

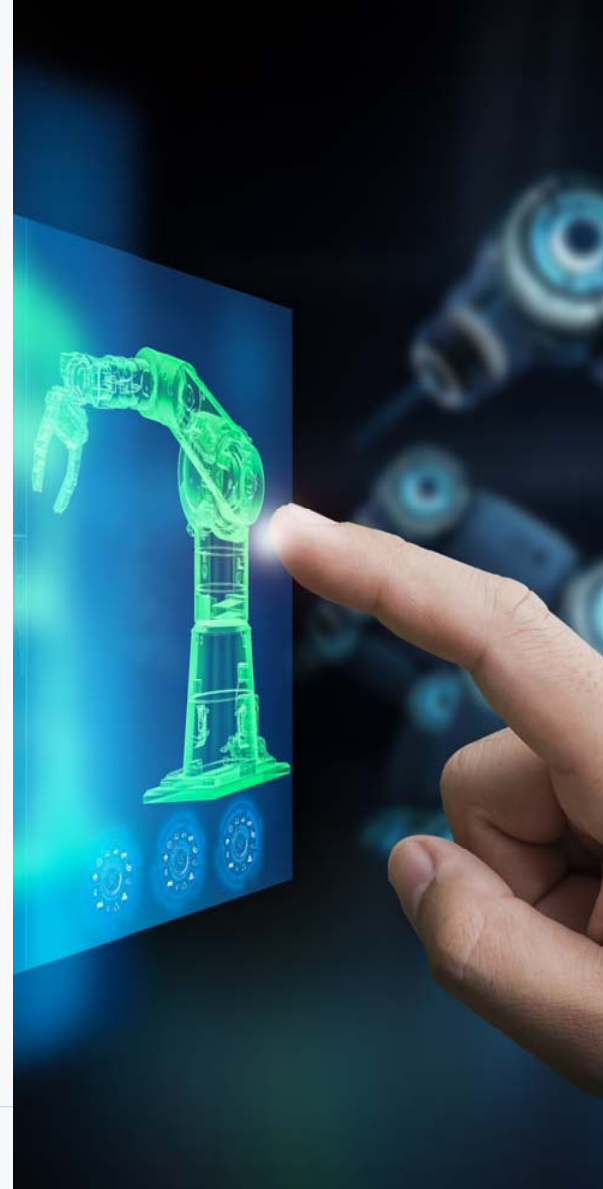


3 STEPS TO IMPROVING NPI

October 2019

AGENDA

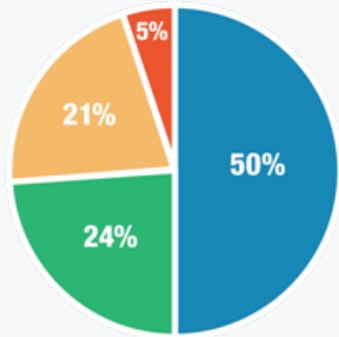
- Research Demographics and Methodology
- The NPI Challenge
- LNS 3-Step Quality Program for NPI Success
 1. A Collaborative Approach
 2. Automating Collaboration
 3. Digitize with Quality 4.0 Use Cases
- “Spill-over Benefits”
- Wrap-up and Recommendations



RESEARCH DEMOGRAPHICS AND METHODOLOGY

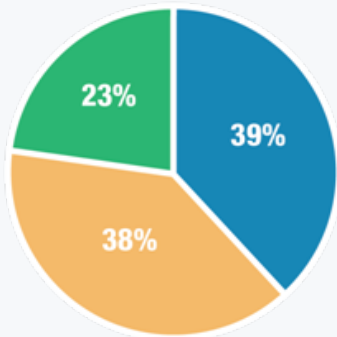


SURVEY DEMOGRAPHICS



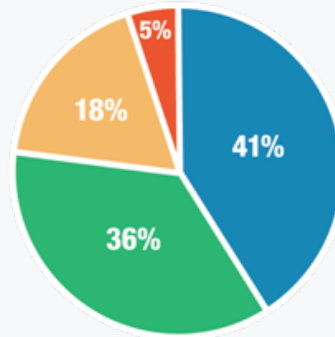
INDUSTRY
COLOR BY MANUFACTURING

- Discrete Manufacturing
- Batch Manufacturing
- Process Manufacturing
- All Others



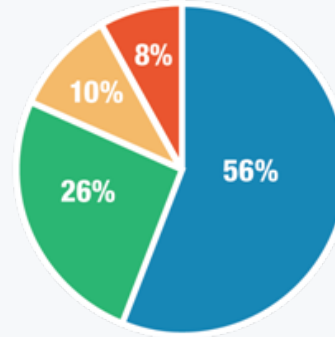
COMPANY SIZE
COLOR BY COMPANY REVENUE

- Large: \$1B+
- Medium: \$250M - \$1B
- Small: >\$250M



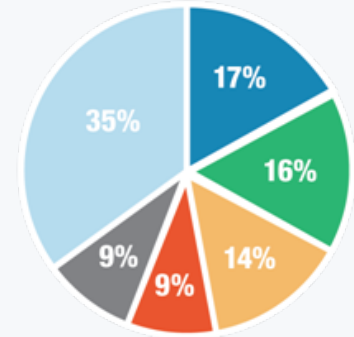
GEOGRAPHY
COLOR BY HQ LOCATION

- North America
- Europe
- Asia/Pacific
- Rest of World



JOB TITLE
COLOR BY ROLE

- Manager
- Director
- Vice president
- President or CxO



JOB FUNCTION
COLOR BY AREA OF RESPONSIBILITY

- Information technology
- Operations
- Quality
- Finance
- Engineering
- All Others

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2 Surveys with a total of 1,470 responses



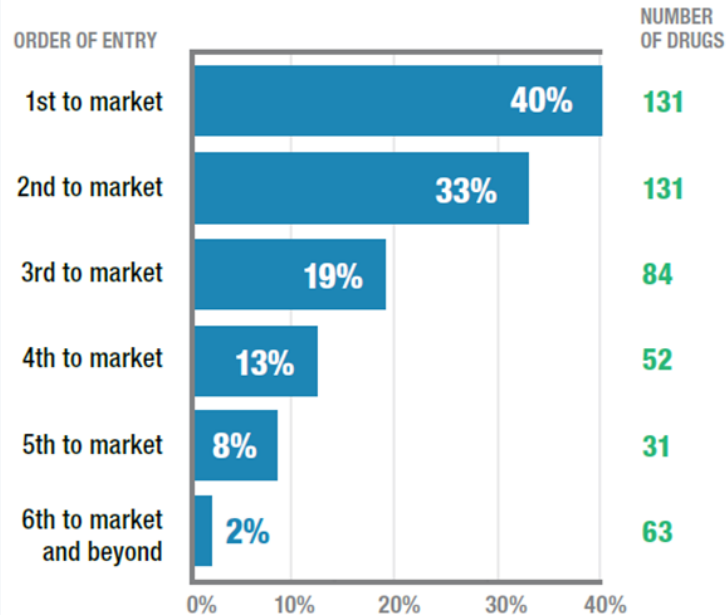
THE NPI CHALLENGE



TIME TO MARKET PRESSURES

First Entrants on Average Achieve Higher Market Share Ten Years After Launch²

Average market share (measured by sales), 10 years after first launch in class, %



Pace of technology drives time to market (TTM) pressures for some

Science-rich products have a different pace, but TTM is possibly a higher risk with longer lasting effects

Manufacturers leveraging systems engineering, 3D modeling, simulation, collaboration have reduced TTM by 30%

PRODUCT AND CONFIGURATION COMPLEXITY

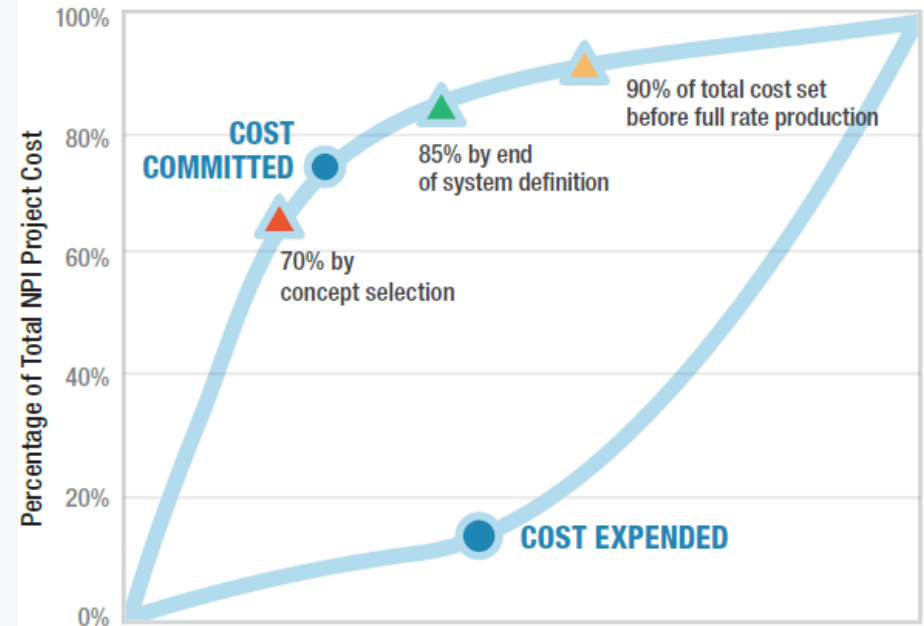
Pharmaceuticals: product personalization, traceability. FDA's blockchain oversight project

Discrete: from mechanical to software-driven, product personalization

¹ Sherman, Marty, and Bill Kobren. "Product Support Should-Cost Opportunities." DAU News. November 2, 2017. Accessed March 29, 2018. <https://www.dau.mil/library/defense-atl/blog/Product-Support-Should-Cost-Opportunities>.



