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
2 Surveys with a total of 1,470 responses
THE NPI CHALLENGE
TIME TO MARKET PRESSURES

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%

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

<table>
<thead>
<tr>
<th>ORDER OF ENTRY</th>
<th>NUMBER OF DRUGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st to market</td>
<td>131</td>
</tr>
<tr>
<td>2nd to market</td>
<td>131</td>
</tr>
<tr>
<td>3rd to market</td>
<td>84</td>
</tr>
<tr>
<td>4th to market</td>
<td>52</td>
</tr>
<tr>
<td>5th to market</td>
<td>31</td>
</tr>
<tr>
<td>6th to market and beyond</td>
<td>63</td>
</tr>
</tbody>
</table>

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

- 1st to market: 40%
- 2nd to market: 33%
- 3rd to market: 19%
- 4th to market: 13%
- 5th to market: 8%
- 6th to market and beyond: 2%
PRODUCT AND CONFIGURATION COMPLEXITY

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

Discrete: from mechanical to software-driven, product personalization

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UNPRECEDENTED VISIBILITY

NPI failure and underperformance increasingly visible/risky

Impacts B2B and B2C

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
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
SUPPLIER MANAGEMENT MIRRORS
NPI CHALLENGES

**SUPPLIER MANAGEMENT: CRITICAL CHALLENGES**

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late engagement in product development</td>
<td>46%</td>
</tr>
<tr>
<td>No integrated approach to supplier management</td>
<td>39%</td>
</tr>
<tr>
<td>Disparate systems and data sources</td>
<td>29%</td>
</tr>
<tr>
<td>Poor supplier quality or compliance</td>
<td>29%</td>
</tr>
<tr>
<td>Lack real-time visibility to supply chain performance</td>
<td>27%</td>
</tr>
<tr>
<td>Lack of supplier competencies</td>
<td>20%</td>
</tr>
<tr>
<td>Lack of change management</td>
<td>18%</td>
</tr>
<tr>
<td>Lack top management support</td>
<td>10%</td>
</tr>
</tbody>
</table>

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MANAGEMENT SYSTEMS AND DIGITAL ENABLERS

EQMS
- Reporting
- Analytics
- Configurability
- Mobility
- Interoperability

ERP
- Purchasing Controls
- LMS
- Financial Reporting

EH&S
- Incident Management
- Expense Management
- SOPs

FSM
- RCMA
- Service
- Incidents

PLM
- System Engineering/VOC
- Quality Development (e.g. APQPS)
- Product Risk (e.g. FMEA)

CRM
- Customer Complaints
- Sentiment Analysis
- Warranty Management

LIMS & CAE
- Physical/Functional Test
- Quality Events
- Tooling Management
- Results

MOM
- In-Line and At-Line Testing
- SPC
- HACCP
- NC Reporting

SCM
- Supplier Selection
- Supplier Controls
- Supplier Communication
- Supplier Risk

EQMS ADOPTION

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

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ROLE OF THE QUALITY DISCIPLINE: WHERE ARE THEY?

Roles planning to use IIoT to monitor and improve quality:

- **Information Technology**: 21% Quality Improvement Data, 22% Quality Monitoring Data
- **Research and Development**: 15% Quality Improvement Data, 13% Quality Monitoring Data
- **Engineering**: 10% Quality Improvement Data, 14% Quality Monitoring Data
- **Operations**: 12% Quality Improvement Data, 11% Quality Monitoring Data
- **Marketing**: 5% Quality Improvement Data, 9% Quality Monitoring Data
- **Quality**: 6% Quality Improvement Data, 5% Quality Monitoring Data

<table>
<thead>
<tr>
<th>Status</th>
<th>Quality</th>
<th>Engineering</th>
<th>IT</th>
<th>Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>No initiatives underway</td>
<td>29%</td>
<td>5%</td>
<td>6%</td>
<td>17%</td>
</tr>
<tr>
<td>Not sure</td>
<td>26%</td>
<td>10%</td>
<td>11%</td>
<td>31%</td>
</tr>
<tr>
<td>Company has initiative(s), team sees no value in being involved</td>
<td>6%</td>
<td>30%</td>
<td>6%</td>
<td>9%</td>
</tr>
<tr>
<td>Company has initiative(s), team has no time to be involved</td>
<td>12%</td>
<td>15%</td>
<td>14%</td>
<td>3%</td>
</tr>
<tr>
<td>Company has initiative(s), team hasn’t yet committed involvement</td>
<td>12%</td>
<td>10%</td>
<td>17%</td>
<td>17%</td>
</tr>
<tr>
<td>Company has initiative(s), team is actively engaged</td>
<td>9%</td>
<td>2%</td>
<td>33%</td>
<td>17%</td>
</tr>
<tr>
<td>Company has initiative(s), team is helping to lead</td>
<td>6%</td>
<td>5%</td>
<td>14%</td>
<td>6%</td>
</tr>
</tbody>
</table>
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

