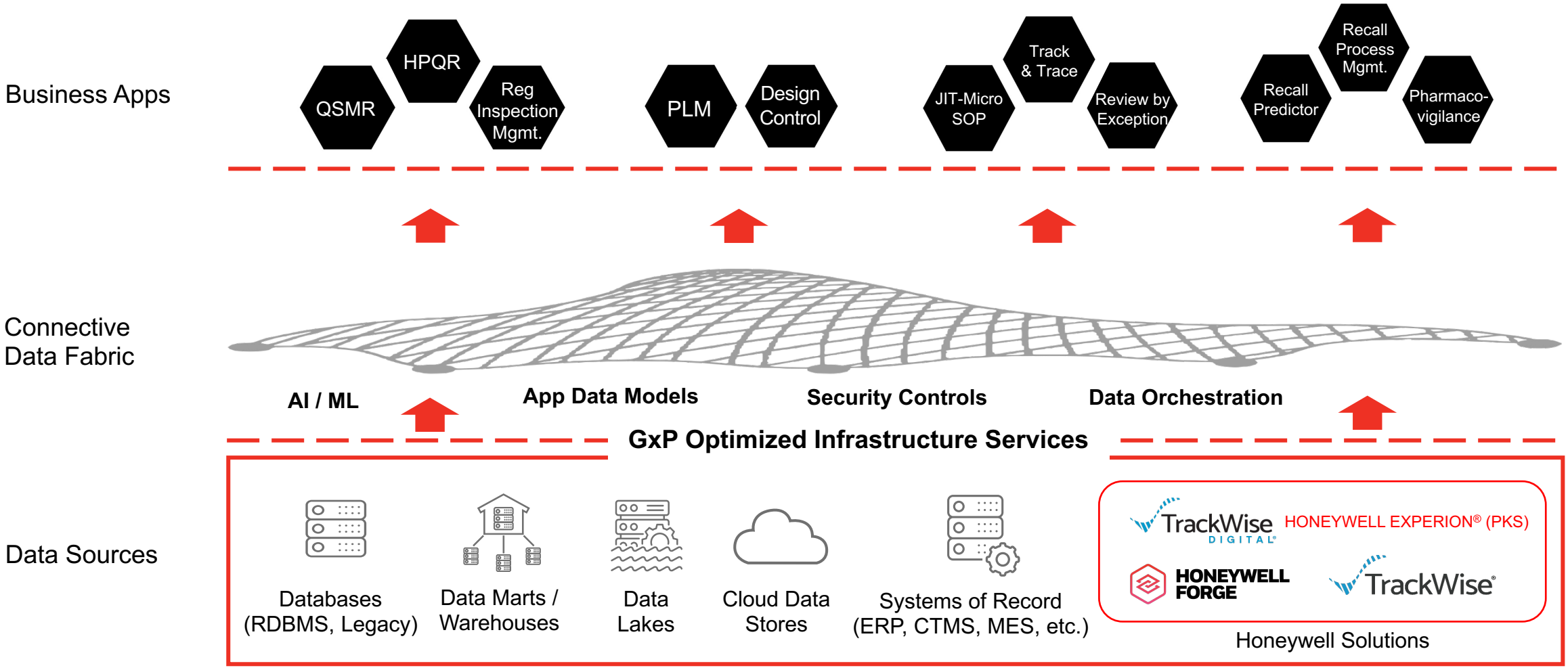


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DON'T DISRUPT YOUR BUSINESS

How it Fits Together

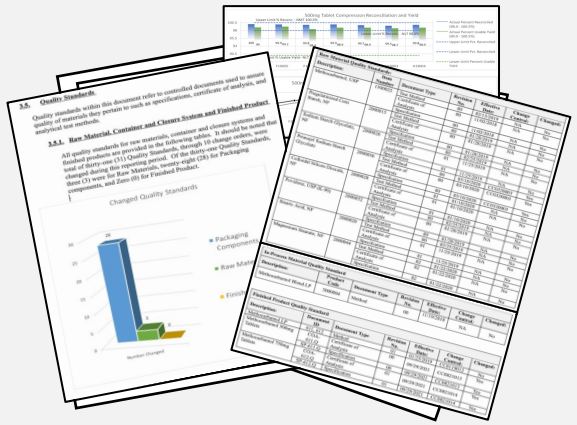


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FIRST APPLICATION - APQR

Pharmaceutical and Biotechnology companies are required to complete Annual Product Quality Reviews per Pharma GMP regulations.



WHAT'S IN AN APQR?

- Chapters with Graphs and Statistical Calculations
- Raw Data Tables with Deviations
- Review Commentary & Annotations
- Cross functional actions assignment
- Review and Approval of the reports

This is often a manual, labor-intensive process that typically takes:

