Implementing an Electronic System for CAPA and Complaints: Challenges and Opportunities

119th AFDO Annual Educational Conference

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June 22, 2015

Mallinckrodt Pharmaceuticals

Implementing an Electronic System for CAPA and Complaints: Challenges and Opportunities

- What are you talking about?
- Whose Idea Was This Anyway?
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- IQ, OQ, PQ: Der Hexenkessel
- Training AKA You Run 6.2 Miles!
- Go Live! … “There are only 2 kinds of people…”
- Final Thoughts: It Was The Best Of Times, it Was The Worst Of Times

What are you (am I) talking about?

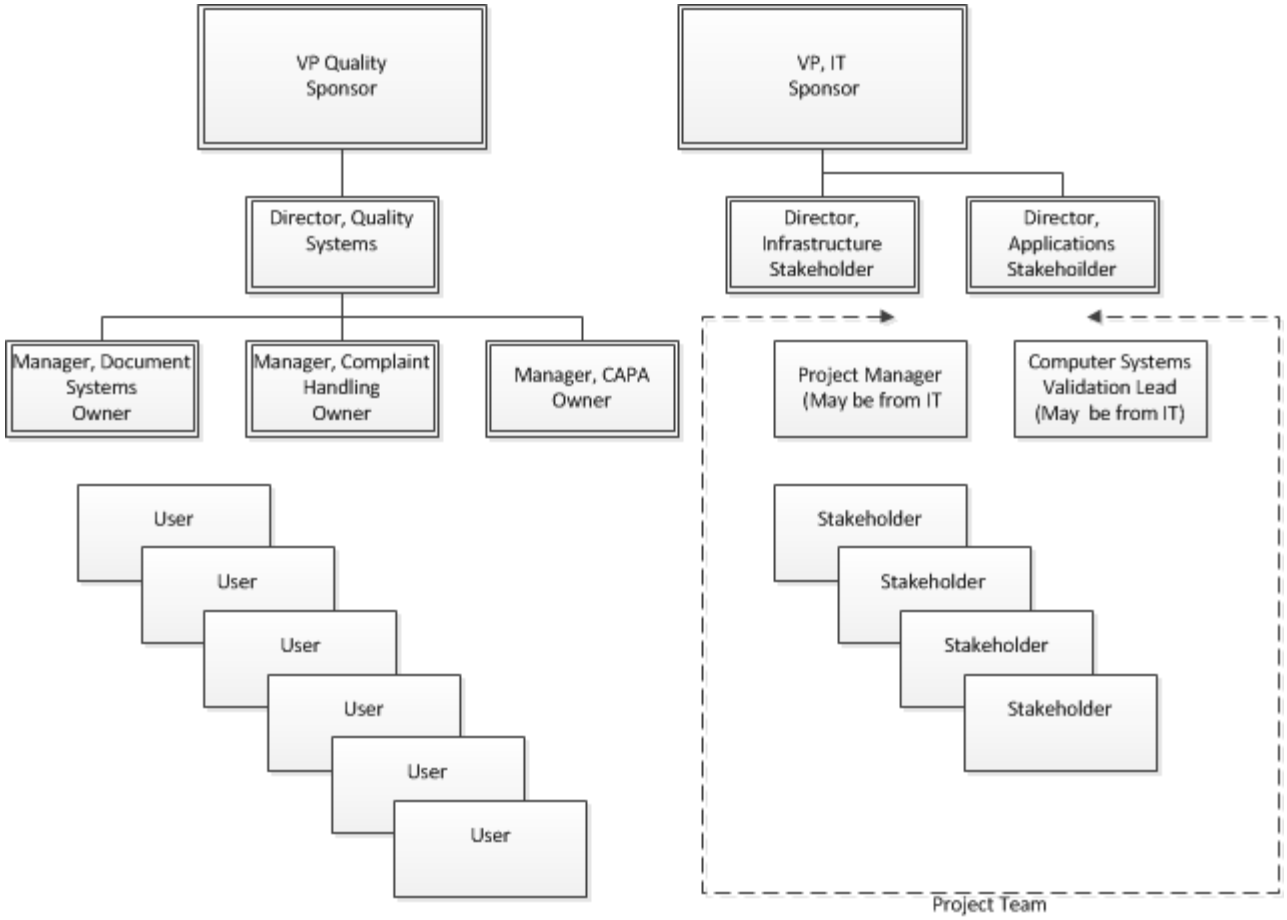
- For the following topics…
- Challenges
  - Why are these items a potential problem?
- Opportunities:
  - How can the problems be avoided?
- *Bottom Line: "Polarities are in the nature of things. How we act, how we respond to those polarities – that is where we separate greatness from mediocrity." Polly LaBarre*

Whose Idea Was This Anyway?

