

Communicating the Value of Validation (IV&V)

By Mary Jo Egbert, PMP

Introduction

- Mary Jo Egbert, PMP is a graduate of Georgian Court University and was a Genetics Research Assistant at Kings College of London, England, United Kingdom.
- She is an independent expert, sort after to validate complex, as well as customized engineering equipment and scientific laboratory instrumentation.

Management Expertise

Mary Jo's Credentials include:

- PMP (Project Management Professional)
- Black Belt in Six Sigma
- Certified in Lean Management
- Certified in Total Quality Management

- Project Manager/Consultant to Fortune 500
Pharmaceutical and Medical Device Companies

Dale Carnegie

- American inspirational speaker and writer. Famous for corporate training, self improvement and interpersonal skills. Management Expert.
- One of the core ideas in his books is it is possible to change other people's behavior by changing one's reaction to them (Wikipedia, 2012).
- Books: "How to Stop Worrying and Start Living" and "How to Enjoy Your Life and Your Job."

Robert Kiyosaki

- American investor, financial literacy advocate, motivational speaker and management expert.
- Core ideas in his books are financial literacy, creativity and thinking outside the box.
- Books: “Rich Dad, Poor Dad”, “Cashflow Quadrant” and the “Rich Dad Series” of books that cover topics such as Real Estate, etc.

Validation

- Computer System Validation:

Establishing documented evidence which provides a high degree of assurance that a computerized system will consistently perform according to predetermined specifications and quality attributes.

IV&V:

- The NASA IV&V Program provides confidence and integrity in software that cannot be found elsewhere (NASA, 2012).
- Software IV&V...increases the probability the software being delivered is safe, within cost and meets schedule (NASA, 2012).

So Why the Opposition?

- Customers groaning about IV&V?
- Tired of hearing validation is a waste of time?
- Always hearing:
 - “How much is this going to cost?”
 - “How long is this going to take?”
 - “All this is red tape!”

Value Realization

- The VALUE is not being REALIZED!!!
- Clients are only looking at costs and obstacles.
 - These may or may not have anything directly to do with your validation project.
 - Roadblocks tend to include fear, cynicism, laziness (Robert Kiyosaki)
- Not focusing on achievements.
- May not even realize the accomplishments!

Client Scenario

- During a X-Ray Diffractometer validation a software bug was discovered.
- The software bug enabled the operator to ramp the generator (hardware) to unsafe levels.
- The generator could have exploded resulting in employee injury and damage to facilities in excess of one million dollars!

Skill Sets

- **Hard Skills:** IQ, occupational skills (Physics, Pearl Script, etc.)
- **Soft Skills:** Interpersonal skills (communication, body language, humor, etc.)
- IT, Engineers, Scientists tend to focus on hard skills...

Soft Skills

- Soft Skill Communication Tips
 - Be clear on front end
 - How will success be measured?
 - Identify problems early on
 - Talk in terms of other people's interests (Dale Carnegie)
 - Ask questions
 - Smile 😊
- Managers
 - Employees perform in ways that are consistent with their manager's expectations (Dale Carnegie)

Accomplishments

- Record and communicate accomplishments to stakeholders during the validation project:
- Use action verbs
- Be clear and concise
- Quantify whenever possible
- Communicate how you saved money, time, resources or prevented disaster!

Examples

- Bad: Wrote sheet attached to instruments.
- Good: Implemented “Quick Start” Program, cutting lab instrument costs by 25%.

- Bad: Responsibilities included validation.
- Good: Saved Johnson & Johnson \$41,500. off the bottom line of a \$122,000. validation project.

Techniques

- Choose analysis techniques that best display the type of value delivered:
- Return on Investment (ROI)
 - Ideal for showing project monetary profits. Can simplify to a quick, easy to understand calculation:

$$\text{ROI} = \text{profit} / \text{investment} * 100\%$$

Client Scenario

- Large Medical Device company determined small supplying machine shop was non-compliant with validation guidelines. Machine shop was not to be granted any new projects.
- Accomplishment: Saved company by reinstating two million dollars in revenue in less than four months.
- $ROI = 2,000,000. / 60,000 = 3,333.33\%$

Techniques (Con't)

Decision Tree Analysis

- Great for displaying risk events associated with cost.
- Content can be leveraged from the risk assessment performed during the validation.
- May advance into EMV and/or various modeling and simulation techniques such as Monte Carlo.
- Show your customer the dollars you saved them by making a good decision during the project!!!

Take Action!

- Communicate Accomplishments
- Use Analysis Techniques

And remember:

- Customer objections can mean opportunity
(Robert Kiyosaki)

Conclusion

Communicating the value of validation is one of the many approaches applied by Mary Jo Egbert. Mary Jo is always happy to meet to further discuss technical management approaches. Please feel free to contact her at (732) 600 1670 or mje350@msn.com.