

Key Considerations for Evaluating and Selecting the Best Electronic QMS Software

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Agenda



- ▶ Build the Right Team
- ▶ Define the Requirements
- ▶ Hosting, Installation and Licensing
- ▶ System Configuration
- ▶ Security Roles & Permissions
- ▶ Training and Support
- ▶ Cost
- ▶ Additional Considerations
- ▶ Creating an Objective Selection Guide

Why Do Software Implementations Fail?

- ▶ Not enough resources
- ▶ Wrong people are involved
- ▶ Key people are left out
- ▶ Requirements are not clearly defined or understood
- ▶ Lack of confidence in the software

Develop the Plan



Before you begin evaluating softwares.....

- ▶ Determine the scope
- ▶ Build the team
- ▶ Define requirements

Outputs of this stage include:

- ▶ Defined team with roles and responsibilities
- ▶ First draft of system requirements

Build the RIGHT Team



- ▶ Properly resource the team....but don't over resource
- ▶ Establish clear roles
- ▶ Make sure to include go-fors
- ▶ Include the difficult people



Define the Requirements



- ▶ Focus on the “What”
- ▶ Regulatory requirements (e.g. FDA, EU, ITAR, FCC)
- ▶ Quality requirements
- ▶ Other business requirements
- ▶ Prioritize the requirements

#	Requirements & Options	Priority
1	The system must be able to add new documents	1
2	The system must be able to change existing documents	1
3	The system must be able to obsolete documents	1
4	The system must maintain a revision history for each document	1
5	The system must require approvals before proposed changes become effective	1
6	The system must prohibit the editing of controlled documents	1
7	The system must include a mechanism for expediting high priority changes	3

Evaluation



Begin to evaluate for:

- ▶ Satisfaction of requirements
- ▶ Cost
- ▶ Effort to implement

Outputs of this phase include:

- ▶ Finalized requirements
- ▶ Determination of 2-3 finalists

Hosting, Installation and Licensing

Plan

Evaluate

Select

Validate

Implement

Hosting Options:

- ▶ Internal
- ▶ External



Installation Options:

- ▶ Client
- ▶ Server



Licensing Options:

- ▶ Workstation
- ▶ Concurrent
- ▶ Site



System Configuration



Commercial-Off-The-Shelf

- ▶ Easier and quicker to validate
- ▶ Requires less resources to implement and maintain
- ▶ Less flexibility, must be willing to adjust internal workflows
- ▶ Canned reporting (maintained by vendor)

Configurable / Customizable

- ▶ Offer more options and functionality
- ▶ Easier to integrate with other systems
- ▶ Can potentially replicate current system
- ▶ Custom reporting (maintained by customer)

Security Roles and Permissions



What controls do you currently employ?

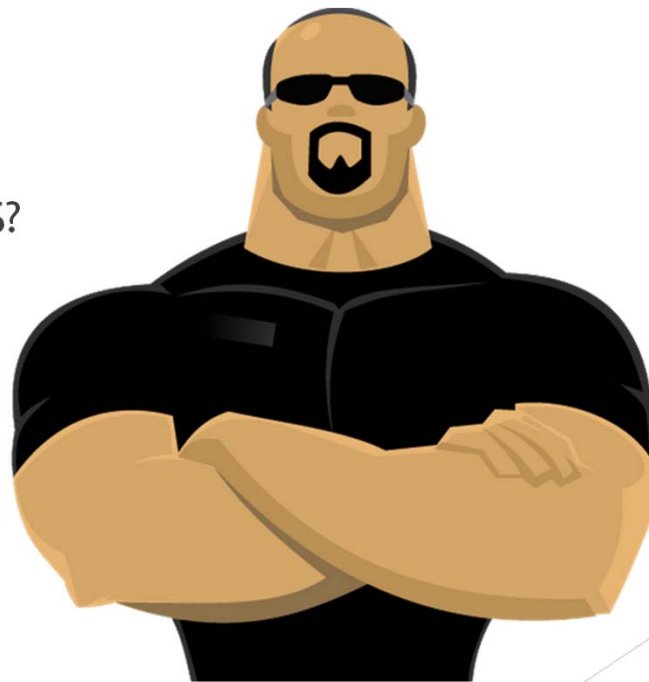
- ▶ Authority matrices
- ▶ Limited availability of software

What controls are available in the EQMS?

