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”

Risk Level
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

- Identify Risks
- Evaluate Risks
- Treatment of Risks
- Take Action

Potential but not realized Hazards: Survey improvement areas
How can we determine the impact of potential events?
Where can we measure impact and determine improvement?
Change Management, Process Improvements, Etc.

• 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
Risk in Operations
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 is used to:
- Filter Events
- Determine Severity
- Prioritize
- Effectiveness

Risk-based Tools

Risk in Operations

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?

- MOBILE
- AR / VR
- CLOUD
- DATA

QMS

- MACHINE LEARNING
- RISK MANAGEMENT
- PREDICTIVE MAINTENANCE
- BIG DATA

IIoT
What is Quality’s Digital Transformation?

**MOBILE**

**AR / VR**

**CLOUD**

**DATA**

**Employing the Mobile EcoSystem:**
Leverage mobile for Real-time Audits
Real-time Inspections and monitoring
Offline and Online is key!

**QMS**

**IloT**

- MACHINE LEARNING
- RISK MANAGEMENT
- PREDICTIVE MAINTENANCE
- BIG DATA

www.etq.com
What is Quality’s Digital Transformation?

**Augmented and Virtual Reality:**
Enhances the Employee Training impact
Better training results; record and track
Better collaboration across Operations

- MOBILE
- AR / VR
- CLOUD
- DATA
- IIoT

QMS

- MACHINE LEARNING
- RISK MANAGEMENT
- PREDICTIVE MAINTENANCE
- BIG DATA
What is Quality’s Digital Transformation?

Cloud-Based Technologies:
- Tighter integration with Supply-Chain
- Limitless access from all over the world
- Lessens the IT Infrastructure burden

- MOBILE
- AR / VR
- CLOUD
- DATA
- IIoT

- MACHINE LEARNING
- RISK MANAGEMENT
- PREDICTIVE MAINTENANCE
- BIG DATA

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What is Quality’s Digital Transformation?

Data Collection and Analytics:
Pull in data from Quality Events
Predictive Alerts and Cross-Process data
Feeds into the overall Data/Risk Picture

MOBILE
AR / VR
CLOUD
DATA

QMS

MACHINE LEARNING
RISK MANAGEMENT
PREDICTIVE MAINTENANCE
BIG DATA

IIoT
What is Quality’s Digital Transformation?

Quality outputs that Contribute to the IIoT:

- Machine Learning
- Risk Management
- Predictive Maintenance
- Big Data

QMS

MOBILE
AR / VR
CLOUD
DATA

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
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

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Today (%)</th>
<th>Next Year (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remote monitoring</td>
<td>29%</td>
<td>26%</td>
</tr>
<tr>
<td>Energy efficiency</td>
<td>25%</td>
<td>23%</td>
</tr>
<tr>
<td>Asset reliability</td>
<td>24%</td>
<td>22%</td>
</tr>
<tr>
<td>Quality improvement</td>
<td>23%</td>
<td>21%</td>
</tr>
<tr>
<td>Production visibility</td>
<td>23%</td>
<td>20%</td>
</tr>
<tr>
<td>Internet enabled products</td>
<td>22%</td>
<td>18%</td>
</tr>
<tr>
<td>Business model transformation, e.g. selling capacity</td>
<td>19%</td>
<td>18%</td>
</tr>
<tr>
<td>Asset and material tracking</td>
<td>19%</td>
<td>18%</td>
</tr>
<tr>
<td>Traceability and serialization</td>
<td>17%</td>
<td>16%</td>
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<tr>
<td>Customer access to information</td>
<td>15%</td>
<td>15%</td>
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<tr>
<td>Improving safety</td>
<td>12%</td>
<td>12%</td>
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<tr>
<td>Supplier visibility</td>
<td>6%</td>
<td>8%</td>
</tr>
<tr>
<td>Improving environmental performance</td>
<td>5%</td>
<td>5%</td>
</tr>
</tbody>
</table>

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

IIoT

OPERATIONAL EXCELLENCE

CULTURE OF QUALITY

OUTPUT

OUTPUT

ERP
PLM
QMS
MES
SCM

MACHINE LEARNING
RISK MANAGEMENT
BIG DATA
PREDICTIVE MAINTENANCE

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Quality’s role in IIoT

Digital Transformation introduces new technologies to consume Quality Management
Technology Applied to Key operational areas impacts how we improve efficiency, manage Risks, and foster change.
Everywhere 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.
Quality’s role in IIoT

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**: Breeds better insights into operations, OOE, Efficiencies = OPERATIONAL EXCELLENCE
- **Risk-Based Thinking in the QMS**: Risk-Based Thinking in the QMS is the beginning of this transformation = Extends Quality beyond the department
- **Culture of Quality**: Fosters a broadening of the Quality effort beyond the Quality Department – a true culture of Quality

**Related Technologies**
- Machine Learning
- Risk Management
- Big Data
- Predictive Maintenance