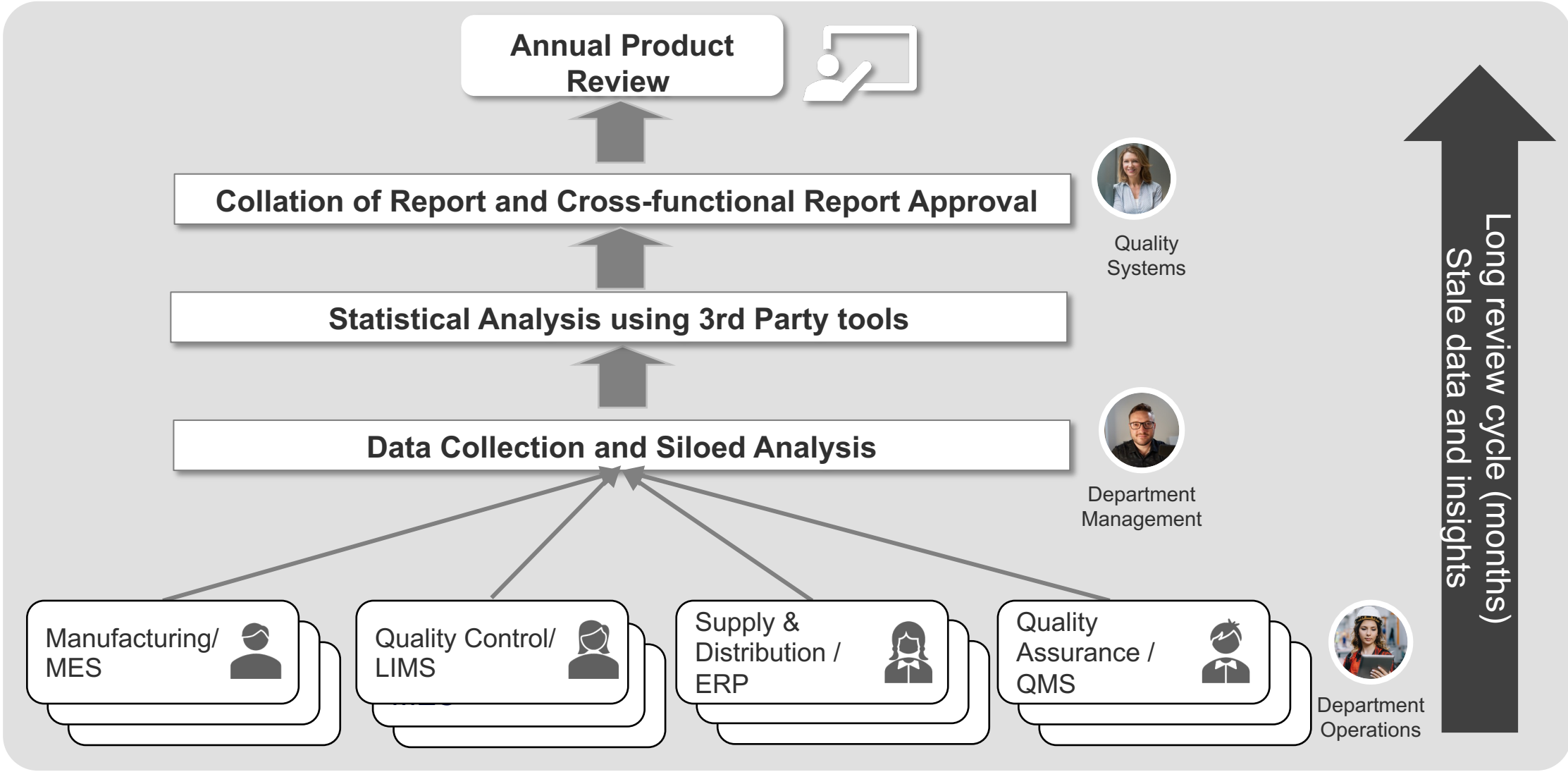
- 1-3 months to collect data
- 2-4 months to analyze, review, and collate

STRUCTURED REPORT IN CHAPTERS WITH DATA CHARTS AND LIMITS

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PROBLEM: DISCONNECTED DATA INHIBIT QUALITY REVIEWS



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HONEYWELL PRODUCT QUALITY REVIEW - SOLUTION

Standard API Connectors

Automated Data Collection

Familiar Analytics Output

Automated Review Coordination/ Compilation



Systems of Record
ERP, LIMS, MES, QMS, EBR, etc.

Review & Comment



Collect | Analyze | Collaborate | Consume

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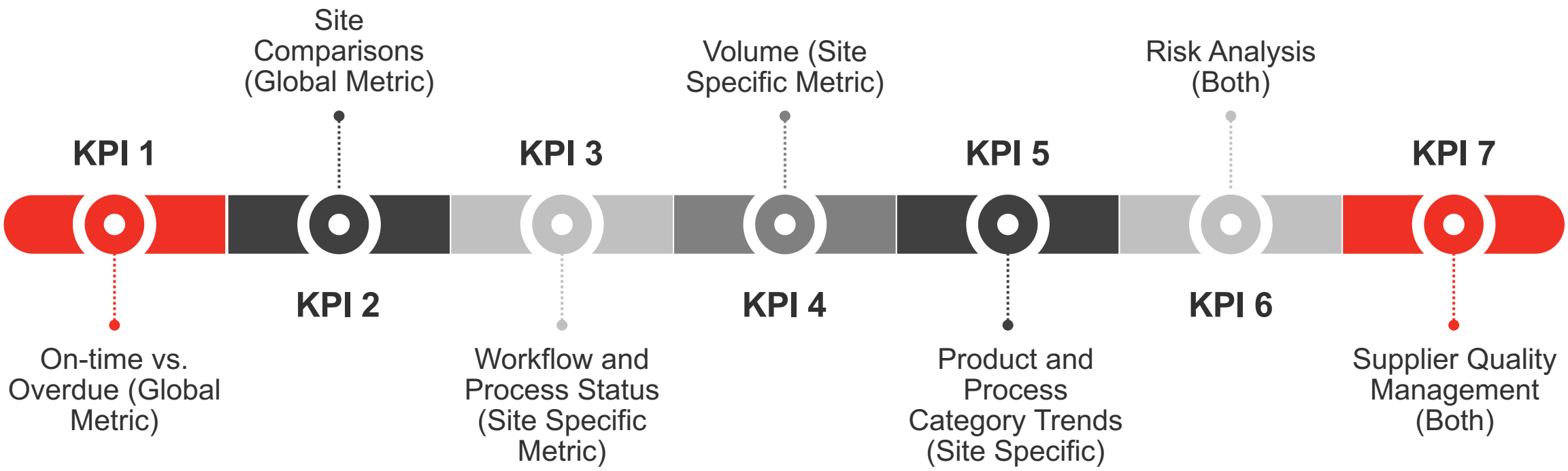
7 Must Have KPIs



