EQMS Solution Selection Best Practices for Global Enterprises

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Agenda

• About LNS Research
• EQMS drivers
• Strategies for gaining executive support over the project lifecycle
• How to develop a core set of EQMS requirements and a long-term solution vision for success
• Must-have EQMS functionality
• Evaluation best practices
• Recommendations
About LNS Research

*LNS is technology research firm that helps clients innovate and achieve operational excellence.*

We deliver the market intelligence and thought leadership needed to move markets forward.

Our differentiators:
- Experienced analysts
- Primary research
- Deep industry contacts
- Interactive data visualizations
Research Model

- **Strategic Objectives**
  - What can take your organization to the next level?

- **Metrics**
  - Which metrics align to your Strategic Objectives?
  - How do you compare to Market Leaders?

- **Benchmark Performance**
  - Where is your company’s performance gaps in metrics?

- **Model of Operational Excellence**
  - What set of people, process, and technology capabilities should be implemented to close the performance gap?

- **Measure, Validate, and Improve**
  - Incorporate learning from benchmarking work into future endeavors
Research Demographics

- 1200+ LNS Research’s Quality Management Survey
LNS Research’s Council Members Include:

ALCOA  
Starbucks  
Lindt  
Owens-Illinois  
Kellogg's  
L’Oreal  
Corbion  
Whirlpool  
Onyx Pharmaceuticals  
Plexus  
BIO-RAD  
DAIKIN McQuay  
Newell Rubbermaid  
Motor Harley-Davidson  
Oriflame Sweden  
Fresenius Medical Care  
Zimmer  
Discount Tire

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EQMS Drivers
EQMS Drivers

Issues in quality management are consistent

Top Operational Challenges

- Disparate quality systems and data sources: 37%
- Quality is considered a ‘department’ not a ‘responsibility’: 34%
- Quality metrics are not effectively measured: 34%
- No formal process for managing risk: 25%
- No formal process for continuous improvement: 22%
- Lack of visibility into supplier quality: 20%
- No formal process for capturing non-conformances: 14%
- Audit and compliance management is ad-hoc: 14%
- Engineering lacks feedback on quality: 14%
- Lack of executive support: 11%

Unfortunately, as organizations have introduced technology as demands presented, especially in core processes, a patchwork of fragmented tools came into being.
### EQMS Drivers

**Processes automated using software**

<table>
<thead>
<tr>
<th>Process</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Control</td>
<td>48%</td>
</tr>
<tr>
<td>Non-Conformances/Corrective and Preventative</td>
<td>46%</td>
</tr>
<tr>
<td>Employee Training</td>
<td>37%</td>
</tr>
<tr>
<td>Complaint Handling</td>
<td>35%</td>
</tr>
<tr>
<td>Statistical Process Control (SPC)</td>
<td>28%</td>
</tr>
<tr>
<td>Change Management</td>
<td>26%</td>
</tr>
<tr>
<td>Reporting</td>
<td>25%</td>
</tr>
<tr>
<td>Audit Management</td>
<td>25%</td>
</tr>
<tr>
<td>Supplier Quality Management</td>
<td>22%</td>
</tr>
<tr>
<td>Calibration Management</td>
<td>20%</td>
</tr>
<tr>
<td>Compliance Management</td>
<td>20%</td>
</tr>
<tr>
<td>Failure Mode and Effects Analysis (FMEA)</td>
<td>15%</td>
</tr>
<tr>
<td>Environment, Health, and Safety (EH&amp;S)</td>
<td>14%</td>
</tr>
</tbody>
</table>
Companies are increasing their spend on the goals of achieving quality excellence.

Technology continues to evolve and EQMS providers continue to invest and enhance functionality and delivery options.
Executive Support
Evaluating Maturity

- As maturity progresses, decisions tend to be made with proactivity in mind
- Market leaders ultimately make decisions with predictability
## Maturity & Competitive Advantage