- **Owner**
  - The person who really owns the system; has responsibility for its implementation
- **Administrator**
  - The person who designs and runs the day to day operation of the system
- **Sponsor**
  - The person(s), usually more senior, who has ultimate responsibility for the funding and usually human resources for the implementation and operation of the system
- **Stakeholders**
  - Key users required to design and implement the system because of their role in its use; usually implementation team members
- **Users**
  - The persons who utilize the system to get work done

- *Bottom Line: Lack of commitment or buy in from anyone of these roles can decrease system use and acceptance*

Organizational Awareness



Show Me The Money…Twice!

- How Much Does it Cost?
  - Hardware
  - Software
  - Maintenance
  - SAS
  - Consultants
  - Other:
    - Travel
    - Audits
    - Internal employees
- How Much Does it Save?
  - Maybe nothing – Compliance Issue?
  - Do the analysis – it is worth the “cost”
- Bonus Question: How Much Faster Can You Get It Done?
- *Bottom Line: Be prepared for financial discussions…they matter and you can avoid issues later if you do your homework! Its always better if you can show that the solution you are implementing can not ONLY improve compliance, but improve efficiency and/or decrease expenses as well…and if you can do it sooner rather than later.*

Cost Analysis Example

Data extracted from LMS for the year 2013			
Task Eliminated by Integration	Hours	Average Hourly Rate	Cost/1 Year
Plant #1			
Add Course	588		
Add Course to Org	79		
Add Item to Curriculum	455		
Add New Course Version	78		
Attach uploaded file	770		
Retire or Permanently disable old course version	71		
Upload new file	13		
Subtotal	2,053	$ 31.13	$ 63,909.89
Plant #2			
Add Course	22		
Add Course to Org	6		
Add Item to Curriculum	198		
Add New Course Version	104		
Attach uploaded file	50		
Retire or Permanently disable old course version	107		
Upload new file	46		
Subtotal	533	$ 25.00	$ 13,331.50
Plant #3			
Add Course	41		
Add Course to Org	11		
Add Item to Curriculum	346		
Add New Course Version	47		
Attach uploaded file	31		
Retire or Permanently disable old course version	16		
Upload new file	30		
Subtotal	521	$ 25.00	$ 13,027.50
Total	3,107		$ 90,268.89
Project Budget			$ 100,000.00
ROI		1.11	13.3 months