Costs Determined Long Before Expenditure¹

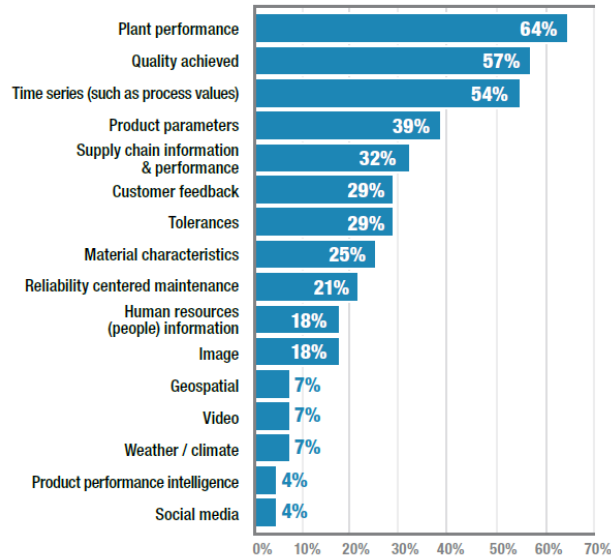


NPI Project Timeline From Concept to Full Rate Production



UNPRECEDENTED VISIBILITY

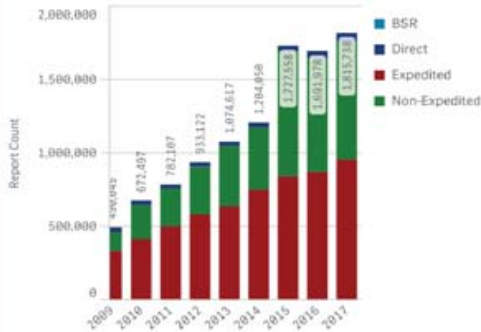
What types of data are used in your enterprise analytics system?



FDA Adverse Events Reporting System (FAERS) Public Dashboard

Total Reports **14,840,598** Serious Reports (excluding death) **8,434,750** Death Reports **1,491,711**

Reports received by Year and Report Type



Reports received by Year and Report Type

	Total Reports	Expedited	Non-Expedited
Total Reports	14,840,598	7,834,038	6,244,018
2017	1,815,738	951,656	803,516
2016	1,691,978	869,959	771,026
2015	1,727,558	839,197	846,702
2014	1,204,050	746,074	423,744
2013	1,074,617	634,816	411,411
2012	933,122	577,515	326,586



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Impacts B2B and B2C

NPI failure and underperformance increasingly visible/risky

Amplifies all other dynamics; manufacturers must adapt

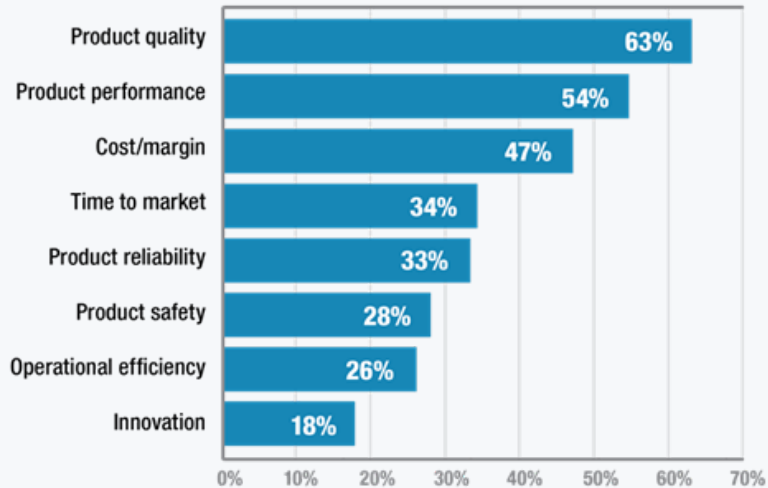


DEFINING NPI SUCCESS

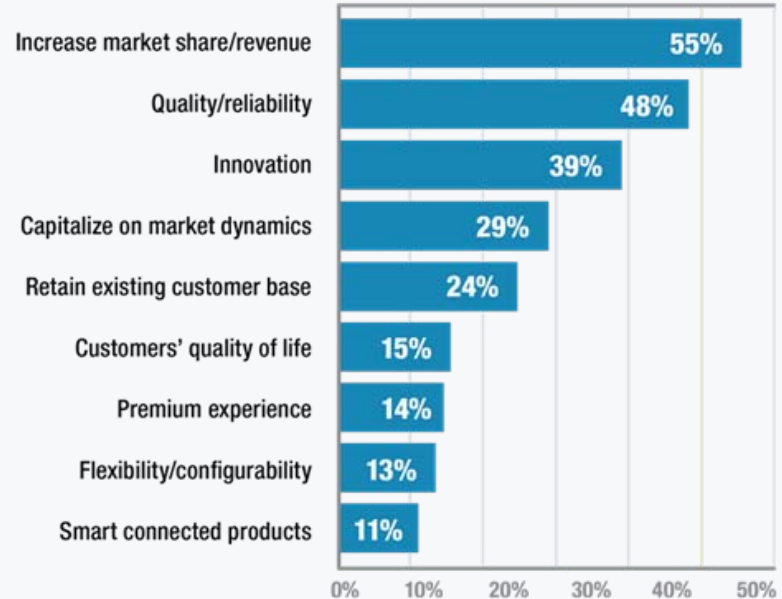
Increasing importance: as much as 50% of growth now tied to NPI in many industries

How does your organization define “successful” NPI?

Select all that MUST be met and do not include secondary criteria.

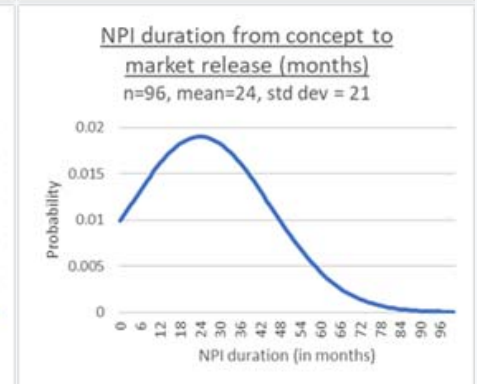
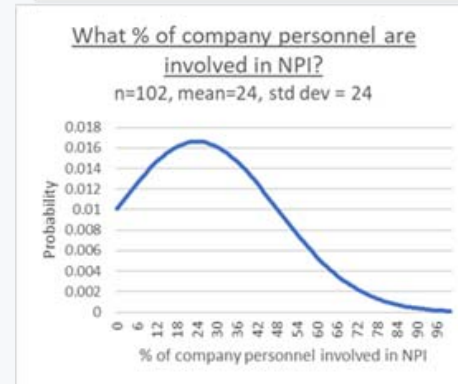
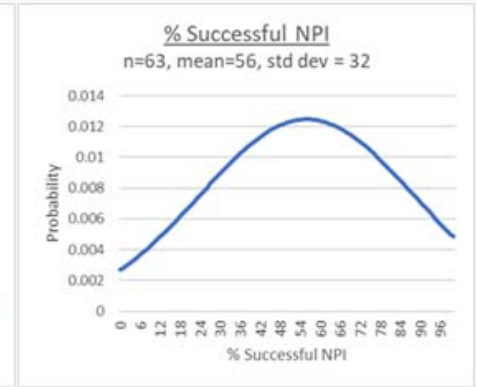
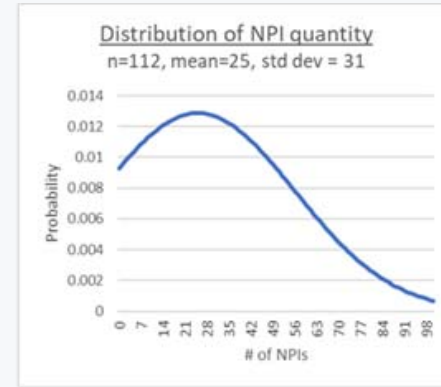


What are the top objectives for NPI? (select up to three)



BIG INVESTMENT IN NPI WITH UNEVEN RESULTS

- Big investment in NPI:
 - 24 months
 - 25% of corporate personnel
 - LOTS of new products
- “At least” 44% of new products fail to meet all, or even most, of their success criteria



NPI CHALLENGES

- 14 of 19 challenges are core “process challenges” and under a corporation’s control to change
 - 10 of 19 are internal processes
 - 2 are alignment with suppliers
 - 2 are data and systems
- Only 1 is clearly external: “Changes in Market Dynamics”
- We have found the enemy, and it is us!**
The challenges are around cross-functional collaboration



CHALLENGES TO ACHIEVE NPI OBJECTIVES (14 out of 19 are process deficiencies)

Quality management issues	28%	
Product validation	26%	
Departmental silos and misalignment	25%	
Collaboration with increasingly complex supply chain	23%	
Meeting time to market requirements	22%	
Development to manufacturing handoff	17%	
Ineffective change management	17%	
Scale pilot processes, equipment, and systems to volume	16%	
Ineffective risk management	15%	
Late cycle changes	15%	
Compliance management and regulatory submissions	13%	
Disparate systems and data sources	12%	
Insufficient competencies or difficulty attracting and retaining top talent	11%	
Changes in market economics	11%	
Budget	9%	
Supplier logistics and delivery	8%	
Ineffective metrics	7%	
Misalignment between delivered product and market needs	5%	
Lack of top management support	4%	

