How To Build Quality Into Commissioning And Validation (And Save Your Company Over A Million Dollars A Day)

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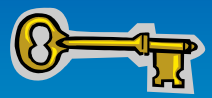
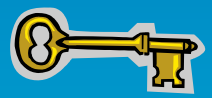
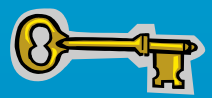
5 Keys To Build In Quality



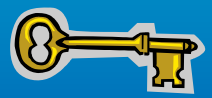
Selecting Highly Talented People



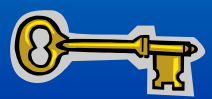
Proper Planning



Good Requirements & Design



Leverage



Buy In

Example 1 (Talent)

You need to validate a key piece of equipment and you think it will take about 6 months to do. It is critical to the validation of your key product, which will bring in $400 million to your company (when approved). You can't do it yourself, nor can you do it in-house. You contact two validation consulting firms.

Firm A: Recommends one person @ $75/hr and anticipates 6 months of effort.

Firm B: Recommends one person @ $125/hr, and anticipates 4 months of effort.

Who Do You Choose + How Do You Decide?

Before You Answer, Consider:

1. How long have Firm A and Firm B been in business in your industry? If it is less than 5 years, do you want to be their guinea pig? (How long do guinea pigs live?) You may know that approximately 90% of businesses fail in the first 5 years. What if they fail during your project?

2. Will your company remember how much money you saved them or will they remember the number of problems and delays that arose based on your selection?

3. How many letters of recommendation do Firm A and Firm B have? Their letters of recommendation are their commitment to past quality and a good indication of future quality.

Before You Answer, Consider:

4. How many years of experience do the people they propose have? Perhaps you think that you will save money because they plan to send you a junior-level person. Will that keep the price down when yours is the first or second system they've ever worked on?

5. When you interviewed each candidate, what indication did you get that he/she had performed the same task(s) numerous times? What did he/she say that demonstrated that he/she could provide superior value?

6. What do you think will happen when there is a problem with the equipment? Which person do you think will know what to do?

Before You Answer, Consider:

7. What will happen when you and your Quality Assurance representative review their work? How will the quality of their work reflect on you? How do you feel about “re-work”? How will re-work make you look? What will happen when your clients and the FDA review the work?

8. What are Firm A and Firm B’s commitment to keeping the contractor/consultant you select on the job throughout the project?

Answers to the eight questions listed above may be difficult for you to quantify. So here is a way to quantify them by assigning weights to the values of the questions.

To Answer Example 1:

	Weight	Firm A	Firm B
Question 1	Maximum of 10		
Question 2	N/A	N/A	N/A
Question 3	Maximum of 10		
Question 4	Maximum of 20		
Question 5	Maximum of 30		
Question 6	Maximum of 10		
Question 7	Maximum of 10		
Question 8	Maximum of 10		
Total (out of 100 points)			

Answer For Example 1:

Question 1: Less than 5 years is 3, 5 – 10 years is 7, over 10 years is 10 points

Question 2: N/A

Question 3: Assign one point for each letter, maximum of 10 points.

Question 4: Assign one point for each year of experience, maximum of 20 points

Question 5: Assign one point for each time that he/she has performed the work you require, maximum of 10 points. Assign 5 points for each explanation that indicated that he/she would do a superior job, maximum of 20 points. Maximum for Question 5 is 30 points

Answer For Example 1 Cont'd:

Question 6: Assign 3 points if he/she gives you a low level, 7 points for a medium level, or 10 points for a high level of confidence that he/she would know how to handle a problem with the equipment.

Question 7: Assign 3 points if the firm gives you a low level, 7 points for a medium level, or 10 points for a high level of confidence that the firm will keep the contractor or consultant you select on the job throughout the project

Question 8: Assign 3 points if he/she gives you a low level, 7 points for a medium level, or 10 points for a high level of confidence that he/she will do the caliber of work that you and your Quality Assurance representative review will accept the first time.

