EQMS Solution Selection Best Practices for Global Enterprises

Rob Harrison
Research Analyst

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

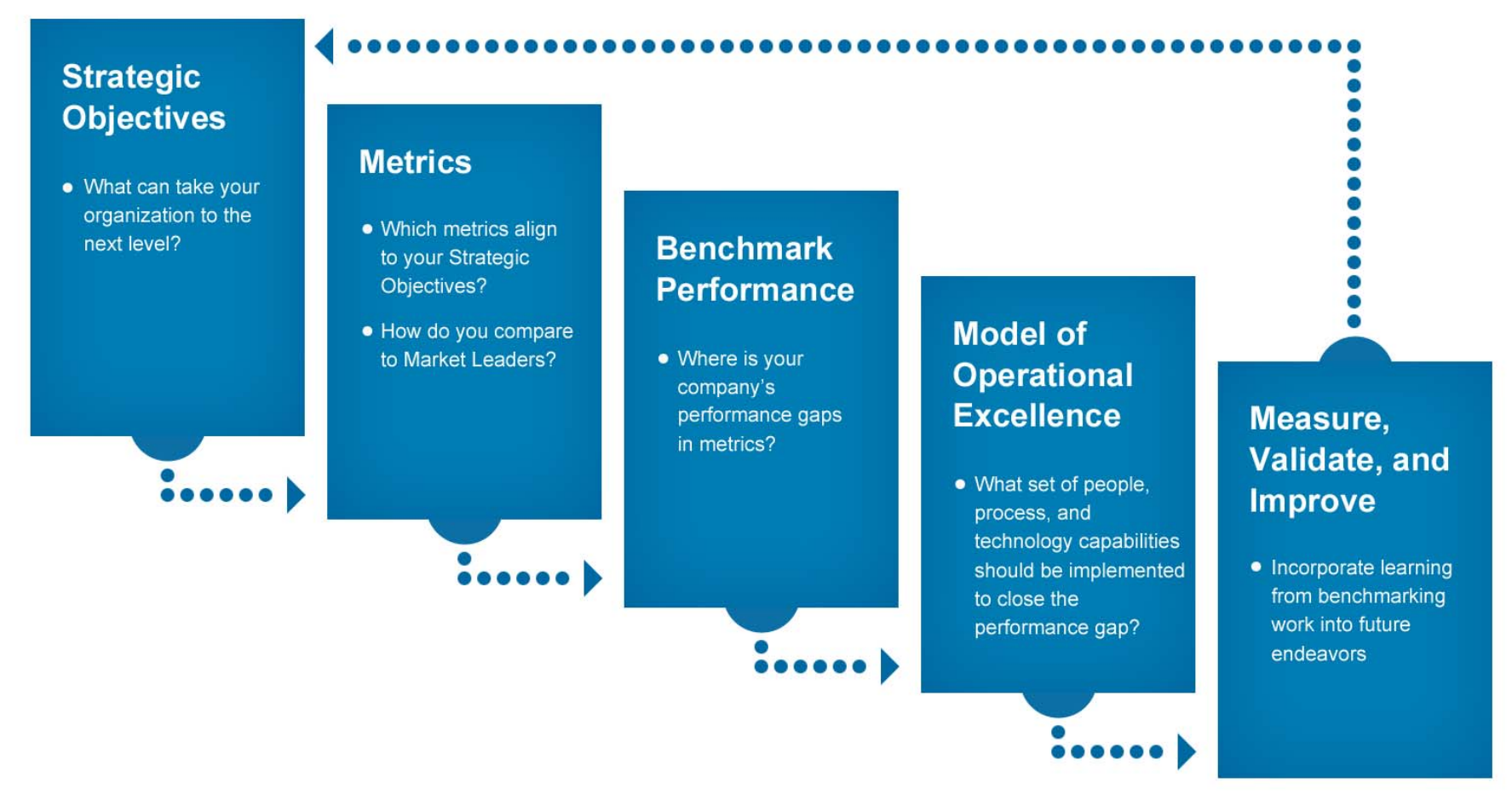
LNS is technology research firm that helps clients innovate and achieve operational excellence.

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

Our differentiators:

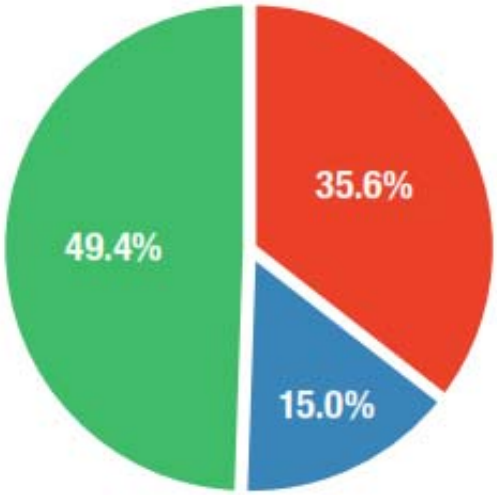
- ❑ Experienced analysts
- ❑ Primary research
- ❑ Deep industry contacts
- ❑ Interactive data visualizations

Research Model



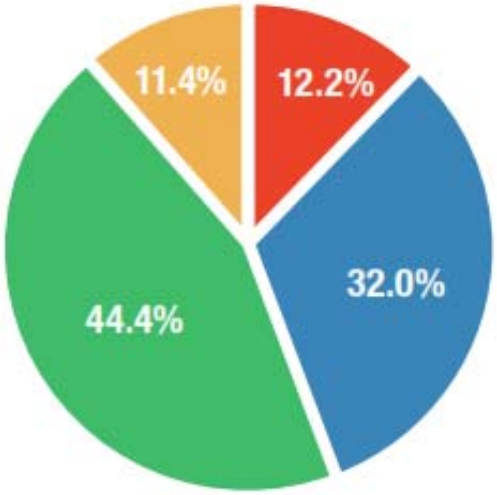
Research Demographics

- 1200+ LNS Research's Quality Management Survey



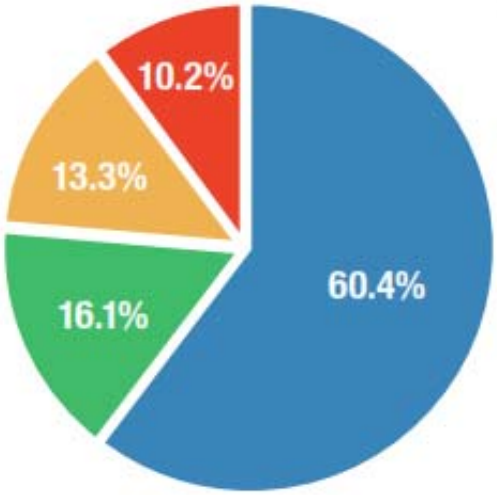
COLOR BY
COMPANY REVENUE

- Small: $0 - $250MM
- Medium: $250MM - $1BB
- Large: $1BB+



COLOR BY HQ LOCATION

- North America
- Europe
- Rest of the World
- Asia / Pacific



COLOR BY INDUSTRY

- Discrete Manufacturing
- F&B / CPG
- Life Sciences
- Process Manufacturing

LNS Research's Council Members Include:

FRESENIUS
MEDICAL CARE

EQMS Drivers

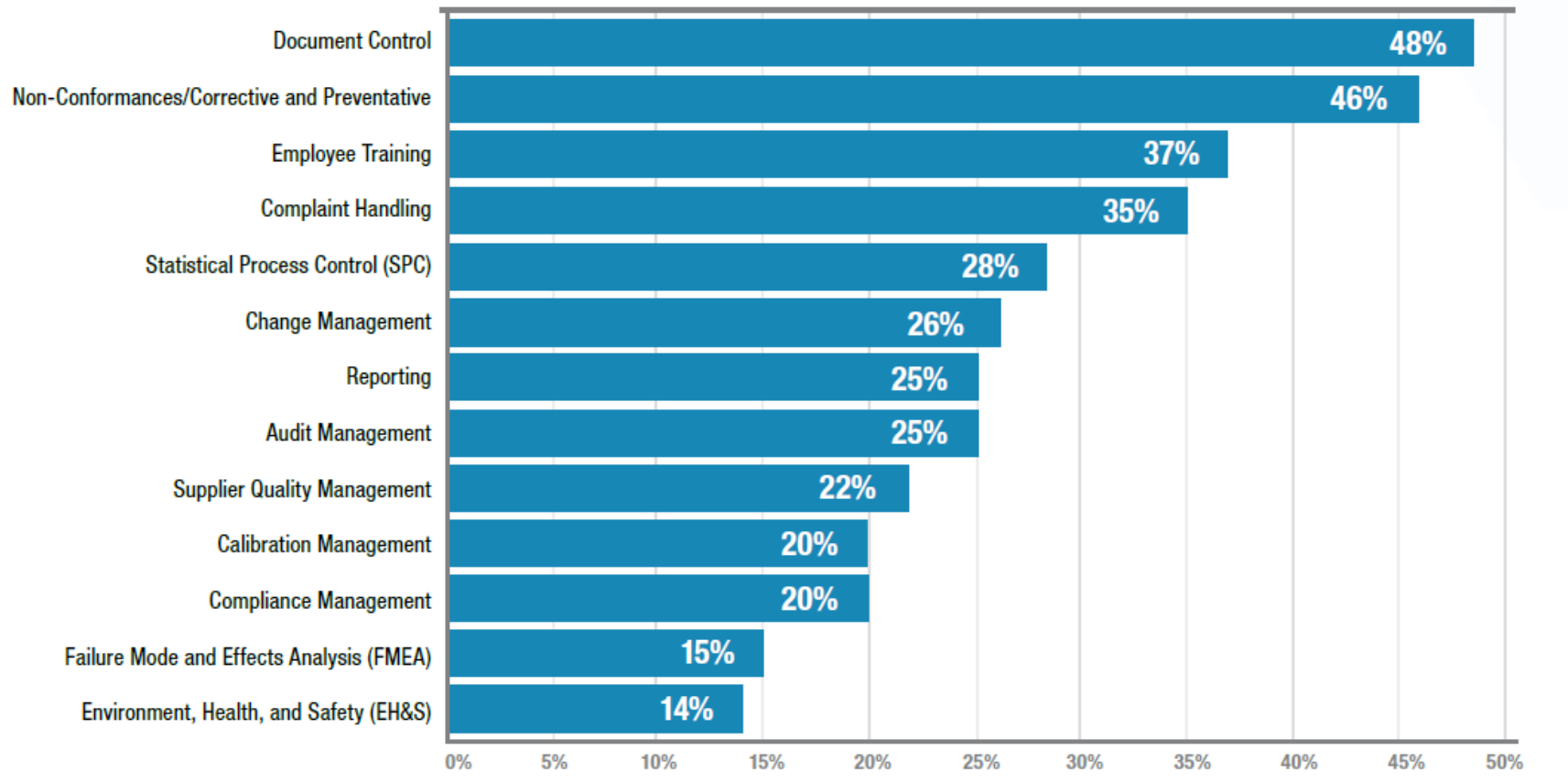
EQMS Drivers

Issues in quality management are consistent

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

EQMS Drivers

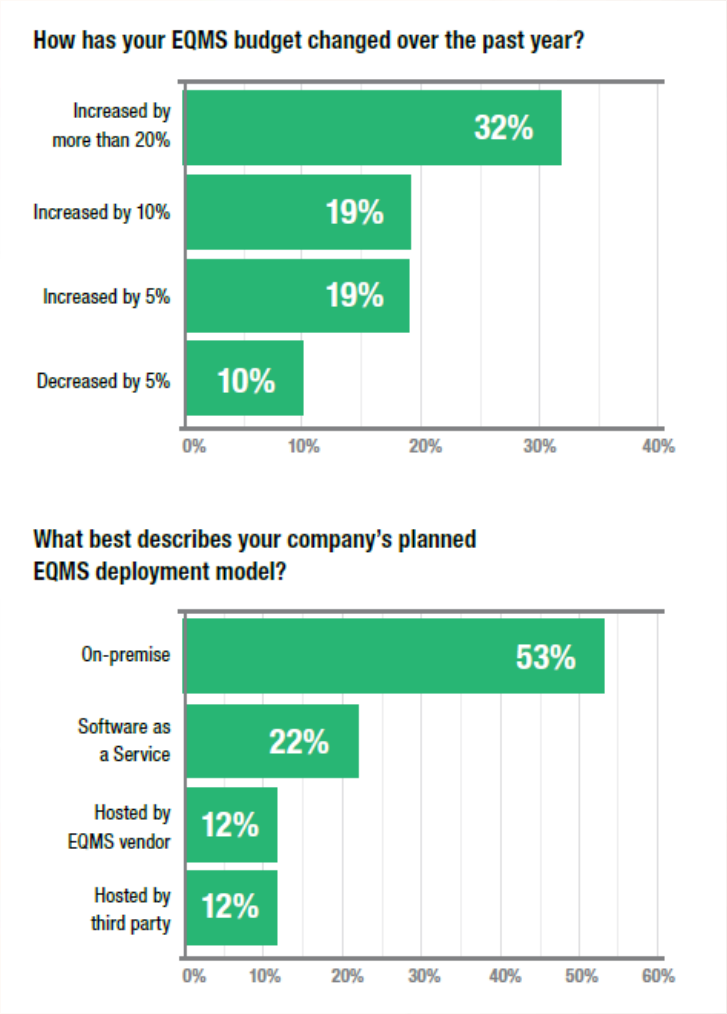
Processes automated using software



EQMS Budget & Delivery Model

