Webinar Presenters

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Risk Management and Quality across the Value Chain by Increasing Visibility
What do these brands have in common?
Responsible for the Largest Recalls

2010 – Gas Pedal Recall
8.1M vehicles recalled
89 deaths
**Total Cost = $3.2Bn**

2014 - Ignition Switch
30.4M cars/ recalled
124 deaths & 250+ injuries
**Total Cost = $14.1 Bn**

2016 - Battery Fires
2.5M devices recalled
96 reported fires in 2 mos.
**Total Cost = $5.3 Bn**

2015 - Emissions Tests
11M vehicles recalled
**Total Cost = $18.3 Bn**

2000 - Tire failure/Ford SUVs
6.5M tires recalled
271 deaths & 800 injuries
**Total Cost = $5.6 Bn**

2008+ - Faulty Air bags
100M inflators recalled worldwide
**Total Cost = $24 Bn**

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Agenda

1. The importance of Quality in manufacturing
2. How Risk Management enhances Quality
3. Foundational changes for success
4. Quality begins on the inside
5. Expanding Quality and Risk visibility across the value chain
6. Build the business case for executive buy-in
The Importance of Quality Management

“Must do” (Compliance)
- ISO 9001/2015

“Want to do” (Business drivers)
- Improve quality in every process and every product
- Reduce costs
- Maintain brand reputation and consumer confidence
The Cost of Poor Quality (COPQ)

- Foundation of Quality Management: *Do it right the first time*
- COPQ includes direct and indirect costs = 15% - 40% of sales*

*Source: isixsigma.com*
Risk Management Enhances Quality Visibility

- Quality management offers a continuous improvement process to support quality specifications
- Risk management provides visibility into opportunities and hazards that could impact product quality
Risk and Quality Collaboration

**RISK MANAGEMENT**
- Assemble team
- List failure modes & effects
- Rank severity
- List potential causes
- Rank likelihood
- List process controls
- Rank detection
- Calculate RPN
- Take action on high priority RPNs

**QUALITY MANAGEMENT**
- Nonconformances
- Investigation & root cause analysis
- Corrective and Preventive Actions
- Management of Change
- Audits & questionnaires
- Supplier management & SQM
- Customer complaints

**SHARED PROCESSES**
- Hazard analysis
- Audits
- Investigations
- CAPAs
- MOCs
- Reporting
- Document Control

RPN – Risk Priority Number
Challenges to Achieving Quality Objectives

- Disparate quality systems and data sources: 37%
- Quality metrics are not effectively measured: 37%
- Quality is considered a “department” not a “responsibility”: 36%
- No formal process for managing risk: 24%
- Lack of visibility into supplier quality: 23%
- No formal process for capturing nonconformances: 22%

% of Total Respondents

LNS Research
Quality Begins on the Inside: Foundation for Success

Digitization

Process automation

Integrated systems
Quality Begins on the Inside: Quality and Risk Working Together

Case study: Chemical company – product contamination

Raw material costs $75,000

COPQ >$750,000
Quality and Risk outside your Four Walls
Value Chain Visibility

▪ 52% of product recalls are a result of supplier and contract vendor issues*
▪ Lack of visibility into Vendor processes and procedures
▪ Use a Quality Management system that manages and connects with your partners

Case study: Supplier Quality is a tough nut to crack

▪ 700 illnesses
▪ 9 deaths
▪ $1Bn industry losses
▪ 25% drop in peanut butter sales
▪ Supplier filed bankruptcy
▪ Executives faced federal criminal charges

*Recall Execution Effectiveness study, Deloitte.
Building the Business Case for Executive Buy-in

1. Identify the decision makers
2. Complete a project definition and needs analysis
3. Determine objectives and the desired outcomes for implementing a QMS
4. Address the ROI
5. Success criteria and measures
6. Monthly meetings
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