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AUTOMATING CSV: PART 2

A SYNERGY SUCCESS STORY

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Further, Together

AGENDA

THE SYNERGY BEGINS

CONNECTING CSV'S RISK CONCEPTS

PAVING THE WAY FOR A NEW QUALITY CULTURE

EMPOWERING TEAMS TO CONTROL EXECUTION

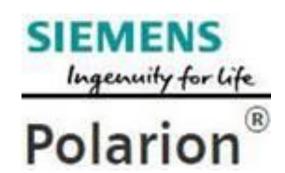NEXT STEPS

Q&A

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THE SYNERGY BEGINS
MEDTRONIC ADOPTS COVIDIEN TOOL

Two **software validation** processes **harmonized** into one

An **application lifecycle** tool that **manages** software development **projects**

CSV Achievement

Tool adoption supports a **risk based approach** whereby streamlining **evidence collection** and **assurance activities**

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QUALITY & EFFICIENCY IMPROVEMENTS
CALL FOR CHANGE
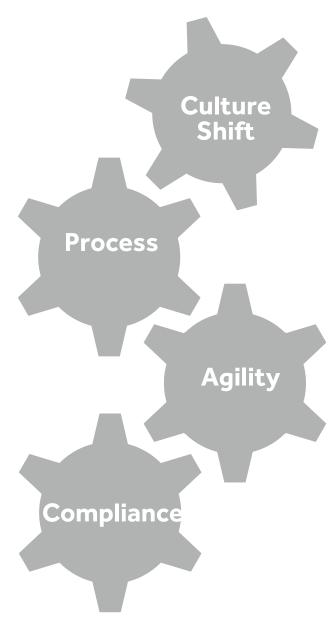
Reduce the # of non –
conformances
leveraging the
Polarion ALM system
automation, estimate
*$425K annually cost
avoidance (8 CAPA's)*

Changing IT Landscape

Reduce Cost of Compliance

Time to Market

Regulation Changes

Culture Shift

Process

Agility

Compliance

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CSV RISK MANAGEMENT AUTOMATION
POLARION

WHAT IS IT ?

An **application lifecycle** tool that **manages** software development **projects**

Requirements Management

Test & Quality Management

Variant Management

Issue & Defect Management

ALM

Build & Release Management

Change & Configuration

Resource Management

Audits, Metrics, Reports

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CONNECTING CSV'S RISK CONCEPTS

Scale validation **activities** based on **risk**

Leverage **vendor audits**

System **risk** or **risk-based** functions

Risk Based Approach

Vendor Audits

Unscripted, Ad hoc Testing

Scale the **level** of **vendor audit** to the **risk** of the **application**

Leverage **vendor's testing** to further **scale** validation effort

All functionality is **tested** but only **high risk** functionality requires **documented** testing

Low/medium risk testing only requires high level **summary** of testing

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CONNECTING CSV'S RISK CONCEPTS

Risk	Patient/Product	Quality System	Assurance Approach
	From failure, event, or consequence with potential to cause:	Software that supports the:	
Low	• Minor harm to a patient.	• Implementation of a quality system activity but is not in a regulation	Ad-Hoc Testing
Medium	• Significant but temporary harm or reversible damage to a patient	• Indirect implementation of a quality system activity, defined in a regulation.	Unscripted Testing
High	• Death, life-threatening harm, or irreversible damage to a patient.	• Direct implementation of a quality system activity, defined in a regulation.	Scripted Testing

Implementation Definitions	
Out of the Box	Feature works simply by installing the software and adding necessary master data (e.g. products, BOM, routes, etc.).
Configured	Feature is enabled through the setting of parameters without changing the code of the software
Custom	Feature requires programming or change to software code

Risk Rating	Assurance Activities
5	Requirement validated through robust scripted testing
4	Requirement validated through limited scripted testing
3	Requirement validated through unscripted testing
2	Requirement validated through ad-hoc testing
1	Relies on vendor audit and base-line assurance

		Implementation Method		
		Out of the Box	Configured	Custom
Patient Risk	High	3	4	5
	Medium	2	3	4
	Low	1	2	3
	None	1	1	1

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PAVING WAY FOR A NEW QUALITY CULTURE
RISK BASED TESTING FOR IT SOFTWARE

System Level

A software system is:

Validated – part of the IT quality processes impact per Val plan

Non-Validated – not part of the IT quality process per scope doc

Change Level Risk HIGH	Change Level Risk MEDIUM	Change Level Risk LOW
• Add traceability from Requirements to Design to Test case	• Standard traceability Requirements to Test cases	• Standard traceability Requirements to Test cases
• Test all new requirements	• Formal testing of all new requirement for IT system testing	• Informal testing for IT system
• Execute formal regression testing	• Informal execution of regression testing	• Informal testing for UAT
	• Informal execution of UAT	

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EMPOWERING TEAMS TO CONTROL EXECUTION
TESTING ELEMENTS

Formal Testing

⚠ Requires **pre-approved** test cases ➡

⚠ Requires formal entry into testing phase ➡

⚠ Requires Role base tester training ➡

⚠ Requires independent review of executed test results ➡

⚠ Requires all requirements are traced to test cases ➡

⚠ Requires dispositioned defects for all failed executions ➡

Informal Testing

✅ Requires **human readable** test cases

✅ Requires formal entry into testing phase

✅ Requires Role base tester training

✅ Requires independent review of executed test results

✅ Requires all requirements are traced to test case

✅ Requires dispositioned defects for all failed executions

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EMPOWERING TEAMS TO CONTROL EXECUTION
NEW WORKFLOW REQUEST IS AN ITERATIVE CENTRIC WORKFLOW
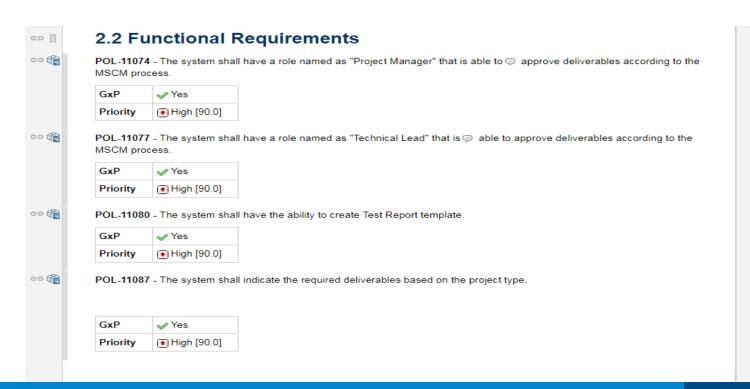
Process **integration to Polarion**

POL-11055 _____ integration to Polarion
Sections 1-3, and Requirements Deliverables to be Completed prior to Approved To Proceed
Sections 4-5, and Design and (un-executed) Test Deliverables to be Completed prior to Approved To Test
Section 6, and All Tests Successfully Executed prior to Ready for Production
All eSignatures must be obtained before system advances automatically to "Move To Production"

Leverage **work items** workflow

2.2 Functional Requirements

POL-11074 - The system shall have a role named as "Project Manager" that is able to 💬 approve deliverables according to the MSCM process.

GxP	✔ Yes
Priority	⬆ High [90.0]

POL-11077 - The system shall have a role named as "Technical Lead" that is 💬 able to approve deliverables according to the MSCM process.

GxP	✔ Yes
Priority	⬆ High [90.0]

POL-11080 - The system shall have the ability to create Test Report template.

GxP	✔ Yes
Priority	⬆ High [90.0]

POL-11087 - The system shall indicate the required deliverables based on the project type.

GxP	✔ Yes
Priority	⬆ High [90.0]

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EMPOWERING TEAMS TO CONTROL EXECUTION
CURRENT CONTAINER EXECUTED IN AN ITERATIVE TEST RESULTS

5.6 Test Cases/Test Script Inventory

The step number, description and expected results are contained in the test cases work items

BPC-21159 - Material Requisition Item Number Bar Code Fix

Step Instruction	Expected Result
Verify that test BPC-21106-SFT was created, reviewed and approved. Verify that it was successfully executed and dispositioned as pass. The executed test and objective evidence is attached	Test was created, reviewed and approved. The test was then successfully executed and dispositioned.

6.2 Traceability Matrix

Requirements	Test Script
BPC-21489	BPC-21106-SFT

Test Results

Test Case Id	Title	Test Result	Date	Test Run
BPC-21159	Material Requisition Item Number Bar Code Fix	✅ Passed	Fri Aug 19 13:31:37 EDT 2016	BPC-12965 Test Run

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NEXT STEPS

- Leverage critical thinking for assurance activities
- Increase onboarding of regulated projects whereby reducing number of CAPAs and audit findings for non-ALM projects
- Expand gains into more software teams
  - ❑ More automated testing
  - ❑ Develop end to end use cases
  - ❑ Identify reusable test cases
  - ❑ Apply risk based testing is align with actual testing effort

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