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

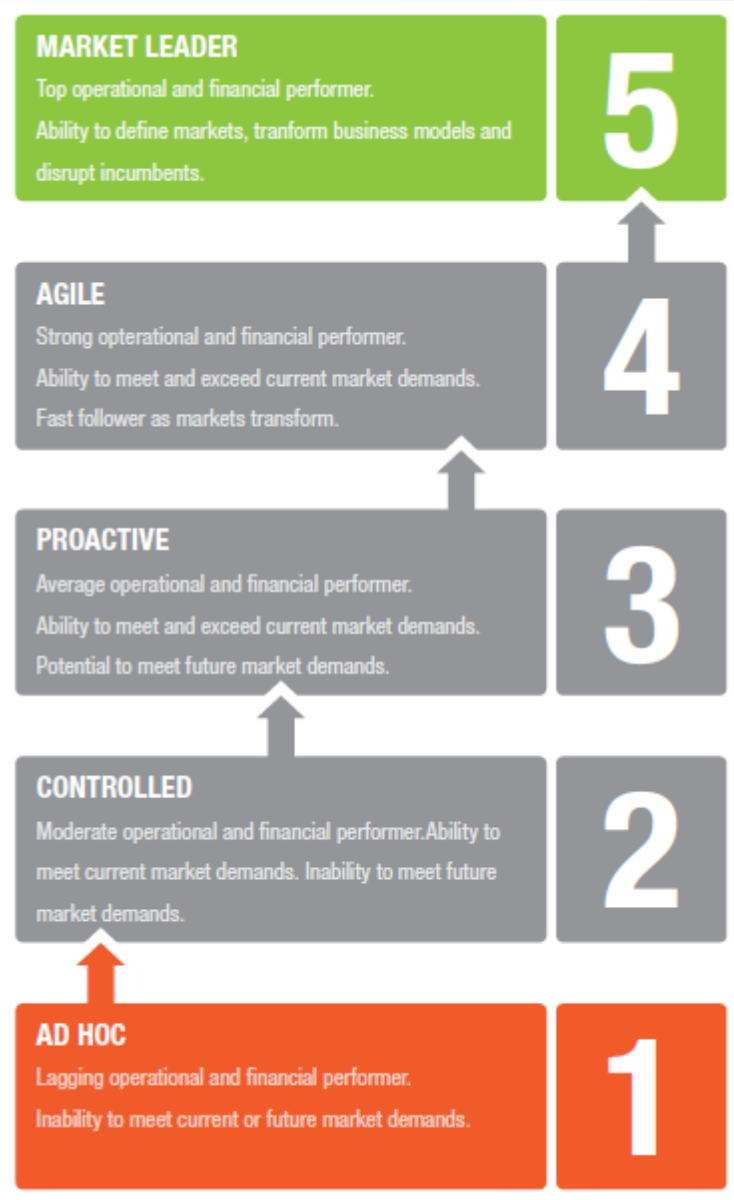


Executive Support

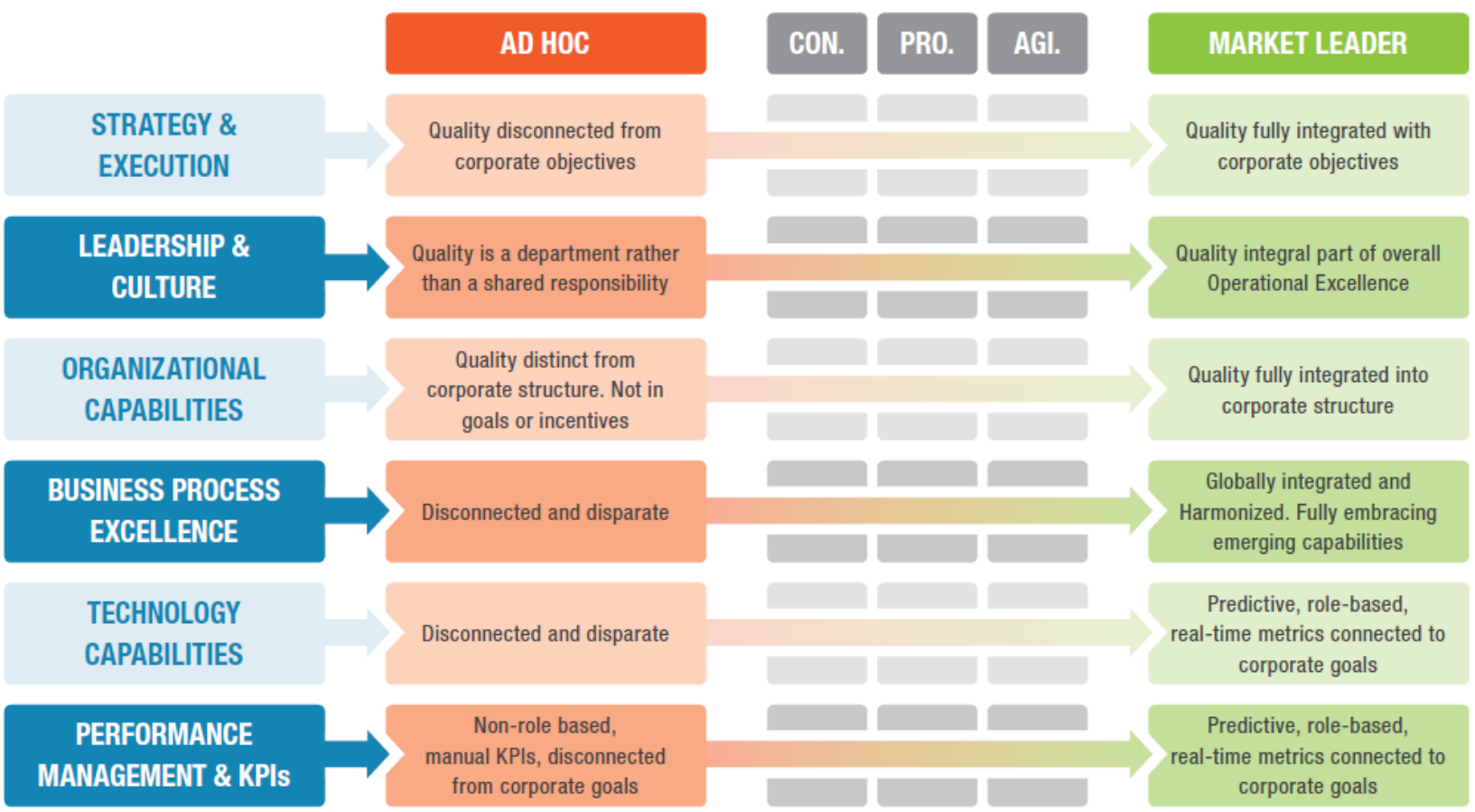
Current State

Evaluating Maturity

- As maturity progresses, decisions tend to be made with proactivity in mind
- Market leaders ultimately make decisions with predictability

