Achieving Operational Excellence:  
How to Create a Culture of Quality for Desired Outcomes

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What we’re covering today

- What is Operational Excellence?
- What is the current state of the market?
- What are the key components to moving to an Operational Excellence mindset
Not just about the requirements....

It’s the mindset.

There should be a company-wide commitment/leadership around Quality.

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Not just about the requirements....

It’s the mindset.

- Quality for “external parties” (suppliers)
- Quality for People within your company
- Commitment to Quality for Customers
Not just about the requirements....

It’s the mindset.

Quality for People within your company

Commitment to Quality for Customers

TECHNOLOGY
Compliance Management

- Compliance is:
  - Quality
  - Operations
  - Safety
  - Governance
  - Risk
  - Regulatory
  - Financial
  - Sustainability

It’s BROAD.

[It’s also only a component of a larger theme]
Relationship of Compliance and Operational Excellence

- **Compliance**
  - Adherence to Guidelines
  - Specifications created by a standards body
  - Required in order to do business in certain industries
  - Abiding by both industry regulations and government legislation

- **Operation Excellence**
  - Adherence to company strategy
  - Specifications created to the sustainable improvement of key performance metrics.
  - Abiding by process to foster long-term change in organizational culture, not just remain in “compliance”

What’s Required  What’s Desired

Mindset Shift.
What’s Driving Quality Management?

Where is your current focus in Quality?

- **Registration to ISO and similar international standards**: 27%
- **Meeting customer and product regulatory requirements**: 41%
- **Product and process improvement driven by quality (e.g. reduce risks and variations)**: 22%
- **Strategic directives for operational efficiency (e.g. reduce costs and product defects)**: 10%

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Operational Excellence: Starts with People
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Challenge: Conversations around Quality are disparate? How can we create a single “Story of Quality” and tap into companywide, tribal knowledge?
Operational Excellence: Starts with People

OpEx brings people to a central place

A → B
Operational Excellence: Starts with People

OpEx brings people to a central place
Operational Excellence: Process Alignment

Aligning Processes to connect from one to the next – desired state is a true story from start to finish

Example:
Customer Complaint

Connects to:
Investigation / Risk Assessment

Connects to:
Corrective Action

Connects to:
Change Management

Becomes a report / Metric to demonstrate Quality

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Aligning Processes to connect from one to the next – desired state is a true story from start to finish

Example:
Customer Complaint

Desired State:
The Quality Report
Provides a full report on the history of an occurrence, from event detection to event correction.

Result:
an Audit /Inspection ready state

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Aligning Processes, connecting from one place to the next ensures no information is lost, the story of Quality is constant, and gives you full traceability on the entire process.

Fostering traceability throughout the process....
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!
What does the market view as risk?

Most Common Risk Areas

- Operations: 49%
- Safety: 21%
- Quality: 16%
- Financial: 8%
- Leadership: 2%
- Documentation...
Risk Levels by Risk Area

- Quality
- Safety
- Leadership
- Financial
- Documentation
- Operations

- Acceptable
- Tolerable
- Undesirable
- Intolerable
**Reasons for Assessing Risk**

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing Processes</td>
<td>17%</td>
</tr>
<tr>
<td>NonConformances</td>
<td>22%</td>
</tr>
<tr>
<td>Personnel</td>
<td>10%</td>
</tr>
<tr>
<td>Process Management</td>
<td>17%</td>
</tr>
<tr>
<td>Supplier Management</td>
<td>8%</td>
</tr>
<tr>
<td>Environmental, Health and Safety</td>
<td>17%</td>
</tr>
<tr>
<td>Other</td>
<td>13%</td>
</tr>
</tbody>
</table>

**Manufacturing Processes:** inconsistencies in the manufacturing process poses risk

**NonConformances:** Defects in products leading to risk

**Personnel:** Improper Training and Resource planning poses a risk

**Process Management:** Processes are not well-defined and could lead to high risk events

**Supplier Management:** Risks associated with Supplier non-compliance

**Environmental, Health and Safety:** Risks to the environment, health and safety within the organization

**Other:** Risks associated with other items
Yeah but...
How do I start my risk management journey?
Planning your QMS with risk in mind...

- Identify risks and opportunities to influence QMS performance
- Determine how you’re going to handle those risks
- Build risk treatment options
- Define actions to address these risks
Planning your QMS with risk mind...

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

How to start Identifying risks?
- Survey your operations
- Audit, Survey, collect, analyze

Hazard

Operational
- Severity
- Frequency

Financial
- Severity
- Frequency

Environmental
- Severity
- Frequency

Manufacturing
- Severity
- Frequency
Planning your QMS with risk in mind...

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

- 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

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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”

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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

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Planning your QMS with risk in mind

1. **Identify Risks**
2. **Evaluate Risks**
3. **Treatment of Risks**
4. **Take Action**

**DOCUMENT YOUR ACTIVITIES**

- How? Audit Findings, Survey Results, Report on Findings
- Document your Evaluation: Control your methods, tools, processes
- Document the treatment, the overall decision factors
- Link Assessments to Actions taken, improvements made

**Document the process in order to have traceability.**
Planning your QMS with risk in mind

Identify Risks → Evaluate Risks → Treatment of Risks → Take Action

Proactive Continuous Improvement

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!
Planning your QMS with risk in mind

Operational Excellences leverages risk to EXPAND the story of Quality to others in the organization.

They may not all “speak” quality, but they certainly will speak RISK.

Identify Risks
Evaluate Risks
Treatment of Risks
Take Action

Proactive Continuous Improvement
Potential but not realized Hazards: Survey improvement areas
How can we determine the impact of potential events?
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Operational Excellence: Relies on meaningful reporting

Reporting: Have the ability to produce metrics on problem areas and their causes

The Takeway:

We’re doing what’s “required”
Are we doing what's “desired”?

Operational Excellence drives for deeper look into Key Performance indicators to achieving improvement.

24% are not doing this, and 34% are partially doing this.

Majority is not getting the desired effect!
Operational Excellence: Relies on meaningful reporting

We may be reporting, but are we getting the whole story?
What is the “single source of the truth”?
Centralization of the data brings in people, processes and technology into a single source – more data, but organized in a meaningful way!
Operational Excellence: Manages change effectively

Culture of Continuous Improvement
Change Management is a process that impacts all areas of the business.
By incorporating the same connected process to our change, we can manage more efficiently.
Summary

- Operational Excellence assumes we’ve controlled the required, and are ready to move to desired outcomes
- Operational Excellence revolves around
  - People: Having a centralized way to consume company-wide knowledge
  - Processes: Having a process that provides a connected way from event detection to event correction
  - Factors in Risk: leverages risk-based thinking to “level the playing field”
  - Builds meaningful, actionable reports: A “Single Source of the Truth”
  - Drives Change management: Treats as a process that is efficient and repeatable
- Move from just Required, to Desired – impact the business on a strategic level
Thank you! Questions?

**EtQ**

- Designed for small workgroups in Quality, EHS and Compliance looking to track events, issue action items and launch corrective actions.
- Designed especially for SMB companies that are looking for full functionality in an affordable SaaS solution.
- Designed for global, multi-site deployments, with the need to integrate compliance across the enterprise.

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