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7 KPIS YOUR QMS SHOULD PROVIDE

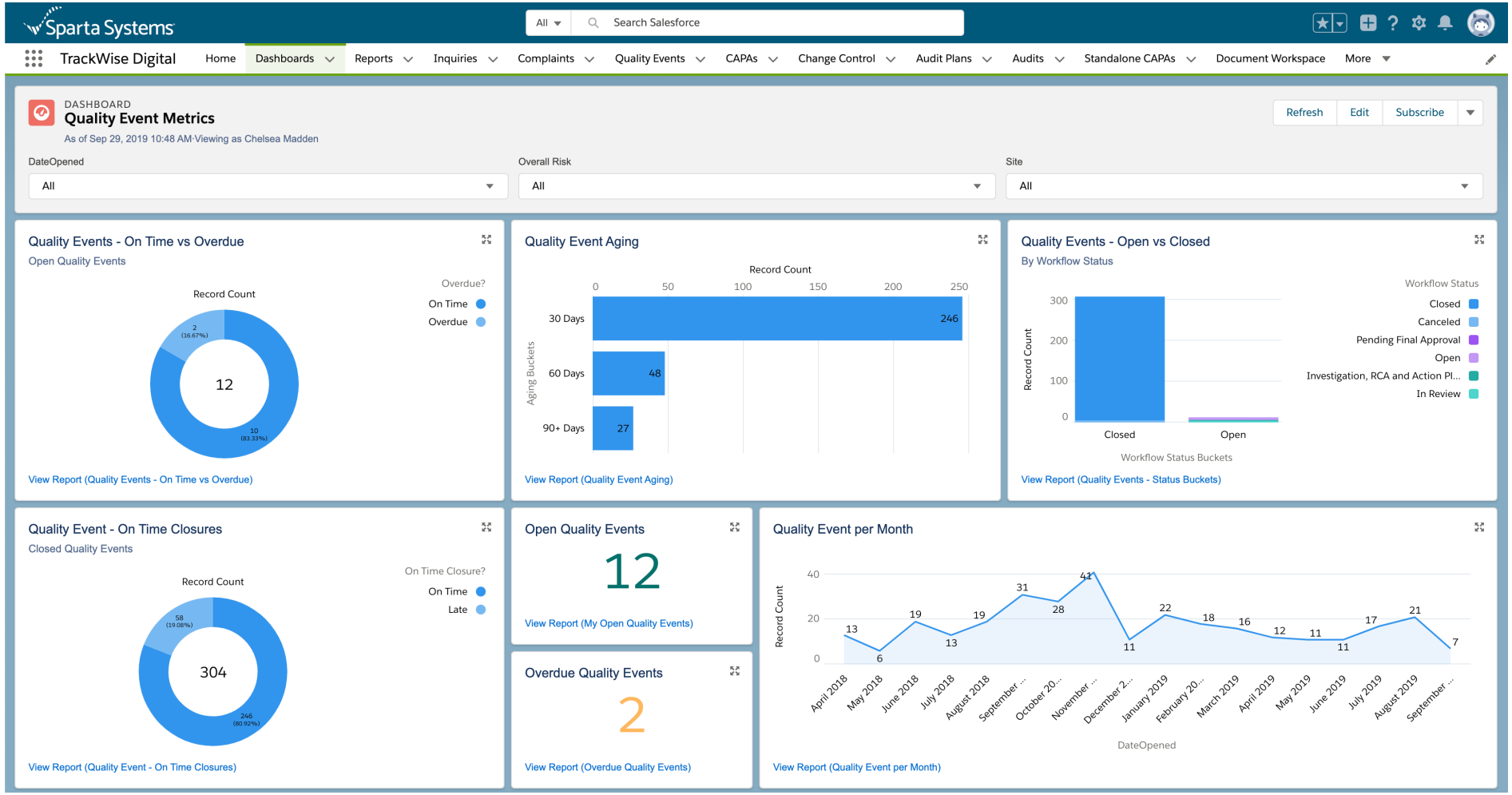


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KPI 1 – ON-TIME VS. OVERDUE (GLOBAL METRIC)