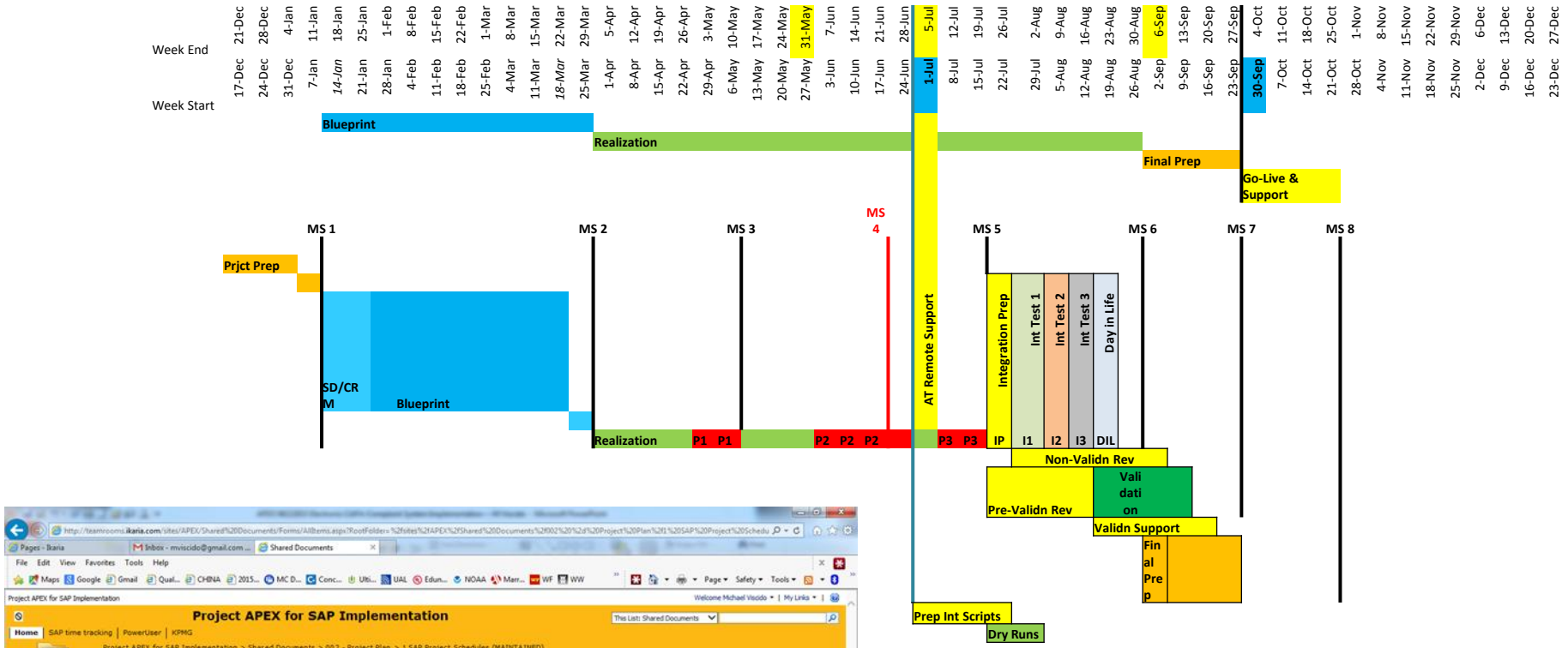
We Need A Plan: Normandy Revisited

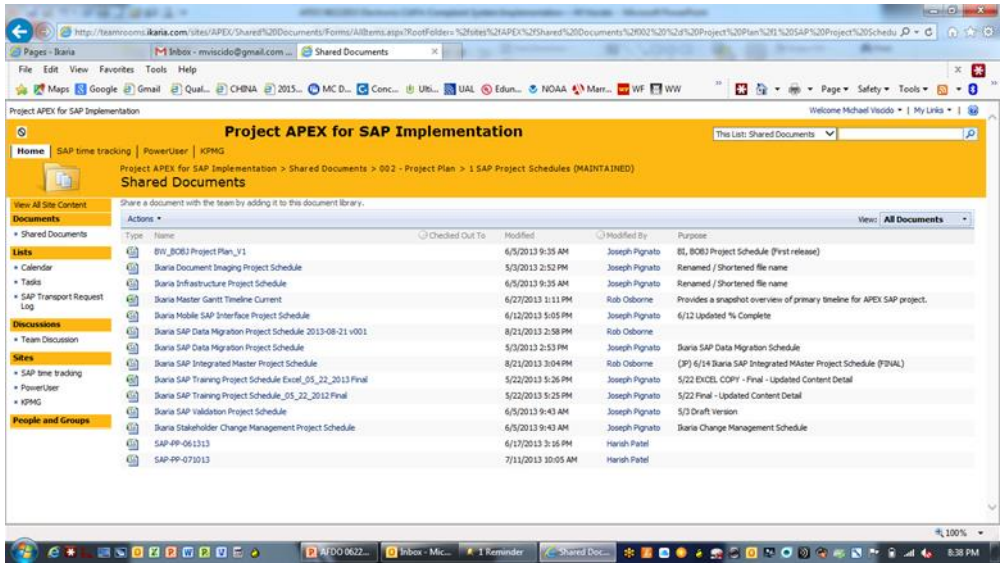
- How?
  - It depends on the project, the organization and the team
  - It may be simple or complex
- Why?
  - It helps the project manager
  - It helps the team members
  - It helps sponsors/management
  - In short, it is one tool for communication
- *Bottom Line: A plan is one of the best ways to ensure others that the effort is on-track, for real and that they should pay attention*

