



SUCCESSFUL PROJECT MANAGEMENT FOR SOFTWARE DEVELOPMENT AND VALIDATION

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

The Project Pathway



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PLANNING

/ FAILURE TO PLAN IS PLANNING TO FAIL

Book Ends

- **Validation Project Plan**
- **Validation Project Summary Report**



Project Plan

- Kickoff Meeting



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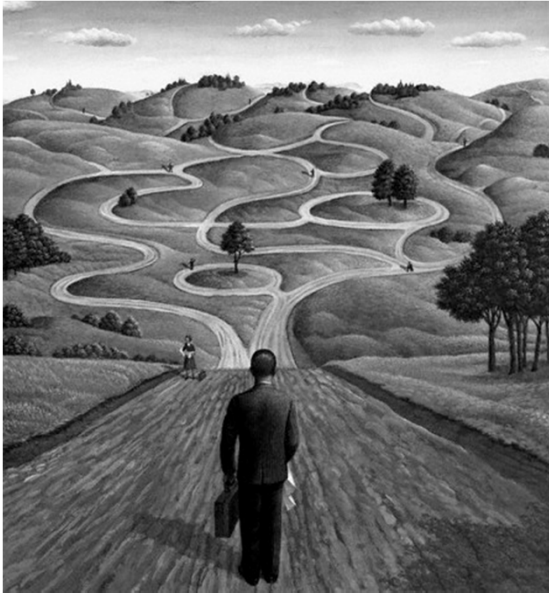
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STRATEGY

/ 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**



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COMMITMENT

/ FOLLOW THE MONEY

Project Sponsors



- **Project Champions**
- **VMP Signers**
- **Statement of criticality**



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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



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DEPENDENCIES

/ DON'T GET SQUEEZED

Scheduling



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



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Schedule Traps



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



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SUPPORT PROCESSES

/ ARE THE CORNERSTONES IN PLACE?