SUPPLIER MANAGEMENT MIRRORS NPI CHALLENGES

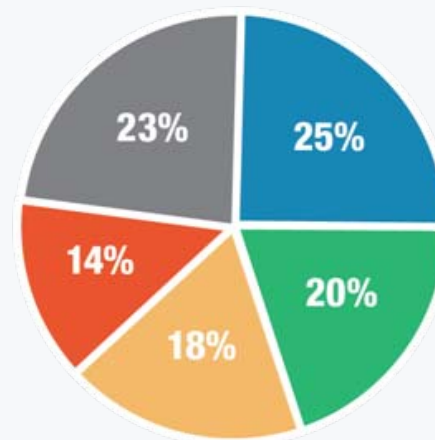
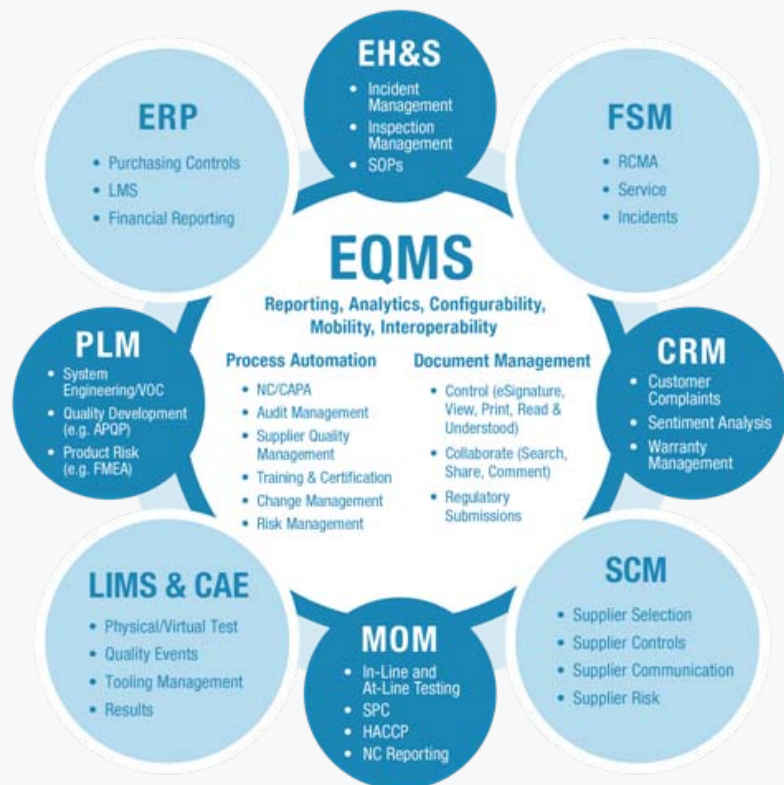
SUPPLIER MANAGEMENT: CRITICAL CHALLENGES

Late engagement in product development	46%	
No integrated approach to supplier management	39%	
Disparate systems and data sources	29%	
Poor supplier quality or compliance	29%	
Lack real-time visibility to supply chain performance	27%	
Lack of supplier competencies	20%	
Lack of change management	18%	
Lack top management support	10%	

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MANAGEMENT SYSTEMS AND DIGITAL ENABLERS



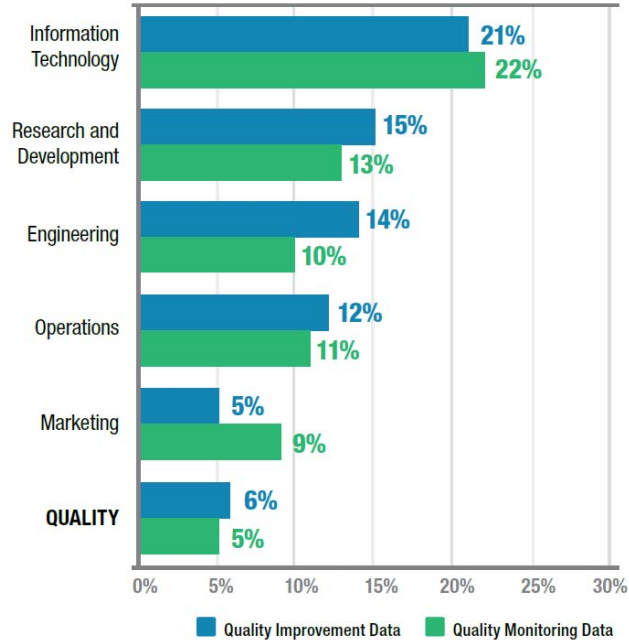
EQMS ADOPTION







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ROLE OF THE QUALITY DISCIPLINE: WHERE ARE THEY?

ROLES PLANNING TO USE IIoT TO MONITOR AND IMPROVE QUALITY



	 QUALITY	 ENGINEERING	 IT	 OPERATIONS
No initiatives underway	29%	5%	6%	17%
Not sure	26%	10%	11%	31%
Company has initiative(s), team sees no value in being involved	6%	30%	6%	9%
Company has initiative(s), team has no time to be involved	12%	15%	14%	3%
Company has initiative(s), team hasn't yet committed involvement	12%	10%	17%	17%
Company has initiative(s), team is actively engaged	9%	2%	33%	17%
Company has initiative(s), team is helping to lead	6%	5%	14%	6%

LNS 3-Step Quality Program for NPI Success

1. A COLLABORATIVE APPROACH



TOP THREE KEYS TO NPI SUCCESS

KEY #1: Establish strategic alignment and collaboration across disciplines.

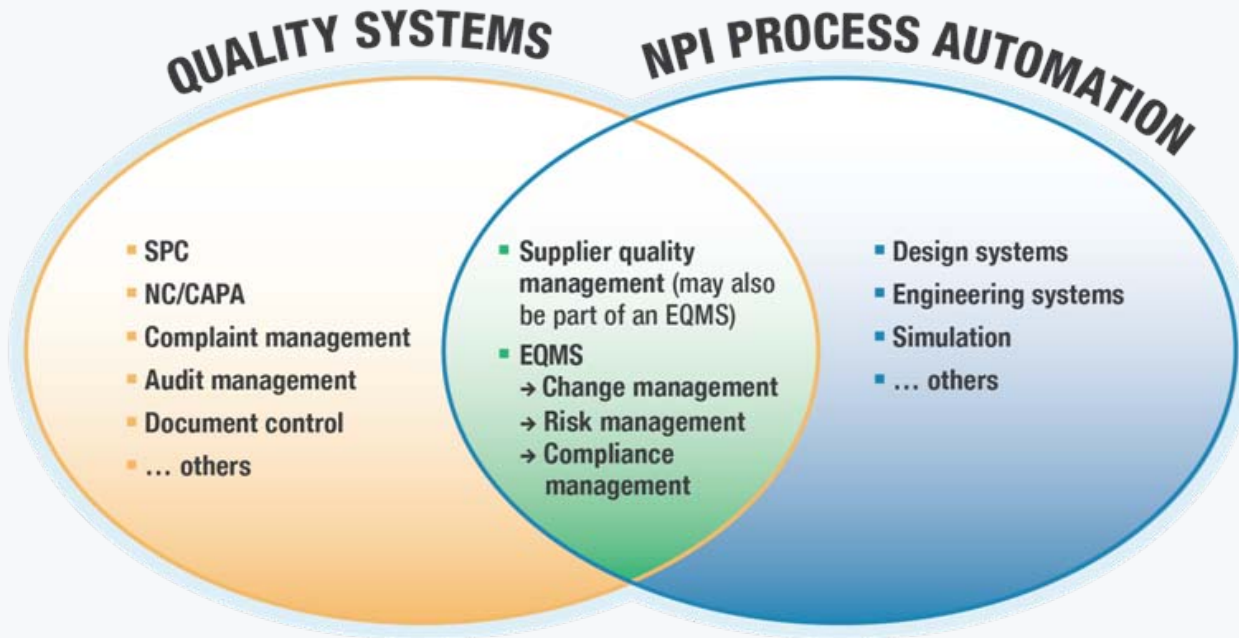
Desire to deliver quality products is universal