- ▶ System-level permissions
- ▶ Module-level permissions
- ▶ Item-level permissions

How are these controls maintained?

- ▶ Canned Security Roles
- ▶ Customizable Security profiles



Training & Support



Training Options:

- ▶ Web-based
- ▶ On-Site
- ▶ Third Party

Support Options:

- ▶ Web, Email, Phone
- ▶ Hours of Operation
- ▶ Time Zone

Cost



- ▶ Purchase Price
- ▶ Licenses
- ▶ Yearly/Monthly Service Agreement
- ▶ Upgrade fees
- ▶ Third Party Implementation



Additional Considerations



- ▶ Development environments
- ▶ Additional modules
- ▶ Reports and exports of data
- ▶ Intuitive design
- ▶ Integration with other softwares
- ▶ Backups and Upgrades
- ▶ Software Enhancements

Select



Activities in the phase:

- ▶ Complete Software Selection Guide

Outputs of this phase include:

- ▶ Selection of software

Software Selection Guide



Software Selection Guide: Change Control Example					
#	Requirements & Options	Priority	Software #1	Software #2	Software #3
3	The system must be able to obsolete documents	1	Yes, handled through a normal change request	Yes, handled through an obsolescence request	
4	The system must maintain a revision history for each document	1	Yes, revision history is pulled from change request and stored in system	Yes, revision history is pulled from change request and printed on doc	
7	The system must include a mechanism for expediting high priority changes	3	Not built in, must create a user field	Yes	
10	Hosting Options:		Internally only	Both Internally and Externally	
11	Installation Options:		Both Client and Server	Both Client and Server	
12	Licensing Options:		Workstation and Concurrent	All 3, Workstation, Concurrent and Site	
13	System Configuration:		Commerical-Off-The-Shelf	Customizable	
14	Available Security Permissions:		Both System and Module	All 3, System, Module and Item	
15	Maintenance of Security Permissions:		Canned Security Roles Only	Both Canned Security Roles and Customizable Security Profiles	
16	Available Training and Support:		24-7 Support Web-Based training	24-7 Support Web-Based training, User Groups	
17	Purchase Price:		\$20,000.00	\$40,000.00	
18	License Purchase Price:		\$1,000.00	Site license, included in purchase	
19	Yearly Service Agreement Cost:		\$10,000.00	10% of purchase price	

Validate



Activities in the phase:

- ▶ Install Software
- ▶ Develop workflows
- ▶ Perform risk assessments
- ▶ Establish Security Roles
- ▶ Finalize System Configuration
- ▶ Create test criteria from requirements

Outputs of this phase include:

- ▶ Completion of software validation, ready for implementation

Implementation



Activities in the phase:

- ▶ Population of Live Environment
- ▶ Training

Outputs of this phase include:

- ▶ Software Launch

How Software Implementations Succeed

- Wrong people are involved,
Key people are left out → Build the RIGHT Team
- Requirements are not clearly
defined or understood → Define the requirements early with
the Team
- Not enough resources → Objectively evaluate each software to
fully understand the resources
required to validate and implement
- Lack of confidence in the
software → Thoroughly validate the software using
the requirements developed from the
Team

Questions?

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The right side of the slide features a decorative graphic composed of several overlapping, semi-transparent green triangles and polygons. The colors range from a light, pale green to a dark, forest green. The shapes are arranged in a way that creates a sense of depth and movement, with some shapes appearing to be layered behind others. The overall effect is a modern, abstract design element.