Answer For Example 1 Cont'd:

- How many of you would say that this adequately represents the situation?

Answer For Example 1 Cont'd:

Reducing the time from 6 months to 4 months is a savings of 60 days. **If your product generates over $1,000,000.00/day you've just lost your firm $60,000,000.00!**

From this you may be reminded of the old adages, **"you get what you pay for", "time is money", or "cheap can be expensive, and expensive can be cheap**"

To summarize, Example 1 illustrates the importance of choosing highly talented individuals.

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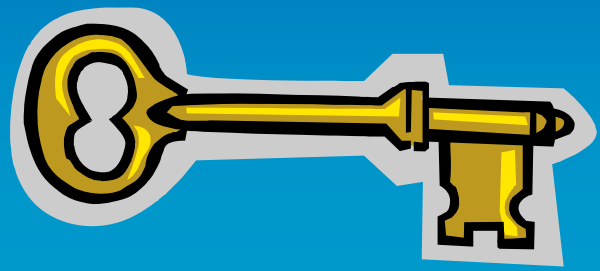

Selecting Highly Talented People is Key

Example 2 (Proper Planning)

Your company is building a new (or adding to an existing) facility. When is the right time to begin commissioning and validation?

Let’s discuss what happens when it occurs at the wrong time

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Recently, a client did not involve commissioning and validation early. Here is a short list of many problems that occurred:

1. They did not learn that documentation should be specified in PO, 2 – 4 weeks prior to delivery with % of PO assigned to it, (some vendor documentation was delayed, some was not received at all because it was not specified)

2. No one was assigned responsibility for document receipt and organization, so it was not organized which slowed the rate of commissioning and validation

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3. Commissioning and validation were not informed prior to installation, so installation documentation was lost, or was inadvertently repeated

4. Commissioning and validation did not meet with vendors during start up to ask key questions. So protocols had errors which caused deviations which caused delays, and omissions which detracted from their quality

5. Validation was not involved in reviewing designs and proposals which resulted in design, cleaning, and sterilization issues

6. Validation was not involved in reviewing vendor's software which resulted in problems with electronic records and signatures

To Build In Quality

Requires Planning Properly, Which Includes Identifying:

1. The Project Phases And When To Involve Commissioning And Validation Personnel
2. The Personnel, Constraints, Responsibilities, and Potential Problems Involved
3. Personnel issues (vacations, team chemistry, a member is re-assigned, terminated, or quits, union goes on strike)
4. Technical issues (doesn't work due to improper installation or poor design, doesn't fit in the design space, damaged during shipping/assembly)

To Build In Quality

Requires Planning Properly, Which Includes Identifying:

5. Environmental issues (waste treatment and disposal)
6. Financial issues (approved budget was less than the requested budget, cost overruns due to other issues)
7. Timing issues (estimate was insufficient, problems resulted in more tasks)
8. **Expect problems, plan for them and how to handle them (in advance), handling them before they affect your project**

To Build In Quality

Requires Planning Properly, Which Includes Identifying:

9. Build A Schedule (build in time for some of the issues mentioned above)

10. Storage Location For Documentation

11. Filing Strategy/Responsibility For Documentation (Paper/Electronic) And Number Of Copies

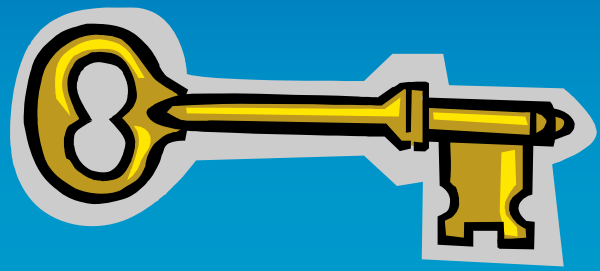
12. Procurement Process: Deliverables (i.e. spare parts, manuals, SOPs), Expected Delivery, and Percentages Associated With Arrival, Installation, and Start-up.