Plan Example 1

#	Task	Due Date	Status	Completion Date
1	Meet with the team to gather inputs	03/31/2014	Complete	04/01/2014
2	Meet with the team to introduce the differences of out of box versus what is the current process	04/15/2014	Complete	04/08/2014
3	Create mock SOPs and WIs	04/30/2014	Complete	05/07/2014
4	Install new system on the DEV server	05/15/2014	Complete	05/05/2014
5	Set up users	05/20/2014	Complete	05/09/2014
6	Demo the new system	05/30/2014	Complete	05/29/2014
7	Revisit inputs	06/15/2014	Complete	05/29/2014
8	Final Decision as to 'go-no-go' for OOB	06/15/2014	Complete	07/02/2014
9	Work with MC Architects to design form with Minor Changes (DEV environment)	TBD:		
10	Schedule multiple "play and learn" sessions in DEV	ORIG: 07/30/2014 CURR: 30 days after Task 9 is completed		
11	Tweak SOPs and WIs as needed	ORIG: 08/15/2014 CURR: 45 days after Task 9 is completed		
12	Install into QA	ORIG: 08/15/2014 CURR: 45 days after Task 9 is completed		
13	Set up users in QA	ORIG: 08/20/2014 CURR: 5 days after Task 12 is completed		
14	Create/Approve PQs	ORIG: 08/20/2014 CURR: 25 days after Task 12 is completed		
15	Run PQs	ORIG: 08/31/2014 CURR: 5 days after Task 14 is completed		
16	Perform trainings	ORIG: 09/15/2014 CURR: 10 days after Task 15 is completed		
17	Install into PROD and set up users	ORIG: 09/20/2014 CURR: 10 days after Task 15 is completed		
18	Issue procedures	ORIG: 09/20/2014 CURR: 1-2 days after Task 17 is completed		
19	Go live	ORIG: 09/20/2014 CURR: 1-2 days after Task 17 is completed		

Plan Example 2





Requirements:

- User Requirement Specifications (URS) should be simply stated (in the user's words so users can understand them)
  - High level
  - Descriptive
  - Testable
  - Clear
  - Simple
  - Traceable
  - Necessary
- Good URS documents ensure user expectations are met
- Others:
  - Functional Requirements
  - Detailed Design Requirements
- Trace matrix
  - Ensures that all items are tested…when done correctly
- *Bottom Line: Clear, testable requirements that state/confirm user needs will help ensure the final "product' is what was intended and works! All requirements must be complete and should be verified to mean the same things to all stakeholders.*

Requirements Document Example

3.0 USER REQUIREMENTS

3.1 Fields to Add

Requirement ID	Requirement Description
URS 1.1	On T2, the field 'Report Date' must be displayed, and the User must be able to enter a date.
URS 1.2	On T2, the field 'Event Date' must be displayed, and the User must be able to enter a date.
URS 1.3	On T6, the field 'Report #' must be displayed, and the User must be able to enter a report number.
URS 1.4	In the Header the User must be able to link MC documents and forms and open them in the 'InfoCard Links'; they must be available at all times throughout the draft complaint.
URS 1.5	The Complaint Tab (T3) field 'Reporter Phone' must have formatting assigned to it and must allow for entry of extensions.
URS 1.6	The T4 drop-down list for the 'Was this on a patient?' field must have the following Options: Yes, No, Unknown.
URS 1.7	The T4 drop-down list for the field 'Post-Evaluation Customer Follow-Up Requested' must have the following Options: Yes, No.
URS 1.8	The T5 field, 'RMF Category' must have the following Options: RMF-1, RMF-2, RMF-3, Other, N/A.
URS 1.9	The T5 field, 'Resolution Code' must be a data structure that can be managed by the Ikaria MC Subadmin.
URS 1.10	The User must be able to enter up to 200 characters into the T5 field 'Additional S/Ns', located just above 'Recovery of Product'.
URS 1.11	The User must be able to enter up to 250 characters into the T5 field 'UDI', located two fields below 'Lot Number'.

Requirement #	Requirement Description	FRS Reference
21 CFR 11.1c	Computer Systems, Hardware and Software are readily available for audit, review and or inspection by FDA at agency request.	
21 CFR 11.10a	Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	
21 CFR 11.10b	The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency.	
21 CFR 11.10c	Protection of records to enable their accurate and ready retrieval throughout the records retention period.	
21 CFR 11.10d	The ability to limit System Access to authorized individuals.	
21 CFR 11.10e	Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.	
21 CFR 11.10e	Record changes shall not obscure previously recorded information.	
21 CFR 11.10e	Audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	
21 CFR 11.10f	Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	
21 CFR 11.10g	Use of authority checks to ensure that only authorized individuals can use the system.	