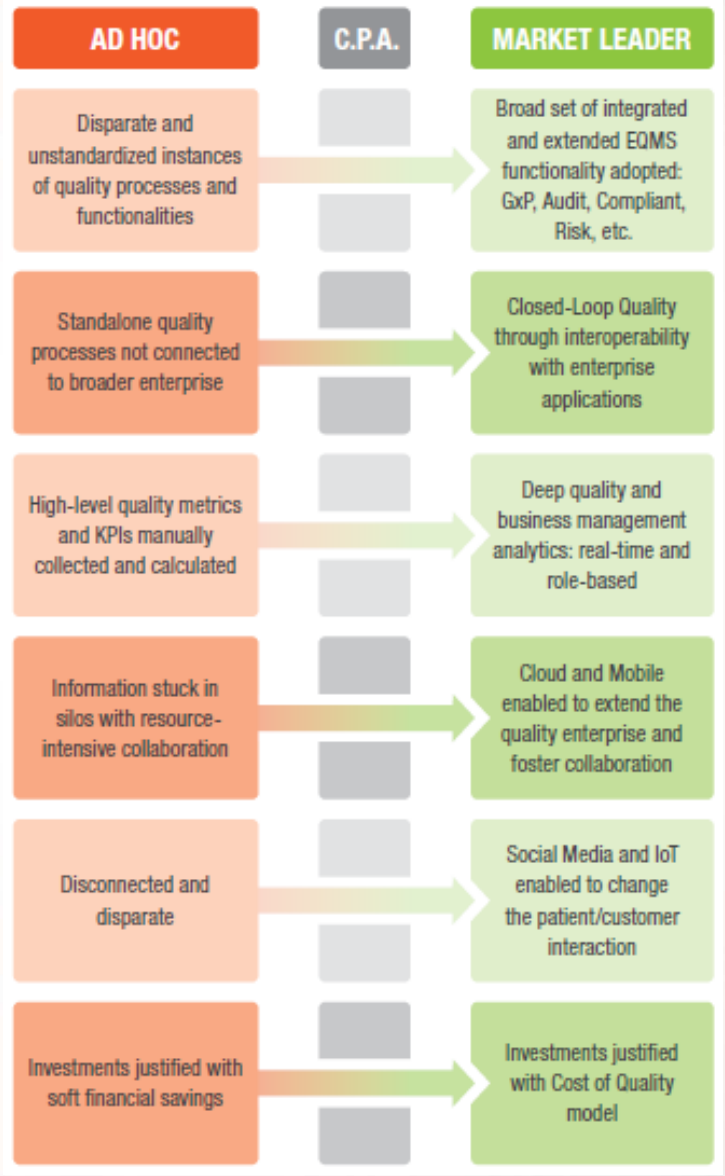


Maturity & Competitive Advantage



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,
$8B manufacturing services company

EQMS Solution Selection Best Practices

EQMS Solution Selection Best Practices

The Keys to Ensuring the Best Fit and Successful Implementation

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

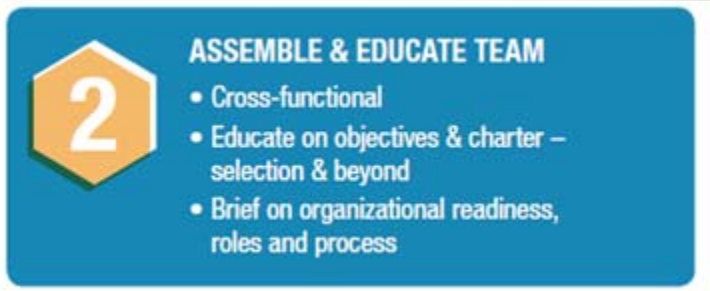
- Master document outlining how technology facilitates achievement of quality objectives
- As is – to be vision
- Include impact – driver for quality culture
- Scope (process, geography, BU)
- Matrix of gaps & existing technology
- Outline phases
- Consistent comms - ‘evangelists’

“We distilled our project charter to a single page”

Director Global QEHS Systems, $5B CPG manufacturer

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



"Our selection team consisted of listeners and doers - everyone understood clearly what was required of them"
Director Global QEHS Systems