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### Top 3 Objectives by Discipline

<table>
<thead>
<tr>
<th>OPERATIONS</th>
<th>PRODUCT DEVELOPMENT / PRODUCT MANAGEMENT</th>
<th>QUALITY / COMPLIANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product quality</td>
<td>Product quality, reliability, safety</td>
<td>Customer requirements, industry standards, regulations</td>
</tr>
<tr>
<td>Product quality</td>
<td>Product quality, reliability, safety</td>
<td>68%</td>
</tr>
<tr>
<td>Production efficiency</td>
<td>Product performance differentiation</td>
<td>Total cost of quality</td>
</tr>
<tr>
<td>Manufacturing agility</td>
<td>Corporate financial targets</td>
<td>48%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quality metrics (complaints, efficiency)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>26%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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NPI: COLLABORATION REQUIRED

QUALITY SYSTEMS
- SPC
- NC/CAPA
- Complaint management
- Audit management
- Document control
- … others

NPI PROCESS AUTOMATION
- Supplier quality management (may also be part of an EQMS)
- EQMS → Change management → Risk management → Compliance management
- Design systems
- Engineering systems
- Simulation
- … others

Disciplines Embedded in NPI
- 69% Quality
- 57% Manufacturing
- 49% Supply Chain
- 37% Compliance
- 35% Procurement
- 34% Safety
- 33% Reliability
- 33% Marketing
- 27% Diagnostics
- 23% Environmental
- 22% Sustainment
- 19% Risk
- 9% Digital Transformation

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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.


26% improvement in NPI in adopting at least 2 Quality Management Processes
SUPPLIER MANAGEMENT PRACTICES & NPI

20% improvement in NPI in adopting more than 5 Supplier Mgmt Practices

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**

- Requirements: 91%
- Risk: 80%
- New product test: 68%
- Supplier management: 48%
- Production planning: 47%

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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

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

NPI Success Rate

- **21.2%** higher median successful NPI with Cross-functional process to share compliance
- **19.7%** higher median successful NPI with EQMS / ERP integration
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

Disparate quality systems and data sources
Quality metrics not measured effectively
Quality is “department” not a “responsibility”
No formal process to manage risk
Lack of visibility into supplier quality
No formal process for continuous improvement
Ad hoc audit and compliance management
No formal process to capture non-conformance
Lack of executive support
Engineering lacks feedback on quality

QUALITY 4.0 ADOPTION

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ALL 33 Q4.0 USE CASES DROVE IMPROVEMENT IN NPI

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

Top use cases for improving NPI (best bang for buck):
1. Online marketplaces - 5-star data analysis
2. Warranty data: Machine Learning pattern assessment
3. Predictive supplier goods variance reduction
4. Customer complaints - ML/AI pattern assessment
5. Remote operations centers (consolidating expertise)
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
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
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@lns-global.com
Supply Chain Quality in New Product Introductions (NPI)

Morgan Palmer – CTO, ETQ
25 years rooted in Quality Management

Over 300 employees focused on Quality

Successful across multiple industries

Quality Creates®
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
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

IGNITE

ACCELERATE

EXPAND

TRANSFORM

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
- Securing internal and other supplier data
- On-going training and support

1. Suppliers register for SSO authentication during on-boarding
2. Leverage ETQ’s groups & locations to secure w/ monitoring scripts
3. Embedded link to video training & workflow ticketing
ETQ PPAP Implementation

Standard Process

“...Supplier Approves Requirements before PO”

Configure Application

Workflows, Attributes, Groups & Users

Continuous Improvement

ERP Integration

Can’t create PO until Supplier Approves PO

Leverage the data to drive process improvements
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

**Inputs**
- Late POs
- DPMO
- Lead Time
- Actual Delivery Cycle
- Supplier Deviation
- Infancy

**Augmented by**
- Critical Part Ratio
- PPAP’s Completed

**Algorithm**
- Part Clustering Algorithm (EZDI)
- Data preparation logic
- Part-Supplier scoring calculation
- Aggregate scores by Supplier & Parts

**Output**
- Part cluster vs. commodity code
- Merge data sets & combine w/ cluster
- Mathematical scoring based on population written in R
- Review suppliers & part numbers

Supplier Engagement Initiative & PPAP Review Board
Q&A

Need a more food & bev friendly graphic
Thank you!