Leverage to build momentum for culture, full participation

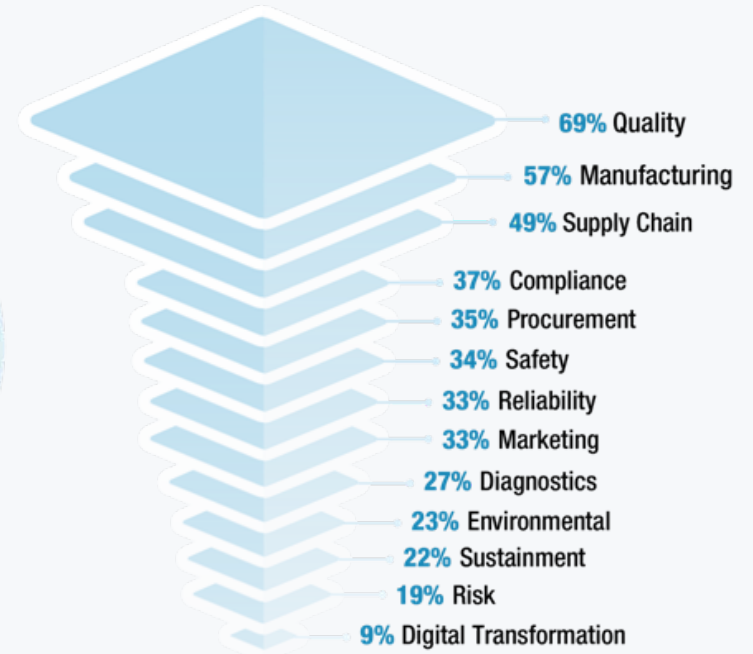
Top 3 Objectives by Discipline



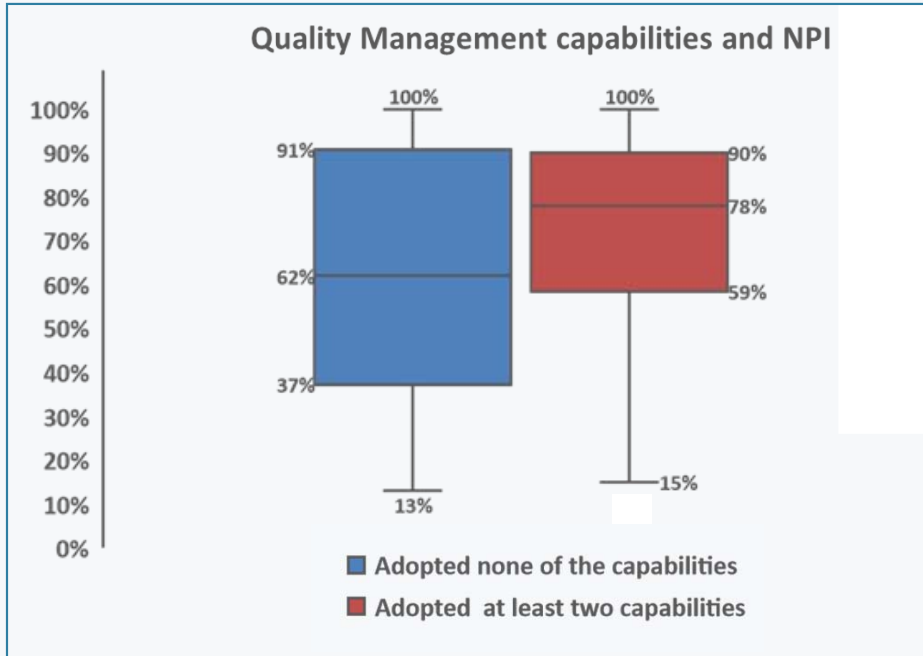
NPI: COLLABORATION REQUIRED



Disciplines Embedded in NPI



QUALITY MANAGEMENT CAPABILITIES & NPI

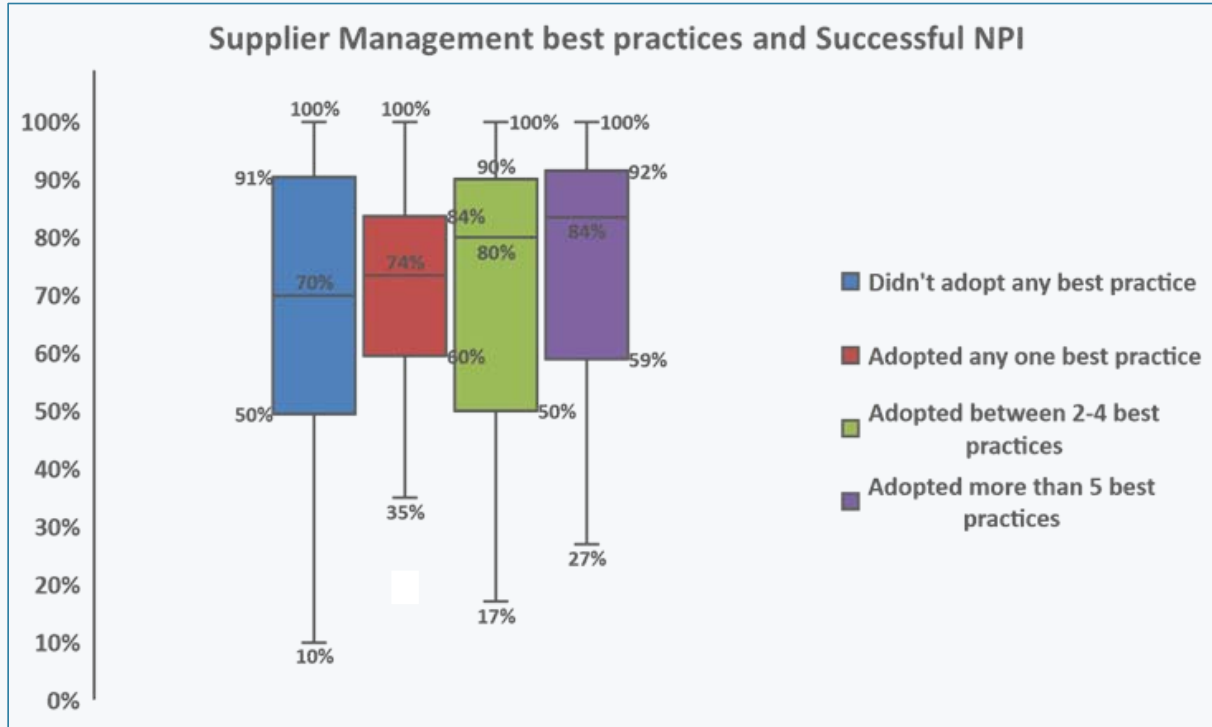


6 Quality Management Processes

1. Closed-loop processes established to connect quality across design, manufacturing, and suppliers.
2. Cross-functional teams in place to manage quality across design, manufacturing, and suppliers.
3. Formal NC/CAPA processes established across company.
4. Real-time visibility of quality metrics in customer service.
5. Real-time visibility of quality metrics in engineering.
6. Real-time visibility of quality metrics in manufacturing.

26% improvement in NPI in adopting at least 2 Quality Management Processes

SUPPLIER MANAGEMENT PRACTICES & NPI



6 Supplier Management Practices:

1. Standardized escalation processes exist for supplier quality and non-compliance events.
2. Statistical analysis used to monitor and analyze real-time supplier quality data.
3. Supplier quality data collected automatically through web-based portal.
4. Supplier scorecards established to measure and monitor performance.
5. Suppliers are included in design for quality initiatives.
6. Integration between EQMS and Supply Chain Management (SCM)

LNS 3-Step Quality Program for NPI Success

2. AUTOMATING COLLABORATION

While the Engineering / R&D / Design function is highly automated with a plethora of CAD, PLM, and simulations tools, the cross-functional work of NPI is often largely unautomated.

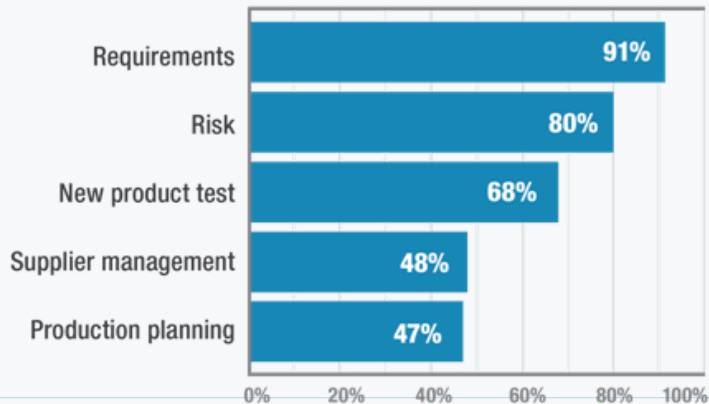
OBSTACLES TO COLLABORATIVE, CROSS-FUNCTIONAL NPI

KEY #2: Invest in collaborative technologies and processes to ensure collaboration across disciplines and teams.

Three common challenges negatively impact NPI success

These challenges have substantial negative impact on NPI success

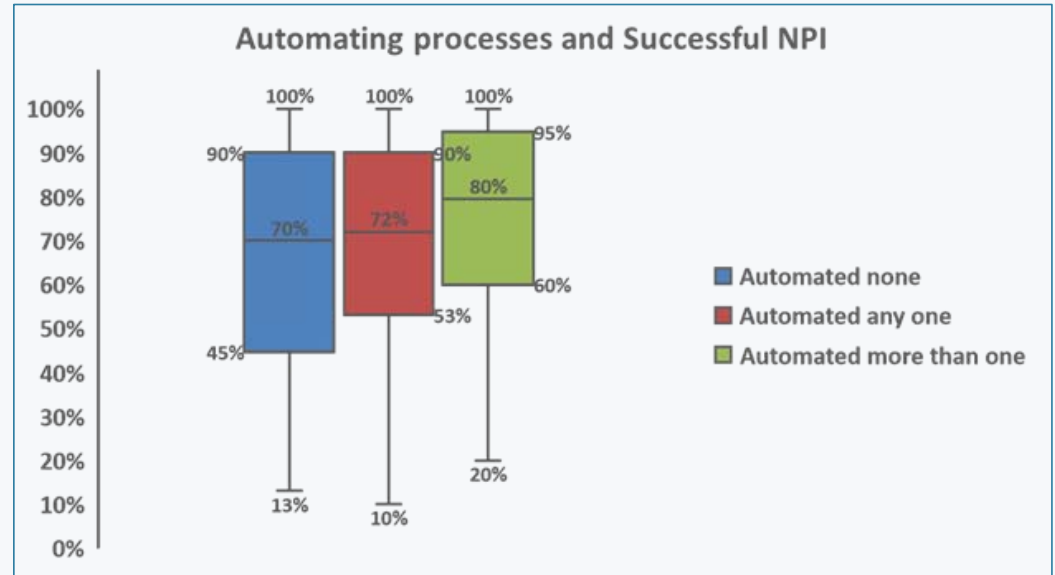
USES SPREADSHEETS AND E-DOCUMENTS TO MANAGE CRITICAL NPI DATA



AUTOMATING QUALITY MANAGEMENT PROCESSES

Automating with software

- Change Management
- Risk Management
- Supplier Quality Management
- Statistical Process Control

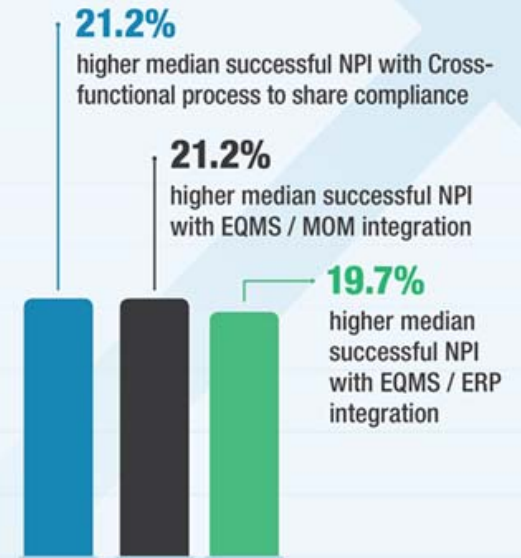


14% improvement in NPI in automating more than 1 Quality Process

OUTCOMES: IMPROVED NPI

	NOT ADOPTED	ADOPTED	IMPROVEMENT
EQMS / MOM integration	66%	80%	21.2%
Cross-functional process to share compliance	66%	80%	21.2%
EQMS / ERP integration	66%	79%	19.7%
Automate APQP with software	68%	81%	19.1%
Automate PPAP with software	68%	79%	16.2%
Customer service has real-time visibility of quality metrics	63%	73%	15.9%
EQMS / SCM integration	67%	76%	13.4%
Automate change management with software	67%	74%	10.4%
Cross-functional team to manage quality across design, manufacturing and suppliers	67%	71%	6.0%
Formal NC/CAPA processes enterprise-wide	68%	71%	4.4%

