SUCCESSFUL PROJECT MANAGEMENT FOR SOFTWARE DEVELOPMENT AND VALIDATION

John Hannon
ISPE Product Show
Track 4, Session 1
September 26, 2018

The Project Pathway
PLANNING
/ FAILURE TO PLAN IS PLANNING TO FAIL

Book Ends

- Validation Project Plan
- Validation Project Summary Report
Project Plan

- Kickoff Meeting

STRATEGY

THE PATH IS BROAD, NARROW THE APPROACH
Nailing the Strategy

- GAMP hardware / software classification
- Leveraging supplier activities
- E2500 approach
- Integrating C&Q of automation and process equipment
- Risk-based approach
  - Impact assessment
  - Functional Risk Assessment
- The role of the Quality Organization

COMMITMENT / FOLLOW THE MONEY
Project Sponsors

- Project Champions
- VMP Signers
- Statement of criticality

ESCALATION
/ THE SQUEAKY WHEEL GETS THE GREASE
Escalation

- Get involved early
- Interject in engineering and design reviews
- Participate in business analysis and elicitation of stakeholder needs
- Establish a process for escalation

DEPENDENCIES
/ DON'T GET SQUEEZED
Scheduling

- Develop a milestone-drive schedule
- Identify and communicate dependent activities

Schedule Traps

- Resource limits
- Inflexible milestones
- Punchlist activities not recaptured
- Completion for the sake of completion
Support Processes

- Document management and review
- Configuration management
- Project change management
- Issue resolution
- SOPs/Templates for deliverables
Effective Measurement

- Every person makes commitments
- Life happens, commitments are negotiated
- Each person updates their progress
- Shared tracking tools
- Automated reporting tools
- Automated schedule updates
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Action item is complete
Action item is on target
Action item is overdue but will not impact schedule
Action item is overdue and may impact schedule

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### Project Results for the Week: Earned Value $119609 / Actual Spend $93704 = 1.277% ratio

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### UNCOMMUNICATED EXPECTATIONS

/ RECIPE FOR RESENTMENT
Supplier Turn-over Data

- Specifications
- Maintenance Data
- Procedures (maintenance, administrative)
- In process quality check data
- Software listings
- Deliverable formats

Other Examples of Uncommunicated Expectations

- Solve design problems through troubleshooting
- Insufficient utility feeds
- Complexity beyond scope of work
- Coordinated start up (aka unit integration testing)
UNDOCUMENTED TESTING

/ AVOID THE TEMPTATION

Don’t Do It
FAIL FAST
/ ANYONE WHO HAS NEVER MADE A MISTAKE HAS NEVER TRIED ANYTHING NEW – ALBERT EINSTEIN

Project Risk Elements

- New (untried) technology
- Missing skilled resources
- Missing proper tools
- Outside of standards and guidance
- Operating in a new environment
- Improper metrics
FOCUS ON THE CRITICAL
/ DON'T GET LOST IN THE WEEDS

SCOPE & THE TRIPLE CONSTRAINTS OF QUALITY, SCHEDULE, AND COST

What
How Good?
How Fast?
How Cheap?

www.TheProjectManagementBlueprint.com
Test Rigor (Low to High)

- Test certificate provided by vendor
- Test document completed by vendor
- Test via visual inspection
- Test via code comparison
- Test under software simulated conditions
- Test under hardware simulated conditions
- Test under actual conditions, dry
- Test under actual conditions, using water
- Test under actual conditions, using analog materials
- Test under actual conditions, using actual materials

DATA MIGRATION

/ DATA IS A PRECIOUS THING AND WILL LAST LONGER THAN THE SYSTEMS THEMSELVES.
Data Migration

- Crucial aspect of IT projects
- Migration tools must be validated
- Must have data dependency models
  - Parent data must be loaded before child data
  - Support data must be loaded before mainstream data
  - Missing data must be generated

TRACEABILITY
/ LEAVE BREADCRUMBS
Traceability is Non-Linear

**DO**
- Trace user requirements to risk elements
- Trace user requirements to functional requirements
- Trace functional requirements to IQ/OQ/PQ tests
- Put FRS references in each test case
- Make the DQ report into the Traceability Matrix

**DON'T**
- Trace functional requirements to detail design elements
- Trace the detail design elements to the configuration
- Trace commissioning, FAT, or SAT testing

**REPORTING**
/ WRAP IT UP
GO LIVE
/ YOU DON'T DROWN BY FALLING WATER, YOU DROWN BY STAYING THERE.
Go Live is not the End of the Project

- Checklist – one week before Go Live
- Checklist – one day before Go Live
- Checklist – day of Go live
- Activities after Go Live
  - Shadow users
  - Immediate helpdesk response
  - Follow up training
  - Issues resolution / Punchlist management

The Project Pathway
QUESTIONS?

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