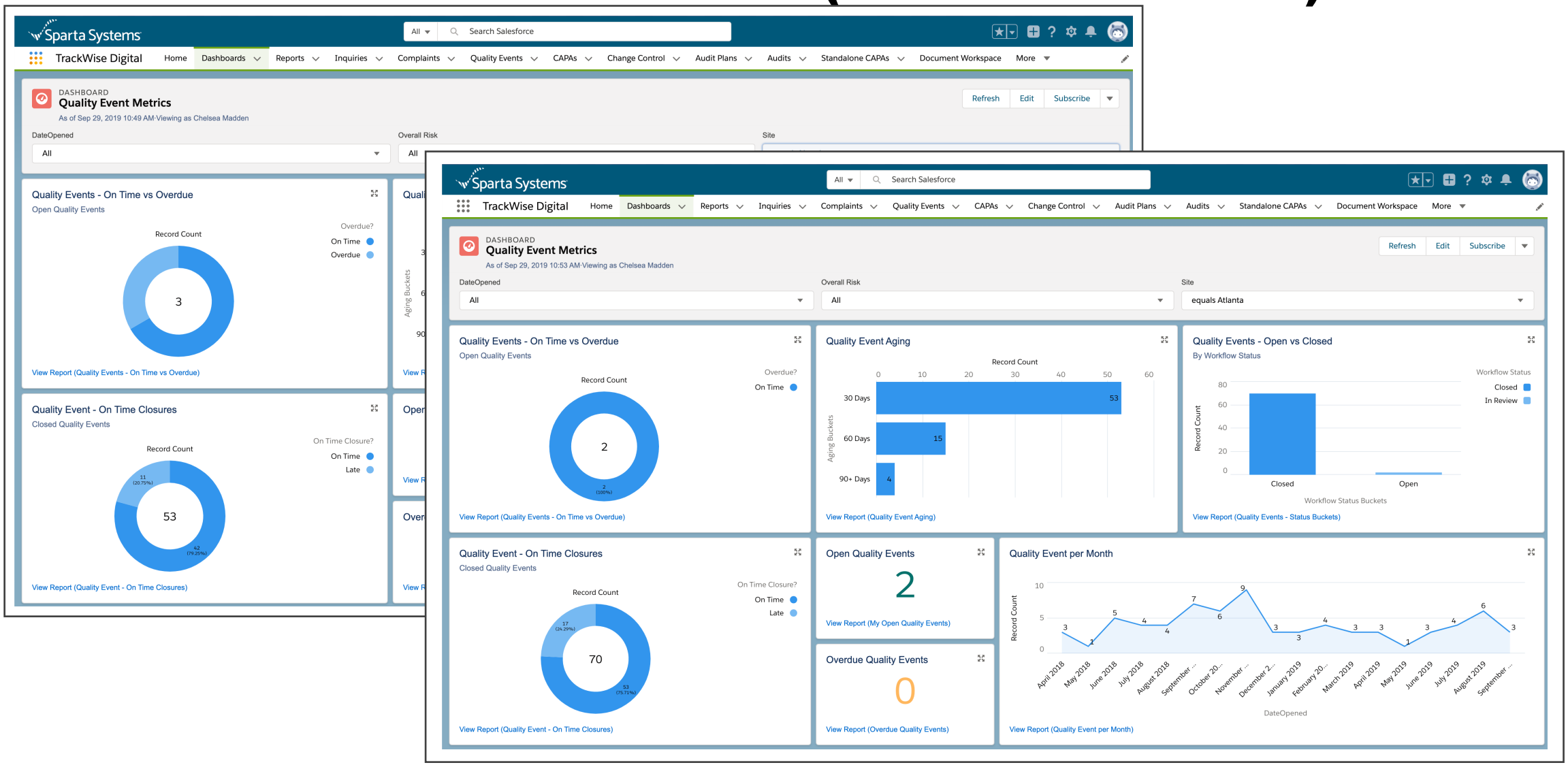
As an Executive, I would like to monitor: Quality Performance, Unaddressed Issues, Frequently Late Issues



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KPI 2 – SITE COMPARISONS (GLOBAL METRIC)