NPI Success Rate



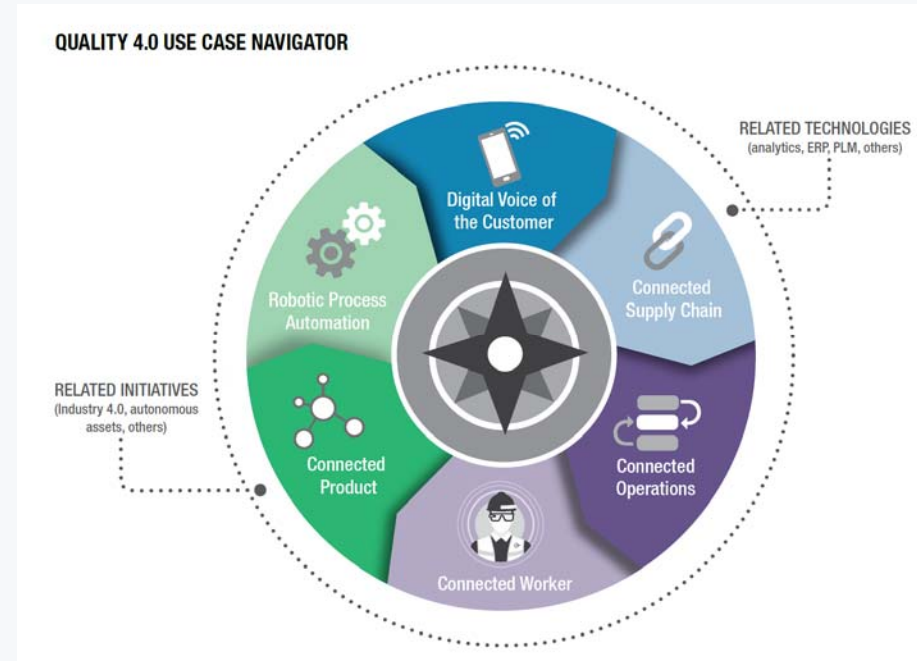
LNS 3-Step Quality Program for NPI Success
3. DIGITIZE WITH QUALITY 4.0 USE CASES



QUALITY 4.0 DEFINED

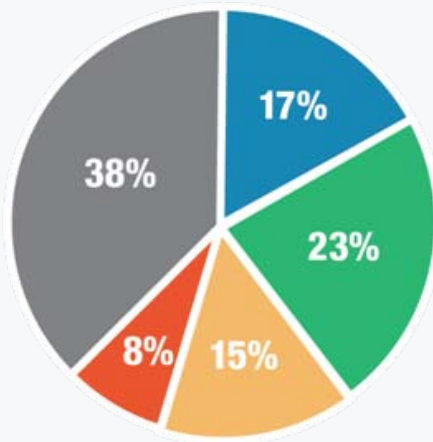
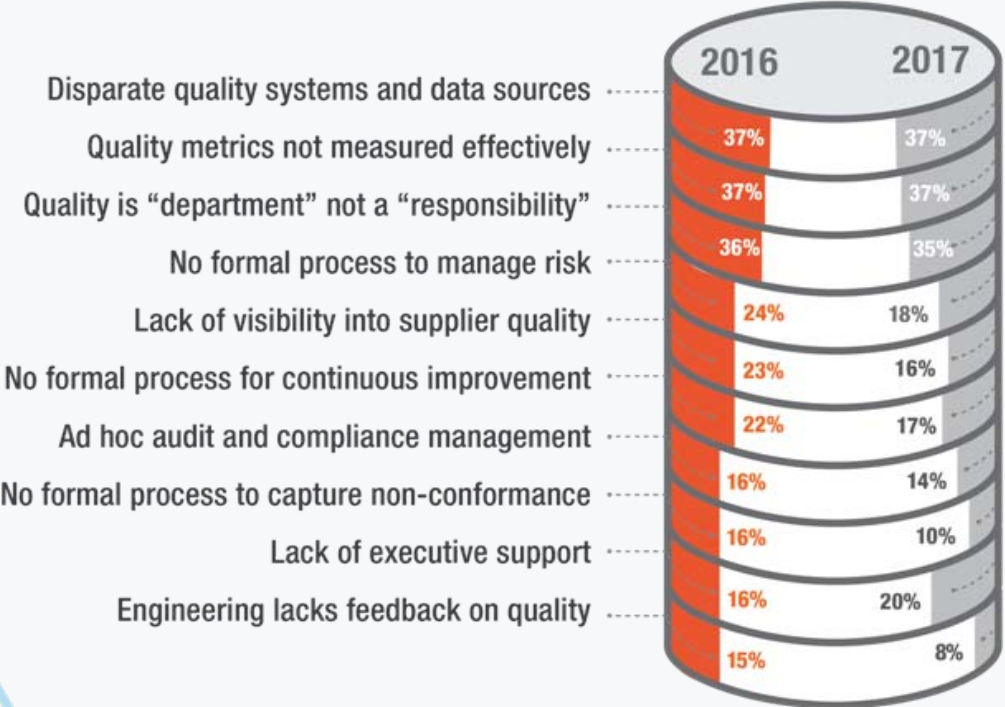
Quality 4.0 is the Digitalization of the Quality process via the application of traditional and Industrie 4.0 technologies (IIoT, Advanced Analytics, Cloud, Digital Twins) to improve quality monitoring and outcomes

- Builds on and improves conventional quality methods
- Quality data enhanced with other data from manufacturing, sensors, supply chain, product lifecycle and consumers to drive new insights
- Insights to be used throughout the organization
- To improve the business and offering an opportunity to change the role of Quality within the corporation



BEYOND “TRADITIONAL” TO QUALITY 4.0

Despite all the investment and effort to improve quality, little appears to change



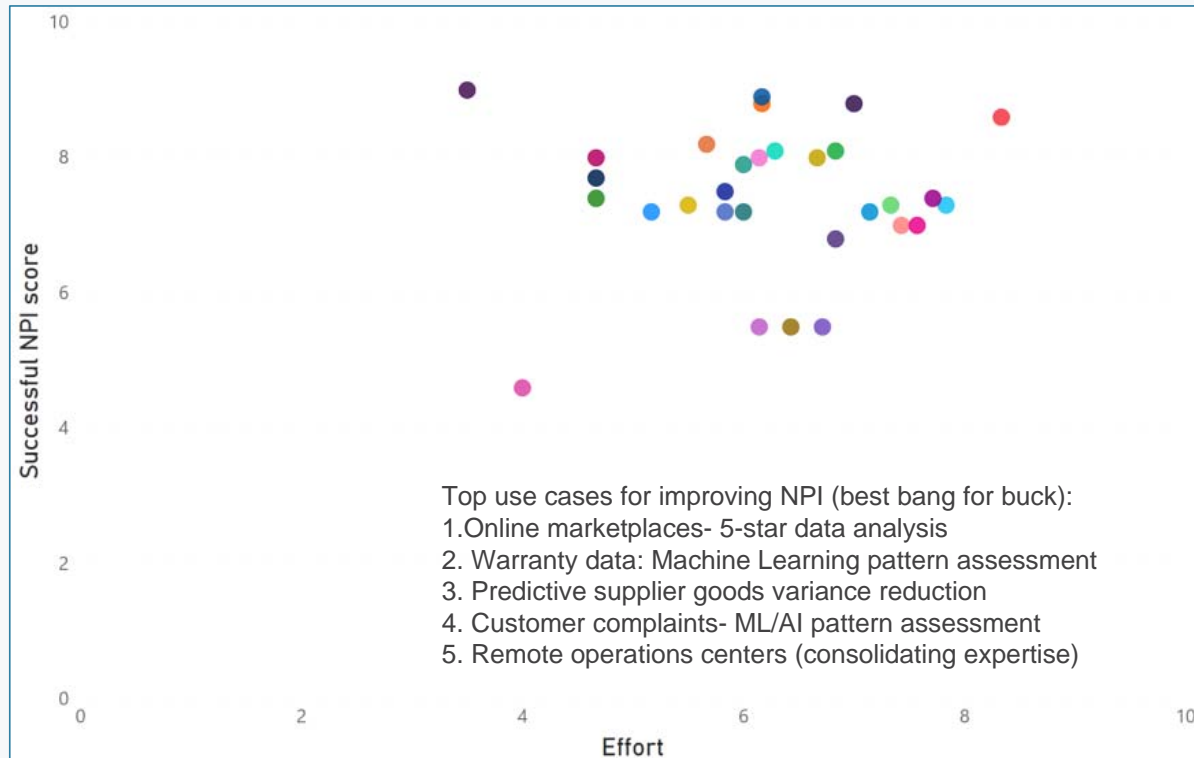
QUALITY 4.0 ADOPTION

- Implemented
- Piloted
- Budgeted within 1 year
- Planned within 3 years
- No plans



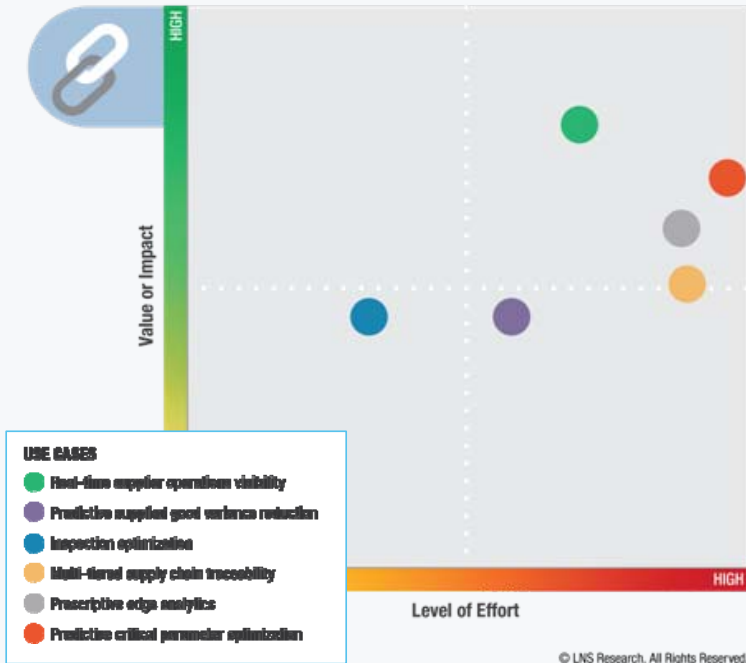
ALL 33 Q4.0 USE CASES DROVE IMPROVEMENT IN NPI

People who adopted a Quality 4.0 initiative have 18% better successful NPI rates.