<table>
<thead>
<tr>
<th>Category</th>
<th>Ad Hoc</th>
<th>Con.</th>
<th>Pro.</th>
<th>Agi.</th>
<th>Market Leader</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategy &amp; Execution</td>
<td>Quality disconnected from corporate objectives</td>
<td></td>
<td></td>
<td></td>
<td>Quality fully integrated with corporate objectives</td>
</tr>
<tr>
<td>Leadership &amp; Culture</td>
<td>Quality is a department rather than a shared responsibility</td>
<td></td>
<td></td>
<td></td>
<td>Quality integral part of overall Operational Excellence</td>
</tr>
<tr>
<td>Organizational Capabilities</td>
<td>Quality distinct from corporate structure. Not in goals or incentives</td>
<td></td>
<td></td>
<td></td>
<td>Quality fully integrated into corporate structure</td>
</tr>
<tr>
<td>Business Process Excellence</td>
<td>Disconnected and disparate</td>
<td></td>
<td></td>
<td></td>
<td>Globally integrated and Harmonized. Fully embracing emerging capabilities</td>
</tr>
<tr>
<td>Technology Capabilities</td>
<td>Disconnected and disparate</td>
<td></td>
<td></td>
<td></td>
<td>Predictive, role-based, real-time metrics connected to corporate goals</td>
</tr>
<tr>
<td>Performance Management &amp; KPIs</td>
<td>Non-role based, manual KPIs, disconnected from corporate goals</td>
<td></td>
<td></td>
<td></td>
<td>Predictive, role-based, real-time metrics connected to corporate goals</td>
</tr>
</tbody>
</table>
Evaluate Technology Maturity

- Technology should be deployed with the mindset that it will support (not replace) business process and human resources
- Tangible ROI
- Managing risk
- Cost of Quality across the value chain
  - Supplier quality management
  - Waste reduction
  - NCRs
  - Customer complaints
  - Track & accelerate NPI
Prioritize and Phase In

- Map technology to quality objectives by process (customer sentiment & operational and quality excellence)
- Project charter: inclusive, communicative & transparent
- Finite tactical and strategic configuration and deployment goals
- Track efficiencies and provide $ ROI at every opportunity

“New quality tools enable Quality as a competitive advantage”
VP Global Quality, $&B manufacturing services company
The selection of an EQMS solution is a complex undertaking that demands multi-level, multi-regional, cross-functional, and inter-departmental collaboration.
EQMS Solution Selection Best Practices

The Keys to Ensuring the Best Fit and Successful Implementation

Key elements include:

- Defining and ratifying the project charter
- Identifying, educating, and empowering the team
- Researching vendor landscape
- Constructing the request for proposal (RFP)
- Conducting objective evaluations
- Piloting a solution and awarding a decision
Defining and ratifying the project charter

- Master document outlining how technology facilitates achievement of quality objectives
- As is – to be vision
- Include impact – driver for quality culture
- Scope (process, geography, BU)
- Matrix of gaps & existing technology
- Outline phases
- Consistent comms - ‘evangelists’
Identifying, educating, and empowering the team

- Cross-functional team with key roles for IT
  - Quality (exec / corporate / plant / engineers)
  - IT leadership + IT SMEs
  - R&D & engineering
  - Regulatory
  - Manufacturing ops
  - Packaging & logistics
  - EHS
  - Sales & customer service
  - Finance, legal & field support

- Organizational readiness

“Our selection team consisted of listeners and doers - everyone understood clearly what was required of them”

Director Global QEHS Systems
Researching vendor landscape

- Avoid immediate bias (establish terms with IT)
- From informal beginnings through formal information collation
- Develop central repository and collate, share and communicate collateral & findings
- Web searches and subscribe to free online events
- Utilize events, peer networks & groups
- Leverage analyst content including solution selection guides and spotlight research
EQMS Selection Persona

Bias
- IT towards existing enterprise solutions (typically ERP/BPM)
- Evidence of end user bias for quality group (adoption is key to success)
Researching vendor landscape

- Establish long list for inclusion in RFI / RFP process
- Be candid with vendors – describe timeline and YOUR process
- Ongoing research may be parallel to RFP construction
Constructing the request for proposal (RFP)

- **RFP Core**

  - **Legal:** NDA, Statements of non-liability
  - **Vendor Info:** Financial, Org Structure, Domain expertise, Customer References, Release Schedule & Roadmap
  - **Functional, Non Functional & Technical Requirements:** Migration/Integration
  - **Licensing Structure, Implementation Costs, Support & Maintenance:** Doc: MSA, Doc: SLA
  - **Implementation Methodology, Training & Project Support**
Build Requirements

- Subject matter experts (technical & process)
- Cross-functional selection team
- Vision of to-be - improve processes
- Database platform, on premise / cloud, browser agnostic etc.
- Functionality by process
- Security
Requirements

- Interoperable (APQP-FMEA-Audit-CAPA-Documents-NCRs-Incidents-Risk)
- Integration (ERP, PLM, CRM, MES, SPC)
- Security (Federated (sso) + Roles + supplier access)
- Configurable: Modules, workflows, forms, notifications
Requirements