Trace Matrix Example

7.1 Global System Requirements

Requirement #	Requirement Description	References
URS-Global-001	Application compatibility - the system must be capable of supporting multiple common office application types including but not limited to Microsoft Office, Visio, Microsoft Project, Adobe, and other Windows accessible file types.	**Documentation ref:** o SQA_Tech-003 – 10.x.x HW/SW Requirements Specification **PQ Test Ref:** o PRT-PQ-1458 o PRT-PQ-1459, Section 8.4, 8.7, 8.10 o PRT-PQ-1460 o PRT-PQ-1463, Sections 8.5, 8.13, 8.16, 8.30, 8.34, 8.37, 8.42 o PRT-PQ-1464, Sections 8.5, 8.13, 8.16, 8.30, 8.34, 8.37, 8.42 o PRT-PQ-1465
URS-Global-002	The system must allow multiple users accessing the system's interface and database functions simultaneously.	**Documentation ref:** o Tested generally in TOQ / PQ
URS-Global-003	The system must be compatible with the following standard business databases: Microsoft SQL Server or Oracle Database Server.	**Documentation ref:** o Val-Doc-496 – Database IQ o SQA_Tech-003 – 10.x.x HW/SW Requirements Specification **PQ Test Ref:** o This is indirectly tested. The IQ defines the database type used in testing.
URS-Global-004	Database Backup / Restore – the system must allow capabilities for the periodic backup of the critical systems data and operational code.	**Documentation ref:** o SOP-IT-0066 Backup and Restore
URS-Global-005	Database Backup / Restore – the system must allow capabilities for the restoration and/or recovery of all system data.	**Documentation ref:** o SOP-IT-0066 Backup and Restore

Risk: Bomb Our Position!

- Risk must be assessed
  - Project
    - This assessment focuses on overall project risk and mitigations, e.g. money, people, timing, external issues, etc.
  - Application
    - This assessment focuses on the actual software application, e.g. what issues might be caused by software problems, 21 CFR part 11, QSR/GMP compliance, functional failures, etc.
- Formal or Informal
  - Sorry, no such thing!
- *Bottom Line: A good risk assessment will not only ensure that potential problems are review and mitigated as needed, BUT will help to ensure and communicate to others that the "solution/tool" developed has been appropriately vetted for use.*

Risk Assessment Example

System / Equipment / Instrumentation: Virtual servers internally hosting the solution at corporate data center

Computer-Related System / Software: MasterControl Suite version 10.x

Question No.	Question	Risk Level 0 = No Risk 1 = Low 2 = Medium 3 = High	Yes/ No	Points	Comments
Business Risk					
18	Does the system have any impact on employee Health & Safety?	3	NO	0	
19	Would a prolonged system failure have a major business impact?	3	YES	3	
20	Could a system malfunction compromise the integrity of any business-critical data?	3	YES	3	
21	Is the system used for business-critical traceability purposes?	3	YES	3	
22	Is the system not in commercial widespread usage?	1	NO	0	
23	Does the system require 24hour / 7day uptime?	1	YES	1	Support services requires this level of uptime.
24	Will additional external technical expertise be required during implementation?	1	YES	1	
25	Is this a 'complex' project (estimated as taking >12 months and/or involving > 8 persons)	1	YES	1	
26	Has the system been purchased or leased from a new or unapproved supplier?	2	NO	0	
27	Has the system been in commercial usage for less than 18 months?	3	NO	0	
28	Does the system have direct involvement with meeting customer satisfaction goals?	3	NO	0	
29	Is the system a multi-site system?	2	YES	2	
30	Does the system utilize external resources for routine operation?	2	NO	0	
31	Does the system interface with any other system(s)?	2	YES	2	Interfaces with SAP and Argus.
32	Does the system utilize a new technology?	2	NO	0	
	Business Risk - Total Score:			**16**	