Quality 4.0 provides a pivotal mechanism to transform business.

IMPACT/EFFORT MATRIX: CONNECTED SUPPLY CHAIN



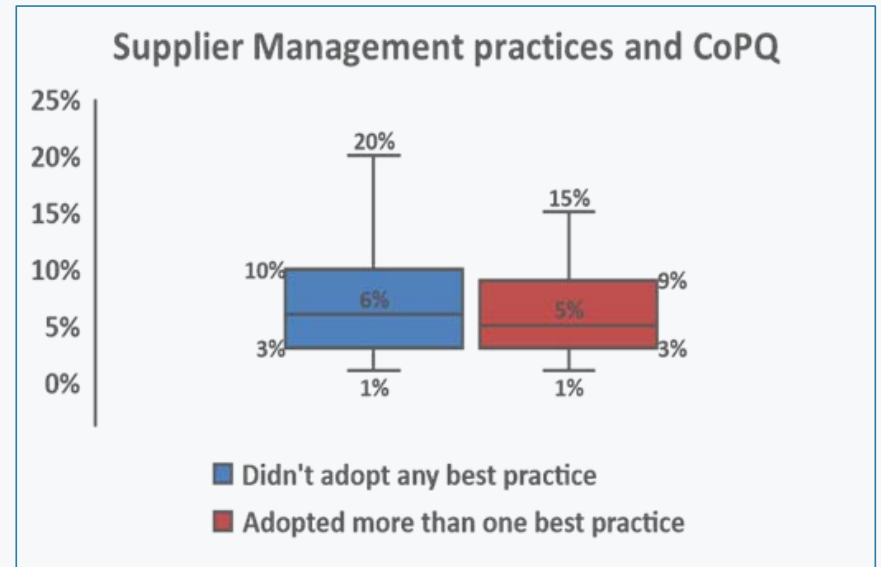
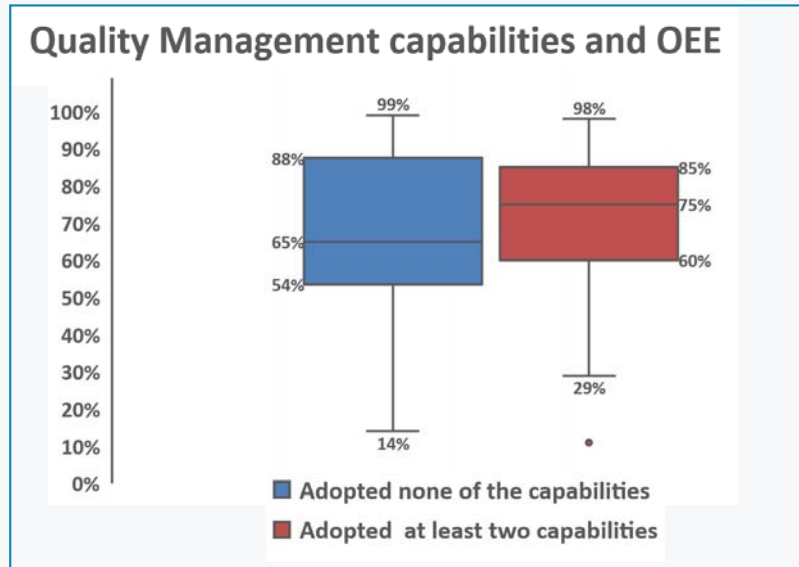
- Leaders in the deployment of Quality 4.0 Connected Supplier use cases performed 22% better than others in successful NPI.
- NPI can be improved by an average of 33% with each of 6 Quality 4.0 Connected Supplier use cases.
- Real-time Supplier Operations Visibility was most closely associated with manufacturing metrics leadership of all 33 use cases.
- Meaningful improvement was evident independent of a company's starting quality maturity levels (companies of all maturity levels improved).

SPILL-OVER BENEFITS



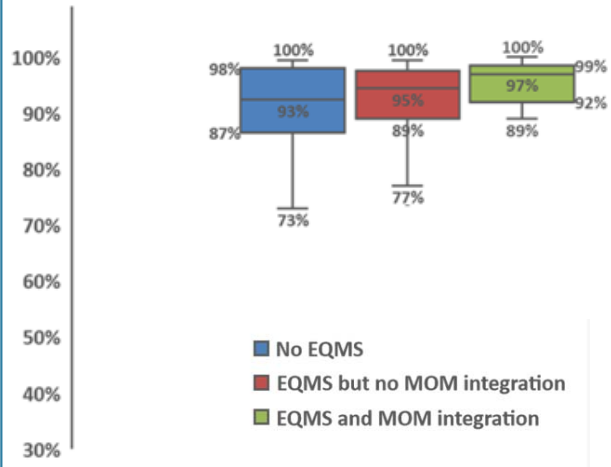
COLLABORATION IMPROVES MANUFACTURING & QUALITY

Improvements in NPI correlate closely with improvements in Quality and Manufacturing. Leaders in NPI were also 21% better in their multiple quality and 4.7% better in their multiple manufacturing metrics.

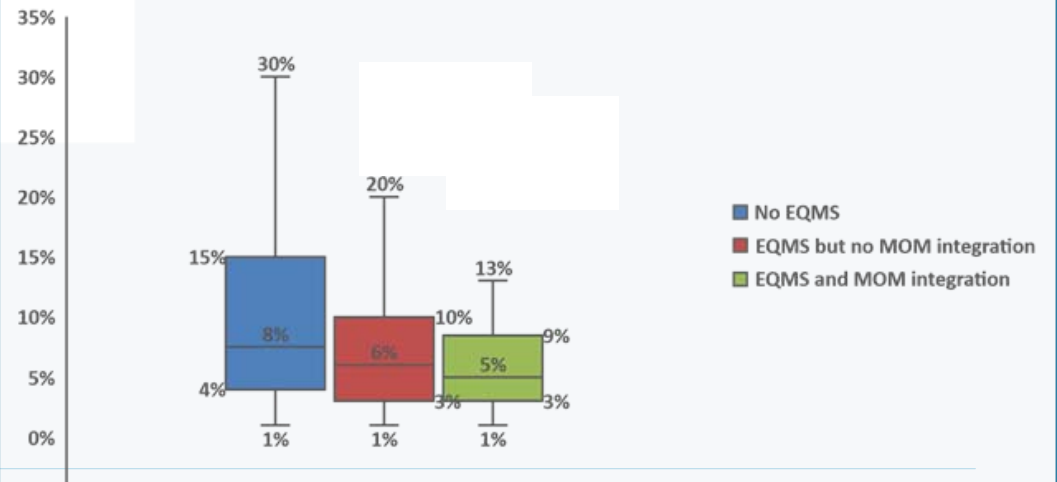


AUTOMATING COLLABORATION IMPROVES MFG & QUALITY

EQMS and MOM integration vs First Pass Yield



EQMS and MOM integration vs Cost of Poor Quality



ENGAGING IN Q4.0 DELIVERS MFG AND QUALITY VALUE

- Each of the 6 use cases showed an average of 31.5% improvement on the quality and manufacturing metrics as well.
- Implementation of all 33 Use Cases delivered improvements in Quality & Manufacturing
- The more the use cases implemented, the better the performance across all 3 sets of metrics
- Quality 4.0 helps companies at whatever level of quality maturity specifically including the most mature in quality
- Uniquely delivers improved CoPQ without increasing CoGQ

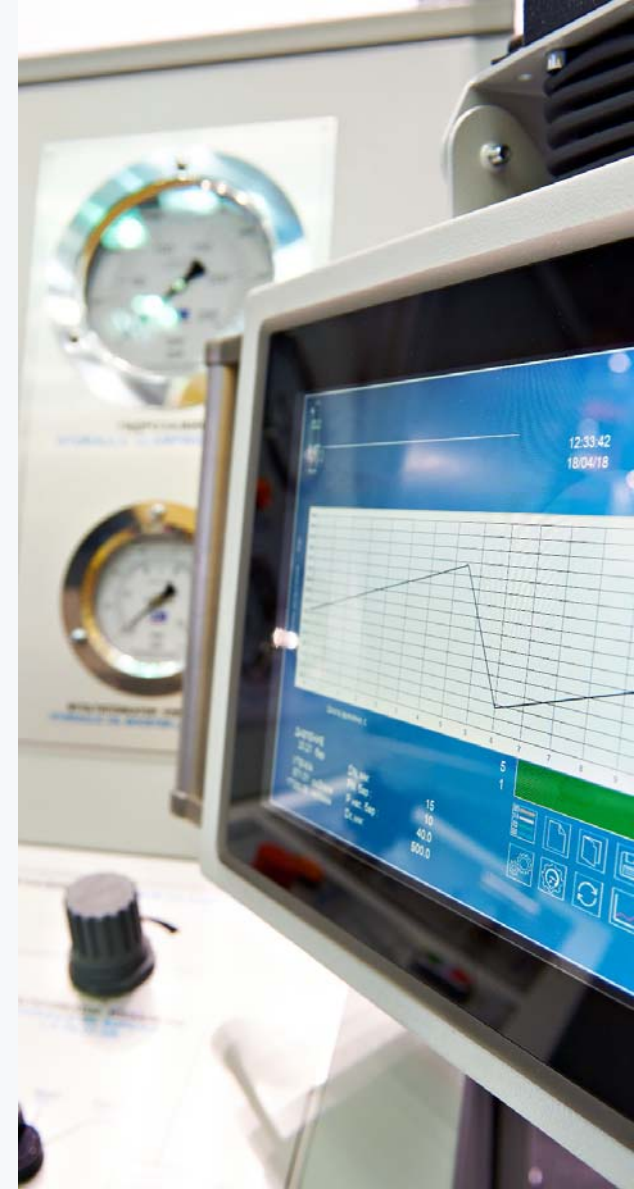
% USE CASES ADOPTED	# MANUFACTURING KPIs	# QUALITY KPIs
>10	88	70
6-10	74	57
≤ 5	73	51

WRAP-UP AND RECOMMENDATIONS



SUMMARY

- NPI is important yet inconsistently successful
- Process challenges around collaboration are the primary barrier to improved performance
 - NPI > Product Design and involves much of the enterprise
- LNS' 3-Step Quality Plan delivers improved NPI
 - Independent of quality maturity & without meaningfully increasing the CoGQ
- Supplier Quality should be a key focus
- NPI success correlates with quality and manufacturing success