- **Organizational readiness**

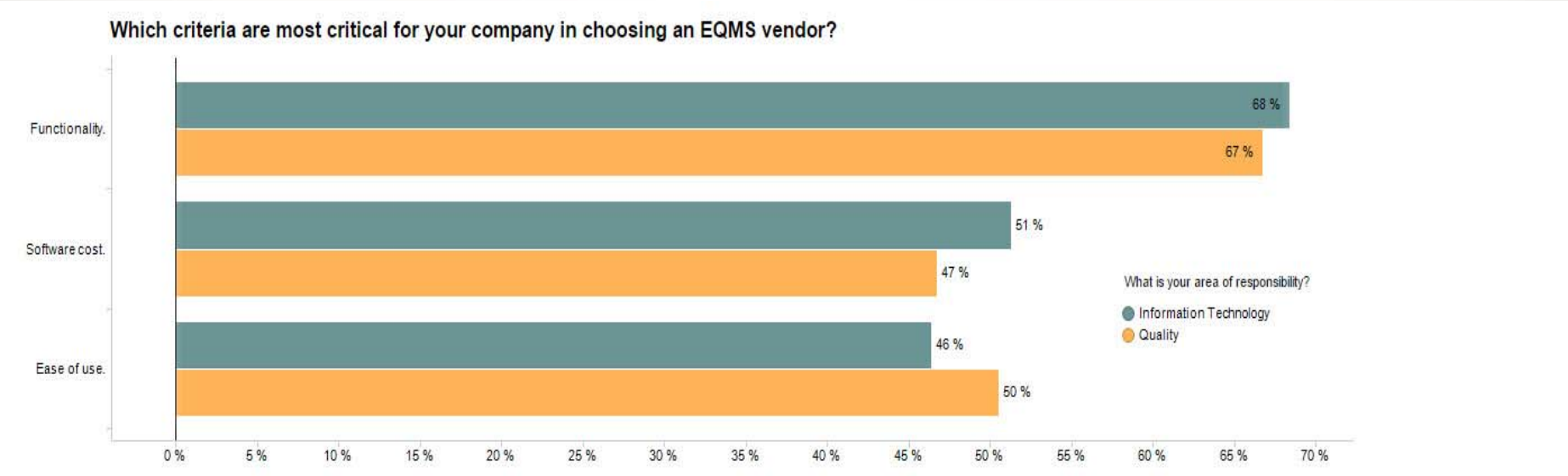
Researching vendor landscape

- 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

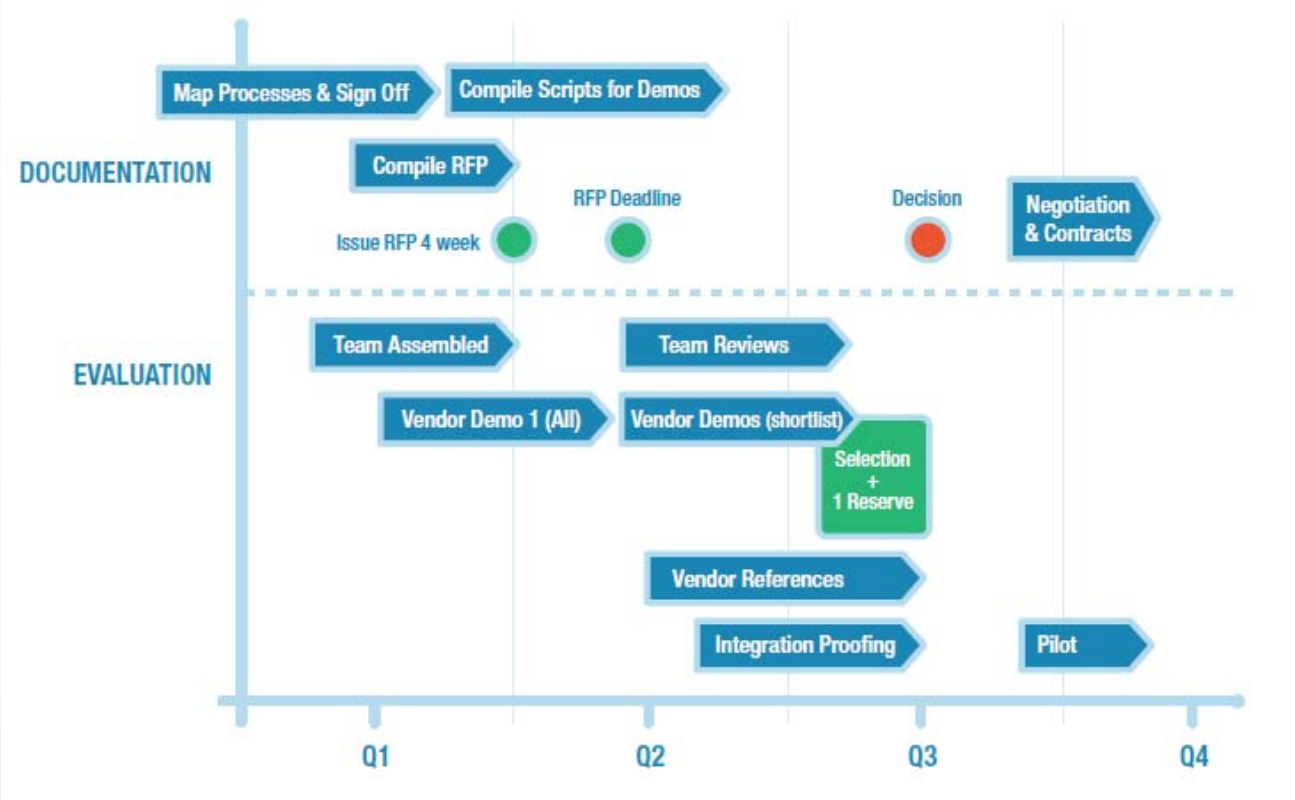
Bias

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



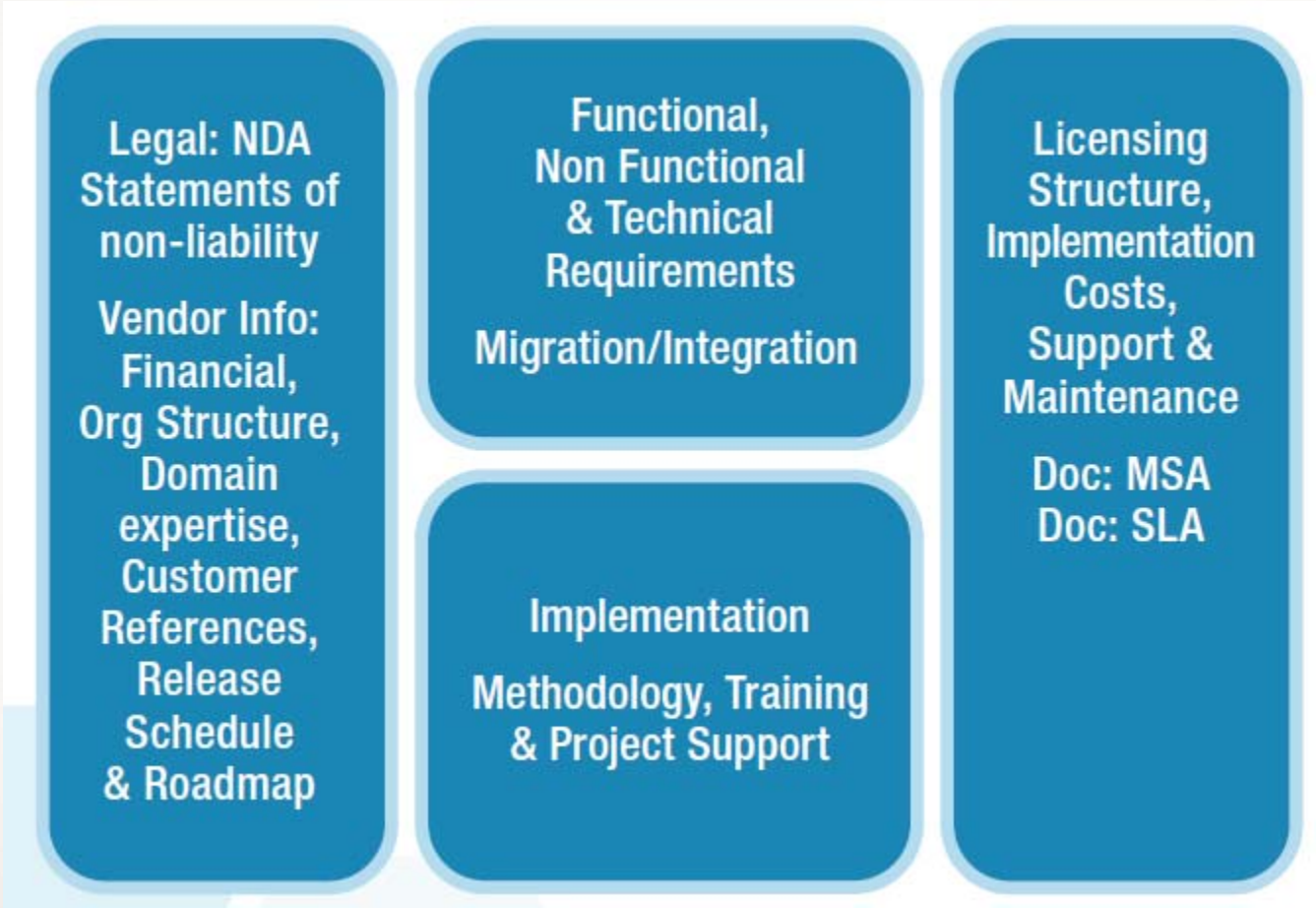
