DECISION CRITERIA VS. SELECTION CRITERIA

A PRAGMATIC APPROACH TO QMS SOLUTION EVALUATION

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INTRODUCTION

The selection process for a QMS solution typically requires the evaluation of key variables and considerations—from the user-friendliness of a system to deployment options, capabilities or security and, of course, the vendor itself.

However, to make the right choice for your business, it's important to evaluate potential solutions against two related dimensions—decision criteria and selection criteria.



WHY QMS VENDOR SELECTION STARTS WITH YOUR DECISION CRITERIA

Your decision criteria are derived directly from your QMS business case and remain closely aligned to your priority business case drivers. It highlights the most important criteria in vendor selection. While many organizations move straight from their business case to a shopping list of desirable solution characteristics, most commonly known as selection criteria, the key to a successful QMS project is ensuring your decision criteria reflects the reasons your business case was successful and approved.

Your decision criteria will ensure the QMS business case justifications are fulfilled, whereas selection criteria represents the more specific solution characteristics that will satisfy decision criteria parameters.

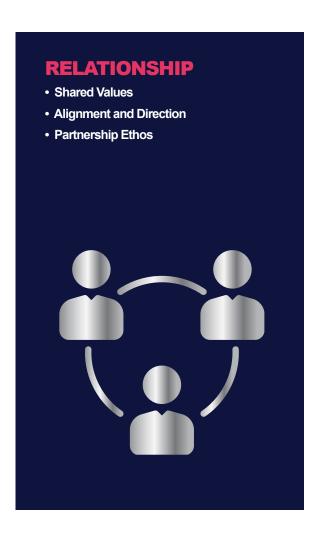
Decision criteria can be described as a set of principles, guidelines and requirements which an organization uses to make a decision. Decision criteria is critical in guiding vendor selection, enabling organizations to choose the system that best meets its overall needs.



DECISION CRITERIA TO CONSIDER FOR QMS INVESTMENT

ECONOMIC • Efficiency • Return on Investment • Risk





TRANSLATING DECISION CRITERIA INTO THE RIGHT SELECTION CRITERIA

After you've built out your decision criteria, the next step is to complete your subsequent selection criteria for the QMS and QMS vendor itself. Your decision criteria will ensure the QMS business case justifications are fulfilled, whereas selection criteria represent the more specific solution and vendor characteristics that will satisfy decision criteria parameters.



ECONOMIC DECISION AND SELECTION CRITERIA



How viable is your potential QMS?

EFFICIENCY

- · Standardized best practice processes
- · Superior usability that ensures efficient and effective throughput
- · Increased use of automation
- Faster time to valuable insights
- · Robust integration that results in a single source of the truth



VALUE AND ROI

- A vendor that embodies innovation on behalf of the industry
- Vendor domain expertise, proof points and references
- QMS business case alignment, fulfilling cost vs. business benefit expectations
- · Cost savings and faster time to value



RISK

- A long history of creating compliant systems that are known by the regulators
- Reporting ease to enable proactive oversight and decision making
- Supplier quality management (SQM) capabilities that integrate external suppliers and 3rd parties into the QMS value chain
- A vendor that is focused on your industry



TECHNICAL DECISION AND SELECTION CRITERIA



Does the QMS meet your requirements?

TECHNICAL REQUIREMENTS

- Process-specific technical requirements
- An established and sustainable platform/system
- A vendor that understands your core requirements
- Know-how on configuring the most effective solution for your business based on thousands of previous system deployments



FUNCTIONAL CAPABILITIES

- · Inherent capabilities that support the company's digital roadmap (e.g. Al, IoT, ML)
- Seamless integration with adjacent systems and processes
- SQM to manage and collaborate with suppliers and contract manufacturers
- · Risk management that integrates with other quality management processes



TECHNOLOGY GOALS

- · Flexibility/configurability vs. degree of standardization
- Fulfill internal IT, data security and architectural needs
- Enable goal of a single QMS across your global business
- · Achieve modern, harmonized quality processes and system integrations
- A system that will match the pace of your company's growth



RELATIONSHIP DECISION AND SELECTION CRITERIA



How closely aligned are you with a potential vendor? You'll not only want to determine that your QMS vendor will meet your economic and technical criteria, but you'll also want to ensure that you share similar values and are aligned in quality objectives.

SHARED VALUES

- Unwavering focus on quality management
- · Long standing and respected heritage in the industry
- · A complete and total understanding of patient centricity
- · Consistently using innovation to achieve business value



ALIGNMENT AND DIRECTION

- Proven commitment to customer success and patient-centric innovation
- Sustained market leadership in QMS with unrivalled domain expertise
- · Ensures voice of customer is the foundation for roadmap and strategy
- · Incorporates industry and regulator feedback, to pinpoint areas for innovation



PARTNERSHIP ETHOS

- Mutual trust that transcends expectations, engagement, goals and more
- Relationships with industry regulators
- Industry focused user groups to support peer-to-peer collaboration on QMS best practice
- Business strategy based partnership that supports customers' goals and aspirations at all levels



CLOSING THOUGHTS

Although fundamental to ensuring a successful QMS selection process, decision criteria often remain an internal and informally agreed set of guidelines. Your selection criteria will enable you to pinpoint the vendors that are more closely aligned with your quality goals and will ensure a successful relationship.

Build out your decision criteria for your QMS investment as well as your selection criteria for your QMS capabilities and vendor and use a combination of the two to guide or create a formal RFI or RFP process that prospective vendors must follow. This will result in the selection of a quality solution provider that will meet your current needs as well as those in the future.



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