RECOMMENDATIONS

- Learn from Early Adopters
 - Data and Systems are critical to NPI acceleration
 - The “Power of More”
 - Correlation of Value
- Transformation requires change
 - Design Engineering and Supply Chain must expand their thinking
 - Quality Must Engage
- Commit to Quality 4.0 now



THANK YOU

tom.comstock@lms-global.com

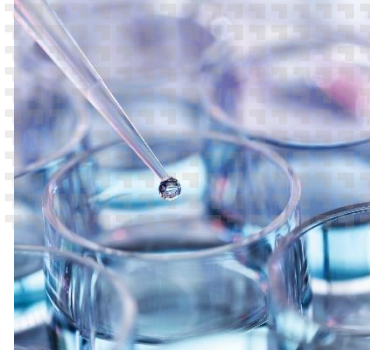
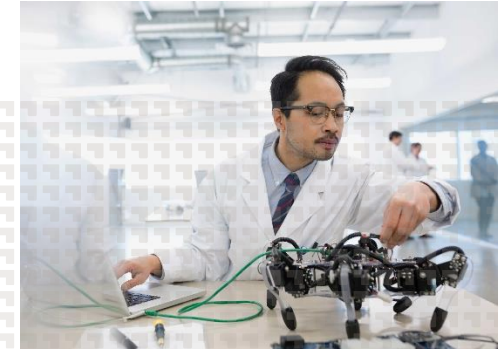




Supply Chain Quality in New Product Introductions (NPI)

Morgan Palmer – CTO, ETQ





etq¹ Quality Creates.™

25 years rooted
in Quality
Management

Over 300 employees
focused on Quality

Successful across
multiple industries

ETQ Reliance applications are delivered in an easy-to-consume set of solutions

ETQ Insights

Visual dashboarding and advanced visual analytics

Quality Essentials

Quality by Design

Supply Chain Quality

**Nonconformance
Handling**

Health & Safety

**Environmental
Management**

**Enterprise Risk
Management**

**Complaints
Management**

ETQ Reliance Platform

Easily adapt, integrate, and administer ETQ Reliance applications

ETQ Insights

Visual dashboarding and advanced visual analytics

Supply Chain Quality:

Ensure finished product quality with automated control and visibility over all elements of your supply chain, from local manufacturers to global suppliers. Track suppliers and materials, build qualitative and quantitative supplier ratings, trigger actions for supplier quality.

Process Applications

- Product Part Approval Process (PPAP)
- Receiving and Inspection
- Supplier Corrective Action (SCAR)
- Supplier and Material Qualification
- Supplier Rating

ETQ Reliance Platform

Easily adapt, integrate, and administer ETQ Reliance applications

Your Quality Journey

TRANSFORM

EXPAND

ACCELERATE

IGNITE

Improve
Supply Chain
Quality

State of Supply Chain Quality

Standard Practice

- Qualification = Supplier audits
- Quality = Incoming inspections
- Performance = On time delivery
- Supplier collaboration by email and phone
- Exception-based controls

Best Practice

- Qualification = Calculated risk
- Quality = Proactive view
- Performance = Real-time metrics in online scorecard
 - Continuously optimize control levels (e.g., audit frequency, inspection AQL)

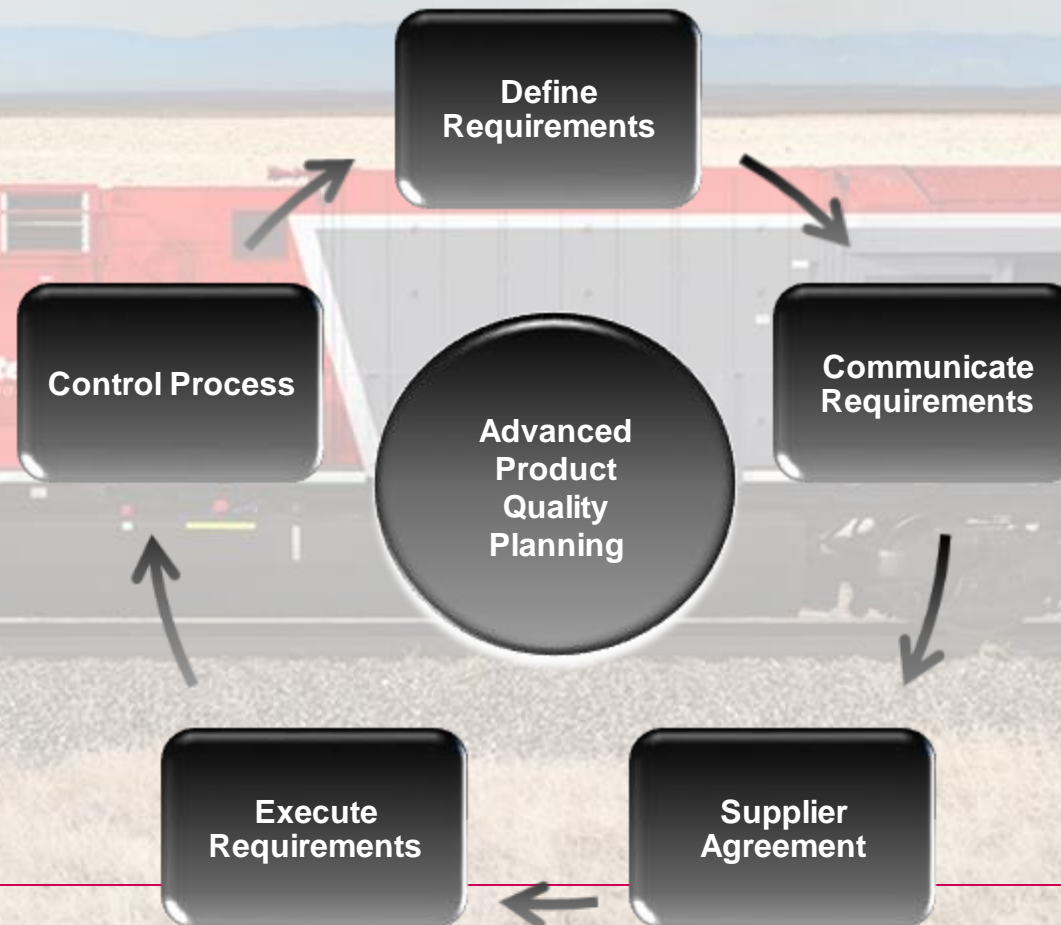
Example: Production Part Approval Process (PPAP)



15-20 orders per year
17,000 parts per **locomotive**
55% parts are purchased
2% parts are new
+
4,000 supplier-part
changes per year

PPAP at Wabtec

- Rigorous, risk-based process to ensure Supply Chain Quality



Challenges with the Old Process

- Requirements buried in email
- Unclear ownership ...*who's on first?*
- Process cycle and quality unknown
- Disconnected and high risk of escape



Add PPAP to QMS

Challenges with Online Supplier Collaboration

- Getting access to the system

1

Suppliers register for SSO authentication during on-boarding

- Securing internal and other supplier data

2

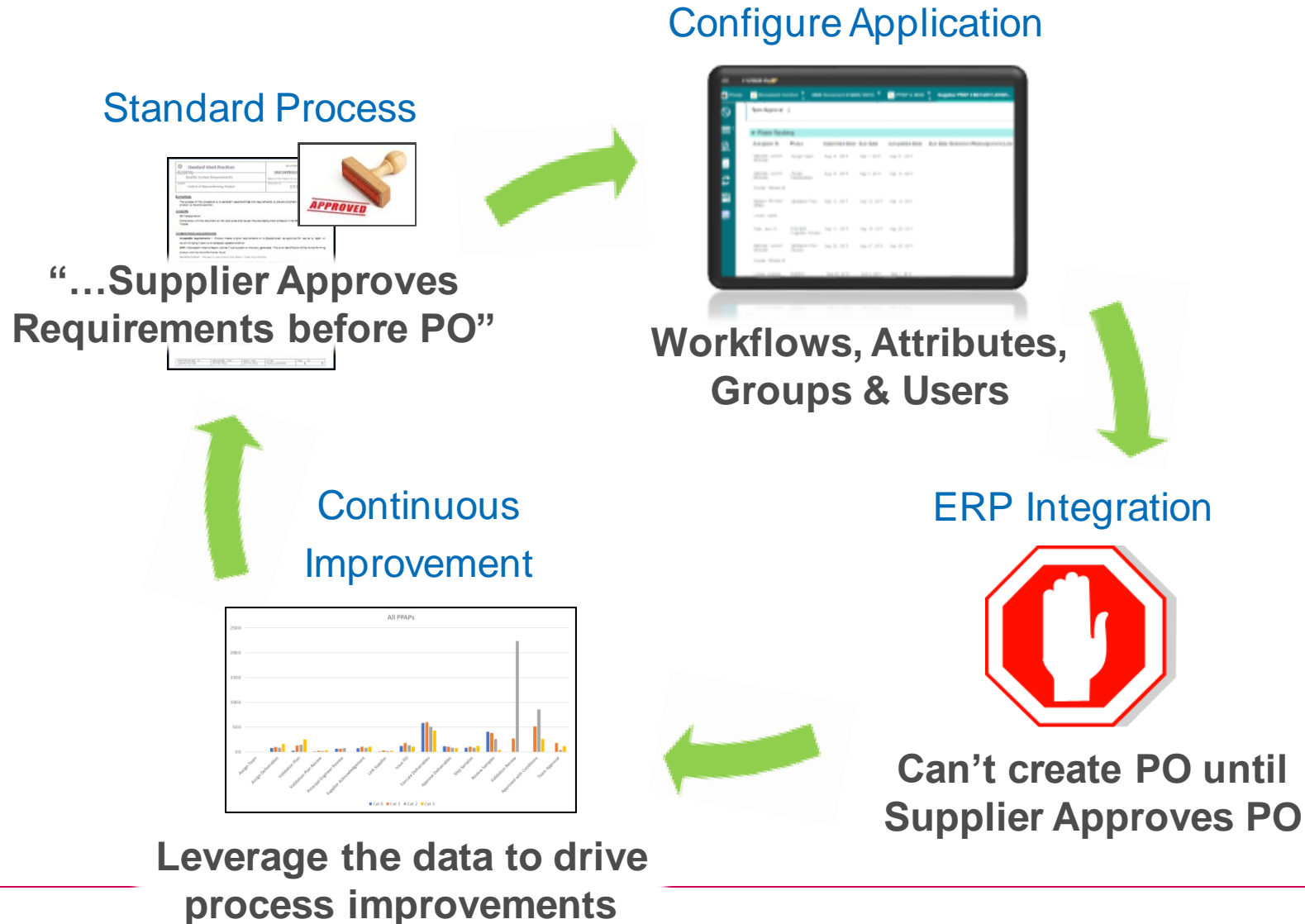
Leverage ETQ's groups & locations to secure w/ monitoring scripts