Support Processes



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

MEASUREMENT

/ TALE OF THE TAPE

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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EQUIPMENT	DOC TYPE	ACTUAL	P-Reviewed	Submitted	Reviewed	Approved	Executed	Reported	Closed
HPLC #3	IOQ	15-Sep	28-Sep	11-Oct	25-Oct	8-Nov	22-Nov	29-Nov	6-Dec
HPLC #5	IOQ	15-Sep	28-Sep	11-Oct	25-Oct	8-Nov	22-Nov	29-Nov	6-Dec
HPLC #4	IOQ	15-Sep	28-Sep	11-Oct	25-Oct	8-Nov	22-Nov	29-Nov	6-Dec
GC #2	IOQ	15-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
GC #1	IOQ	15-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
GC #3	IOQ	15-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
GC #4	IOQ	15-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
IR	IOQ	19-Sep	19-Sep	19-Oct	2-Nov	16-Nov	30-Nov	7-Dec	14-Dec
Spectrophotometer #1	IOQ	20-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
Spectrophotometer #2	IOQ	20-Sep	3-Oct	17-Nov	7-Nov	21-Nov	28-Nov	5-Dec	12-Dec
TOC	IOQ	20-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
Flow Cytometer #1	IOQ	20-Sep	4-Oct	18-Oct	1-Nov	15-Nov	29-Nov	6-Dec	13-Dec
Flow Cytometer #2	IOQ	20-Sep	4-Oct	18-Oct	1-Nov	15-Nov	29-Nov	6-Dec	13-Dec
Nephelometer #1	IOQ	20-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
Nephelometer #2	IOQ	20-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
Microplate reader #1	IOQ	20-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
Microplate reader #2	IOQ	20-Sep	3-Oct	17-Oct	31-Oct	14-Nov	28-Nov	5-Dec	12-Dec
Electrophoresis #1	IOQ	20-Sep	4-Oct	18-Oct	1-Nov	15-Nov	29-Nov	6-Dec	13-Dec
Electrophoresis #2	IOQ	20-Sep	4-Oct	18-Oct	1-Nov	15-Nov	29-Nov	6-Dec	13-Dec
Lab Data Management Network	IOQ	12-Oct	26-Oct	9-Nov	16-Nov	23-Nov	7-Dec	14-Dec	21-Dec
Lab Data Management System (LDMS)	IOQ	30-Sep	14-Oct	28-Oct	11-Nov	18-Nov	2-Dec	9-Dec	16-Dec
Vitech	IOQ	11-Oct	14-Oct	19-Oct	7-Nov	21-Nov	5-Dec	12-Dec	19-Dec
Absorbance Reader	IOQ	11-Oct	14-Oct	19-Oct	2-Nov	16-Nov	30-Nov	7-Dec	14-Dec
PROJECT	RP	1-Dec	4-Dec	7-Dec	10-Dec	13-Dec	16-Dec	19-Dec	22-Dec
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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Document Progress Summary														
System	CFA	Work To	Document #	Type	TC DEV	1 Drafted	2 Internally R	3 Issued for R	4 Comments	5 Pre-Execu	6 TC EXE	6 Execution	7 Issues Reso	8 Execution R
BAS	06 - IG	BAS-QV	CV-62-40607-290-HW-IOQ	IOQ		22-Sep-2015	24-Sep-2015	26-Sep-2015	28-Sep-2015	30-Sep-2015		07-Oct-2015	11-Oct-2015	14-Oct-2015
BAS	06 - IG	BAS-QV	CV-62-40607-217-SW-IOV	IOV	100 %	15-May-2015	126 19-May-2015	124 19-May-2015	126 28-May-2015	119 25-Jun-2015	93 0 %	03-Oct-2015	07-Oct-2015	10-Oct-2015
BAS	06 - IG	BAS-QV	CV-62-40607-217-HW-IOV	IOV	100 %	19-May-2015	112 26-May-2015	107 25-Jun-2015	79 25-Jun-2015	81 25-Jun-2015	83 0 %	23-Sep-2015	27-Sep-2015	30-Sep-2015