• Reporting & Analytics
• Mobility (responsive design + app ecosystem)
• Migration tools/templates etc.
• Extensibility potential (acquisitions + additional processes)
Functional requirements

Quality Management System (example)

- Audit Management
  - Planning / scheduling & availability (search interrogate + visual)
  - Protocols library (content / build)
  - Protocols build, sections, conditional sections, questions, cloning
  - Scoring & weighting
  - Guidance, evidence (uploads & pictures)
  - Interop: findings – NCR – CAPA (context)
  - Collaboration
  - More....
Functional requirements

- Include high-level processes in RFP if possible
- Base detailed demo script around these
Develop standard costs template for:
- Licensing
- Implementation
- Project management
- Training
- Ongoing support
- Maintenance & enhancement

Multiple approaches to licensing are available, construct the template to accommodate:
- License bands
- Concurrency,
- Subscription
- Hosting and/or hardware
- Other costs
Implementation

Approach and resources for implementation:

- Methodology
- Example plans with resource levels (turnkey through train-trainer)
- Implementation tools & aids library
- Professional services credentials
Evaluation

Remote demonstrations

• Limit time
• Provide bulleted (must-hit) list
• Use standard (high level) evaluation criteria
• You MUST see evidence of regulatory compliance experience if applicable to you here – no exception
• Look for elegance in interoperability, best practices & reporting/analytics
• Identify flexibility in forms, workflows and report generation

!! Beware the sandbox
Questions for references.

- Configuration vs. customization
- Application performance
- Implementation timescale
- Overall fit and post-sale support
- User adoption challenges encountered
- Integration points
- Data migration
- Change/new feature request process
- Licensing levels required based on final roll-out (especially for concurrent models)
- Insight into actual ROI and the perception of the solution overall
- Release schedule and version in use versus current available
In depth demonstrations

- Multi-process deep dive
- Vendors provided scripts
- Ideally F2F
- You MUST see detail of regulatory compliance experience if applicable to you here – no exception
- Examples of interoperability and best practices
- Expect detailed configuration of forms, workflows and report generation
- Require dashboards/scorecard build example
Conducting objective evaluations

• Detailed evaluation/scoring using requirements

<table>
<thead>
<tr>
<th>EQMS Criteria with Description</th>
<th>Criteria Comment (Evaluator)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical</td>
<td></td>
</tr>
<tr>
<td>Offline capability</td>
<td>Native apps for inspections/audits - local storage if not connected</td>
</tr>
<tr>
<td>Integration capabilities</td>
<td>Mainframe (Veh integration / HR data etc)</td>
</tr>
<tr>
<td>Ability to add Corporate Branding</td>
<td>JM Family Branding &amp; colors</td>
</tr>
<tr>
<td>Localization (Languages)</td>
<td>E.D. Spanish</td>
</tr>
<tr>
<td>Notifications-engine</td>
<td>Required for all processes/configurable - trg updates, new docs, failed &amp; completed tasks</td>
</tr>
<tr>
<td>Reporting Platform</td>
<td>Crystal, SSRS or other for building reports in addition to OOTB library</td>
</tr>
</tbody>
</table>

Documents & Training

1. A Document Control (SOXs/Wos/Policies/etc)
   - Can assign owner and/or owners of document (persons and/or roles)
   - Ability to assign single or multiple reviewers (serial or broadcast)
   - Can force signatures (or equivalent) for approvals
   - Allow comments by reviewers & bounce-back
   - Ability to track changes to documents (full audit trail - what, who, when)
   - Ability to work on documents (unseen by non owners/approvers until p)
   - Auto-version increments & unique identifiers for documents
   - Multiple (configurable) fields for categories & other metadata
   - Provides personal library by user profile (role/work area/ad hoc etc)
   - Can acknowledge/user having read latest published version + allows sl
   - Can associate with role/work areas/processes/shop/location etc (links)
   - Upload attachments (also controlled) of any type
   - Convert to PDF (or equivalent locked type)
   - Watermarks (configurable) for printed documents

| Vendor 1 |
|-----------------|-----------------|-----------------|
| Needs/requirements | Importance (Role/Team) | Score | FINAL | Comments |
| Yes - unreserved | Low              | 1.5 | 1.5 | Lorem ipsum...null sine blah |
| Yes - unreserved | Medium           | 1.5 | 3 | Lorem ipsum...null sine blah |
| Yes - unreserved | Low              | 1.5 | 1.5 | Lorem ipsum...null sine blah |
| Yes - unreserved | Medium           | 1.5 | 3 | Lorem ipsum...null sine blah |
| Yes - unreserved | Low              | 1.5 | 1.5 | Lorem ipsum...null sine blah |
| Yes - unreserved | Medium           | 1.5 | 3 | Lorem ipsum...null sine blah |