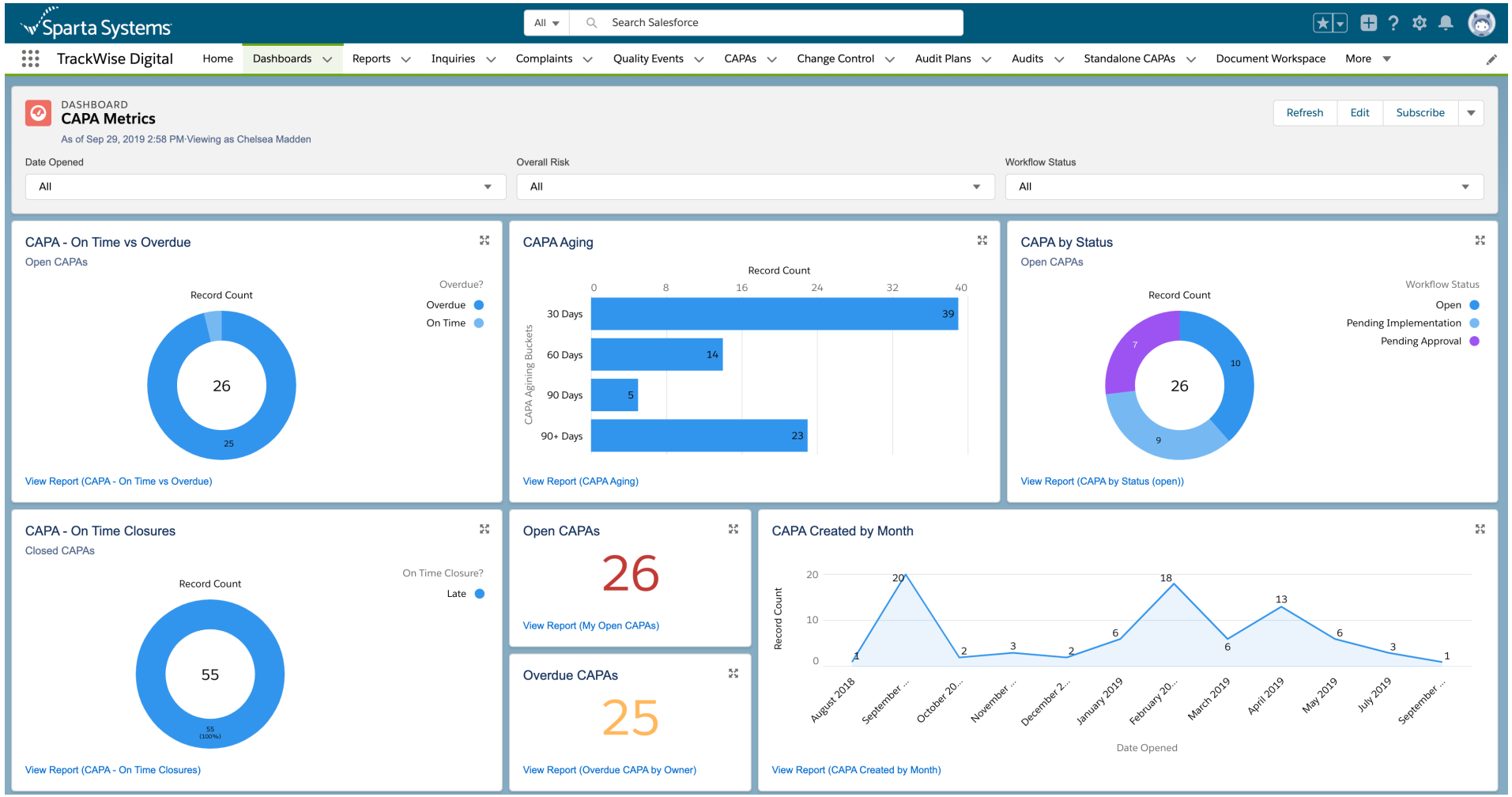


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KPI 3 – WORKFLOW AND PROCESS STATUS (GLOBAL METRIC)

As an Executive, I would like to track # of records in each State, bottlenecks, Year over Year Comparisons