Researching vendor landscape

- 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



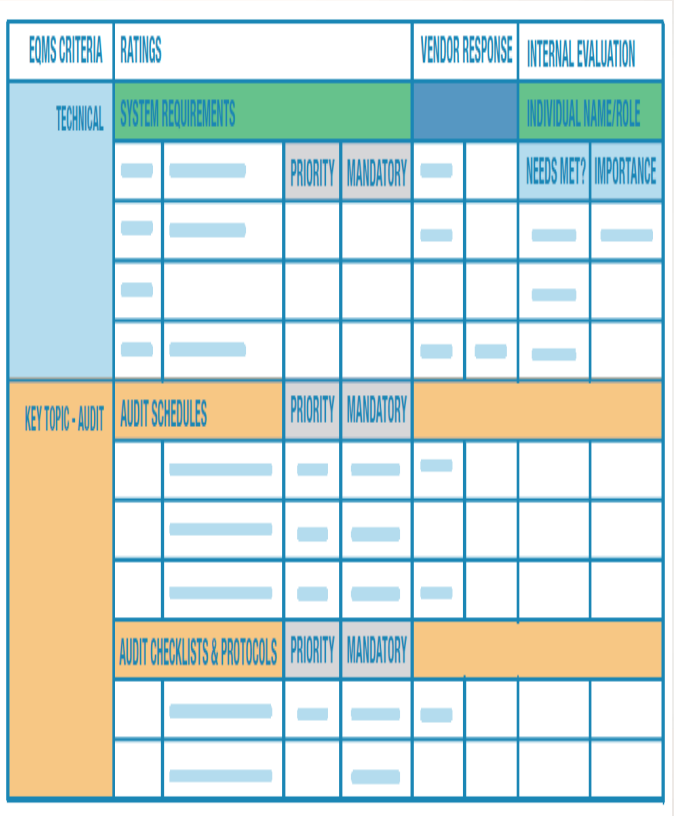
Constructing the request for proposal (RFP)

- **RFP Core**



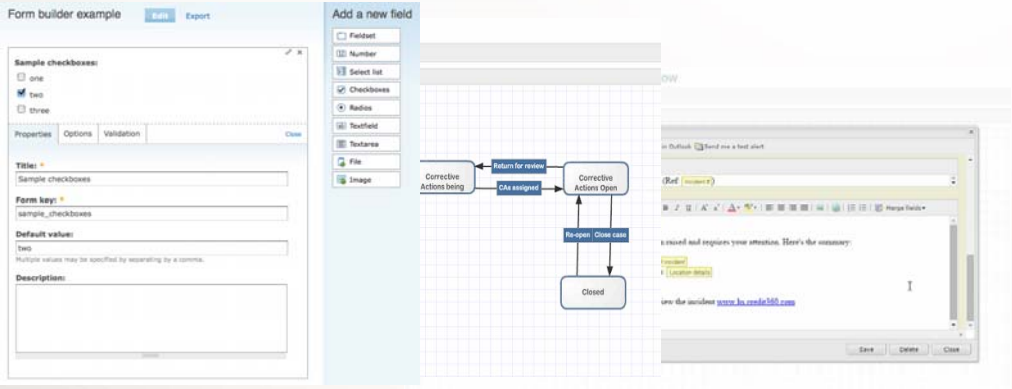
Build Requirements

- 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)