BAS	06 - IG	BAS-QV	CV-62-40607-216-SW-IOV	IOV	100 %	15-May-2015	193 19-May-2015	191 19-May-2015	193 28-May-2015	186 25-Jun-2015	160 0 %	09-Dec-2015	13-Dec-2015	16-Dec-2015
BAS	06 - IG	BAS-QV	CV-62-40607-216-HW-IOV	IOV	100 %	19-May-2015	179 28-May-2015	172 28-May-2015	174 28-May-2015	176 25-Jun-2015	150 0 %	29-Nov-2015	03-Dec-2015	06-Dec-2015
BAS	06 - IG	BAS-QV	CV-62-40607-215-SW-IOV	IOV	100 %	14-May-2015	177 15-May-2015	178 15-May-2015	180 27-May-2015	170 25-Jun-2015	143 0 %	22-Nov-2015	26-Nov-2015	29-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-215-HW-IOV	IOV	100 %	19-May-2015	162 28-May-2015	155 28-May-2015	157 28-May-2015	159 25-Jun-2015	133 0 %	12-Nov-2015	16-Nov-2015	19-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-214-SW-IOV	IOV	100 %	14-May-2015	125 15-May-2015	126 16-May-2015	127 27-May-2015	118 25-Jun-2015	91 0 %	01-Oct-2015	05-Oct-2015	08-Oct-2015
BAS	06 - IG	BAS-QV	CV-62-40607-214-HW-IOV	IOV	100 %	19-May-2015	110 22-May-2015	109 28-May-2015	105 28-May-2015	107 25-Jun-2015	81 0 %	21-Sep-2015	25-Sep-2015	28-Sep-2015
BAS	06 - IG	BAS-QV	CV-62-40607-212-SW-IOV	IOV	100 %	14-May-2015	118 20-May-2015	114 20-May-2015	116 27-May-2015	111 25-Jun-2015	84 0 %	24-Sep-2015	28-Sep-2015	01-Oct-2015
BAS	06 - IG	BAS-QV	CV-62-40607-212-HW-IOV	IOV	100 %	19-May-2015	103 21-May-2015	103 28-May-2015	98 28-May-2015	100 25-Jun-2015	74 0 %	14-Sep-2015	18-Sep-2015	21-Sep-2015
BAS	06 - IG	BAS-QV	CV-62-40607-211-SW-IOV	IOV	100 %	19-May-2015	156 21-May-2015	156 21-May-2015	158 27-May-2015	154 25-Jun-2015	127 0 %	06-Nov-2015	10-Nov-2015	13-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-211-HW-IOV	IOV	100 %	19-May-2015	146 21-May-2015	146 28-May-2015	141 28-May-2015	143 25-Jun-2015	117 0 %	27-Oct-2015	31-Oct-2015	03-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-210-SW-IOV	IOV	100 %	14-May-2015	161 17-May-2015	160 18-May-2015	161 27-May-2015	154 25-Jun-2015	127 0 %	06-Nov-2015	10-Nov-2015	13-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-210-HW-IOV	IOV	100 %	19-May-2015	148 20-May-2015	147 28-May-2015	141 28-May-2015	143 25-Jun-2015	117 0 %	27-Oct-2015	31-Oct-2015	03-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-207-SW-IOV	IOV	100 %	14-May-2015	161 20-May-2015	157 21-May-2015	158 27-May-2015	154 25-Jun-2015	127 0 %	06-Nov-2015	10-Nov-2015	13-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-207-HW-IOV	IOV	100 %	18-May-2015	147 19-May-2015	148 26-May-2015	143 25-Jun-2015	115 25-Jun-2015	117 0 %	27-Oct-2015	31-Oct-2015	03-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-206-SW-IOV	IOV	100 %	14-May-2015	189 17-May-2015	188 18-May-2015	189 27-May-2015	182 25-Jun-2015	155 0 %	04-Dec-2015	08-Dec-2015	11-Dec-2015
BAS	06 - IG	BAS-QV	CV-62-40607-206-HW-IOV	IOV	100 %	18-May-2015	175 20-May-2015	175 28-May-2015	169 28-May-2015	171 25-Jun-2015	145 0 %	24-Nov-2015	28-Nov-2015	01-Dec-2015