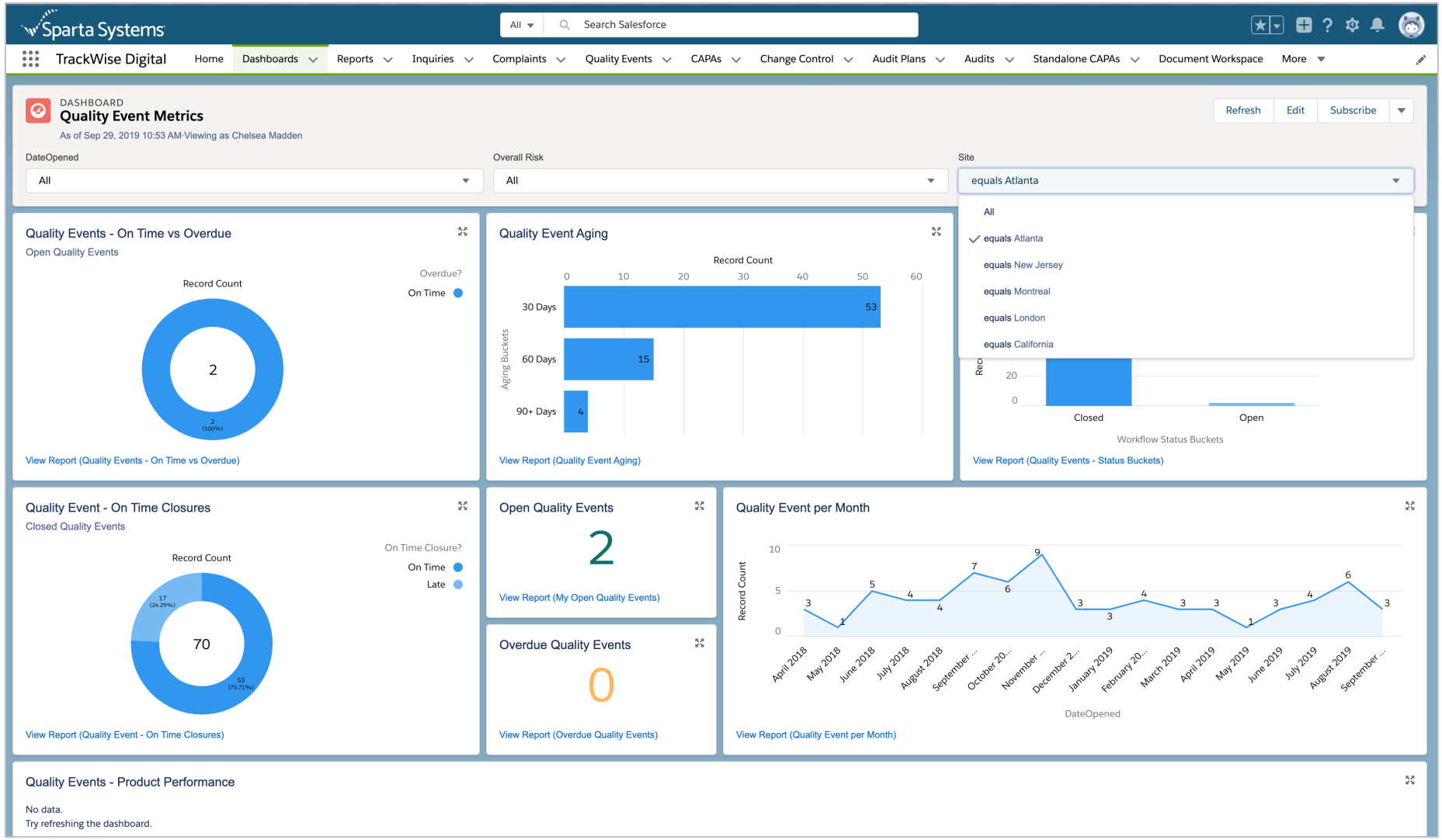


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KPI 4 – VOLUME (SITE SPECIFIC METRIC)

As a Quality Representative for a site, I want to monitor: Where are my issues, What's causing them?

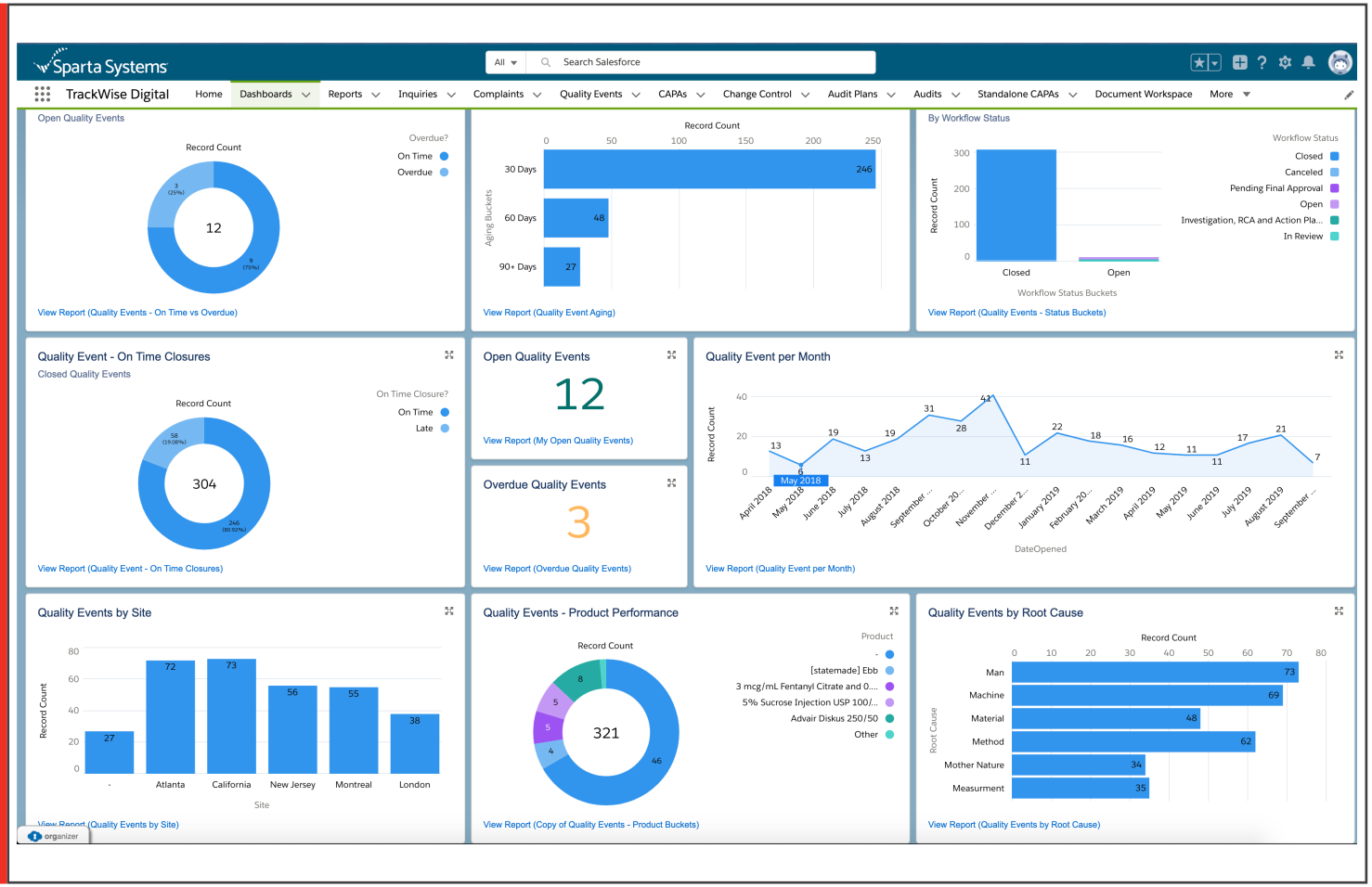


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KPI 5 – PRODUCT AND PROCESS CATEGORY TRENDS (SITE SPECIFIC)

