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## Finding the Will to Climb



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## 1.1 Considering an EQMS Expedition

Selecting, implementing and maintaining a new EQMS can be hugely rewarding. It is also a major undertaking that can involve substantial organisational change.

Before committing to significant time investment, you should get a basic understanding of the capabilities of the latest systems and software. This will show you the potential improvements that can be made through current technology, and might open your eyes to opportunities you hadn't realised existed.

Knowing your fundamental 'must-have' improvements at this preliminary stage will give you a basis for further research into the true value of a project. Just to be clear, we are not talking about carrying out the extensive requirements definition and scoping exercise which we will discuss a little later down the road, merely considering whether you will actually benefit from a new system, what is available, and how much it will cost.

## 1.2 Understand the Whole Undertaking

Distilled to its purest form, this basic diagram shows the four fundamental stages of a project journey:



As illustrated, you should first assess why you want/need an EQMS and establish a value hypothesis to justify implementing one. Then you should analyse what it will mean for your organisation, which compliance summit you have to climb, what risks and obstacles there may be in the way, and the requirements you have (technical, process, people and overall compliance). You should also try and get a guide to help you at this stage, and maybe even prototype your new system. You can then design the solution you need with the appropriate vendor, and decide whether you will manage the system on site, host it or even keep it in the Cloud; before you deliver the project, migrate your existing documents and continue to manage the system compliance over its whole lifecycle. Finally, you should check that you have achieved your value hypothesis by measuring what has been achieved over the time period required.

Once you have a good grasp of this approach you should start applying it to your specific project, rather than bypassing the internal assessment and analysis phases (and in some cases even sensible planning of an EQMS implementation). Don't go straight into the procurement phase – as has become almost standard practice for many organisations. Why this happens is a complete mystery to the authors of this guide, and one of the major reasons it has been written. It could be the demands of working today do not allow sufficient preparation time- this is a mistake.

### **1.3 Confirming Your Journey Will Be Rewarding**

As exciting and fulfilling as they are, all expeditions need funding. Achieving any improvement goals you set will incur cost in advance, along the way, and after you complete the project; and you should determine how long it will take to get a return on your investment (ROI) before fully committing financially.

If you're taking your first steps to procure a new electronic quality management system (EQMS) – for example to replace a paper-based document management system, then there are many factors that could affect your ROI.

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Some of these costs and returns are direct. You'll need a lot less paper, ink, printer parts, office space for archives, and so on. On the other hand, the ongoing costs of a computer system, storage capacity, backup software, as well as electricity to make it all work, will cancel out some of those savings to a greater or lesser extent.

Physical documents that are to be archived digitally will also need to be scanned. But unless this process is covered by formal procedures with the people scanning correctly trained and that training documented, the scanned records will not be a 'certified' copy of the original record allowing the original to be destroyed. The upshot is that the original has to be managed as well, potentially negating the cost benefit of the change (in fact costs will increase as two records need to be managed).

In addition to physical factors, a change in working practices will also affect the cost/return equation. Time will be saved if people don't have to leave their seat, locate a document, and return to their workspace during reviews. This is especially true in instances where the document is lost and must be replaced.

Then there are the wonders of workflows that mean you can distribute documents globally for review and approval, collaborate on them and sign them electronically without the need for a pen\*, scanner or the dreaded fax machine. This will create more time for activities that add real value, rather than manual document administration and routing.

(\*yes it really is possible to do this, and is legally binding!)

Some indirect costs and savings centre on improved efficiency, increased compliance (making scrutiny from external and/or internal parties easier to manage), and changes in the number of staff necessary for the business to function properly (see some examples in the following diagram).

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| Direct Costs  | Indirect Costs   |
|---|--|
| Paper and Printing  | Environmental costs of paper   |
| Filing and storage  | Lost business due to burdensome QMS  |
| Fax, Electricity, Computers                                 | Reputational damage from lost records or documents that cannot be found during audit |
| Postage and Couriers  | Lack of consistency across multiple geographic sites and regulatory failure          |
| Scanning  | Inefficiencies and lack of continuous quality improvement                            |
| Employees cost handling paper, filing, retrieving, routing, | Employee 'wellbeing' doing non-value add activities                                  |
| Use of Excel to manage quality processes                    | Negative impact on 'Quality culture'   |
| Manual training management                                  | Records unreadable/lost long time ahead  |

**Note:** a further advantage of having all the quality activities managed and stored in one database is that all the data, if measured properly, can be used to identify otherwise hidden trends, subsequently highlighting continuous improvement. This will have measurable value, as audits become easier and quality improves.

**Ultimately, you have to make the clear decision to go digital, validate the processes, discard your paper and rely on an electronic copy of records to make the transition worthwhile in the long term.**

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You can see from some of the examples listed that the ROI will be very specific to your organisation. You will probably have started to think about installing an electronic system for efficiency or compliance reasons, but you should also consider the reputational damage and implementation failure correction costs that are not significant until they occur. These should feature prominently in your ROI as associated risks (see risk section page 38).