BAS	06 - IG	BAS-QV	CV-62-40607-205-SW-IOV	IOV	100 %	14-May-2015	175 27-May-2015	164 27-May-2015	166 27-May-2015	168 25-Jun-2015	141 0 %	20-Nov-2015	24-Nov-2015	27-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-205-HW-IOV	IOV	100 %	19-May-2015	160 19-May-2015	162 22-May-2015	161 27-May-2015	158 25-Jun-2015	131 0 %	10-Nov-2015	14-Nov-2015	17-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-204-SW-IOV	IOV	100 %	21-May-2015	111 21-May-2015	113 21-May-2015	115 26-May-2015	112 25-Jun-2015	86 0 %	24-Sep-2015	28-Sep-2015	01-Oct-2015
BAS	06 - IG	BAS-QV	CV-62-40607-204-HW-IOV	IOV	100 %	19-May-2015	103 19-May-2015	105 19-May-2015	107 26-May-2015	102 25-Jun-2015	74 0 %	14-Sep-2015	18-Sep-2015	21-Sep-2015
BAS	06 - IG	BAS-QV	CV-62-40607-203-SW-IOV	IOV	100 %	14-May-2015	175 19-May-2015	172 19-May-2015	174 26-May-2015	169 25-Jun-2015	141 0 %	20-Nov-2015	24-Nov-2015	27-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-203-HW-IOV	IOV	100 %	18-May-2015	161 19-May-2015	162 19-May-2015	164 26-May-2015	159 25-Jun-2015	131 0 %	10-Nov-2015	14-Nov-2015	17-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-202-SW-IOV	IOV	100 %	14-May-2015	114 14-May-2015	116 15-May-2015	117 26-May-2015	108 25-Jun-2015	80 0 %	20-Sep-2015	24-Sep-2015	27-Sep-2015
BAS	06 - IG	BAS-QV	CV-62-40607-202-HW-IOV	IOV	100 %	15-May-2015	103 18-May-2015	102 19-May-2015	103 26-May-2015	98 25-Jun-2015	70 0 %	10-Sep-2015	14-Sep-2015	17-Sep-2015
BAS	06 - IG	BAS-QV	CV-62-40607-201-SW-IOV	IOV	100 %	14-May-2015	177 15-May-2015	178 15-May-2015	180 26-May-2015	171 25-Jun-2015	143 0 %	22-Nov-2015	26-Nov-2015	29-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-201-HW-IOV	IOV	100 %	14-May-2015	167 18-May-2015	165 18-May-2015	167 26-May-2015	161 25-Jun-2015	133 0 %	12-Nov-2015	16-Nov-2015	19-Nov-2015
BAS	06 - IG	BAS-QV	CV-62-40607-003-SW-IOV	IOV	100 %	13-May-2015	72 14-May-2015	73 14-May-2015	75 26-May-2015	65 25-Jun-2015	37 0 %	08-Aug-2015	12-Aug-2015	15-Aug-2015
BAS	06 - IG	BAS-QV	CV-62-40607-003-HW-IOV	IOV	100 %	16-May-2015	89 19-May-2015	88 20-May-2015	89 26-May-2015	85 25-Jun-2015	27 72 %	29-Jul-2015	02-Aug-2015	05-Aug-2015
BAS	06 - IG	BAS-QV	CV-62-40607-002-SW-IOV	IOV	100 %	13-May-2015	92 14-May-2015	93 14-May-2015	95 26-May-2015	85 25-Jun-2015	57 0 %	28-Aug-2015	31-Sep-2015	04-Sep-2015
BAS	06 - IG	BAS-QV	CV-62-40607-002-HW-IOV	IOV	100 %	16-May-2015	79 19-May-2015	78 19-May-2015	80 26-May-2015	75 25-Jun-2015	47 83 %	18-Aug-2015	22-Aug-2015	25-Aug-2015
BAS	06 - IG	BAS-QV	CV-62-40607-001-SW-IOV	IOV	100 %	13-May-2015	115 14-May-2015	116 15-May-2015	117 26-May-2015	108 25-Jun-2015	80 0 %	20-Sep-2015	24-Sep-2015	27-Sep-2015
BAS	06 - IG	BAS-QV	CV-62-40607-001-HW-IOV	IOV	100 %	14-May-2015	104 19-May-2015	101 19-May-2015	103 26-May-2015	98 25-Jun-2015	70 0 %	10-Sep-2015	14-Sep-2015	17-Sep-2015
BAS	08 - Admin/Commons	BAS-QV	CV-62-40606-PLAT-IOV	IOV	100 %	27-Jun-2015	29-Jun-2015	01-Jul-2015	03-Jul-2015	05-Jul-2015	100 %	07-Jul-2015	11-Jul-2015	14-Jul-2015
					21 %					597	11 %			