| Vendor 4 |
|-----------------|-----------------|-----------------|
| Needs/requirements | Importance (Role/Team) | Score | FINAL | Comments |
| Yes - unreserved | High             | 1.5 | 4.5 | Lorem ipsum...null sine blah |

| Vendor 2 |
|-----------------|-----------------|-----------------|
| Needs/requirements | Importance (Role/Team) | Score | FINAL | Comments |
| Yes - unreserved | High             | 1.5 | 4.5 | Lorem ipsum...null sine blah |

| Vendor 3 |
|-----------------|-----------------|-----------------|
| Needs/requirements | Importance (Role/Team) | Score | FINAL | Comments |
| Yes - unreserved | High             | 1.5 | 4.5 | Lorem ipsum...null sine blah |

| Vendor 5 |
|-----------------|-----------------|-----------------|
| Needs/requirements | Importance (Role/Team) | Score | FINAL | Comments |
| Yes - unreserved | High             | 1.5 | 4.5 | Lorem ipsum...null sine blah |
In most scenarios, overarching/common requirements can be woven into scripts:

- Workflow rules
- Configured forms
- Notifications & escalations (email, etc.)
- Task listing, delegation, scheduling & calendars
- Integrated lookup
- Access privileges, roles & security
- Reporting out of the box & analytics
- Attachments & uploads
- Data imports
- Mobile capability & offline use
Conducting objective evaluations

- **Scripts (multiple user personas)**

  **CAPA Management Demonstration Script - Quality**

  In preparation for the upcoming demonstration of your software solution for CAPA Management
  module, we have prepared the following documents:

  - CAPA Management Workflow - Quality
  - Sample Data - Quality

  The CAPA Workflow shall be used as a guide for demonstrating the types of features that the
  participants will be interested in viewing. The CAPA covers 5 types of events: Customer complaints,
  internal non-conformances, external non-conformances, Preventive actions and Management of
  change.

  Using the Workflow and the Data documents as a guide:

  - Demonstrate for each type of event the steps in the workflow process.
  - Begin the demonstration as an infrequent user.
  - Demonstrate, at each step, the required login to the system for each specific user.
  - Demonstrate how to complete a Root Cause Analysis (eg, 5 Whys, Fishbone) using the CAPA
    solution tools.
  - Demonstrate how to attach files, including photographs, word documents, excel files.
  - The following XXX Personnel (roles included in Sample CAPA Data) can be used for
    demonstration of notifications of events, assignment of corrective actions, etc.

    - Jim Jones – Jim.Jones@rubbermaid.com
    - Jane Smith – Jane.S@rubbermaid.com

  - Demonstrate the ability to interact with the software solution as much as possible during the
    demo (i.e. send emails to the XXX Personnel - listed above with links to access the system, allow
    XXX Personnel to navigate the system and access various screens and reports, etc.).

    - Generate CAPA logs for each of the XXX locations.
    - Create roll-up reports. If additional data is required, it should be generated by vendor.
    - Demonstrate how data can be viewed, trended, exported, tabulated, graphed, etc.
    - Demonstrate software solution capability for generating dashboards for different levels and
      geographies of the organization. In this demonstration the viewing of the dashboard should be from
      the user perspective (i.e., the gain or benefits)
Decision / Pilot

- Meet very soon after in-depth evaluation to compare/compile results
- Decision demands majority support for success
- Consider a clearly defined short pilot for initial selection to prove out performance, availability, and some configuration simple process mock scenario.
Recommendations

• Establish the project charter
• Recruit/assign multi-region, cross-functional selection team
• Selection team must meet regularly and maintain all documentation centrally
• The request for proposal design is critical. Involve all stakeholders and provide templates to vendors
• Allow enough freedom outside of the RFP templates for vendors but not to undermine cross-vendor comparison
• Direct vendors in demonstrations using scripts and provide process diagrams where possible
Recommendations

- Vendors assessed against templates for requirements
- Shortlisted vendors should be met F2F and closed door analysis done very soon after final vendor demo
- Closely scrutinize references with specific criteria regarding functionality, adoption, release schedule, implementation, etc.
- Consider a clearly defined short pilot for initial selection to prove out performance, availability, and some configuration
Thank You!!