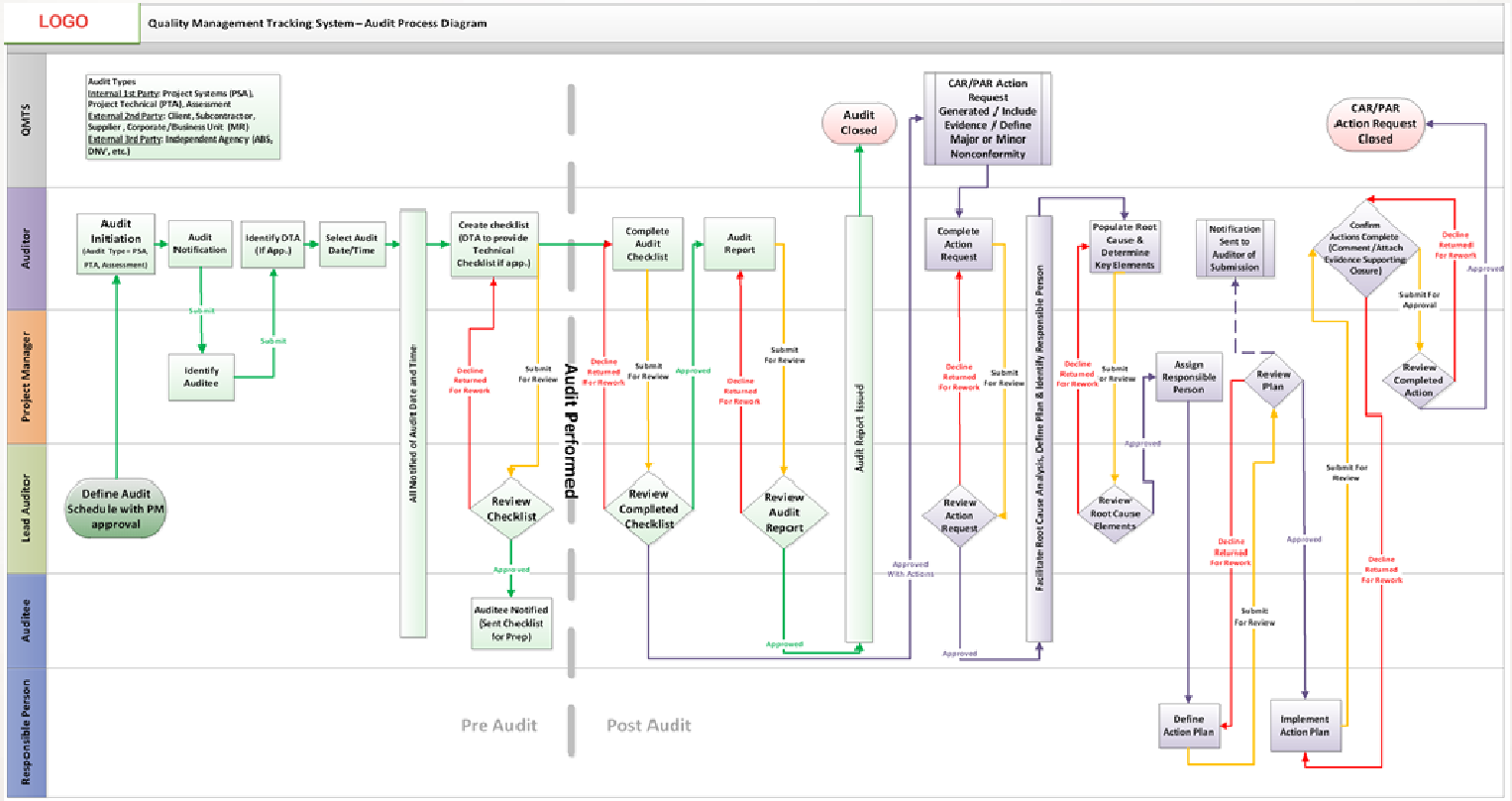
Functional requirements

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



Costs

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

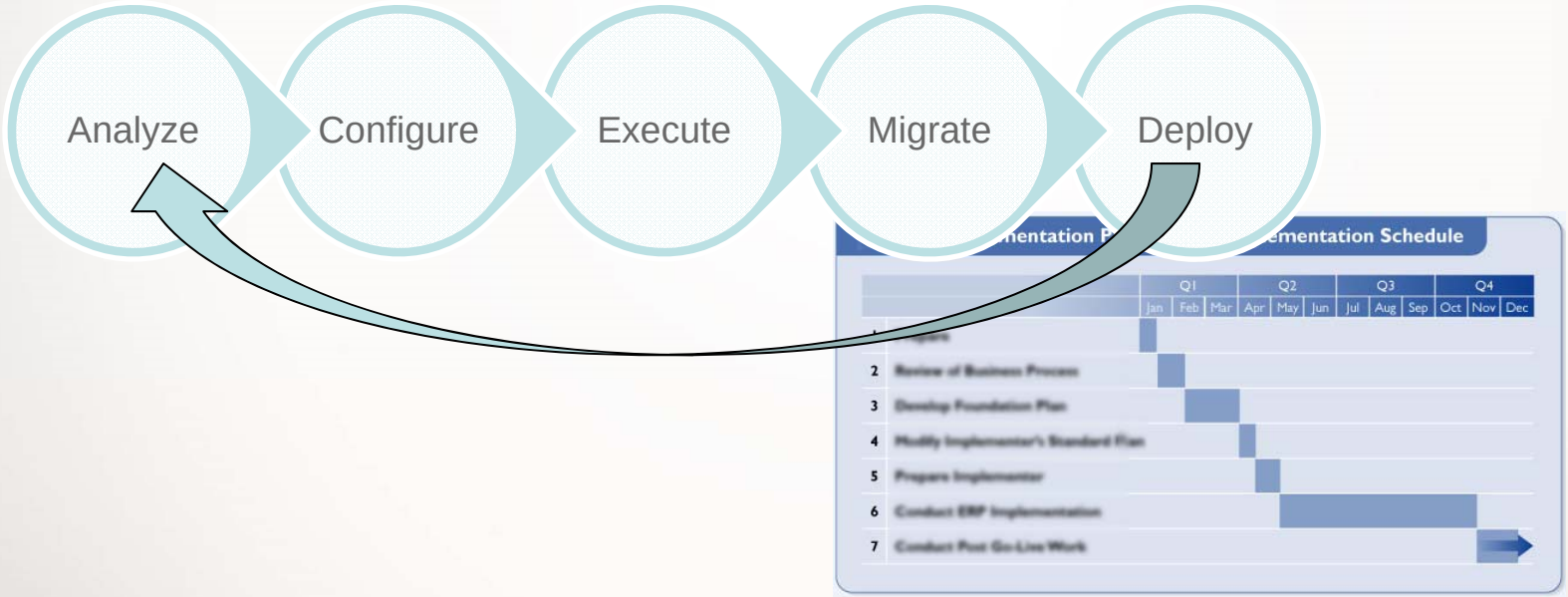
Five Year Total Cost Summary - Subscription Licensed

COSTS	TOTAL	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
HARDWARE						
SOFTWARE LICENSING						
THIRD PARTY SOFTWARE						
APPLICATION SOFTWARE						
DOCUMENTATION & TRAINING						
MAINTENANCE						
INSTALLATION						
INTEGRATION						
LEGACY DATA LOADING						
PROJECT MANAGEMENT						
SUPPORT						
TOTAL:						

Implementation

Approach and resources for implementation:

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

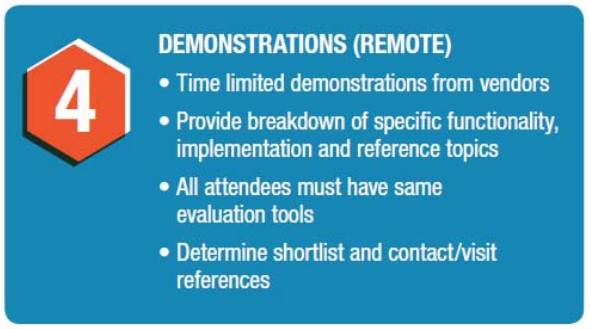


Evaluation

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



References

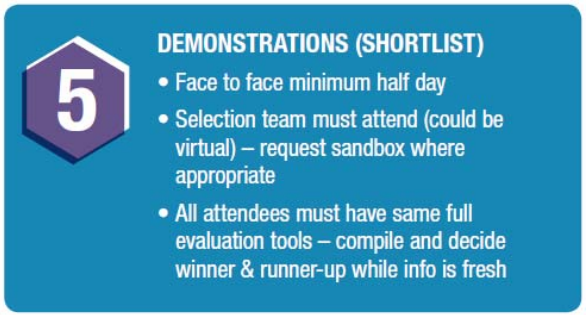
Questions for references.

- 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

Evaluation

In depth demonstrations

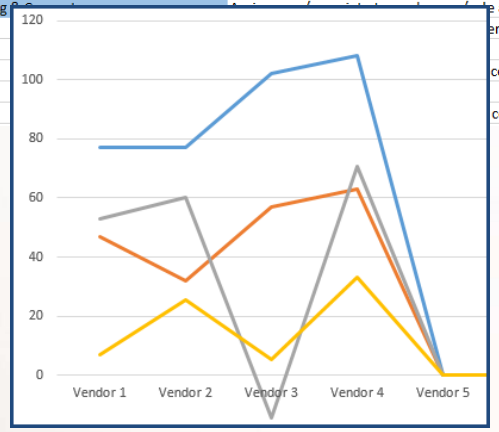
- **Multi-process deep dive**
- **Vendors provided scripts**
- **Ideally F2F**
- **You MUST see detail of regulatory compliance experience if applicable to you here – no exception**
- **Examples of interoperability and best practices**
- **Expect detailed configuration of forms, workflows and report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

