Benchmarking Risk and Compliance with your Peers: How Do You Measure Up?

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What we’re covering today

- Compliance – what are we talking about?
- Shift in the mindset of compliance along with operational excellence
- Compliance Grader – questions and results from peers
- Measuring Risks – what is being tracked in Risk management today?
- How to build a risk management program for your organization
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

Mindset Shift.

What’s Desired
Not just about the processes….

It’s the mindset.

There should be a company-wide commitment/leadership around Quality Safety and Compliance.
The Compliance Grader

• We wanted to see where companies stood in their compliance, and how it factored to their operational excellence goals:
Compliance Grader – Questions

- Document Control, Training and Deviations
- Corrective Action Timeliness
- Audit Management Controls
- Reporting and Key Compliance Metrics
- Customer Feedback and Action planning
- Change Management Processes
- Risk Management Processes

Scores

<table>
<thead>
<tr>
<th>Strong Compliance Grade</th>
<th>85-100 pts.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Companies are in compliance and controlling processes</td>
<td></td>
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<table>
<thead>
<tr>
<th>Good Compliance Grade</th>
<th>70-85 pts.</th>
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<tbody>
<tr>
<td>Better compliance management and control, with only a few areas of improvement needed</td>
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<table>
<thead>
<tr>
<th>Neutral Compliance Grade</th>
<th>50-69 pts.</th>
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<tr>
<td>Some areas of improvement are needed</td>
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<table>
<thead>
<tr>
<th>Poor Compliance Grade</th>
<th>0-50 pts.</th>
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<tbody>
<tr>
<td>All or a majority of the areas are not in control</td>
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Making the Grade – Compliance Stats

Overall Result:
- 58% are scoring well in their compliance
- 26% are just getting by
- 16% are in poor compliance

This is aggregate – to truly see where compliance is needed, we need to drill down!
Making the Grade – Documentation and Training

The Takeway:
Documentation and Training are key aspects of compliance...
Companies are tracking well – it’s a requirement and part of the core to compliance.

Document Control: Documents are reviewed consistently every 1 to 2 years
- Yes: 60%
- Partially: 18%
- No: 22%

Training: Training records are tracked and maintained
- Yes: 62%
- Partially: 26%
- No: 12%

Deviations: You can approve a temporary deviation for a specification/element that is clearly visible on the document
- Yes: 46%
- Partially: 18%
- No: 36%
Making the Grade – Corrective Action

The Takeway:
Overdue Corrective Actions are a major source of non-compliance!
Making The Grade – Audit Management

The Takeaway:
Are we doing audits properly? Are we looking at it from a risk-based view?

Audits: Audit checklists include a reference to the most at risk controls in the quality and safety system.
Making the Grade – Managing Change

The Takeway:
We are managing change well – processes are in place and seem to work.
Making the Grade - 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!

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Making the Grade – Post-Market Feedback

Post-Market: Are tracking customer feedback and the resulting actions

The Takeway:

50/50 – Customer feedback is critical towards what is desired.

Customer-focused continuous improvement is needed!
Making the Grade – Risk Management

Risk: User of risk assessment to prioritize the relative value of corrective actions

The Takeway:
Risk is still a concept that is not fully utilized by organizations.
Making the Grade – Risk Management

Risk: Use of risk management to identify continuous improvement initiatives

The Takeway:

Leveraging Risk is the link from taking compliance related activities and driving towards operational excellence and improvement.

How does risk take what’s required and drive towards what’s desired?
More on Risk Management

Risk is a major area for improvement

But...what does the data say?
Risk Tracking – the tool

- We provided a simple Risk Assessment tool

http://risktracker.versetools.com/
### Risk Categories

<table>
<thead>
<tr>
<th>Probability (P)</th>
<th>Frequent</th>
<th>Probable</th>
<th>Occasional</th>
<th>Improbable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity (S)</td>
<td>Negligible</td>
<td>Marginal</td>
<td>Critical</td>
<td>Catastrophic</td>
</tr>
</tbody>
</table>

- **Acceptable Risk:** No recall, regulatory reporting or Corrective Action is required. However, you may want to consider for improvements to the product or processes.

- **Tolerable Risk:** You may want to issue a recall only for events resulting in a physical injury or cost impact. While a Corrective Action is not required, you may want to consider voluntary action.

- **Undesirable Risk:** This risk is As Low as Possible, but undesirable for the business. A recall or investigation is likely unless there is clear mitigation. Corrective Action is usually required unless there is a documented reason.

- **Intolerable Risk:** Requires a product recall, investigation, and immediate action on the product or process. A Corrective Action must be initiated and a regulatory report may be required.
Risk Levels by Risk Area

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

Acceptable  Tolerable  Undesirable  Intolerable

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**Reasons for Assessing Risk**

- **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…

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

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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
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”
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

Identify Risks → Evaluate Risks → Treatment of Risks → 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!
Summary

• Understand the shift in combining your compliance management with Operational Excellence

• Companies are doing well at many things required, but still have work on what’s desired

• Build a program that incorporates risk into your Quality program

• Risk is becoming a new standard of thinking – “risk-based thinking”

• Plan your QMS with risk in mind