With all of these factors to track, it is highly recommended that you start a list (register) of ROI items (and risks!) at the outset of the project, and keep adding to it as you go along.

#### **1.4 Obtaining Expedition Funding (the Chicken or the Egg?)**

It is probably worth getting an idea of what your organisation would be willing to pay for an EQMS before getting too carried away (The Chicken?). EQMS are often deemed 'discretionary purchases' and move down the financial priority list when 'obligatory purchases' are needed to keep you in business, or 'hard stop purchases' become necessary due to a known regulatory or compliance deadline that has to be met. Most senior management teams won't sanction a spend 'because it is a good idea', so the work you have done so far on the ROI, including reputational/compliance risks (which if not addressed could make the purchase 'obligatory'), should help you achieve a sensible budget.

Also be aware that you will need to rely on internal resource for a lot of the implementation activities (or use some specialist vendors that can provide consultancy as well as software products), so there will be an associated cost here.

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You may be asked to get a rough idea of costs from different vendors for software licensing, implementation and support & maintenance, as well as any consultancy services you might need (The Egg?), before going to get a budget figure.

A sensible move would be to get agreement to spend some money on a consultant (mountain guide) to help you determine what would be a good fit for your organisation (see 'readiness assessment' page 35). You can also use an EQMS to see how it will fit into your organisation. This is akin to a 'front end study' or 'prototyping' exercise if you are looking for a justification to de-risk the larger process.

### 1.5 Choosing Your Expedition Leaders

Assuming you get the go ahead with a provisional budget granted, an EQMS implementation is a change management journey that must be planned, resourced and executed correctly in order to reap the full commercial and operational benefit. A dedicated project manager from your team should be appointed (and from your EQMS vendor once selected), and should be given all of the resources, authority and support they will need to lead the expedition all the way to the summit.

These leaders should start to draw up a plan defining the activities, roles, responsibilities, timelines and document deliverables (as laid out in this guide), which eventually should be agreed and signed-off by the project sponsor(s) at the highest level possible in your company. This backing will be of huge importance as change is delivered into the organisation. It is crucial that decisions of the project are backed by senior management so it is not deemed to be 'quality' or 'IT' led, and so there is no 'back door' route to interfere in project delivery.

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If possible in your organisation, leaders should not work in isolation by surging ahead of the rest of the team. A project steering group should be formed, meeting regularly to support the project team with prioritisation of activities, to agree any (inevitable) changes to scope / timing / resource changes and risk mitigation as well as providing input into policy decisions. These meetings should be documented and will be very beneficial to capture new requirements and changes to the original project intent as the expedition moves onwards and upwards.

## **1.6 Finding the Right Guide**

Only a few of the potentially complex challenges that may need to be overcome on your journey have been outlined in previous pages. Therefore, as with any real mountain expedition, it soon becomes clear that talking to someone that a. knows how to get to where you want to go, b. knows the merits of different technical solutions, equipment and techniques, c. has real, practical experience of having successfully done it before on a number of occasions and d. will guide you along the assessment and planning stages, which can save time, money and sanity as the project unfolds.

A good 'mountain guide' will facilitate effective discussion, properly assess your current situation and desired goals, analyse your organisation in the context of an EQMS, and produce an action plan to ensure all aspects of your journey through the Compliance Mountains are properly considered. This expertise has to be paid for, but it will significantly increase the chances of the expedition running smoothly, on time, and to your budget. In truth it represents a fraction of the financial, time and reputational cost of installing a system that does not work for you or get you where you want to go.

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Consulting an expert specialising in EQMS (usually in the preparation phase) will help you:

- See how your business and its processes currently operate
- Identify the shortfalls of your current system and processes (paper or electronic)
- Formalise the characteristics that the new system should have (or continue to have) to ensure that progress is made quickly and cost effectively
- Decide which type of EQMS best fits your needs in terms of regulatory requirements, scalability, complexity, usability and flexibility
- Specify the requirements that you want the system to have, possibly using an example EQMS to see how your processes and people will adapt

Some vendors that started life as consultancy businesses and have experience of other vendors' products, can provide this guidance. Or there are many consultants who can provide you with the skills you need. Make sure that the scope of their participation is clearly defined and ensure that they understand your business and processes so they can challenge what you currently do and ensure you get the most value from their services. Most of all they should be pragmatic and able to explain complex technical environments so all can understand them.

With the estimated ROI of the project calculated, budget agreed, an expedition team and leader in place, and hopefully a guide in play, your focus can turn to establishing the key parameters of your project. Spending time in the 'map room' assessing your organisation, analysing your requirements, specifying necessary equipment and possibly pre-project testing will pay great dividends in the longer-term delivery, and should not be bypassed due to an eagerness to start a project in earnest.

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