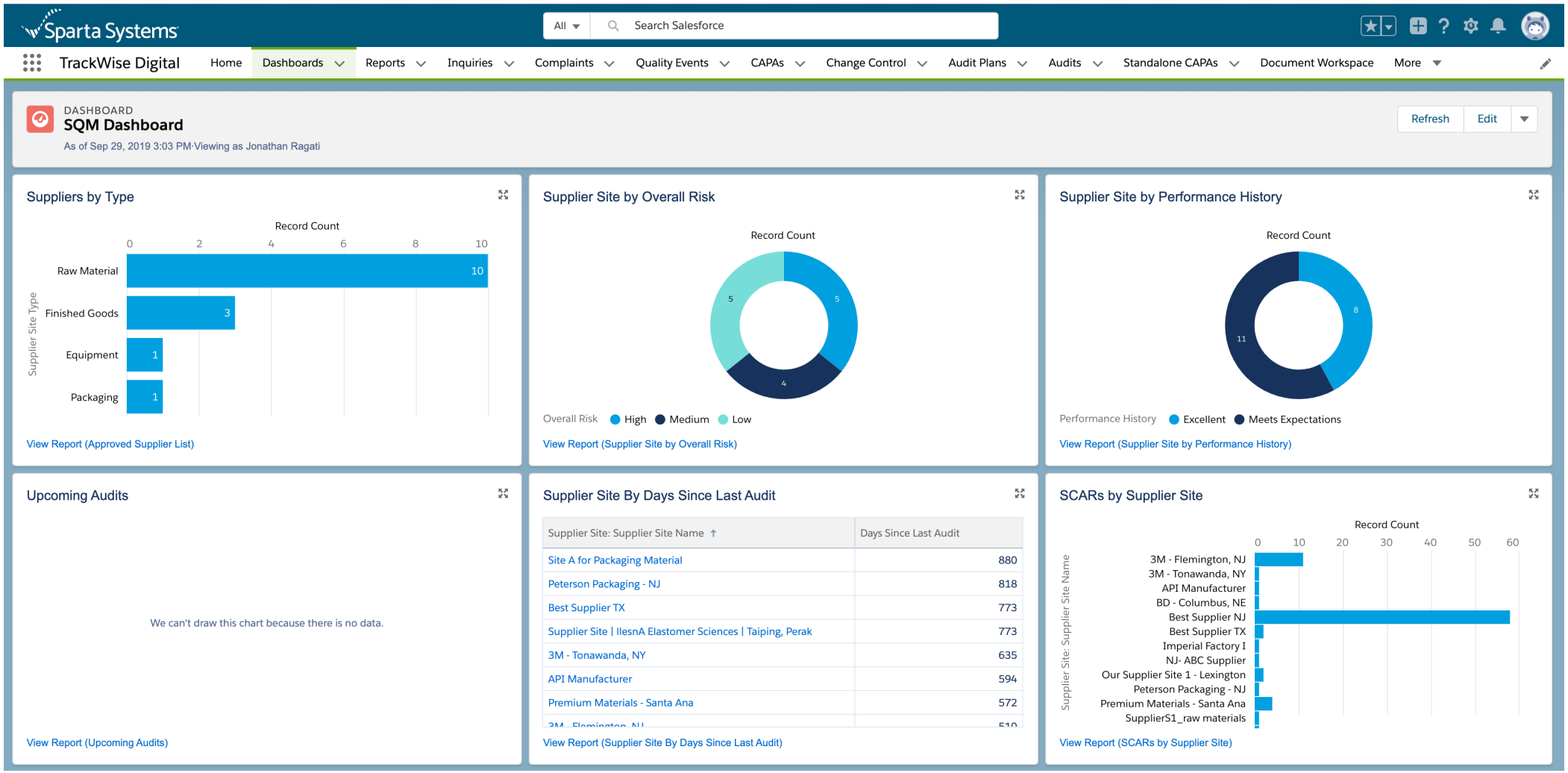
As a Quality Representative for a site, I want to monitor: Commonalities, Root Causes, Problem Codes