Risk Assessment Example 2

Section No.	Question	Answer	Comments
11.10(e)	Is there a defined retention period for the audit trail documentation?	Yes	
11.10(e)	Is the audit trail documentation retained at least as long as that required for the electronic record?	Yes	
11.10(e)	Is the audit trail documentation available for review and copying?	Yes	
11.10(f)	Does the system have the capability to control the sequence in which users may view screens?	Yes	
11.10(f)	Does the system have the capability to detect when an entry is made out of the normal sequence?	Yes	
11.10(g)	Does the system restrict users to specific functions?	Yes	
11.10(g)	Does the system restrict users to specific documents?	Yes	
11.10(g)	Does the system restrict users to specific workstations by function or document?	No	
11.10(h)	Does the system record the location (node) of the workstation where each entry is made?	No	
11.10(i)	Is there a user-training program for all categories of system users?	Yes	
11.10(i)	Are there training records for users, developers, and maintenance personnel?	Yes	Training records are maintained.
11.10(i)	Are training records available for all system users?	Yes	Training records are maintained.
11.10(j)	Does the company have a written policy concerning the use of electronic signatures?	Yes	GQPO-002, Electronic Signature Management
11.10(k1)	Are written records kept of the number and possession of copies of all system documentation?	Yes	
11.10(k2)	Does every system documentation change have a change history and approvals?	Yes	This is limited to validation documentation.
11.10(k2)	Is there an approved procedure for the control, change, distribution, and destruction of system documentation?	Yes	

IQ, OQ, PQ: Der Hexenkessel

- Qualifications
  - Installation Qualification
    - Ensures proper installation of software
    - Ensures proper hardware is available
  - Operational Qualification
    - To ensure software meets design/functional requirements
    - Typically done by developer/vendor; review by customer
  - Process Qualification
    - Primary check to ensure software works and meets user requirements
    - This is where you ensure the thing works!!
- Different environments
  - Development
  - QA
  - Production
- *Bottom Line: Make sure you perform qualifications in QA and Production and use people from different areas who are not protocol authors.*

PQ Example

Pre-execution Approval
By signing / dating in the sp
this protocol for execution a

Role
Author
System Owner
Business Process Owner
Validation
Quality Assurance

This protocol was executed

Post-execution Approval
By signing / dating in the sp
the completed protocol res

TITLE
System Owner
Business Process Owner
Validation
Quality Assurance

12. Complaint OOB Test #2

Objective	To verify that the Out of Box Complaints Minor Change Plus routes the Complaint forms to the appropriate personnel during a reportable complaint configuration, presents the appropriate pages in editable or read-only mode, preserves all data, and correctly records electronic signatures during the Data Complete, Data Rejection, Approval functions, and Issue Review
Procedure	Manually launch a Customer Complaints Advanced Cyl form and complete the following configurations, documenting the results in the spaces provided. The camera symbol is the required location for a screenshot (📷) The printer symbol is the required location for a printout record (🖨)
Acceptance Criteria	Acceptance requires that all process test steps are successfully executed. The actual results should exactly match the expected results for all process test steps.

Test	Test Instructions	Expected Result	Actual Result
9.1	Login to the MasterControl Application Suite as a user with rights to launch and process the ***Customer Comp Adv Cyl*** form. Access the Start Task > Forms page for the Forms selection and ensure that the test Process (**Customer Comp Adv Cyl** form) is available to be launched. Launch the Customer Complaints Advanced Cyl Form. Document the User ID, Form Template Number, and Revision in Actual Results.	User is logged in and the form to be tested is available in the Forms list. Customer Comp Adv Cyl form is launched. User ID, Form Template Number, and Revision are documented in Actual Results.	User ID: 2PQUSER21 Form Template Number: SP-FRM-0033 Revision: 04 Pass/Fail? Pass 🖨 (Print Complaint Form as launched and label)