- On-going training and support

3

Embedded link to video training & workflow ticketing

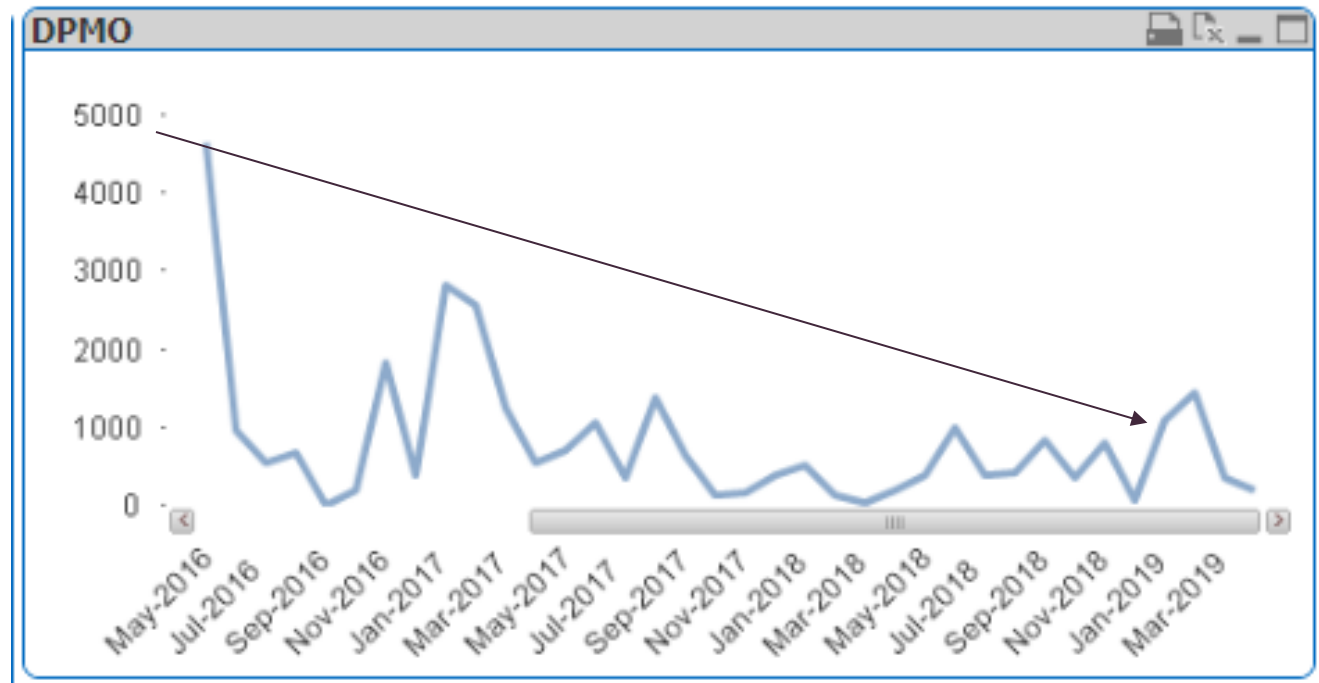
ETQ PPAP Implementation



Results

- ✓ 50% process handoffs eliminated
- ✓ 18,000 hours saved annually
- ✓ \$0.8M productivity savings

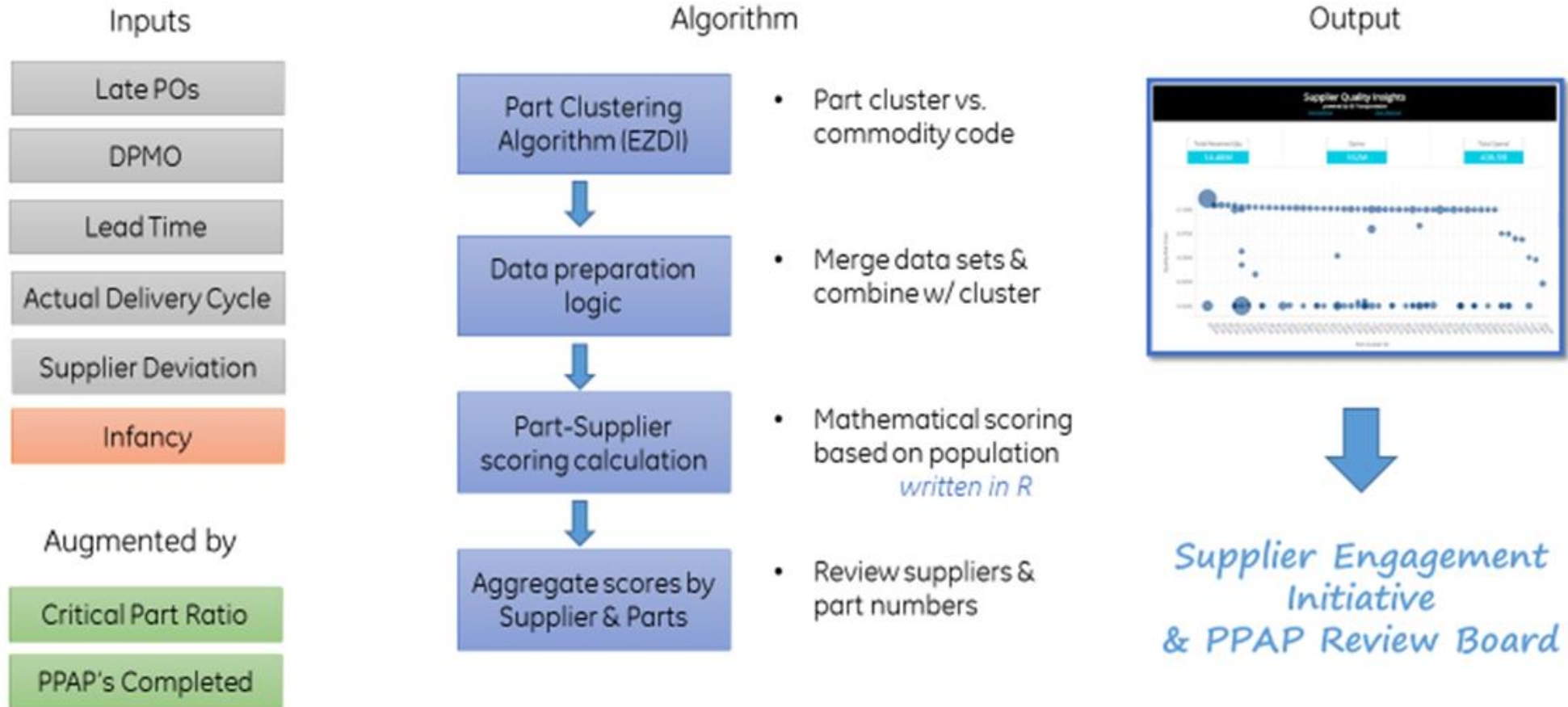
Supplier DPMO



Positive DPMO Trend & 70% Supplier w/ 0 defects

Quality 4.0: Machine Learning Improves Decisions

QML Risk Analytics Overview





Need a more food & bev friendly graphic

Q&A



Additional Supply Chain Resources

etq.com/resources



Webinars & Videos

Case Study/Kimberly-Clark



Consumer Packaged Goods

Kimberly-Clark Streamlines Supplier Management with ETQ

Kimberly-Clark (K-C) operates on a large scale, so its operations involve many different locations and external suppliers. Its previous contract process became a major pain point as the company expanded.

Case Study / Subway



Food and Beverage

Subway® Speeds Up Vendor Approval with ETQ Reliance™

With a worldwide presence, SUBWAY® is constantly growing its supply chain. It uses a strict approval process to meet legal requirements and ensure high quality.

The Business Need

It was experiencing issues with the amount of time it would take to get the legal documents negotiated, reviewed, signed and approved. The process took several months—email communication caused frequent delays. There was no traceability or tracking aside from manual spreadsheets that were not always maintained, so tracking or finding documents became almost impossible.

Progress Bar: Lets users see their progress status through the 10 steps of the form.

Documents Uploaded to Request Form: This grid shows what documents are required from a given vendor and tracks when they are uploaded.

Document Tracker View: Since up to hundreds of requests may be in progress at a time, they need to quickly see



Analyst Reports, Whitepapers & Guides

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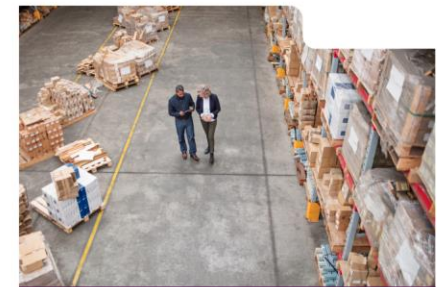
Key Success Factors to Access Your Supplier Relationship Management Program

Supplier relationship management is an effective tool to deliver increased value beyond cost savings. Learn how supply chain

has the key to the most successful SRM program

In this Gartner

- Key challenges in building
- Recommendations for program
- How to create a culture of creation
- Characteristics



etq Quality Creates

Whitepaper

Supplier Quality is Only as Strong as Your Weakest Link

As a company's supplier list grows, so does the looming risk of a supplier quality failure. With even one recall able to decimate stock value and brand reputation, it's up to manufacturers to proactively manage supplier quality—or face the eventual consequences.

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Thank you!