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KPI 6 – SUPPLIER QUALITY

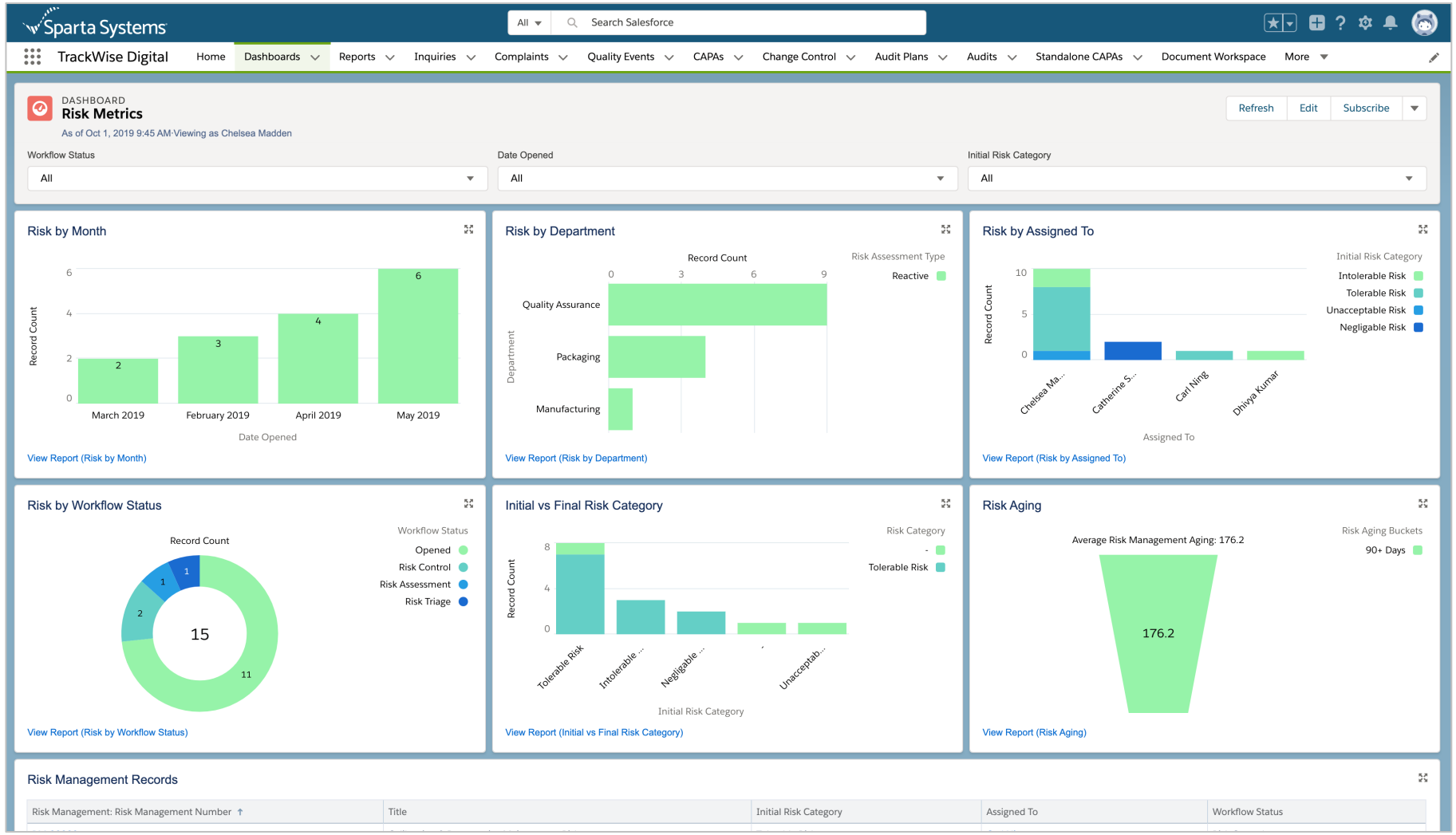


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KPI 7 – RISK ANALYSIS

As a Quality Representative … (SK –see if Risk on CAPA is better story)



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Building the Business Case



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A BUSINESS CASE IS MORE THAN A VALUE PROPOSITION

- A value proposition is just half of a Business Case. It is the Return On Investment – the ROI
- We need to compare the ROI with the “I” – the Investment and demonstrate a positive return
- We may not always get a positive result but that can be offset by significant elements of value - impossible to quantify - patient safety and brand protection



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WHY IS A BUSINESS CASE SO IMPORTANT FOR QMS INVESTMENT?

- Competing for funding
- The Digital Transformation race
- Quality seen as a cost center
- Rising TCoQ
- “Do more with less”
- Increasing shift to prevention



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WHY BUILDING A BUSINESS CASE IS STILL SO DIFFICULT

- Measuring avoidance is challenging & viewed with skepticism
- What is the true cost of recall and impact on brand reputation?
- What is the cost of significant regulatory action?
- What is the cost of patient safety, lost customer confidence, competitive advantage?



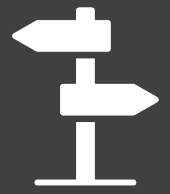
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THREE CATEGORIES OF VALUE PROPOSITION THAT SHOULD BE IDENTIFIED AND ARTICULATED



Savings

Actual cost reduction resulting from a quality process improvement and its impact anywhere across the business



Avoidance

The ability to maintain current budgets, offset future increases or repurpose resources to a more value-added activity



Brand Protection

Protecting brand loyalty and customer confidence – very intangible but easily recognizable and valuable

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BUSINESS CASE SCENARIOS – EVALUATION CRITERIA

Leadership, Strategy & Organization

- Management Understanding
- Strategic Plan Development
- Quality Competency Observation
- Organizational Alignment

Business Process Optimization

- Definition & Adoption
- Training & Enablement
- Continuous Improvement

Where are you now? Quality Management in your organization today.

Where do you want to be? The Quality Management you need to succeed.

How do you get there? How to build and focus your QMS business case.

Technology Enablement

- System architecture & Integration
- Automation & Collaboration
- Accessibility

Measurement

- Strategy
- Analytics & Reporting
- Capture & Governance

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WHERE/HOW TO FOCUS YOUR BUSINESS CASE?

How do we move from connected quality to Proactive Digital Quality?

- Focus on **complete** external collaboration
- Focus on **customer/patient** centricity
- Focus on completing the data handoff and **visualized output** between systems
- Focus on **enabling** the workforce



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CONNECTED
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THANK YOU

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