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Project Results for the Week: Earned Value \$119609 / Actual Spend \$93704 = 1.277% ratio									
Total	Drafted	P-Reviewed	Submitted	Reviewed	Approved	Execute	Report	Closure	
3	2	2	2	2	2	NA	NA	NA	Plan
48	48	48	48	48	48	48	48	48	Template
12	12	12	12	12	12	NA	NA	NA	SOP
12	12	12	12	12	12	6	6	6	Train
21	21	21	21	21	20	19	19	19	IOQs
This week	0	0	0	0	0	1	1	1	Since 4-22
96	94	94	94	94	93	73	73	73	Total Docs



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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



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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)



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UNDOCUMENTED TESTING

/ AVOID THE TEMPTATION

Don't Do It



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FAIL FAST

/ ANYONE WHO HAS NEVER MADE A MISTAKE HAS NEVER TRIED ANYTHING NEW –
ALBERT EINSTEIN

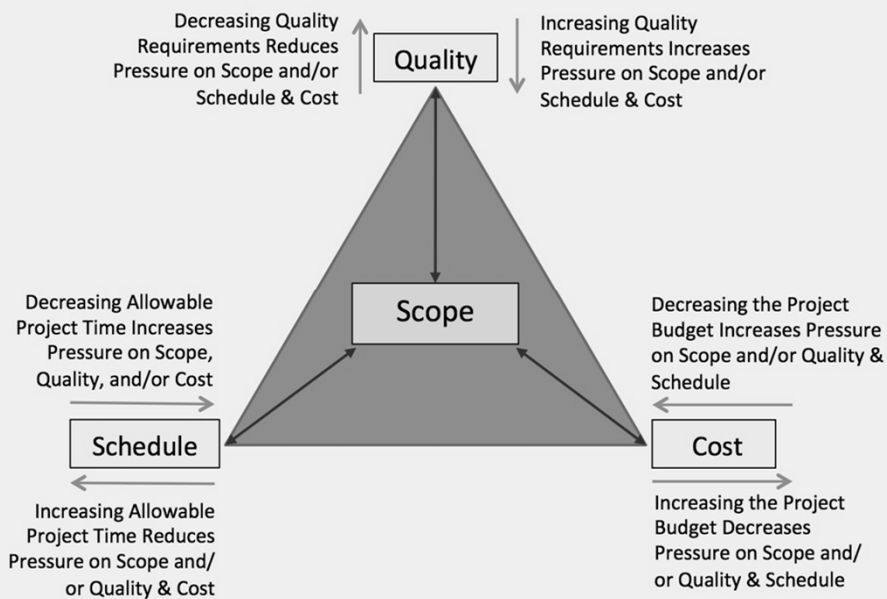
Project Risk Elements



- 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

+



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



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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



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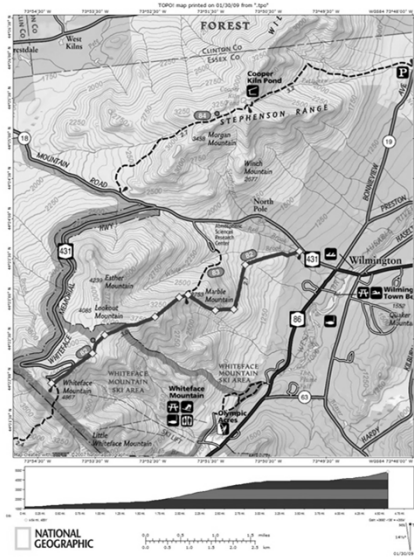
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TRACEABILITY

/ 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 configuration1
- Trace commissioning, FAT, or SAT testing2



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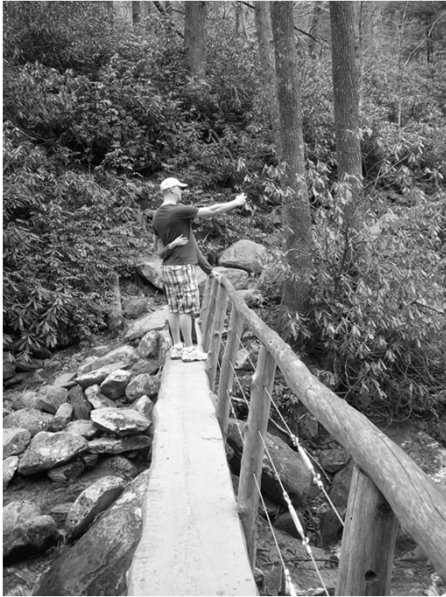
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REPORTING

/ WRAP IT UP

Testing Reports



- **Background / Overview**
- **Results Summary**
- **Deviations / Non-conformances**
- **Modifications**
- **Conclusions**



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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



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The Project Pathway



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QUESTIONS?

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