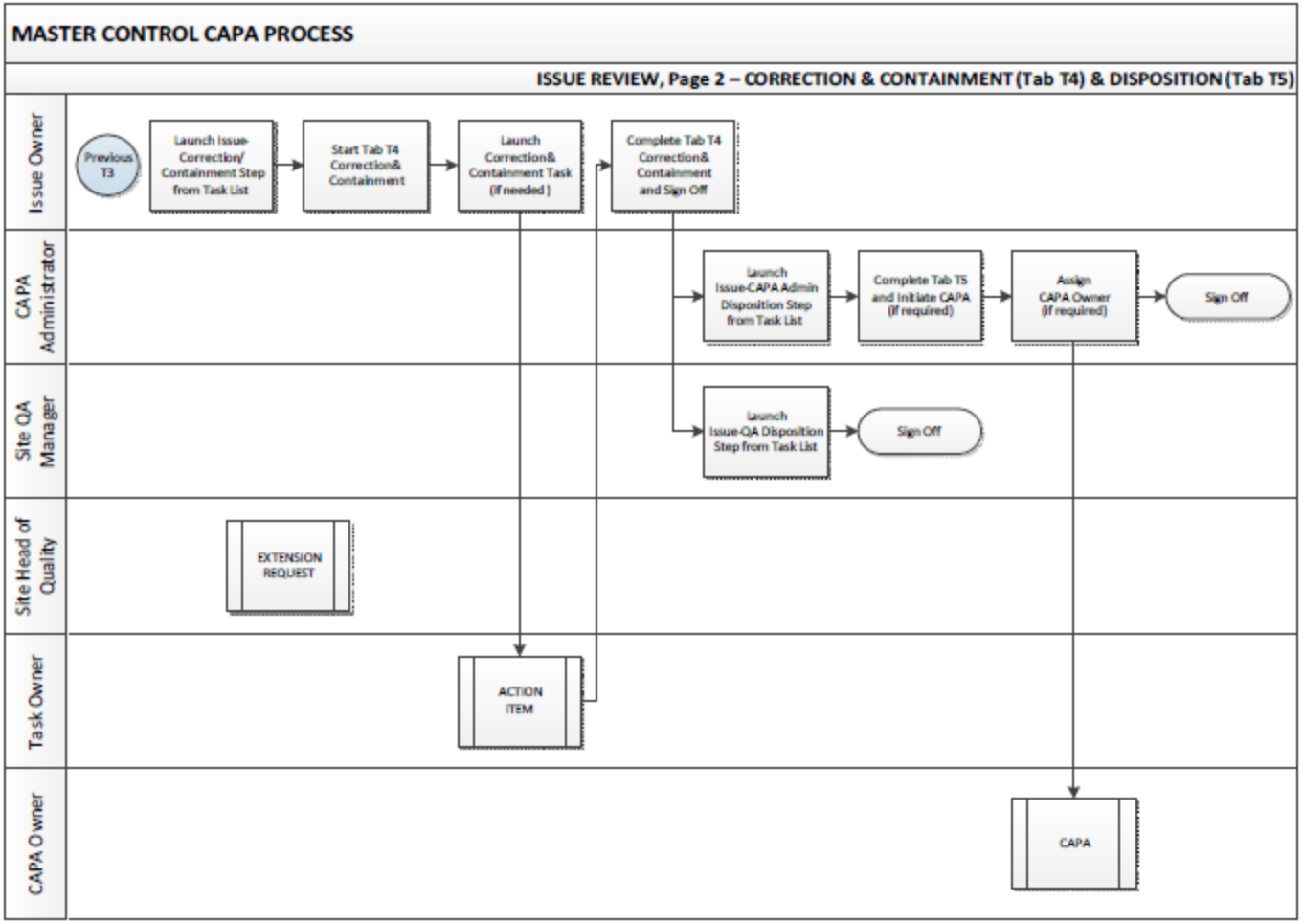
Completed by: [redacted] Date: 11/20/2014 Reviewed by: [redacted] Date: 11/20/2014

Training AKA You Run 6.2 Miles!

- Training
  - Needs to be planned
  - Needs to be organized
  - Needs to be supported
  - Needs to be attended
- Training Elements
  - Plan, forethought
  - Materials
  - Location(s)/venue
  - Trainers
  - Materials
  - Follow-up
- *Bottom Line: Don't make this an afterthought…plan, develop, pilot and train (hands on) users at various levels and roles.*

Sample Work Instruction

Attachment 5 – Issue Review, Page 2: Correction & Containment (Tab T4) & Disposition (Tab T5)



Go Live! … “There are 2 kinds of people…”

- The moment of truth
  - Ensure IT support
  - Ensure SME support
  - Ensure “back-out” plan in place

- *Bottom Line: Now that you are live, don’t let off the gas…support and troubleshooting here are essential to a well received roll out that will lead to long term acceptance by users and an implementation that is deemed successful by management.*

Final Thoughts: It Was The Best Of Times, it Was The Worst Of Times

- Communicate, communicate, communicate
  - Within
  - Without
  - Up
  - Down
  - Across
- Potential Results
  - Better consistency
  - Improved data access
  - Improved metrics transparency
  - *Bottom Line: "There are no secrets to success. It is the result of preparation, hard work, and learning from failure." Colin Powell*
    - *Don't expect miracles without hard work. Unfortunately, if it is your team's first go-around, it might not be pretty!*

Questions