To Build In Quality

- Success is 1% inspiration and 99% perspiration! It is planned for, a foregone conclusion, via careful and detailed planning.

So build in quality through proper planning.

To Build In Quality



Proper Planning is Key

To Build In Quality

Requires Good Requirements & Design

- Requirements – there are several types (i.e. user, design, and purchase) all should be clear, concise, quantifiable, and verifiable/testable.
- Purchase Requirements should allow Purchasing to know exactly what to buy.
- When req'ments are imprecise, it is difficult to design a system that incorporates them, and it is difficult to test them.

Example 3 (Good Requirements & Design)

Which of the following are examples of good requirements?

1 The mixer shall spin at a minimum of 80 rpm clockwise

2 A variable-speed planetary mixer, with 316 SS process contact parts, shall mix liquids with viscosities of 1 – 2 cp at a minimum of 80 rpm

Example 3 (Good Requirements & Design)

3 Sterilization Requirement: The fermenter with shall be capable of being Sterilized-In-Place (i.e. 55 mins at 121C)

To Build In Quality

Requires Good Design, Expect An Iterative Process:

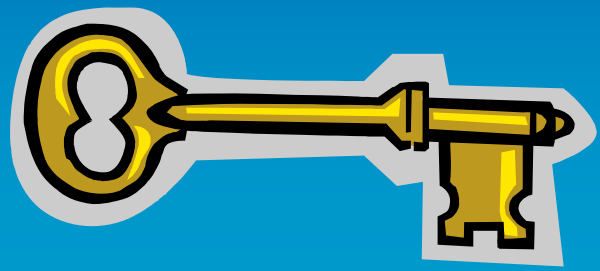
- Work with a multi-disciplined group of internal resources including, but not limited to those responsible for: Project Management, QA, QC, Validation, Manufacturing, Materials Management. Then incorporate their recommendations into the design.
- Major Iteration 1: have it reviewed by the multi-disciplined group of internal resources. Incorporate their comments and **get their acceptance and buy-in.**
- Major Iteration 2: have it reviewed by them PLUS objective outside parties, i.e. consultants with expertise in design, commissioning and validation.

To Build In Quality

Requires Good Design, Expect An Iterative Process :

- Major Iteration 2: have it reviewed by them PLUS objective outside parties, i.e. consultants with expertise in design, commissioning and validation.
- Major Iteration 3: have it reviewed by ex-FDA (who are now consultants, when applicable) NOTE: this step may be merged with the previous step.
- Major Iteration 4: have it reviewed by local FDA representatives (when applicable)

To Build In Quality



Good Requirements & Design Are Key

To Build In Quality

Requires Leverage:

In this internet age, it is likely that existing information can be leveraged. (Why “re-invent the wheel). Instead, I recommend that you:

- Obtain vendor information to create SOPs and operational tests.
- Use commissioning data to support installation, operational and performance testing.
- Build from your/consultants existing protocols and SOPs.

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Requires Leverage:

- Ask experts for suggestions (i.e. people you've met through ISPE, PDA, BIO, etc)
- Contact others at your firm from different sites with similar responsibilities (some large firms create validation committees with people from different divisions/sites)
- Build relationships with validation consulting firms. Some firms do this because they know that it is mutually beneficial.

Leverage Whatever You Can!

To Build In Quality

Requires Buy-in:

- Involving all directly and in-directly affected disciplines. (Doesn't mean that everyone is involved to the same degree, it means that everyone feels that their opinions have been heard and respected).

- Sharing with Management and getting their buy-in early and periodically thereafter. Management is likely to be able to provide valuable insights.

To Build In Quality

Requires Buy-in:

- Get agreement within the team regarding:
  - Definitions
  - Project Scope
  - Timing
  - Test Methodology
  - Applicable Guidelines/Regulations

Building Quality Into Your Commissioning And Validation Involves:

THE END

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