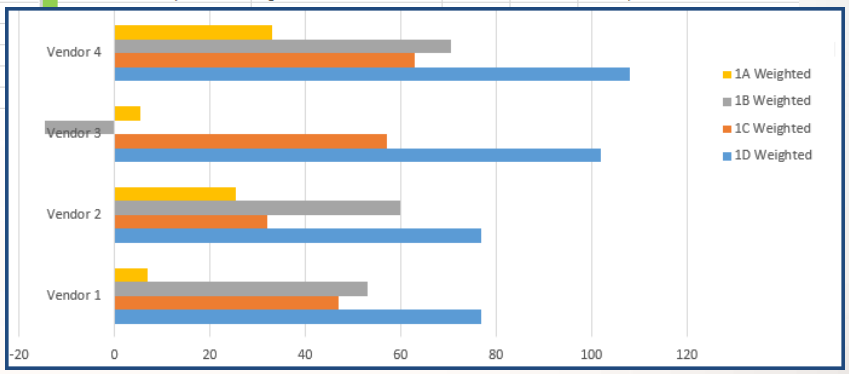


Conducting objective evaluations

- **Detailed evaluation/scoring using requirements**

	EQMS Criteria with Description		VENDOR 1				
		Criteria Comment (Evaluator)					
Technical	IT System Requirements		Meets Need?	Importance (Role/Team)	Score 1	FINAL	Comments
	Offline capability	Native apps for inspections/audits - local storage if not connected	Yes - unreservedly	Low	1.5	1.5	lorem ipsum…nill sine blah
	Integration capabilities	Mainframe (Veh integration / HR data etc)	Yes - unreservedly	Medium	1.5	3	lorem ipsum…nill sine blah
	Ability to add Corporate Branding	JM Family Brending & colors	Yes - unreservedly	Low	1.5	1.5	lorem ipsum…nill sine blah
	Localization (Languages)	E.G. Spanish	Yes - unreservedly	Medium	1.5	3	lorem ipsum…nill sine blah
	Notifications engine	Required for all processes/configurable - trg updates, new docs, failed ir	Yes - unreservedly	Low	1.5	1.5	lorem ipsum…nill sine blah
	Reporting Platform	Crystal, SSRS or other for building reports in addition to OOTB library	Yes - unreservedly	Low	1.5	1.5	lorem ipsum…nill sine blah
			Section Total		18	39	
Documents & Training	1-A Document Control (SOPs/Wis/Policies etc	Can assign owner and/or owners of document (persons and/or roles)	Yes - requires configuration	Low	1	1	lorem ipsum…nill sine blah
		Ability to assign single or multiple reviewers (serial or broadcast)	Yes - requires configuration	Low	1	1	lorem ipsum…nill sine blah
		Can force signatures (or equivalent) for approvals	Yes - requires configuration	Low	1	1	lorem ipsum…nill sine blah
		Allow comments by reviewers & bounce-back	Yes - requires configuration	Low	1	1	lorem ipsum…nill sine blah
		Ability to track changes to documents (full audit trail - what, who & whe	Yes - unreservedly	Low	1.5	1.5	lorem ipsum…nill sine blah
		Ability to work on documents (unseen by non owners/approvers until pu	Yes - unreservedly	Low	1.5	1.5	lorem ipsum…nill sine blah
		Auto-version increments & unique identifiers for documents	Yes - unreservedly	Low	1.5	1.5	lorem ipsum…nill sine blah
		Multiple (configurable) fields for categories & other meta data	Unsure - need more detail	Low	0	0	lorem ipsum…nill sine blah
		Provides personal library by user profile (role/work area/ad-hoc etc)	Unsure - need more detail	Low	0	0	lorem ipsum…nill sine blah
		Can acknowledge (user) having read latest published version + allows su	Unsure - need more detail	Low	0	0	lorem ipsum…nill sine blah
		Can associate with roles/work areas/processes/shop/location etc (links	Unsure - need more detail	High	0	0	lorem ipsum…nill sine blah
		Upload attachments (also controlled) of any type	No - missed requirement	High	-1	-3	lorem ipsum…nill sine blah
		Convert to PDF (or equivalent locked type)	Yes - unreservedly	High	1.5	4.5	lorem ipsum…nill sine blah
		Watermarks (configurable) for printed documents	No - entirely absent feature	High	-1	-3	lorem ipsum…nill sine blah
			1A - Section Total		8	7	
	1B - Training &	e and auto generate Trg Needs	Yes - unreservedly	High	1.5	4.5	lorem ipsum…nill sine blah
		er / new trg req					
		courses					
		competencies					

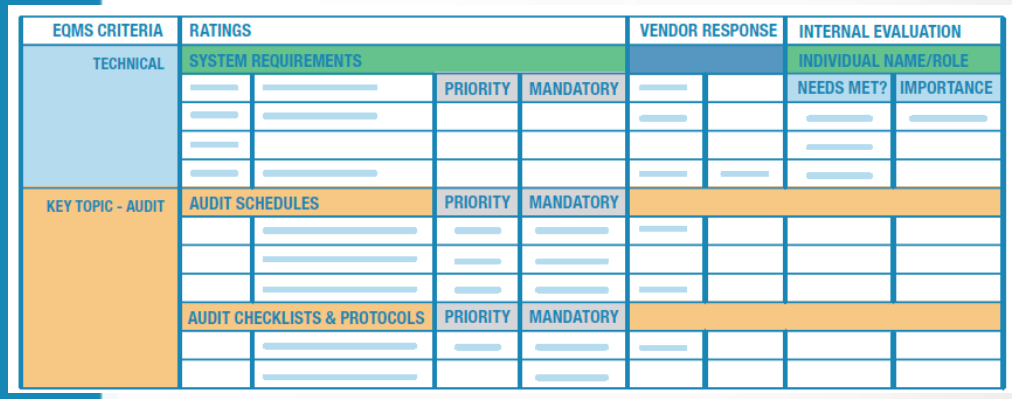




Evaluation Objectivity

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 xxxx 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.

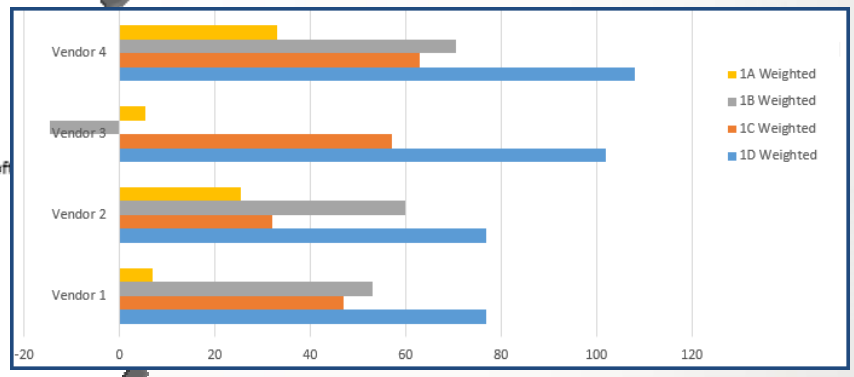
Using the Workflow and the Data documents as a guide:

- 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 (e.g. 5 Why, fishbone) using the soft solution tools.
- Demonstrate how to attach files, including photographs, word documents, excel files.
- The following xxxx Personnel (roles included in Sample CAPA Data) can be used for demonstration of notifications of events, assignment of corrective actions, etc.

§ Jim Jones – jim.j@rubbermaid.com

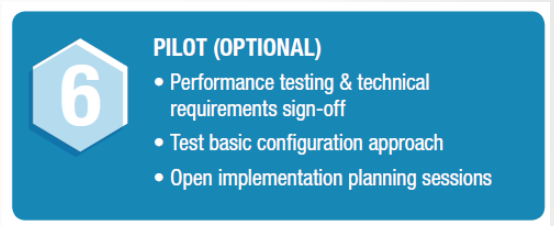
§ Jane Smith – jane.s@rubbermaid.com

- Demonstrate the ability to interact with the software solution as much as possible during the demo (i.e. send emails to the xxxx Personnel listed above with links to access the system, allow xxxx Personnel to navigate the system and access various screens and reports, etc.).
- Generate CAPA logs for each of the xxxx 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's perspective. (exclude login requirements)



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!!